Dossier zur Nutzenbewertung gemäß § 35a SGB V

Tisagenlecleucel (Kymriah®)

Novartis Pharma GmbH

Modul 4 A - Separater Anhang 4-H.2 (Teil 2)

Refraktäre oder rezidivierte pädiatrische akute lymphatische B-Zell-Leukämie

Studie CCTL019B2205J (ENSIGN)

Stand: 31.08.2023

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Table 194a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (65.0)	6 (30.0)	3 (15.0)
Blood and lymphatic system disorders			
- Total	6 (30.0)	6 (30.0)	0
Febrile neutropenia	6 (30.0)	6 (30.0)	0
Immune system disorders			
- Total	12 (60.0)	3 (15.0)	2 (10.0)
Cytokine release syndrome	12 (60.0)	3 (15.0)	2 (10.0)
Nervous system disorders			
- Total	1 (5.0)	1 (5.0)	0
Seizure	1 (5.0)	1 (5.0)	0
Renal and urinary disorders			

Group term Preferred term	All patients N=20 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (5.0)	1 (5.0)	0
Acute kidney injury	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (5.0)	1 (5.0)	0
Hypoxia	1 (5.0)	1 (5.0)	0
Vascular disorders			
- Total	2 (10.0)	1 (5.0)	1 (5.0)
Hypotension	2 (10.0)	1 (5.0)	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (67.6)	12 (35.3)	7 (20.6)
Blood and lymphatic system disorders			
- Total	13 (38.2)	13 (38.2)	0
Febrile neutropenia	13 (38.2)	13 (38.2)	0
General disorders and administration site conditions			
- Total	1 (2.9)	0	0
Pyrexia	1 (2.9)	0	0
Immune system disorders			
- Total	23 (67.6)	5 (14.7)	5 (14.7)
Cytokine release syndrome	23 (67.6)	5 (14.7)	5 (14.7)
Nervous system disorders			

Group term Preferred term	All patients N=34 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	6 (17.6)	2 (5.9)	0
Encephalopathy	4 (11.8)	2 (5.9)	0
Seizure	2 (5.9)	0	0
Renal and urinary disorders			
- Total	1 (2.9)	1 (2.9)	0
Acute kidney injury	1 (2.9)	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.9)	0	0
Hypoxia	2 (5.9)	0	0
Vascular disorders			
- Total	5 (14.7)	3 (8.8)	2 (5.9)
Hypotension	5 (14.7)	3 (8.8)	2 (5.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (70.0)	2 (20.0)	3 (30.0)
Blood and lymphatic system disorders			
- Total	2 (20.0)	2 (20.0)	0
Febrile neutropenia	2 (20.0)	2 (20.0)	0
General disorders and administration site conditions			
- Total	1 (10.0)	0	0
Pyrexia	1 (10.0)	0	0
Immune system disorders			
- Total	6 (60.0)	0	3 (30.0)
Cytokine release syndrome	6 (60.0)	0	3 (30.0)
Renal and urinary disorders			

Group term Preferred term	All patients N=10 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (10.0)	0	1 (10.0)
Acute kidney injury	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (10.0)	0	1 (10.0)
Hypoxia	1 (10.0)	0	1 (10.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Age: <10 years

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (16.7)	0	0
General disorders and administration site conditions			
- Total	3 (16.7)	0	0
Pyrexia	3 (16.7)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (19.4)	5 (16.1)	0
Blood and lymphatic system disorders			
- Total	3 (9.7)	3 (9.7)	0
Febrile neutropenia	3 (9.7)	3 (9.7)	0
General disorders and administration site conditions			
- Total	2 (6.5)	1 (3.2)	0
Pyrexia	2 (6.5)	1 (3.2)	0
Renal and urinary disorders			
- Total	1 (3.2)	1 (3.2)	0
Acute kidney injury	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Age: >=18

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Age: <10 years

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (9.1)	1 (9.1)	0
Nervous system disorders			
- Total	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	1 (9.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (4.5)	0	1 (4.5)
Blood and lymphatic system disorders			
- Total	1 (4.5)	0	1 (4.5)
Febrile neutropenia	1 (4.5)	0	1 (4.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Age: >=18

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing=Any time post CTL019 infusion Sub group=Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (75.0)	7 (35.0)	3 (15.0)
Blood and lymphatic system disorders			
- Total	6 (30.0)	6 (30.0)	0
Febrile neutropenia	6 (30.0)	6 (30.0)	0
General disorders and administration site conditions			
- Total	3 (15.0)	0	0
Pyrexia	3 (15.0)	0	0
Immune system disorders			
- Total	12 (60.0)	3 (15.0)	2 (10.0)
Cytokine release syndrome	12 (60.0)	3 (15.0)	2 (10.0)
Nervous system disorders			

Group term Preferred term	All patients N=20 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	2 (10.0)	2 (10.0)	0
Seizure	2 (10.0)	2 (10.0)	0
Renal and urinary disorders			
- Total	1 (5.0)	1 (5.0)	0
Acute kidney injury	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (5.0)	1 (5.0)	0
Hypoxia	1 (5.0)	1 (5.0)	0
Vascular disorders			
- Total	2 (10.0)	1 (5.0)	1 (5.0)
Hypotension	2 (10.0)	1 (5.0)	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing=Any time post CTL019 infusion Sub group=Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	26 (76.5)	14 (41.2)	8 (23.5)
Blood and lymphatic system disorders			
- Total	15 (44.1)	14 (41.2)	1 (2.9)
Febrile neutropenia	15 (44.1)	14 (41.2)	1 (2.9)
General disorders and administration site conditions			
- Total	3 (8.8)	1 (2.9)	0
Pyrexia	3 (8.8)	1 (2.9)	0
Immune system disorders			
- Total	23 (67.6)	5 (14.7)	5 (14.7)
Cytokine release syndrome	23 (67.6)	5 (14.7)	5 (14.7)
Nervous system disorders			

Group term Preferred term	All patients N=34 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	6 (17.6)	2 (5.9)	0
Encephalopathy	4 (11.8)	2 (5.9)	0
Seizure	2 (5.9)	0	0
Renal and urinary disorders			
- Total	2 (5.9)	2 (5.9)	0
Acute kidney injury	2 (5.9)	2 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.9)	0	0
Hypoxia	2 (5.9)	0	0
Vascular disorders			
- Total	5 (14.7)	3 (8.8)	2 (5.9)
Hypotension	5 (14.7)	3 (8.8)	2 (5.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing=Any time post CTL019 infusion Sub group=Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (70.0)	2 (20.0)	3 (30.0)
Blood and lymphatic system disorders			
- Total	2 (20.0)	2 (20.0)	0
Febrile neutropenia	2 (20.0)	2 (20.0)	0
General disorders and administration site conditions			
- Total	1 (10.0)	0	0
Pyrexia	1 (10.0)	0	0
Immune system disorders			
- Total	6 (60.0)	0	3 (30.0)
Cytokine release syndrome	6 (60.0)	0	3 (30.0)
Renal and urinary disorders			

Group term Preferred term	All patients N=10 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (10.0)	0	1 (10.0)
Acute kidney injury	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (10.0)	0	1 (10.0)
Hypoxia	1 (10.0)	0	1 (10.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (66.7)	11 (36.7)	5 (16.7)
Blood and lymphatic system disorders			
- Total	9 (30.0)	9 (30.0)	0
Febrile neutropenia	9 (30.0)	9 (30.0)	0
Immune system disorders			
- Total	19 (63.3)	3 (10.0)	5 (16.7)
Cytokine release syndrome	19 (63.3)	3 (10.0)	5 (16.7)
Nervous system disorders			
- Total	3 (10.0)	1 (3.3)	0
Encephalopathy	2 (6.7)	1 (3.3)	0
Seizure	1 (3.3)	0	0

Group term Preferred term	All patients N=30 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (6.7)	0	0
Hypoxia	2 (6.7)	0	0
Vascular disorders			
- Total	4 (13.3)	4 (13.3)	0
Hypotension	4 (13.3)	4 (13.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (67.6)	9 (26.5)	8 (23.5)
Blood and lymphatic system disorders			
- Total	12 (35.3)	12 (35.3)	0
Febrile neutropenia	12 (35.3)	12 (35.3)	0
General disorders and administration site conditions			
- Total	2 (5.9)	0	0
Pyrexia	2 (5.9)	0	0
Immune system disorders			
- Total	22 (64.7)	5 (14.7)	5 (14.7)
Cytokine release syndrome	22 (64.7)	5 (14.7)	5 (14.7)
Nervous system disorders			

Group term Preferred term	All patients N=34 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	4 (11.8)	2 (5.9)	0
Encephalopathy	2 (5.9)	1 (2.9)	0
Seizure	2 (5.9)	1 (2.9)	0
Renal and urinary disorders			
- Total	3 (8.8)	2 (5.9)	1 (2.9)
Acute kidney injury	3 (8.8)	2 (5.9)	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.9)	1 (2.9)	1 (2.9)
Hypoxia	2 (5.9)	1 (2.9)	1 (2.9)
Vascular disorders			
- Total	3 (8.8)	0	3 (8.8)
Hypotension	3 (8.8)	0	3 (8.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Gender: Male

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (11.1)	2 (7.4)	0
Blood and lymphatic system disorders			
- Total	2 (7.4)	2 (7.4)	0
Febrile neutropenia	2 (7.4)	2 (7.4)	0
General disorders and administration site conditions			
- Total	1 (3.7)	0	0
Pyrexia	1 (3.7)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Gender: Female

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (20.7)	3 (10.3)	0
Blood and lymphatic system disorders			
- Total	1 (3.4)	1 (3.4)	0
Febrile neutropenia	1 (3.4)	1 (3.4)	0
General disorders and administration site conditions			
- Total	4 (13.8)	1 (3.4)	0
Pyrexia	4 (13.8)	1 (3.4)	0
Renal and urinary disorders			
- Total	1 (3.4)	1 (3.4)	0
Acute kidney injury	1 (3.4)	1 (3.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Gender: Male

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (5.0)	1 (5.0)	0
Nervous system disorders			
- Total	1 (5.0)	1 (5.0)	0
Seizure	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Gender: Female

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (7.1)	0	1 (7.1)
Blood and lymphatic system disorders			
- Total	1 (7.1)	0	1 (7.1)
Febrile neutropenia	1 (7.1)	0	1 (7.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing=Any time post CTL019 infusion Sub group=Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	22 (73.3)	12 (40.0)	5 (16.7)
Blood and lymphatic system disorders			
- Total	9 (30.0)	9 (30.0)	0
Febrile neutropenia	9 (30.0)	9 (30.0)	0
General disorders and administration site conditions			
- Total	1 (3.3)	0	0
Pyrexia	1 (3.3)	0	0
Immune system disorders			
- Total	19 (63.3)	3 (10.0)	5 (16.7)
Cytokine release syndrome	19 (63.3)	3 (10.0)	5 (16.7)
Nervous system disorders			

Group term Preferred term	All patients N=30 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	4 (13.3)	2 (6.7)	0
Encephalopathy	2 (6.7)	1 (3.3)	0
Seizure	2 (6.7)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (6.7)	0	0
Hypoxia	2 (6.7)	0	0
Vascular disorders			
- Total	4 (13.3)	4 (13.3)	0
Hypotension	4 (13.3)	4 (13.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing=Any time post CTL019 infusion Sub group=Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	26 (76.5)	11 (32.4)	9 (26.5)
Blood and lymphatic system disorders			
- Total	14 (41.2)	13 (38.2)	1 (2.9)
Febrile neutropenia	14 (41.2)	13 (38.2)	1 (2.9)
General disorders and administration site conditions			
- Total	6 (17.6)	1 (2.9)	0
Pyrexia	6 (17.6)	1 (2.9)	0
Immune system disorders			
- Total	22 (64.7)	5 (14.7)	5 (14.7)
Cytokine release syndrome	22 (64.7)	5 (14.7)	5 (14.7)
Nervous system disorders			

Group term Preferred term	All patients N=34 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	4 (11.8)	2 (5.9)	0
Encephalopathy	2 (5.9)	1 (2.9)	0
Seizure	2 (5.9)	1 (2.9)	0
Renal and urinary disorders			
- Total	4 (11.8)	3 (8.8)	1 (2.9)
Acute kidney injury	4 (11.8)	3 (8.8)	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.9)	1 (2.9)	1 (2.9)
Hypoxia	2 (5.9)	1 (2.9)	1 (2.9)
Vascular disorders			
- Total	3 (8.8)	0	3 (8.8)
Hypotension	3 (8.8)	0	3 (8.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	35 (67.3)	18 (34.6)	11 (21.2)
Blood and lymphatic system disorders			
- Total	18 (34.6)	18 (34.6)	0
Febrile neutropenia	18 (34.6)	18 (34.6)	0
General disorders and administration site conditions			
- Total	2 (3.8)	0	0
Pyrexia	2 (3.8)	0	0
Immune system disorders			
- Total	33 (63.5)	7 (13.5)	9 (17.3)
Cytokine release syndrome	33 (63.5)	7 (13.5)	9 (17.3)
Nervous system disorders			

Group term Preferred term	All patients N=52 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	5 (9.6)	3 (5.8)	0
Encephalopathy	3 (5.8)	2 (3.8)	0
Seizure	2 (3.8)	1 (1.9)	0
Renal and urinary disorders			
- Total	2 (3.8)	1 (1.9)	1 (1.9)
Acute kidney injury	2 (3.8)	1 (1.9)	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (7.7)	1 (1.9)	1 (1.9)
Hypoxia	4 (7.7)	1 (1.9)	1 (1.9)
Vascular disorders			
- Total	6 (11.5)	4 (7.7)	2 (3.8)
Hypotension	6 (11.5)	4 (7.7)	2 (3.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (60.0)	1 (20.0)	0
Blood and lymphatic system disorders			
- Total	1 (20.0)	1 (20.0)	0
Febrile neutropenia	1 (20.0)	1 (20.0)	0
Immune system disorders			
- Total	3 (60.0)	0	0
Cytokine release syndrome	3 (60.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	1 (14.3)	2 (28.6)
Blood and lymphatic system disorders			
- Total	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Immune system disorders			
- Total	5 (71.4)	1 (14.3)	1 (14.3)
Cytokine release syndrome	5 (71.4)	1 (14.3)	1 (14.3)
Nervous system disorders			
- Total	2 (28.6)	0	0
Encephalopathy	1 (14.3)	0	0
Seizure	1 (14.3)	0	0

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal and urinary disorders			
- Total	1 (14.3)	1 (14.3)	0
Acute kidney injury	1 (14.3)	1 (14.3)	0
Vascular disorders			
- Total	1 (14.3)	0	1 (14.3)
Hypotension	1 (14.3)	0	1 (14.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (11.4)	3 (6.8)	0
Blood and lymphatic system disorders			
- Total	1 (2.3)	1 (2.3)	0
Febrile neutropenia	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
- Total	3 (6.8)	1 (2.3)	0
Pyrexia	3 (6.8)	1 (2.3)	0
Renal and urinary disorders			
- Total	1 (2.3)	1 (2.3)	0
Acute kidney injury	1 (2.3)	1 (2.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (60.0)	1 (20.0)	0
Blood and lymphatic system disorders			
- Total	1 (20.0)	1 (20.0)	0
Febrile neutropenia	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
- Total	2 (40.0)	0	0
Pyrexia	2 (40.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (14.3)	1 (14.3)	0
Blood and lymphatic system disorders			
- Total	1 (14.3)	1 (14.3)	0
Febrile neutropenia	1 (14.3)	1 (14.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Race: White

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (3.6)	1 (3.6)	0
Nervous system disorders			
- Total	1 (3.6)	1 (3.6)	0
Seizure	1 (3.6)	1 (3.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Race: Asian

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Race: Other

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (25.0)	0	1 (25.0)
Blood and lymphatic system disorders			
- Total	1 (25.0)	0	1 (25.0)
Febrile neutropenia	1 (25.0)	0	1 (25.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing=Any time post CTL019 infusion Sub group=Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	38 (73.1)	20 (38.5)	11 (21.2)
Blood and lymphatic system disorders			
- Total	18 (34.6)	18 (34.6)	0
Febrile neutropenia	18 (34.6)	18 (34.6)	0
General disorders and administration site conditions			
- Total	5 (9.6)	1 (1.9)	0
Pyrexia	5 (9.6)	1 (1.9)	0
Immune system disorders			
- Total	33 (63.5)	7 (13.5)	9 (17.3)
Cytokine release syndrome	33 (63.5)	7 (13.5)	9 (17.3)
Nervous system disorders			

Group term Preferred term	All patients N=52 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	6 (11.5)	4 (7.7)	0
Encephalopathy	3 (5.8)	2 (3.8)	0
Seizure	3 (5.8)	2 (3.8)	0
Renal and urinary disorders			
- Total	3 (5.8)	2 (3.8)	1 (1.9)
Acute kidney injury	3 (5.8)	2 (3.8)	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (7.7)	1 (1.9)	1 (1.9)
Hypoxia	4 (7.7)	1 (1.9)	1 (1.9)
Vascular disorders			
- Total	6 (11.5)	4 (7.7)	2 (3.8)
Hypotension	6 (11.5)	4 (7.7)	2 (3.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing=Any time post CTL019 infusion Sub group=Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (80.0)	1 (20.0)	0
Blood and lymphatic system disorders			
- Total	1 (20.0)	1 (20.0)	0
Febrile neutropenia	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
- Total	2 (40.0)	0	0
Pyrexia	2 (40.0)	0	0
Immune system disorders			
- Total	3 (60.0)	0	0
Cytokine release syndrome	3 (60.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing=Any time post CTL019 infusion Sub group=Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (85.7)	2 (28.6)	3 (42.9)
Blood and lymphatic system disorders			
- Total	4 (57.1)	3 (42.9)	1 (14.3)
Febrile neutropenia	4 (57.1)	3 (42.9)	1 (14.3)
Immune system disorders			
- Total	5 (71.4)	1 (14.3)	1 (14.3)
Cytokine release syndrome	5 (71.4)	1 (14.3)	1 (14.3)
Nervous system disorders			
- Total	2 (28.6)	0	0
Encephalopathy	1 (14.3)	0	0
Seizure	1 (14.3)	0	0

Group term Preferred term	All patients N=7 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Renal and urinary disorders			
- Total	1 (14.3)	1 (14.3)	0
Acute kidney injury	1 (14.3)	1 (14.3)	0
Vascular disorders			
- Total	1 (14.3)	0	1 (14.3)
Hypotension	1 (14.3)	0	1 (14.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (72.0)	12 (48.0)	4 (16.0)
Blood and lymphatic system disorders			
- Total	13 (52.0)	13 (52.0)	0
Febrile neutropenia	13 (52.0)	13 (52.0)	0
General disorders and administration site conditions			
- Total	1 (4.0)	0	0
Pyrexia	1 (4.0)	0	0
Immune system disorders			
- Total	16 (64.0)	3 (12.0)	3 (12.0)
Cytokine release syndrome	16 (64.0)	3 (12.0)	3 (12.0)
Nervous system disorders			

Group term Preferred term	All patients N=25 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	3 (12.0)	1 (4.0)	0
Seizure	2 (8.0)	0	0
Encephalopathy	1 (4.0)	1 (4.0)	0
Renal and urinary disorders			
- Total	2 (8.0)	2 (8.0)	0
Acute kidney injury	2 (8.0)	2 (8.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (4.0)	0	0
Hypoxia	1 (4.0)	0	0
Vascular disorders			
- Total	3 (12.0)	2 (8.0)	1 (4.0)
Hypotension	3 (12.0)	2 (8.0)	1 (4.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	25 (64.1)	8 (20.5)	9 (23.1)
Blood and lymphatic system disorders			
- Total	8 (20.5)	8 (20.5)	0
Febrile neutropenia	8 (20.5)	8 (20.5)	0
General disorders and administration site conditions			
- Total	1 (2.6)	0	0
Pyrexia	1 (2.6)	0	0
Immune system disorders			
- Total	25 (64.1)	5 (12.8)	7 (17.9)
Cytokine release syndrome	25 (64.1)	5 (12.8)	7 (17.9)
Nervous system disorders			

Group term Preferred term	All patients N=39 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	4 (10.3)	2 (5.1)	0
Encephalopathy	3 (7.7)	1 (2.6)	0
Seizure	1 (2.6)	1 (2.6)	0
Renal and urinary disorders			
- Total	1 (2.6)	0	1 (2.6)
Acute kidney injury	1 (2.6)	0	1 (2.6)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (7.7)	1 (2.6)	1 (2.6)
Hypoxia	3 (7.7)	1 (2.6)	1 (2.6)
Vascular disorders			
- Total	4 (10.3)	2 (5.1)	2 (5.1)
Hypotension	4 (10.3)	2 (5.1)	2 (5.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Ethnicity: Hispanic or Latino

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (21.7)	3 (13.0)	0
Blood and lymphatic system disorders			
- Total	2 (8.7)	2 (8.7)	0
Febrile neutropenia	2 (8.7)	2 (8.7)	0
General disorders and administration site conditions			
- Total	2 (8.7)	0	0
Pyrexia	2 (8.7)	0	0
Renal and urinary disorders			
- Total	1 (4.3)	1 (4.3)	0
Acute kidney injury	1 (4.3)	1 (4.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Ethnicity: Other

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (12.1)	2 (6.1)	0
Blood and lymphatic system disorders			
- Total	1 (3.0)	1 (3.0)	0
Febrile neutropenia	1 (3.0)	1 (3.0)	0
General disorders and administration site conditions			
- Total	3 (9.1)	1 (3.0)	0
Pyrexia	3 (9.1)	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Ethnicity: Hispanic or Latino

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (5.9)	0	1 (5.9)
Blood and lymphatic system disorders			
- Total	1 (5.9)	0	1 (5.9)
Febrile neutropenia	1 (5.9)	0	1 (5.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Ethnicity: Other

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (5.9)	1 (5.9)	0
Nervous system disorders			
- Total	1 (5.9)	1 (5.9)	0
Seizure	1 (5.9)	1 (5.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing=Any time post CTL019 infusion Sub group=Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (80.0)	13 (52.0)	5 (20.0)
Blood and lymphatic system disorders			
- Total	15 (60.0)	14 (56.0)	1 (4.0)
Febrile neutropenia	15 (60.0)	14 (56.0)	1 (4.0)
General disorders and administration site conditions			
- Total	3 (12.0)	0	0
Pyrexia	3 (12.0)	0	0
Immune system disorders			
- Total	16 (64.0)	3 (12.0)	3 (12.0)
Cytokine release syndrome	16 (64.0)	3 (12.0)	3 (12.0)
Nervous system disorders			

Group term Preferred term	All patients N=25 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	3 (12.0)	1 (4.0)	0
Seizure	2 (8.0)	0	0
Encephalopathy	1 (4.0)	1 (4.0)	0
Renal and urinary disorders			
- Total	3 (12.0)	3 (12.0)	0
Acute kidney injury	3 (12.0)	3 (12.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (4.0)	0	0
Hypoxia	1 (4.0)	0	0
Vascular disorders			
- Total	3 (12.0)	2 (8.0)	1 (4.0)
Hypotension	3 (12.0)	2 (8.0)	1 (4.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing=Any time post CTL019 infusion Sub group=Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	28 (71.8)	10 (25.6)	9 (23.1)
Blood and lymphatic system disorders			
- Total	8 (20.5)	8 (20.5)	0
Febrile neutropenia	8 (20.5)	8 (20.5)	0
General disorders and administration site conditions			
- Total	4 (10.3)	1 (2.6)	0
Pyrexia	4 (10.3)	1 (2.6)	0
Immune system disorders			
- Total	25 (64.1)	5 (12.8)	7 (17.9)
Cytokine release syndrome	25 (64.1)	5 (12.8)	7 (17.9)
Nervous system disorders			

Group term Preferred term	All patients N=39 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	5 (12.8)	3 (7.7)	0
Encephalopathy	3 (7.7)	1 (2.6)	0
Seizure	2 (5.1)	2 (5.1)	0
Renal and urinary disorders			
- Total	1 (2.6)	0	1 (2.6)
Acute kidney injury	1 (2.6)	0	1 (2.6)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (7.7)	1 (2.6)	1 (2.6)
Hypoxia	3 (7.7)	1 (2.6)	1 (2.6)
Vascular disorders			
- Total	4 (10.3)	2 (5.1)	2 (5.1)
Hypotension	4 (10.3)	2 (5.1)	2 (5.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	2 (28.6)	3 (42.9)
Blood and lymphatic system disorders			
- Total	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Immune system disorders			
- Total	5 (71.4)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	3 (42.9)
Vascular disorders			
- Total	2 (28.6)	2 (28.6)	0
Hypotension	2 (28.6)	2 (28.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	38 (66.7)	18 (31.6)	10 (17.5)
Blood and lymphatic system disorders			
- Total	19 (33.3)	19 (33.3)	0
Febrile neutropenia	19 (33.3)	19 (33.3)	0
General disorders and administration site conditions			
- Total	2 (3.5)	0	0
Pyrexia	2 (3.5)	0	0
Immune system disorders			
- Total	36 (63.2)	8 (14.0)	7 (12.3)
Cytokine release syndrome	36 (63.2)	8 (14.0)	7 (12.3)
Nervous system disorders			

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	7 (12.3)	3 (5.3)	0
Encephalopathy	4 (7.0)	2 (3.5)	0
Seizure	3 (5.3)	1 (1.8)	0
Renal and urinary disorders			
- Total	3 (5.3)	2 (3.5)	1 (1.8)
Acute kidney injury	3 (5.3)	2 (3.5)	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (7.0)	1 (1.8)	1 (1.8)
Hypoxia	4 (7.0)	1 (1.8)	1 (1.8)
Vascular disorders			
- Total	5 (8.8)	2 (3.5)	3 (5.3)
Hypotension	5 (8.8)	2 (3.5)	3 (5.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Response status at study entry: Primary refractory

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (20.0)	0	0
General disorders and administration site conditions			
- Total	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Response status at study entry: Relapsed disease

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (15.7)	5 (9.8)	0
Blood and lymphatic system disorders			
- Total	3 (5.9)	3 (5.9)	0
Febrile neutropenia	3 (5.9)	3 (5.9)	0
General disorders and administration site conditions			
- Total	4 (7.8)	1 (2.0)	0
Pyrexia	4 (7.8)	1 (2.0)	0
Renal and urinary disorders			
- Total	1 (2.0)	1 (2.0)	0
Acute kidney injury	1 (2.0)	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Response status at study entry: Primary refractory

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Response status at study entry: Relapsed disease

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (6.9)	1 (3.4)	1 (3.4)
Blood and lymphatic system disorders			
- Total	1 (3.4)	0	1 (3.4)
Febrile neutropenia	1 (3.4)	0	1 (3.4)
Nervous system disorders			
- Total	1 (3.4)	1 (3.4)	0
Seizure	1 (3.4)	1 (3.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing=Any time post CTL019 infusion Sub group=Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	2 (28.6)	3 (42.9)
Blood and lymphatic system disorders			
- Total	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
General disorders and administration site conditions			
- Total	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	0
Immune system disorders			
- Total	5 (71.4)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	3 (42.9)
Vascular disorders			

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	2 (28.6)	2 (28.6)	0
Hypotension	2 (28.6)	2 (28.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing=Any time post CTL019 infusion Sub group=Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	43 (75.4)	21 (36.8)	11 (19.3)
Blood and lymphatic system disorders			
- Total	21 (36.8)	20 (35.1)	1 (1.8)
Febrile neutropenia	21 (36.8)	20 (35.1)	1 (1.8)
General disorders and administration site conditions			
- Total	6 (10.5)	1 (1.8)	0
Pyrexia	6 (10.5)	1 (1.8)	0
Immune system disorders			
- Total	36 (63.2)	8 (14.0)	7 (12.3)
Cytokine release syndrome	36 (63.2)	8 (14.0)	7 (12.3)
Nervous system disorders			

Group term Preferred term	All patients N=57 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	8 (14.0)	4 (7.0)	0
Encephalopathy	4 (7.0)	2 (3.5)	0
Seizure	4 (7.0)	2 (3.5)	0
Renal and urinary disorders			
- Total	4 (7.0)	3 (5.3)	1 (1.8)
Acute kidney injury	4 (7.0)	3 (5.3)	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (7.0)	1 (1.8)	1 (1.8)
Hypoxia	4 (7.0)	1 (1.8)	1 (1.8)
Vascular disorders			
- Total	5 (8.8)	2 (3.5)	3 (5.3)
Hypotension	5 (8.8)	2 (3.5)	3 (5.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	43 (69.4)	20 (32.3)	13 (21.0)
Blood and lymphatic system disorders			
- Total	21 (33.9)	21 (33.9)	0
Febrile neutropenia	21 (33.9)	21 (33.9)	0
General disorders and administration site conditions			
- Total	2 (3.2)	0	0
Pyrexia	2 (3.2)	0	0
Immune system disorders			
- Total	41 (66.1)	8 (12.9)	10 (16.1)
Cytokine release syndrome	41 (66.1)	8 (12.9)	10 (16.1)
Nervous system disorders			

Group term Preferred term	All patients N=62 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	7 (11.3)	3 (4.8)	0
Encephalopathy	4 (6.5)	2 (3.2)	0
Seizure	3 (4.8)	1 (1.6)	0
Renal and urinary disorders			
- Total	3 (4.8)	2 (3.2)	1 (1.6)
Acute kidney injury	3 (4.8)	2 (3.2)	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.5)	1 (1.6)	1 (1.6)
Hypoxia	4 (6.5)	1 (1.6)	1 (1.6)
Vascular disorders			
- Total	7 (11.3)	4 (6.5)	3 (4.8)
Hypotension	7 (11.3)	4 (6.5)	3 (4.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	0	0
General disorders and administration site conditions			
- Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (14.8)	5 (9.3)	0
Blood and lymphatic system disorders			
- Total	3 (5.6)	3 (5.6)	0
Febrile neutropenia	3 (5.6)	3 (5.6)	0
General disorders and administration site conditions			
- Total	4 (7.4)	1 (1.9)	0
Pyrexia	4 (7.4)	1 (1.9)	0
Renal and urinary disorders			
- Total	1 (1.9)	1 (1.9)	0
Acute kidney injury	1 (1.9)	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Philadelphia chromosome/BCR-ABL: Positive

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Philadelphia chromosome/BCR-ABL: Negative

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (6.1)	1 (3.0)	1 (3.0)
Blood and lymphatic system disorders			
- Total	1 (3.0)	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	1 (3.0)
Nervous system disorders			
- Total	1 (3.0)	1 (3.0)	0
Seizure	1 (3.0)	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing=Any time post CTL019 infusion Sub group=Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	0	0
General disorders and administration site conditions			
- Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing=Any time post CTL019 infusion Sub group=Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	47 (75.8)	23 (37.1)	14 (22.6)
Blood and lymphatic system disorders			
- Total	23 (37.1)	22 (35.5)	1 (1.6)
Febrile neutropenia	23 (37.1)	22 (35.5)	1 (1.6)
General disorders and administration site conditions			
- Total	6 (9.7)	1 (1.6)	0
Pyrexia	6 (9.7)	1 (1.6)	0
Immune system disorders			
- Total	41 (66.1)	8 (12.9)	10 (16.1)
Cytokine release syndrome	41 (66.1)	8 (12.9)	10 (16.1)
Nervous system disorders			

Group term Preferred term	All patients N=62 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	8 (12.9)	4 (6.5)	0
Encephalopathy	4 (6.5)	2 (3.2)	0
Seizure	4 (6.5)	2 (3.2)	0
Renal and urinary disorders			
- Total	4 (6.5)	3 (4.8)	1 (1.6)
Acute kidney injury	4 (6.5)	3 (4.8)	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.5)	1 (1.6)	1 (1.6)
Hypoxia	4 (6.5)	1 (1.6)	1 (1.6)
Vascular disorders			
- Total	7 (11.3)	4 (6.5)	3 (4.8)
Hypotension	7 (11.3)	4 (6.5)	3 (4.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (66.7)	0	2 (66.7)
Immune system disorders			
- Total	2 (66.7)	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	2 (66.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	41 (67.2)	20 (32.8)	11 (18.0)
Blood and lymphatic system disorders			
- Total	21 (34.4)	21 (34.4)	0
Febrile neutropenia	21 (34.4)	21 (34.4)	0
General disorders and administration site conditions			
- Total	2 (3.3)	0	0
Pyrexia	2 (3.3)	0	0
Immune system disorders			
- Total	39 (63.9)	8 (13.1)	8 (13.1)
Cytokine release syndrome	39 (63.9)	8 (13.1)	8 (13.1)
Nervous system disorders			

Group term Preferred term	All patients N=61 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	7 (11.5)	3 (4.9)	0
Encephalopathy	4 (6.6)	2 (3.3)	0
Seizure	3 (4.9)	1 (1.6)	0
Renal and urinary disorders			
- Total	3 (4.9)	2 (3.3)	1 (1.6)
Acute kidney injury	3 (4.9)	2 (3.3)	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.6)	1 (1.6)	1 (1.6)
Hypoxia	4 (6.6)	1 (1.6)	1 (1.6)
Vascular disorders			
- Total	7 (11.5)	4 (6.6)	3 (4.9)
Hypotension	7 (11.5)	4 (6.6)	3 (4.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Mixed-lineage leukemia rearrangement: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Mixed-lineage leukemia rearrangement: No

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (16.7)	5 (9.3)	0
Blood and lymphatic system disorders			
- Total	3 (5.6)	3 (5.6)	0
Febrile neutropenia	3 (5.6)	3 (5.6)	0
General disorders and administration site conditions			
- Total	5 (9.3)	1 (1.9)	0
Pyrexia	5 (9.3)	1 (1.9)	0
Renal and urinary disorders			
- Total	1 (1.9)	1 (1.9)	0
Acute kidney injury	1 (1.9)	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Mixed-lineage leukemia rearrangement: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Mixed-lineage leukemia rearrangement: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (6.1)	1 (3.0)	1 (3.0)
Blood and lymphatic system disorders			
- Total	1 (3.0)	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	1 (3.0)
Nervous system disorders			
- Total	1 (3.0)	1 (3.0)	0
Seizure	1 (3.0)	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing=Any time post CTL019 infusion Sub group=Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (66.7)	0	2 (66.7)
Immune system disorders			
- Total	2 (66.7)	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	2 (66.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing=Any time post CTL019 infusion Sub group=Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	46 (75.4)	23 (37.7)	12 (19.7)
Blood and lymphatic system disorders			
- Total	23 (37.7)	22 (36.1)	1 (1.6)
Febrile neutropenia	23 (37.7)	22 (36.1)	1 (1.6)
General disorders and administration site conditions			
- Total	7 (11.5)	1 (1.6)	0
Pyrexia	7 (11.5)	1 (1.6)	0
Immune system disorders			
- Total	39 (63.9)	8 (13.1)	8 (13.1)
Cytokine release syndrome	39 (63.9)	8 (13.1)	8 (13.1)
Nervous system disorders			

Group term Preferred term	All patients N=61 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	8 (13.1)	4 (6.6)	0
Encephalopathy	4 (6.6)	2 (3.3)	0
Seizure	4 (6.6)	2 (3.3)	0
Renal and urinary disorders			
- Total	4 (6.6)	3 (4.9)	1 (1.6)
Acute kidney injury	4 (6.6)	3 (4.9)	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.6)	1 (1.6)	1 (1.6)
Hypoxia	4 (6.6)	1 (1.6)	1 (1.6)
Vascular disorders			
- Total	7 (11.5)	4 (6.6)	3 (4.9)
Hypotension	7 (11.5)	4 (6.6)	3 (4.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
- Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Immune system disorders			
- Total	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	0
Nervous system disorders			
- Total	1 (100)	0	0
Encephalopathy	1 (100)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	42 (66.7)	19 (30.2)	13 (20.6)
Blood and lymphatic system disorders			
- Total	20 (31.7)	20 (31.7)	0
Febrile neutropenia	20 (31.7)	20 (31.7)	0
General disorders and administration site conditions			
- Total	2 (3.2)	0	0
Pyrexia	2 (3.2)	0	0
Immune system disorders			
- Total	40 (63.5)	8 (12.7)	10 (15.9)
Cytokine release syndrome	40 (63.5)	8 (12.7)	10 (15.9)
Nervous system disorders			

Group term Preferred term	All patients N=63 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	6 (9.5)	3 (4.8)	0
Encephalopathy	3 (4.8)	2 (3.2)	0
Seizure	3 (4.8)	1 (1.6)	0
Renal and urinary disorders			
- Total	3 (4.8)	2 (3.2)	1 (1.6)
Acute kidney injury	3 (4.8)	2 (3.2)	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.3)	1 (1.6)	1 (1.6)
Hypoxia	4 (6.3)	1 (1.6)	1 (1.6)
Vascular disorders			
- Total	7 (11.1)	4 (6.3)	3 (4.8)
Hypotension	7 (11.1)	4 (6.3)	3 (4.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Hypodiploidy: No

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (16.4)	5 (9.1)	0
Blood and lymphatic system disorders			
- Total	3 (5.5)	3 (5.5)	0
Febrile neutropenia	3 (5.5)	3 (5.5)	0
General disorders and administration site conditions			
- Total	5 (9.1)	1 (1.8)	0
Pyrexia	5 (9.1)	1 (1.8)	0
Renal and urinary disorders			
- Total	1 (1.8)	1 (1.8)	0
Acute kidney injury	1 (1.8)	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Hypodiploidy: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (6.1)	1 (3.0)	1 (3.0)
Blood and lymphatic system disorders			
- Total	1 (3.0)	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	1 (3.0)
Nervous system disorders			
- Total	1 (3.0)	1 (3.0)	0
Seizure	1 (3.0)	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing=Any time post CTL019 infusion Sub group=Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
- Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Immune system disorders			
- Total	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	0
Nervous system disorders			
- Total	1 (100)	0	0
Encephalopathy	1 (100)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing=Any time post CTL019 infusion Sub group=Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	47 (74.6)	22 (34.9)	14 (22.2)
Blood and lymphatic system disorders			
- Total	22 (34.9)	21 (33.3)	1 (1.6)
Febrile neutropenia	22 (34.9)	21 (33.3)	1 (1.6)
General disorders and administration site conditions			
- Total	7 (11.1)	1 (1.6)	0
Pyrexia	7 (11.1)	1 (1.6)	0
Immune system disorders			
- Total	40 (63.5)	8 (12.7)	10 (15.9)
Cytokine release syndrome	40 (63.5)	8 (12.7)	10 (15.9)
Nervous system disorders			

Group term Preferred term	All patients N=63 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	7 (11.1)	4 (6.3)	0
Seizure	4 (6.3)	2 (3.2)	0
Encephalopathy	3 (4.8)	2 (3.2)	0
Renal and urinary disorders			
- Total	4 (6.3)	3 (4.8)	1 (1.6)
Acute kidney injury	4 (6.3)	3 (4.8)	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.3)	1 (1.6)	1 (1.6)
Hypoxia	4 (6.3)	1 (1.6)	1 (1.6)
Vascular disorders			
- Total	7 (11.1)	4 (6.3)	3 (4.8)
Hypotension	7 (11.1)	4 (6.3)	3 (4.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders			
- Total	2 (50.0)	2 (50.0)	0
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Immune system disorders			
- Total	2 (50.0)	1 (25.0)	0
Cytokine release syndrome	2 (50.0)	1 (25.0)	0
Vascular disorders			
- Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	41 (68.3)	19 (31.7)	12 (20.0)
Blood and lymphatic system disorders			
- Total	19 (31.7)	19 (31.7)	0
Febrile neutropenia	19 (31.7)	19 (31.7)	0
General disorders and administration site conditions			
- Total	2 (3.3)	0	0
Pyrexia	2 (3.3)	0	0
Immune system disorders			
- Total	39 (65.0)	7 (11.7)	10 (16.7)
Cytokine release syndrome	39 (65.0)	7 (11.7)	10 (16.7)
Nervous system disorders			

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	7 (11.7)	3 (5.0)	0
Encephalopathy	4 (6.7)	2 (3.3)	0
Seizure	3 (5.0)	1 (1.7)	0
Renal and urinary disorders			
- Total	3 (5.0)	2 (3.3)	1 (1.7)
Acute kidney injury	3 (5.0)	2 (3.3)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.7)	1 (1.7)	1 (1.7)
Hypoxia	4 (6.7)	1 (1.7)	1 (1.7)
Vascular disorders			
- Total	6 (10.0)	4 (6.7)	2 (3.3)
Hypotension	6 (10.0)	4 (6.7)	2 (3.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (25.0)	1 (25.0)	0
Blood and lymphatic system disorders			
- Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (15.4)	4 (7.7)	0
Blood and lymphatic system disorders			
- Total	2 (3.8)	2 (3.8)	0
Febrile neutropenia	2 (3.8)	2 (3.8)	0
General disorders and administration site conditions			
- Total	5 (9.6)	1 (1.9)	0
Pyrexia	5 (9.6)	1 (1.9)	0
Renal and urinary disorders			
- Total	1 (1.9)	1 (1.9)	0
Acute kidney injury	1 (1.9)	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing=>1 year post CTL019 infusion Sub group=BCR-ABL1-like: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing=>1 year post CTL019 infusion Sub group=BCR-ABL1-like: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (6.5)	1 (3.2)	1 (3.2)
Blood and lymphatic system disorders			
- Total	1 (3.2)	0	1 (3.2)
Febrile neutropenia	1 (3.2)	0	1 (3.2)
Nervous system disorders			
- Total	1 (3.2)	1 (3.2)	0
Seizure	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing=Any time post CTL019 infusion Sub group=BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders			
- Total	2 (50.0)	2 (50.0)	0
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Immune system disorders			
- Total	2 (50.0)	1 (25.0)	0
Cytokine release syndrome	2 (50.0)	1 (25.0)	0
Vascular disorders			
- Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing=Any time post CTL019 infusion Sub group=BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	46 (76.7)	22 (36.7)	13 (21.7)
Blood and lymphatic system disorders			
- Total	21 (35.0)	20 (33.3)	1 (1.7)
Febrile neutropenia	21 (35.0)	20 (33.3)	1 (1.7)
General disorders and administration site conditions			
- Total	7 (11.7)	1 (1.7)	0
Pyrexia	7 (11.7)	1 (1.7)	0
Immune system disorders			
- Total	39 (65.0)	7 (11.7)	10 (16.7)
Cytokine release syndrome	39 (65.0)	7 (11.7)	10 (16.7)
Nervous system disorders			

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	8 (13.3)	4 (6.7)	0
Encephalopathy	4 (6.7)	2 (3.3)	0
Seizure	4 (6.7)	2 (3.3)	0
Renal and urinary disorders			
- Total	4 (6.7)	3 (5.0)	1 (1.7)
Acute kidney injury	4 (6.7)	3 (5.0)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.7)	1 (1.7)	1 (1.7)
Hypoxia	4 (6.7)	1 (1.7)	1 (1.7)
Vascular disorders			
- Total	6 (10.0)	4 (6.7)	2 (3.3)
Hypotension	6 (10.0)	4 (6.7)	2 (3.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	17 (89.5)	7 (36.8)	7 (36.8)
Blood and lymphatic system disorders			
- Total	8 (42.1)	8 (42.1)	0
Febrile neutropenia	8 (42.1)	8 (42.1)	0
Immune system disorders			
- Total	16 (84.2)	3 (15.8)	5 (26.3)
Cytokine release syndrome	16 (84.2)	3 (15.8)	5 (26.3)
Nervous system disorders			
- Total	3 (15.8)	2 (10.5)	0
Encephalopathy	2 (10.5)	1 (5.3)	0
Seizure	1 (5.3)	1 (5.3)	0

Group term Preferred term	All patients N=19 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Renal and urinary disorders			
- Total	1 (5.3)	0	1 (5.3)
Acute kidney injury	1 (5.3)	0	1 (5.3)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (10.5)	0	1 (5.3)
Hypoxia	2 (10.5)	0	1 (5.3)
Vascular disorders			
- Total	2 (10.5)	0	2 (10.5)
Hypotension	2 (10.5)	0	2 (10.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	26 (57.8)	13 (28.9)	6 (13.3)
Blood and lymphatic system disorders			
- Total	13 (28.9)	13 (28.9)	0
Febrile neutropenia	13 (28.9)	13 (28.9)	0
General disorders and administration site conditions			
- Total	2 (4.4)	0	0
Pyrexia	2 (4.4)	0	0
Immune system disorders			
- Total	25 (55.6)	5 (11.1)	5 (11.1)
Cytokine release syndrome	25 (55.6)	5 (11.1)	5 (11.1)
Nervous system disorders			

Group term Preferred term	All patients N=45 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	4 (8.9)	1 (2.2)	0
Encephalopathy	2 (4.4)	1 (2.2)	0
Seizure	2 (4.4)	0	0
Renal and urinary disorders			
- Total	2 (4.4)	2 (4.4)	0
Acute kidney injury	2 (4.4)	2 (4.4)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (4.4)	1 (2.2)	0
Hypoxia	2 (4.4)	1 (2.2)	0
Vascular disorders			
- Total	5 (11.1)	4 (8.9)	1 (2.2)
Hypotension	5 (11.1)	4 (8.9)	1 (2.2)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (27.8)	2 (11.1)	0
Blood and lymphatic system disorders			
- Total	1 (5.6)	1 (5.6)	0
Febrile neutropenia	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
- Total	3 (16.7)	0	0
Pyrexia	3 (16.7)	0	0
Renal and urinary disorders			
- Total	1 (5.6)	1 (5.6)	0
Acute kidney injury	1 (5.6)	1 (5.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (10.5)	3 (7.9)	0
Blood and lymphatic system disorders			
- Total	2 (5.3)	2 (5.3)	0
Febrile neutropenia	2 (5.3)	2 (5.3)	0
General disorders and administration site conditions			
- Total	2 (5.3)	1 (2.6)	0
Pyrexia	2 (5.3)	1 (2.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (8.7)	1 (4.3)	1 (4.3)
Blood and lymphatic system disorders			
- Total	1 (4.3)	0	1 (4.3)
Febrile neutropenia	1 (4.3)	0	1 (4.3)
Nervous system disorders			
- Total	1 (4.3)	1 (4.3)	0
Seizure	1 (4.3)	1 (4.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing=Any time post CTL019 infusion Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (100)	7 (36.8)	7 (36.8)
Blood and lymphatic system disorders			
- Total	8 (42.1)	8 (42.1)	0
Febrile neutropenia	8 (42.1)	8 (42.1)	0
General disorders and administration site conditions			
- Total	3 (15.8)	0	0
Pyrexia	3 (15.8)	0	0
Immune system disorders			
- Total	16 (84.2)	3 (15.8)	5 (26.3)
Cytokine release syndrome	16 (84.2)	3 (15.8)	5 (26.3)
Nervous system disorders			

Group term Preferred term	All patients N=19 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	3 (15.8)	2 (10.5)	0
Encephalopathy	2 (10.5)	1 (5.3)	0
Seizure	1 (5.3)	1 (5.3)	0
Renal and urinary disorders			
- Total	2 (10.5)	1 (5.3)	1 (5.3)
Acute kidney injury	2 (10.5)	1 (5.3)	1 (5.3)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (10.5)	0	1 (5.3)
Hypoxia	2 (10.5)	0	1 (5.3)
Vascular disorders			
- Total	2 (10.5)	0	2 (10.5)
Hypotension	2 (10.5)	0	2 (10.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing=Any time post CTL019 infusion Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (64.4)	16 (35.6)	7 (15.6)
Blood and lymphatic system disorders			
- Total	15 (33.3)	14 (31.1)	1 (2.2)
Febrile neutropenia	15 (33.3)	14 (31.1)	1 (2.2)
General disorders and administration site conditions			
- Total	4 (8.9)	1 (2.2)	0
Pyrexia	4 (8.9)	1 (2.2)	0
Immune system disorders			
- Total	25 (55.6)	5 (11.1)	5 (11.1)
Cytokine release syndrome	25 (55.6)	5 (11.1)	5 (11.1)
Nervous system disorders			

Group term Preferred term	All patients N=45 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	5 (11.1)	2 (4.4)	0
Seizure	3 (6.7)	1 (2.2)	0
Encephalopathy	2 (4.4)	1 (2.2)	0
Renal and urinary disorders			
- Total	2 (4.4)	2 (4.4)	0
Acute kidney injury	2 (4.4)	2 (4.4)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (4.4)	1 (2.2)	0
Hypoxia	2 (4.4)	1 (2.2)	0
Vascular disorders			
- Total	5 (11.1)	4 (8.9)	1 (2.2)
Hypotension	5 (11.1)	4 (8.9)	1 (2.2)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	43 (67.2)	20 (31.3)	13 (20.3)
Blood and lymphatic system disorders			
- Total	21 (32.8)	21 (32.8)	0
Febrile neutropenia	21 (32.8)	21 (32.8)	0
General disorders and administration site conditions			
- Total	2 (3.1)	0	0
Pyrexia	2 (3.1)	0	0
Immune system disorders			
- Total	41 (64.1)	8 (12.5)	10 (15.6)
Cytokine release syndrome	41 (64.1)	8 (12.5)	10 (15.6)
Nervous system disorders			

Group term Preferred term	All patients N=64 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	7 (10.9)	3 (4.7)	0
Encephalopathy	4 (6.3)	2 (3.1)	0
Seizure	3 (4.7)	1 (1.6)	0
Renal and urinary disorders			
- Total	3 (4.7)	2 (3.1)	1 (1.6)
Acute kidney injury	3 (4.7)	2 (3.1)	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.3)	1 (1.6)	1 (1.6)
Hypoxia	4 (6.3)	1 (1.6)	1 (1.6)
Vascular disorders			
- Total	7 (10.9)	4 (6.3)	3 (4.7)
Hypotension	7 (10.9)	4 (6.3)	3 (4.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Region: US

	All patients N=56		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (16.1)	5 (8.9)	0
Blood and lymphatic system disorders			
- Total	3 (5.4)	3 (5.4)	0
Febrile neutropenia	3 (5.4)	3 (5.4)	0
General disorders and administration site conditions			
- Total	5 (8.9)	1 (1.8)	0
Pyrexia	5 (8.9)	1 (1.8)	0
Renal and urinary disorders			
- Total	1 (1.8)	1 (1.8)	0
Acute kidney injury	1 (1.8)	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Region: US

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (5.9)	1 (2.9)	1 (2.9)
Blood and lymphatic system disorders			
- Total	1 (2.9)	0	1 (2.9)
Febrile neutropenia	1 (2.9)	0	1 (2.9)
Nervous system disorders			
- Total	1 (2.9)	1 (2.9)	0
Seizure	1 (2.9)	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing=Any time post CTL019 infusion Sub group=Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	48 (75.0)	23 (35.9)	14 (21.9)
Blood and lymphatic system disorders			
- Total	23 (35.9)	22 (34.4)	1 (1.6)
Febrile neutropenia	23 (35.9)	22 (34.4)	1 (1.6)
General disorders and administration site conditions			
- Total	7 (10.9)	1 (1.6)	0
Pyrexia	7 (10.9)	1 (1.6)	0
Immune system disorders			
- Total	41 (64.1)	8 (12.5)	10 (15.6)
Cytokine release syndrome	41 (64.1)	8 (12.5)	10 (15.6)
Nervous system disorders			

Group term Preferred term	All patients N=64 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	8 (12.5)	4 (6.3)	0
Encephalopathy	4 (6.3)	2 (3.1)	0
Seizure	4 (6.3)	2 (3.1)	0
Renal and urinary disorders			
- Total	4 (6.3)	3 (4.7)	1 (1.6)
Acute kidney injury	4 (6.3)	3 (4.7)	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.3)	1 (1.6)	1 (1.6)
Hypoxia	4 (6.3)	1 (1.6)	1 (1.6)
Vascular disorders			
- Total	7 (10.9)	4 (6.3)	3 (4.7)
Hypotension	7 (10.9)	4 (6.3)	3 (4.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	17 (60.7)	8 (28.6)	4 (14.3)
Blood and lymphatic system disorders			
- Total	9 (32.1)	9 (32.1)	0
Febrile neutropenia	9 (32.1)	9 (32.1)	0
General disorders and administration site conditions			
- Total	1 (3.6)	0	0
Pyrexia	1 (3.6)	0	0
Immune system disorders			
- Total	17 (60.7)	4 (14.3)	2 (7.1)
Cytokine release syndrome	17 (60.7)	4 (14.3)	2 (7.1)
Nervous system disorders			

Group term Preferred term	All patients N=28 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	3 (10.7)	2 (7.1)	0
Encephalopathy	2 (7.1)	1 (3.6)	0
Seizure	1 (3.6)	1 (3.6)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (7.1)	0	0
Hypoxia	2 (7.1)	0	0
Vascular disorders			
- Total	4 (14.3)	2 (7.1)	2 (7.1)
Hypotension	4 (14.3)	2 (7.1)	2 (7.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	26 (72.2)	12 (33.3)	9 (25.0)
Blood and lymphatic system disorders			
- Total	12 (33.3)	12 (33.3)	0
Febrile neutropenia	12 (33.3)	12 (33.3)	0
General disorders and administration site conditions			
- Total	1 (2.8)	0	0
Pyrexia	1 (2.8)	0	0
Immune system disorders			
- Total	24 (66.7)	4 (11.1)	8 (22.2)
Cytokine release syndrome	24 (66.7)	4 (11.1)	8 (22.2)
Nervous system disorders			

Group term Preferred term	All patients N=36 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	4 (11.1)	1 (2.8)	0
Encephalopathy	2 (5.6)	1 (2.8)	0
Seizure	2 (5.6)	0	0
Renal and urinary disorders			
- Total	3 (8.3)	2 (5.6)	1 (2.8)
Acute kidney injury	3 (8.3)	2 (5.6)	1 (2.8)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.6)	1 (2.8)	1 (2.8)
Hypoxia	2 (5.6)	1 (2.8)	1 (2.8)
Vascular disorders			
- Total	3 (8.3)	2 (5.6)	1 (2.8)
Hypotension	3 (8.3)	2 (5.6)	1 (2.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Prior SCT therapy: Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (12.0)	1 (4.0)	0
Blood and lymphatic system disorders			
- Total	1 (4.0)	1 (4.0)	0
Febrile neutropenia	1 (4.0)	1 (4.0)	0
General disorders and administration site conditions			
- Total	2 (8.0)	0	0
Pyrexia	2 (8.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Prior SCT therapy: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (19.4)	4 (12.9)	0
Blood and lymphatic system disorders			
- Total	2 (6.5)	2 (6.5)	0
Febrile neutropenia	2 (6.5)	2 (6.5)	0
General disorders and administration site conditions			
- Total	3 (9.7)	1 (3.2)	0
Pyrexia	3 (9.7)	1 (3.2)	0
Renal and urinary disorders			
- Total	1 (3.2)	1 (3.2)	0
Acute kidney injury	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Prior SCT therapy: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (7.1)	1 (7.1)	0
Nervous system disorders			
- Total	1 (7.1)	1 (7.1)	0
Seizure	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Prior SCT therapy: No

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (5.0)	0	1 (5.0)
Blood and lymphatic system disorders			
- Total	1 (5.0)	0	1 (5.0)
Febrile neutropenia	1 (5.0)	0	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing=Any time post CTL019 infusion Sub group=Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (67.9)	10 (35.7)	4 (14.3)
Blood and lymphatic system disorders			
- Total	10 (35.7)	10 (35.7)	0
Febrile neutropenia	10 (35.7)	10 (35.7)	0
General disorders and administration site conditions			
- Total	3 (10.7)	0	0
Pyrexia	3 (10.7)	0	0
Immune system disorders			
- Total	17 (60.7)	4 (14.3)	2 (7.1)
Cytokine release syndrome	17 (60.7)	4 (14.3)	2 (7.1)
Nervous system disorders			

Group term Preferred term	All patients N=28 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	4 (14.3)	3 (10.7)	0
Encephalopathy	2 (7.1)	1 (3.6)	0
Seizure	2 (7.1)	2 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (7.1)	0	0
Hypoxia	2 (7.1)	0	0
Vascular disorders			
- Total	4 (14.3)	2 (7.1)	2 (7.1)
Hypotension	4 (14.3)	2 (7.1)	2 (7.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing=Any time post CTL019 infusion Sub group=Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (80.6)	13 (36.1)	10 (27.8)
Blood and lymphatic system disorders			
- Total	13 (36.1)	12 (33.3)	1 (2.8)
Febrile neutropenia	13 (36.1)	12 (33.3)	1 (2.8)
General disorders and administration site conditions			
- Total	4 (11.1)	1 (2.8)	0
Pyrexia	4 (11.1)	1 (2.8)	0
Immune system disorders			
- Total	24 (66.7)	4 (11.1)	8 (22.2)
Cytokine release syndrome	24 (66.7)	4 (11.1)	8 (22.2)
Nervous system disorders			

Group term Preferred term	All patients N=36 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	4 (11.1)	1 (2.8)	0
Encephalopathy	2 (5.6)	1 (2.8)	0
Seizure	2 (5.6)	0	0
Renal and urinary disorders			
- Total	4 (11.1)	3 (8.3)	1 (2.8)
Acute kidney injury	4 (11.1)	3 (8.3)	1 (2.8)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.6)	1 (2.8)	1 (2.8)
Hypoxia	2 (5.6)	1 (2.8)	1 (2.8)
Vascular disorders			
- Total	3 (8.3)	2 (5.6)	1 (2.8)
Hypotension	3 (8.3)	2 (5.6)	1 (2.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (78.6)	8 (57.1)	1 (7.1)
Blood and lymphatic system disorders			
- Total	8 (57.1)	8 (57.1)	0
Febrile neutropenia	8 (57.1)	8 (57.1)	0
Immune system disorders			
- Total	9 (64.3)	2 (14.3)	1 (7.1)
Cytokine release syndrome	9 (64.3)	2 (14.3)	1 (7.1)
Renal and urinary disorders			
- Total	1 (7.1)	1 (7.1)	0
Acute kidney injury	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	2 (14.3)	1 (7.1)	0
Hypoxia	2 (14.3)	1 (7.1)	0
Vascular disorders			
- Total	1 (7.1)	1 (7.1)	0
Hypotension	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	32 (64.0)	12 (24.0)	12 (24.0)
Blood and lymphatic system disorders			
- Total	13 (26.0)	13 (26.0)	0
Febrile neutropenia	13 (26.0)	13 (26.0)	0
General disorders and administration site conditions			
- Total	2 (4.0)	0	0
Pyrexia	2 (4.0)	0	0
Immune system disorders			
- Total	32 (64.0)	6 (12.0)	9 (18.0)
Cytokine release syndrome	32 (64.0)	6 (12.0)	9 (18.0)
Nervous system disorders			

Group term Preferred term	All patients N=50 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	7 (14.0)	3 (6.0)	0
Encephalopathy	4 (8.0)	2 (4.0)	0
Seizure	3 (6.0)	1 (2.0)	0
Renal and urinary disorders			
- Total	2 (4.0)	1 (2.0)	1 (2.0)
Acute kidney injury	2 (4.0)	1 (2.0)	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (4.0)	0	1 (2.0)
Hypoxia	2 (4.0)	0	1 (2.0)
Vascular disorders			
- Total	6 (12.0)	3 (6.0)	3 (6.0)
Hypotension	6 (12.0)	3 (6.0)	3 (6.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Eligibility for SCT: Yes

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (16.7)	1 (8.3)	0
Blood and lymphatic system disorders			
- Total	1 (8.3)	1 (8.3)	0
Febrile neutropenia	1 (8.3)	1 (8.3)	0
General disorders and administration site conditions			
- Total	1 (8.3)	0	0
Pyrexia	1 (8.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Eligibility for SCT: No

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (15.9)	4 (9.1)	0
Blood and lymphatic system disorders			
- Total	2 (4.5)	2 (4.5)	0
Febrile neutropenia	2 (4.5)	2 (4.5)	0
General disorders and administration site conditions			
- Total	4 (9.1)	1 (2.3)	0
Pyrexia	4 (9.1)	1 (2.3)	0
Renal and urinary disorders			
- Total	1 (2.3)	1 (2.3)	0
Acute kidney injury	1 (2.3)	1 (2.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Eligibility for SCT: Yes

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Eligibility for SCT: No

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (8.0)	1 (4.0)	1 (4.0)
Blood and lymphatic system disorders			
- Total	1 (4.0)	0	1 (4.0)
Febrile neutropenia	1 (4.0)	0	1 (4.0)
Nervous system disorders			
- Total	1 (4.0)	1 (4.0)	0
Seizure	1 (4.0)	1 (4.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing=Any time post CTL019 infusion Sub group=Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (85.7)	9 (64.3)	1 (7.1)
Blood and lymphatic system disorders			
- Total	9 (64.3)	9 (64.3)	0
Febrile neutropenia	9 (64.3)	9 (64.3)	0
General disorders and administration site conditions			
- Total	1 (7.1)	0	0
Pyrexia	1 (7.1)	0	0
Immune system disorders			
- Total	9 (64.3)	2 (14.3)	1 (7.1)
Cytokine release syndrome	9 (64.3)	2 (14.3)	1 (7.1)
Renal and urinary disorders			

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (7.1)	1 (7.1)	0
Acute kidney injury	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (14.3)	1 (7.1)	0
Hypoxia	2 (14.3)	1 (7.1)	0
Vascular disorders			
- Total	1 (7.1)	1 (7.1)	0
Hypotension	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing=Any time post CTL019 infusion Sub group=Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	36 (72.0)	14 (28.0)	13 (26.0)
Blood and lymphatic system disorders			
- Total	14 (28.0)	13 (26.0)	1 (2.0)
Febrile neutropenia	14 (28.0)	13 (26.0)	1 (2.0)
General disorders and administration site conditions			
- Total	6 (12.0)	1 (2.0)	0
Pyrexia	6 (12.0)	1 (2.0)	0
Immune system disorders			
- Total	32 (64.0)	6 (12.0)	9 (18.0)
Cytokine release syndrome	32 (64.0)	6 (12.0)	9 (18.0)
Nervous system disorders			

Group term Preferred term	All patients N=50 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	8 (16.0)	4 (8.0)	0
Encephalopathy	4 (8.0)	2 (4.0)	0
Seizure	4 (8.0)	2 (4.0)	0
Renal and urinary disorders			
- Total	3 (6.0)	2 (4.0)	1 (2.0)
Acute kidney injury	3 (6.0)	2 (4.0)	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (4.0)	0	1 (2.0)
Hypoxia	2 (4.0)	0	1 (2.0)
Vascular disorders			
- Total	6 (12.0)	3 (6.0)	3 (6.0)
Hypotension	6 (12.0)	3 (6.0)	3 (6.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (70.0)	8 (40.0)	3 (15.0)
Blood and lymphatic system disorders			
- Total	8 (40.0)	8 (40.0)	0
Febrile neutropenia	8 (40.0)	8 (40.0)	0
Immune system disorders			
- Total	14 (70.0)	3 (15.0)	2 (10.0)
Cytokine release syndrome	14 (70.0)	3 (15.0)	2 (10.0)
Nervous system disorders			
- Total	4 (20.0)	1 (5.0)	0
Encephalopathy	3 (15.0)	1 (5.0)	0
Seizure	1 (5.0)	0	0

Group term Preferred term	All patients N=20 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (10.0)	0	0
Hypoxia	2 (10.0)	0	0
Vascular disorders			
- Total	4 (20.0)	3 (15.0)	1 (5.0)
Hypotension	4 (20.0)	3 (15.0)	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (65.9)	12 (27.3)	10 (22.7)
Blood and lymphatic system disorders			
- Total	13 (29.5)	13 (29.5)	0
Febrile neutropenia	13 (29.5)	13 (29.5)	0
General disorders and administration site conditions			
- Total	2 (4.5)	0	0
Pyrexia	2 (4.5)	0	0
Immune system disorders			
- Total	27 (61.4)	5 (11.4)	8 (18.2)
Cytokine release syndrome	27 (61.4)	5 (11.4)	8 (18.2)
Nervous system disorders			

Group term Preferred term	All patients N=44 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	3 (6.8)	2 (4.5)	0
Seizure	2 (4.5)	1 (2.3)	0
Encephalopathy	1 (2.3)	1 (2.3)	0
Renal and urinary disorders			
- Total	3 (6.8)	2 (4.5)	1 (2.3)
Acute kidney injury	3 (6.8)	2 (4.5)	1 (2.3)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (4.5)	1 (2.3)	1 (2.3)
Hypoxia	2 (4.5)	1 (2.3)	1 (2.3)
Vascular disorders			
- Total	3 (6.8)	1 (2.3)	2 (4.5)
Hypotension	3 (6.8)	1 (2.3)	2 (4.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (25.0)	3 (15.0)	0
Blood and lymphatic system disorders			
- Total	2 (10.0)	2 (10.0)	0
Febrile neutropenia	2 (10.0)	2 (10.0)	0
General disorders and administration site conditions			
- Total	3 (15.0)	1 (5.0)	0
Pyrexia	3 (15.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Baseline bone marrow tumor burden: High

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (11.1)	2 (5.6)	0
Blood and lymphatic system disorders			
- Total	1 (2.8)	1 (2.8)	0
Febrile neutropenia	1 (2.8)	1 (2.8)	0
General disorders and administration site conditions			
- Total	2 (5.6)	0	0
Pyrexia	2 (5.6)	0	0
Renal and urinary disorders			
- Total	1 (2.8)	1 (2.8)	0
Acute kidney injury	1 (2.8)	1 (2.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Baseline bone marrow tumor burden: Low

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (7.1)	1 (7.1)	0
Nervous system disorders			
- Total	1 (7.1)	1 (7.1)	0
Seizure	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Baseline bone marrow tumor burden: High

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (5.0)	0	1 (5.0)
Blood and lymphatic system disorders			
- Total	1 (5.0)	0	1 (5.0)
Febrile neutropenia	1 (5.0)	0	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing=Any time post CTL019 infusion Sub group=Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (80.0)	10 (50.0)	3 (15.0)
Blood and lymphatic system disorders			
- Total	8 (40.0)	8 (40.0)	0
Febrile neutropenia	8 (40.0)	8 (40.0)	0
General disorders and administration site conditions			
- Total	3 (15.0)	1 (5.0)	0
Pyrexia	3 (15.0)	1 (5.0)	0
Immune system disorders			
- Total	14 (70.0)	3 (15.0)	2 (10.0)
Cytokine release syndrome	14 (70.0)	3 (15.0)	2 (10.0)
Nervous system disorders			

Group term Preferred term	All patients N=20 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	5 (25.0)	2 (10.0)	0
Encephalopathy	3 (15.0)	1 (5.0)	0
Seizure	2 (10.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (10.0)	0	0
Hypoxia	2 (10.0)	0	0
Vascular disorders			
- Total	4 (20.0)	3 (15.0)	1 (5.0)
Hypotension	4 (20.0)	3 (15.0)	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing=Any time post CTL019 infusion Sub group=Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	32 (72.7)	13 (29.5)	11 (25.0)
Blood and lymphatic system disorders			
- Total	15 (34.1)	14 (31.8)	1 (2.3)
Febrile neutropenia	15 (34.1)	14 (31.8)	1 (2.3)
General disorders and administration site conditions			
- Total	4 (9.1)	0	0
Pyrexia	4 (9.1)	0	0
Immune system disorders			
- Total	27 (61.4)	5 (11.4)	8 (18.2)
Cytokine release syndrome	27 (61.4)	5 (11.4)	8 (18.2)
Nervous system disorders			

Group term Preferred term	All patients N=44 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	3 (6.8)	2 (4.5)	0
Seizure	2 (4.5)	1 (2.3)	0
Encephalopathy	1 (2.3)	1 (2.3)	0
Renal and urinary disorders			
- Total	4 (9.1)	3 (6.8)	1 (2.3)
Acute kidney injury	4 (9.1)	3 (6.8)	1 (2.3)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (4.5)	1 (2.3)	1 (2.3)
Hypoxia	2 (4.5)	1 (2.3)	1 (2.3)
Vascular disorders			
- Total	3 (6.8)	1 (2.3)	2 (4.5)
Hypotension	3 (6.8)	1 (2.3)	2 (4.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (60.0)	1 (20.0)	1 (20.0)
Blood and lymphatic system disorders			
- Total	1 (20.0)	1 (20.0)	0
Febrile neutropenia	1 (20.0)	1 (20.0)	0
Immune system disorders			
- Total	3 (60.0)	0	1 (20.0)
Cytokine release syndrome	3 (60.0)	0	1 (20.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	40 (67.8)	19 (32.2)	12 (20.3)
Blood and lymphatic system disorders			
- Total	20 (33.9)	20 (33.9)	0
Febrile neutropenia	20 (33.9)	20 (33.9)	0
General disorders and administration site conditions			
- Total	2 (3.4)	0	0
Pyrexia	2 (3.4)	0	0
Immune system disorders			
- Total	38 (64.4)	8 (13.6)	9 (15.3)
Cytokine release syndrome	38 (64.4)	8 (13.6)	9 (15.3)
Nervous system disorders			

Group term Preferred term	All patients N=59 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	7 (11.9)	3 (5.1)	0
Encephalopathy	4 (6.8)	2 (3.4)	0
Seizure	3 (5.1)	1 (1.7)	0
Renal and urinary disorders			
- Total	3 (5.1)	2 (3.4)	1 (1.7)
Acute kidney injury	3 (5.1)	2 (3.4)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.8)	1 (1.7)	1 (1.7)
Hypoxia	4 (6.8)	1 (1.7)	1 (1.7)
Vascular disorders			
- Total	7 (11.9)	4 (6.8)	3 (5.1)
Hypotension	7 (11.9)	4 (6.8)	3 (5.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Baseline extramedullary disease presence: No

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (17.6)	5 (9.8)	0
Blood and lymphatic system disorders			
- Total	3 (5.9)	3 (5.9)	0
Febrile neutropenia	3 (5.9)	3 (5.9)	0
General disorders and administration site conditions			
- Total	5 (9.8)	1 (2.0)	0
Pyrexia	5 (9.8)	1 (2.0)	0
Renal and urinary disorders			
- Total	1 (2.0)	1 (2.0)	0
Acute kidney injury	1 (2.0)	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Baseline extramedullary disease presence: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (66.7)	1 (33.3)	1 (33.3)
Blood and lymphatic system disorders			
- Total	1 (33.3)	0	1 (33.3)
Febrile neutropenia	1 (33.3)	0	1 (33.3)
Nervous system disorders			
- Total	1 (33.3)	1 (33.3)	0
Seizure	1 (33.3)	1 (33.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Baseline extramedullary disease presence: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing=Any time post CTL019 infusion Sub group=Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (100)	2 (40.0)	2 (40.0)
Blood and lymphatic system disorders			
- Total	2 (40.0)	1 (20.0)	1 (20.0)
Febrile neutropenia	2 (40.0)	1 (20.0)	1 (20.0)
Immune system disorders			
- Total	3 (60.0)	0	1 (20.0)
Cytokine release syndrome	3 (60.0)	0	1 (20.0)
Nervous system disorders			
- Total	1 (20.0)	1 (20.0)	0
Seizure	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing=Any time post CTL019 infusion Sub group=Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	43 (72.9)	21 (35.6)	12 (20.3)
Blood and lymphatic system disorders			
- Total	21 (35.6)	21 (35.6)	0
Febrile neutropenia	21 (35.6)	21 (35.6)	0
General disorders and administration site conditions			
- Total	7 (11.9)	1 (1.7)	0
Pyrexia	7 (11.9)	1 (1.7)	0
Immune system disorders			
- Total	38 (64.4)	8 (13.6)	9 (15.3)
Cytokine release syndrome	38 (64.4)	8 (13.6)	9 (15.3)
Nervous system disorders			

Group term Preferred term	All patients N=59 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	7 (11.9)	3 (5.1)	0
Encephalopathy	4 (6.8)	2 (3.4)	0
Seizure	3 (5.1)	1 (1.7)	0
Renal and urinary disorders			
- Total	4 (6.8)	3 (5.1)	1 (1.7)
Acute kidney injury	4 (6.8)	3 (5.1)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.8)	1 (1.7)	1 (1.7)
Hypoxia	4 (6.8)	1 (1.7)	1 (1.7)
Vascular disorders			
- Total	7 (11.9)	4 (6.8)	3 (5.1)
Hypotension	7 (11.9)	4 (6.8)	3 (5.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (50.0)	2 (50.0)	0
Blood and lymphatic system disorders			
- Total	2 (50.0)	2 (50.0)	0
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Immune system disorders			
- Total	2 (50.0)	0	0
Cytokine release syndrome	2 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	0
Vascular disorders			

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (25.0)	1 (25.0)	0
Hypotension	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	41 (68.3)	18 (30.0)	13 (21.7)
Blood and lymphatic system disorders			
- Total	19 (31.7)	19 (31.7)	0
Febrile neutropenia	19 (31.7)	19 (31.7)	0
General disorders and administration site conditions			
- Total	2 (3.3)	0	0
Pyrexia	2 (3.3)	0	0
Immune system disorders			
- Total	39 (65.0)	8 (13.3)	10 (16.7)
Cytokine release syndrome	39 (65.0)	8 (13.3)	10 (16.7)
Nervous system disorders			

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	7 (11.7)	3 (5.0)	0
Encephalopathy	4 (6.7)	2 (3.3)	0
Seizure	3 (5.0)	1 (1.7)	0
Renal and urinary disorders			
- Total	3 (5.0)	2 (3.3)	1 (1.7)
Acute kidney injury	3 (5.0)	2 (3.3)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (5.0)	1 (1.7)	1 (1.7)
Hypoxia	3 (5.0)	1 (1.7)	1 (1.7)
Vascular disorders			
- Total	6 (10.0)	3 (5.0)	3 (5.0)
Hypotension	6 (10.0)	3 (5.0)	3 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
- Total	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Down syndrome: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (15.4)	4 (7.7)	0
Blood and lymphatic system disorders			
- Total	3 (5.8)	3 (5.8)	0
Febrile neutropenia	3 (5.8)	3 (5.8)	0
General disorders and administration site conditions			
- Total	4 (7.7)	0	0
Pyrexia	4 (7.7)	0	0
Renal and urinary disorders			
- Total	1 (1.9)	1 (1.9)	0
Acute kidney injury	1 (1.9)	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Down syndrome: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Down syndrome: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (6.5)	1 (3.2)	1 (3.2)
Blood and lymphatic system disorders			
- Total	1 (3.2)	0	1 (3.2)
Febrile neutropenia	1 (3.2)	0	1 (3.2)
Nervous system disorders			
- Total	1 (3.2)	1 (3.2)	0
Seizure	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing=Any time post CTL019 infusion Sub group=Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (75.0)	3 (75.0)	0
Blood and lymphatic system disorders			
- Total	2 (50.0)	2 (50.0)	0
Febrile neutropenia	2 (50.0)	2 (50.0)	0
General disorders and administration site conditions			
- Total	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Immune system disorders			
- Total	2 (50.0)	0	0
Cytokine release syndrome	2 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders			

Group term Preferred term	All patients N=4 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	0
Vascular disorders			
- Total	1 (25.0)	1 (25.0)	0
Hypotension	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing=Any time post CTL019 infusion Sub group=Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	45 (75.0)	20 (33.3)	14 (23.3)
Blood and lymphatic system disorders			
- Total	21 (35.0)	20 (33.3)	1 (1.7)
Febrile neutropenia	21 (35.0)	20 (33.3)	1 (1.7)
General disorders and administration site conditions			
- Total	6 (10.0)	0	0
Pyrexia	6 (10.0)	0	0
Immune system disorders			
- Total	39 (65.0)	8 (13.3)	10 (16.7)
Cytokine release syndrome	39 (65.0)	8 (13.3)	10 (16.7)
Nervous system disorders			

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	8 (13.3)	4 (6.7)	0
Encephalopathy	4 (6.7)	2 (3.3)	0
Seizure	4 (6.7)	2 (3.3)	0
Renal and urinary disorders			
- Total	4 (6.7)	3 (5.0)	1 (1.7)
Acute kidney injury	4 (6.7)	3 (5.0)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (5.0)	1 (1.7)	1 (1.7)
Hypoxia	3 (5.0)	1 (1.7)	1 (1.7)
Vascular disorders			
- Total	6 (10.0)	3 (5.0)	3 (5.0)
Hypotension	6 (10.0)	3 (5.0)	3 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	21 (65.6)	10 (31.3)	4 (12.5)
Blood and lymphatic system disorders			
- Total	9 (28.1)	9 (28.1)	0
Febrile neutropenia	9 (28.1)	9 (28.1)	0
Immune system disorders			
- Total	19 (59.4)	2 (6.3)	4 (12.5)
Cytokine release syndrome	19 (59.4)	2 (6.3)	4 (12.5)
Nervous system disorders			
- Total	2 (6.3)	2 (6.3)	0
Encephalopathy	1 (3.1)	1 (3.1)	0
Seizure	1 (3.1)	1 (3.1)	0

Group term Preferred term	All patients N=32 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.1)	0	0
Hypoxia	1 (3.1)	0	0
Vascular disorders			
- Total	2 (6.3)	2 (6.3)	0
Hypotension	2 (6.3)	2 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	22 (68.8)	10 (31.3)	9 (28.1)
Blood and lymphatic system disorders			
- Total	12 (37.5)	12 (37.5)	0
Febrile neutropenia	12 (37.5)	12 (37.5)	0
General disorders and administration site conditions			
- Total	2 (6.3)	0	0
Pyrexia	2 (6.3)	0	0
Immune system disorders			
- Total	22 (68.8)	6 (18.8)	6 (18.8)
Cytokine release syndrome	22 (68.8)	6 (18.8)	6 (18.8)
Nervous system disorders			

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	5 (15.6)	1 (3.1)	0
Encephalopathy	3 (9.4)	1 (3.1)	0
Seizure	2 (6.3)	0	0
Renal and urinary disorders			
- Total	3 (9.4)	2 (6.3)	1 (3.1)
Acute kidney injury	3 (9.4)	2 (6.3)	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (9.4)	1 (3.1)	1 (3.1)
Hypoxia	3 (9.4)	1 (3.1)	1 (3.1)
Vascular disorders			
- Total	5 (15.6)	2 (6.3)	3 (9.4)
Hypotension	5 (15.6)	2 (6.3)	3 (9.4)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Time since enrollment to CTL019 infusion: > Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (20.7)	3 (10.3)	0
Blood and lymphatic system disorders			
- Total	1 (3.4)	1 (3.4)	0
Febrile neutropenia	1 (3.4)	1 (3.4)	0
General disorders and administration site conditions			
- Total	4 (13.8)	1 (3.4)	0
Pyrexia	4 (13.8)	1 (3.4)	0
Renal and urinary disorders			
- Total	1 (3.4)	1 (3.4)	0
Acute kidney injury	1 (3.4)	1 (3.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Time since enrollment to CTL019 infusion: <=Median

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (11.1)	2 (7.4)	0
Blood and lymphatic system disorders			
- Total	2 (7.4)	2 (7.4)	0
Febrile neutropenia	2 (7.4)	2 (7.4)	0
General disorders and administration site conditions			
- Total	1 (3.7)	0	0
Pyrexia	1 (3.7)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Time since enrollment to CTL019 infusion: > Median

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (5.6)	0	1 (5.6)
Blood and lymphatic system disorders			
- Total	1 (5.6)	0	1 (5.6)
Febrile neutropenia	1 (5.6)	0	1 (5.6)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Time since enrollment to CTL019 infusion: <=Median

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (6.3)	1 (6.3)	0
Nervous system disorders			
- Total	1 (6.3)	1 (6.3)	0
Seizure	1 (6.3)	1 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing=Any time post CTL019 infusion Sub group=Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	24 (75.0)	12 (37.5)	5 (15.6)
Blood and lymphatic system disorders			
- Total	11 (34.4)	10 (31.3)	1 (3.1)
Febrile neutropenia	11 (34.4)	10 (31.3)	1 (3.1)
General disorders and administration site conditions			
- Total	4 (12.5)	1 (3.1)	0
Pyrexia	4 (12.5)	1 (3.1)	0
Immune system disorders			
- Total	19 (59.4)	2 (6.3)	4 (12.5)
Cytokine release syndrome	19 (59.4)	2 (6.3)	4 (12.5)
Nervous system disorders			

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	2 (6.3)	2 (6.3)	0
Encephalopathy	1 (3.1)	1 (3.1)	0
Seizure	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			
- Total	1 (3.1)	1 (3.1)	0
Acute kidney injury	1 (3.1)	1 (3.1)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.1)	0	0
Hypoxia	1 (3.1)	0	0
Vascular disorders			
- Total	2 (6.3)	2 (6.3)	0
Hypotension	2 (6.3)	2 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing=Any time post CTL019 infusion Sub group=Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	24 (75.0)	11 (34.4)	9 (28.1)
Blood and lymphatic system disorders			
- Total	12 (37.5)	12 (37.5)	0
Febrile neutropenia	12 (37.5)	12 (37.5)	0
General disorders and administration site conditions			
- Total	3 (9.4)	0	0
Pyrexia	3 (9.4)	0	0
Immune system disorders			
- Total	22 (68.8)	6 (18.8)	6 (18.8)
Cytokine release syndrome	22 (68.8)	6 (18.8)	6 (18.8)
Nervous system disorders			

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	6 (18.8)	2 (6.3)	0
Encephalopathy	3 (9.4)	1 (3.1)	0
Seizure	3 (9.4)	1 (3.1)	0
Renal and urinary disorders			
- Total	3 (9.4)	2 (6.3)	1 (3.1)
Acute kidney injury	3 (9.4)	2 (6.3)	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (9.4)	1 (3.1)	1 (3.1)
Hypoxia	3 (9.4)	1 (3.1)	1 (3.1)
Vascular disorders			
- Total	5 (15.6)	2 (6.3)	3 (9.4)
Hypotension	5 (15.6)	2 (6.3)	3 (9.4)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	2 (28.6)	3 (42.9)
Blood and lymphatic system disorders			
- Total	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Immune system disorders			
- Total	5 (71.4)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	3 (42.9)
Vascular disorders			
- Total	2 (28.6)	2 (28.6)	0
Hypotension	2 (28.6)	2 (28.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (70.0)	6 (30.0)	5 (25.0)
Blood and lymphatic system disorders			
- Total	8 (40.0)	8 (40.0)	0
Febrile neutropenia	8 (40.0)	8 (40.0)	0
Immune system disorders			
- Total	14 (70.0)	2 (10.0)	4 (20.0)
Cytokine release syndrome	14 (70.0)	2 (10.0)	4 (20.0)
Nervous system disorders			
- Total	3 (15.0)	1 (5.0)	0
Encephalopathy	2 (10.0)	1 (5.0)	0
Seizure	1 (5.0)	0	0

Group term Preferred term	All patients N=20 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal and urinary disorders			
- Total	1 (5.0)	1 (5.0)	0
Acute kidney injury	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (5.0)	1 (5.0)	0
Hypoxia	1 (5.0)	1 (5.0)	0
Vascular disorders			
- Total	1 (5.0)	0	1 (5.0)
Hypotension	1 (5.0)	0	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (76.2)	9 (42.9)	2 (9.5)
Blood and lymphatic system disorders			
- Total	8 (38.1)	8 (38.1)	0
Febrile neutropenia	8 (38.1)	8 (38.1)	0
General disorders and administration site conditions			
- Total	2 (9.5)	0	0
Pyrexia	2 (9.5)	0	0
Immune system disorders			
- Total	14 (66.7)	4 (19.0)	1 (4.8)
Cytokine release syndrome	14 (66.7)	4 (19.0)	1 (4.8)
Nervous system disorders			

Group term Preferred term	All patients N=21 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	2 (9.5)	1 (4.8)	0
Encephalopathy	1 (4.8)	1 (4.8)	0
Seizure	1 (4.8)	0	0
Renal and urinary disorders			
- Total	2 (9.5)	1 (4.8)	1 (4.8)
Acute kidney injury	2 (9.5)	1 (4.8)	1 (4.8)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (9.5)	0	1 (4.8)
Hypoxia	2 (9.5)	0	1 (4.8)
Vascular disorders			
- Total	2 (9.5)	1 (4.8)	1 (4.8)
Hypotension	2 (9.5)	1 (4.8)	1 (4.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=Within 8 weeks post CTL019 infusion Sub group=Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (50.0)	3 (18.8)	3 (18.8)
Blood and lymphatic system disorders			
- Total	3 (18.8)	3 (18.8)	0
Febrile neutropenia	3 (18.8)	3 (18.8)	0
Immune system disorders			
- Total	8 (50.0)	2 (12.5)	2 (12.5)
Cytokine release syndrome	8 (50.0)	2 (12.5)	2 (12.5)
Nervous system disorders			
- Total	2 (12.5)	1 (6.3)	0
Encephalopathy	1 (6.3)	0	0
Seizure	1 (6.3)	1 (6.3)	0

Group term Preferred term	All patients N=16 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (6.3)	0	0
Hypoxia	1 (6.3)	0	0
Vascular disorders			
- Total	2 (12.5)	1 (6.3)	1 (6.3)
Hypotension	2 (12.5)	1 (6.3)	1 (6.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Number of previous relapses: 0

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (20.0)	0	0
General disorders and administration site conditions			
- Total	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (21.1)	4 (21.1)	0
Blood and lymphatic system disorders			
- Total	2 (10.5)	2 (10.5)	0
Febrile neutropenia	2 (10.5)	2 (10.5)	0
General disorders and administration site conditions			
- Total	1 (5.3)	1 (5.3)	0
Pyrexia	1 (5.3)	1 (5.3)	0
Renal and urinary disorders			
- Total	1 (5.3)	1 (5.3)	0
Acute kidney injury	1 (5.3)	1 (5.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (11.1)	1 (5.6)	0
Blood and lymphatic system disorders			
- Total	1 (5.6)	1 (5.6)	0
Febrile neutropenia	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
- Total	1 (5.6)	0	0
Pyrexia	1 (5.6)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=>8 weeks to 1 year post CTL019 infusion Sub group=Number of previous relapses: >=3

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (14.3)	0	0
General disorders and administration site conditions			
- Total	2 (14.3)	0	0
Pyrexia	2 (14.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Number of previous relapses: 0

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Number of previous relapses: 1

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (9.1)	1 (9.1)	0
Nervous system disorders			
- Total	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	1 (9.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Number of previous relapses: 2

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (10.0)	0	1 (10.0)
Blood and lymphatic system disorders			
- Total	1 (10.0)	0	1 (10.0)
Febrile neutropenia	1 (10.0)	0	1 (10.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=>1 year post CTL019 infusion Sub group=Number of previous relapses: >=3

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=Any time post CTL019 infusion Sub group=Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	2 (28.6)	3 (42.9)
Blood and lymphatic system disorders			
- Total	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
General disorders and administration site conditions			
- Total	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	0
Immune system disorders			
- Total	5 (71.4)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	3 (42.9)
Vascular disorders			

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	2 (28.6)	2 (28.6)	0
Hypotension	2 (28.6)	2 (28.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=Any time post CTL019 infusion Sub group=Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (80.0)	9 (45.0)	5 (25.0)
Blood and lymphatic system disorders			
- Total	9 (45.0)	9 (45.0)	0
Febrile neutropenia	9 (45.0)	9 (45.0)	0
General disorders and administration site conditions			
- Total	1 (5.0)	1 (5.0)	0
Pyrexia	1 (5.0)	1 (5.0)	0
Immune system disorders			
- Total	14 (70.0)	2 (10.0)	4 (20.0)
Cytokine release syndrome	14 (70.0)	2 (10.0)	4 (20.0)
Nervous system disorders			

Group term Preferred term	All patients N=20 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	4 (20.0)	2 (10.0)	0
Encephalopathy	2 (10.0)	1 (5.0)	0
Seizure	2 (10.0)	1 (5.0)	0
Renal and urinary disorders			
- Total	2 (10.0)	2 (10.0)	0
Acute kidney injury	2 (10.0)	2 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (5.0)	1 (5.0)	0
Hypoxia	1 (5.0)	1 (5.0)	0
Vascular disorders			
- Total	1 (5.0)	0	1 (5.0)
Hypotension	1 (5.0)	0	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=Any time post CTL019 infusion Sub group=Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (85.7)	9 (42.9)	3 (14.3)
Blood and lymphatic system disorders			
- Total	9 (42.9)	8 (38.1)	1 (4.8)
Febrile neutropenia	9 (42.9)	8 (38.1)	1 (4.8)
General disorders and administration site conditions			
- Total	3 (14.3)	0	0
Pyrexia	3 (14.3)	0	0
Immune system disorders			
- Total	14 (66.7)	4 (19.0)	1 (4.8)
Cytokine release syndrome	14 (66.7)	4 (19.0)	1 (4.8)
Nervous system disorders			

Group term Preferred term	All patients N=21 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	2 (9.5)	1 (4.8)	0
Encephalopathy	1 (4.8)	1 (4.8)	0
Seizure	1 (4.8)	0	0
Renal and urinary disorders			
- Total	2 (9.5)	1 (4.8)	1 (4.8)
Acute kidney injury	2 (9.5)	1 (4.8)	1 (4.8)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (9.5)	0	1 (4.8)
Hypoxia	2 (9.5)	0	1 (4.8)
Vascular disorders			
- Total	2 (9.5)	1 (4.8)	1 (4.8)
Hypotension	2 (9.5)	1 (4.8)	1 (4.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 194r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing=Any time post CTL019 infusion Sub group=Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (56.3)	3 (18.8)	3 (18.8)
Blood and lymphatic system disorders			
- Total	3 (18.8)	3 (18.8)	0
Febrile neutropenia	3 (18.8)	3 (18.8)	0
General disorders and administration site conditions			
- Total	2 (12.5)	0	0
Pyrexia	2 (12.5)	0	0
Immune system disorders			
- Total	8 (50.0)	2 (12.5)	2 (12.5)
Cytokine release syndrome	8 (50.0)	2 (12.5)	2 (12.5)
Nervous system disorders			

Group term Preferred term	All patients N=16 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	2 (12.5)	1 (6.3)	0
Encephalopathy	1 (6.3)	0	0
Seizure	1 (6.3)	1 (6.3)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (6.3)	0	0
Hypoxia	1 (6.3)	0	0
Vascular disorders			
- Total	2 (12.5)	1 (6.3)	1 (6.3)
Hypotension	2 (12.5)	1 (6.3)	1 (6.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195a
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Sub group=Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (22.7)	4 (18.2)	0
Blood and lymphatic system disorders			
- Total	4 (18.2)	4 (18.2)	0
Febrile neutropenia	4 (18.2)	4 (18.2)	0
General disorders and administration site conditions			
- Total	1 (4.5)	0	0
Pyrexia	1 (4.5)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (4.5)	0	0
Hypoxia	1 (4.5)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195a
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Sub group=Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (28.2)	8 (20.5)	1 (2.6)
Blood and lymphatic system disorders			
- Total	7 (17.9)	7 (17.9)	0
Febrile neutropenia	7 (17.9)	7 (17.9)	0
General disorders and administration site conditions			
- Total	2 (5.1)	0	0
Pyrexia	2 (5.1)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.1)	0	0
Hypoxia	2 (5.1)	0	0
Vascular disorders			
- Total	3 (7.7)	2 (5.1)	1 (2.6)

Group term Preferred term	All patients N=39 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	3 (7.7)	2 (5.1)	1 (2.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195a
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Sub group=Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (28.6)	2 (14.3)	1 (7.1)
General disorders and administration site conditions			
- Total	3 (21.4)	2 (14.3)	0
Pyrexia	3 (21.4)	2 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (14.3)	2 (14.3)	0
Hypoxia	2 (14.3)	2 (14.3)	0
Vascular disorders			
- Total	1 (7.1)	0	1 (7.1)
Hypotension	1 (7.1)	0	1 (7.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195b
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Sub group=Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (32.5)	9 (22.5)	2 (5.0)
Blood and lymphatic system disorders			
- Total	6 (15.0)	6 (15.0)	0
Febrile neutropenia	6 (15.0)	6 (15.0)	0
General disorders and administration site conditions			
- Total	5 (12.5)	2 (5.0)	0
Pyrexia	5 (12.5)	2 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (7.5)	2 (5.0)	0
Hypoxia	3 (7.5)	2 (5.0)	0
Vascular disorders			
- Total	4 (10.0)	2 (5.0)	2 (5.0)

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (10.0)	2 (5.0)	2 (5.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195b
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Sub group=Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (20.0)	5 (14.3)	0
Blood and lymphatic system disorders			
- Total	5 (14.3)	5 (14.3)	0
Febrile neutropenia	5 (14.3)	5 (14.3)	0
General disorders and administration site conditions			
- Total	1 (2.9)	0	0
Pyrexia	1 (2.9)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.7)	0	0
Hypoxia	2 (5.7)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195c
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Sub group=Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (26.7)	11 (18.3)	2 (3.3)
Blood and lymphatic system disorders			
- Total	9 (15.0)	9 (15.0)	0
Febrile neutropenia	9 (15.0)	9 (15.0)	0
General disorders and administration site conditions			
- Total	5 (8.3)	2 (3.3)	0
Pyrexia	5 (8.3)	2 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.7)	1 (1.7)	0
Hypoxia	4 (6.7)	1 (1.7)	0
Vascular disorders			
- Total	4 (6.7)	2 (3.3)	2 (3.3)

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (6.7)	2 (3.3)	2 (3.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195c
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Sub group=Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (16.7)	0	0
General disorders and administration site conditions			
- Total	1 (16.7)	0	0
Pyrexia	1 (16.7)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195c
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Sub group=Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (33.3)	3 (33.3)	0
Blood and lymphatic system disorders			
- Total	2 (22.2)	2 (22.2)	0
Febrile neutropenia	2 (22.2)	2 (22.2)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (11.1)	1 (11.1)	0
Hypoxia	1 (11.1)	1 (11.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195d
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Sub group=Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (36.7)	7 (23.3)	1 (3.3)
Blood and lymphatic system disorders			
- Total	6 (20.0)	6 (20.0)	0
Febrile neutropenia	6 (20.0)	6 (20.0)	0
General disorders and administration site conditions			
- Total	4 (13.3)	1 (3.3)	0
Pyrexia	4 (13.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (6.7)	0	0
Hypoxia	2 (6.7)	0	0
Vascular disorders			
- Total	2 (6.7)	1 (3.3)	1 (3.3)

Group term Preferred term	All patients N=30 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	2 (6.7)	1 (3.3)	1 (3.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195d
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Sub group=Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (20.0)	7 (15.6)	1 (2.2)
Blood and lymphatic system disorders			
- Total	5 (11.1)	5 (11.1)	0
Febrile neutropenia	5 (11.1)	5 (11.1)	0
General disorders and administration site conditions			
- Total	2 (4.4)	1 (2.2)	0
Pyrexia	2 (4.4)	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (6.7)	2 (4.4)	0
Hypoxia	3 (6.7)	2 (4.4)	0
Vascular disorders			
- Total	2 (4.4)	1 (2.2)	1 (2.2)

Group term Preferred term	All patients N=45 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypotension	2 (4.4)	1 (2.2)	1 (2.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195e
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Sub group=Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (25.0)	1 (12.5)	1 (12.5)
Blood and lymphatic system disorders			
- Total	1 (12.5)	1 (12.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
- Total	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (12.5)	1 (12.5)	0
Hypoxia	1 (12.5)	1 (12.5)	0
Vascular disorders			
- Total	1 (12.5)	0	1 (12.5)

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (12.5)	0	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 195e
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Sub group=Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (26.9)	13 (19.4)	1 (1.5)
Blood and lymphatic system disorders			
- Total	10 (14.9)	10 (14.9)	0
Febrile neutropenia	10 (14.9)	10 (14.9)	0
General disorders and administration site conditions			
- Total	5 (7.5)	1 (1.5)	0
Pyrexia	5 (7.5)	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.0)	1 (1.5)	0
Hypoxia	4 (6.0)	1 (1.5)	0
Vascular disorders			
- Total	3 (4.5)	2 (3.0)	1 (1.5)

Group term Preferred term	All patients N=67 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	3 (4.5)	2 (3.0)	1 (1.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195f
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Sub group=Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	0	0
General disorders and administration site conditions			
- Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195f
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Sub group=Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (26.0)	14 (19.2)	2 (2.7)
Blood and lymphatic system disorders			
- Total	11 (15.1)	11 (15.1)	0
Febrile neutropenia	11 (15.1)	11 (15.1)	0
General disorders and administration site conditions			
- Total	5 (6.8)	2 (2.7)	0
Pyrexia	5 (6.8)	2 (2.7)	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (6.8)	2 (2.7)	0
Hypoxia	5 (6.8)	2 (2.7)	0
Vascular disorders			
- Total	4 (5.5)	2 (2.7)	2 (2.7)

Group term Preferred term	All patients N=73 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (5.5)	2 (2.7)	2 (2.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195g
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Sub group=Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term **Preferred term**	**All grades** **n (%)**	**Grade 3** **n (%)**	**Grade 4** **n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195g
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Sub group=Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (27.8)	14 (19.4)	2 (2.8)
Blood and lymphatic system disorders			
- Total	11 (15.3)	11 (15.3)	0
Febrile neutropenia	11 (15.3)	11 (15.3)	0
General disorders and administration site conditions			
- Total	6 (8.3)	2 (2.8)	0
Pyrexia	6 (8.3)	2 (2.8)	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (6.9)	2 (2.8)	0
Hypoxia	5 (6.9)	2 (2.8)	0
Vascular disorders			
- Total	4 (5.6)	2 (2.8)	2 (2.8)

Group term Preferred term	All patients N=72 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypotension	4 (5.6)	2 (2.8)	2 (2.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195h
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Sub group=Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195h
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Sub group=Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (27.0)	14 (18.9)	2 (2.7)
Blood and lymphatic system disorders			
- Total	11 (14.9)	11 (14.9)	0
Febrile neutropenia	11 (14.9)	11 (14.9)	0
General disorders and administration site conditions			
- Total	6 (8.1)	2 (2.7)	0
Pyrexia	6 (8.1)	2 (2.7)	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (6.8)	2 (2.7)	0
Hypoxia	5 (6.8)	2 (2.7)	0
Vascular disorders			
- Total	4 (5.4)	2 (2.7)	2 (2.7)

Group term Preferred term	All patients N=74 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (5.4)	2 (2.7)	2 (2.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195i
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

Sub group=BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195i
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

Sub group=BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (28.2)	14 (19.7)	2 (2.8)
Blood and lymphatic system disorders			
- Total	11 (15.5)	11 (15.5)	0
Febrile neutropenia	11 (15.5)	11 (15.5)	0
General disorders and administration site conditions			
- Total	6 (8.5)	2 (2.8)	0
Pyrexia	6 (8.5)	2 (2.8)	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (7.0)	2 (2.8)	0
Hypoxia	5 (7.0)	2 (2.8)	0
Vascular disorders			
- Total	4 (5.6)	2 (2.8)	2 (2.8)

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	4 (5.6)	2 (2.8)	2 (2.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195j
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (27.3)	4 (18.2)	1 (4.5)
Blood and lymphatic system disorders			
- Total	4 (18.2)	4 (18.2)	0
Febrile neutropenia	4 (18.2)	4 (18.2)	0
General disorders and administration site conditions			
- Total	2 (9.1)	0	0
Pyrexia	2 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (4.5)	0	0
Hypoxia	1 (4.5)	0	0
Vascular disorders			
- Total	2 (9.1)	1 (4.5)	1 (4.5)

Group term Preferred term	All patients N=22 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypotension	2 (9.1)	1 (4.5)	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 195j
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (26.4)	10 (18.9)	1 (1.9)
Blood and lymphatic system disorders			
- Total	7 (13.2)	7 (13.2)	0
Febrile neutropenia	7 (13.2)	7 (13.2)	0
General disorders and administration site conditions			
- Total	4 (7.5)	2 (3.8)	0
Pyrexia	4 (7.5)	2 (3.8)	0
Respiratory, thoracic and mediastinal disorders			
- Total	4 (7.5)	2 (3.8)	0
Hypoxia	4 (7.5)	2 (3.8)	0
Vascular disorders			
- Total	2 (3.8)	1 (1.9)	1 (1.9)

Group term Preferred term	All patients N=53 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	2 (3.8)	1 (1.9)	1 (1.9)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195k
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Sub group=Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (26.7)	14 (18.7)	2 (2.7)
Blood and lymphatic system disorders			
- Total	11 (14.7)	11 (14.7)	0
Febrile neutropenia	11 (14.7)	11 (14.7)	0
General disorders and administration site conditions			
- Total	6 (8.0)	2 (2.7)	0
Pyrexia	6 (8.0)	2 (2.7)	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (6.7)	2 (2.7)	0
Hypoxia	5 (6.7)	2 (2.7)	0
Vascular disorders			
- Total	4 (5.3)	2 (2.7)	2 (2.7)

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (5.3)	2 (2.7)	2 (2.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195l
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Sub group=Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (28.1)	6 (18.8)	0
Blood and lymphatic system disorders			
- Total	4 (12.5)	4 (12.5)	0
Febrile neutropenia	4 (12.5)	4 (12.5)	0
General disorders and administration site conditions			
- Total	3 (9.4)	0	0
Pyrexia	3 (9.4)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (6.3)	0	0
Hypoxia	2 (6.3)	0	0
Vascular disorders			
- Total	2 (6.3)	2 (6.3)	0

Group term Preferred term	All patients N=32 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypotension	2 (6.3)	2 (6.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195l
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Sub group=Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (25.6)	8 (18.6)	2 (4.7)
Blood and lymphatic system disorders			
- Total	7 (16.3)	7 (16.3)	0
Febrile neutropenia	7 (16.3)	7 (16.3)	0
General disorders and administration site conditions			
- Total	3 (7.0)	2 (4.7)	0
Pyrexia	3 (7.0)	2 (4.7)	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (7.0)	2 (4.7)	0
Hypoxia	3 (7.0)	2 (4.7)	0
Vascular disorders			
- Total	2 (4.7)	0	2 (4.7)

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	2 (4.7)	0	2 (4.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 195m
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Sub group=Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (27.8)	4 (22.2)	1 (5.6)
Blood and lymphatic system disorders			
- Total	3 (16.7)	3 (16.7)	0
Febrile neutropenia	3 (16.7)	3 (16.7)	0
General disorders and administration site conditions			
- Total	2 (11.1)	2 (11.1)	0
Pyrexia	2 (11.1)	2 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (16.7)	1 (5.6)	0
Hypoxia	3 (16.7)	1 (5.6)	0
Vascular disorders			
- Total	1 (5.6)	0	1 (5.6)

Group term Preferred term	All patients N=18 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (5.6)	0	1 (5.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195m
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Sub group=Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (26.3)	10 (17.5)	1 (1.8)
Blood and lymphatic system disorders			
- Total	8 (14.0)	8 (14.0)	0
Febrile neutropenia	8 (14.0)	8 (14.0)	0
General disorders and administration site conditions			
- Total	4 (7.0)	0	0
Pyrexia	4 (7.0)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (3.5)	1 (1.8)	0
Hypoxia	2 (3.5)	1 (1.8)	0
Vascular disorders			
- Total	3 (5.3)	2 (3.5)	1 (1.8)

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	3 (5.3)	2 (3.5)	1 (1.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195n
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Sub group=Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (18.2)	3 (13.6)	0
Blood and lymphatic system disorders			
- Total	2 (9.1)	2 (9.1)	0
Febrile neutropenia	2 (9.1)	2 (9.1)	0
General disorders and administration site conditions			
- Total	1 (4.5)	0	0
Pyrexia	1 (4.5)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (9.1)	1 (4.5)	0
Hypoxia	2 (9.1)	1 (4.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195n
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Sub group=Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (30.2)	11 (20.8)	2 (3.8)
Blood and lymphatic system disorders			
- Total	9 (17.0)	9 (17.0)	0
Febrile neutropenia	9 (17.0)	9 (17.0)	0
General disorders and administration site conditions			
- Total	5 (9.4)	2 (3.8)	0
Pyrexia	5 (9.4)	2 (3.8)	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (5.7)	1 (1.9)	0
Hypoxia	3 (5.7)	1 (1.9)	0
Vascular disorders			
- Total	4 (7.5)	2 (3.8)	2 (3.8)

Group term Preferred term	All patients N=53 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (7.5)	2 (3.8)	2 (3.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195o
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Sub group=Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (14.3)	1 (14.3)	0
Blood and lymphatic system disorders			
- Total	1 (14.3)	1 (14.3)	0
Febrile neutropenia	1 (14.3)	1 (14.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195o
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Sub group=Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (27.9)	13 (19.1)	2 (2.9)
Blood and lymphatic system disorders			
- Total	10 (14.7)	10 (14.7)	0
Febrile neutropenia	10 (14.7)	10 (14.7)	0
General disorders and administration site conditions			
- Total	6 (8.8)	2 (2.9)	0
Pyrexia	6 (8.8)	2 (2.9)	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (7.4)	2 (2.9)	0
Hypoxia	5 (7.4)	2 (2.9)	0
Vascular disorders			
- Total	4 (5.9)	2 (2.9)	2 (2.9)

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	4 (5.9)	2 (2.9)	2 (2.9)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195p
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Sub group=Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (25.0)	1 (25.0)	0
Blood and lymphatic system disorders			
- Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195p
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Sub group=Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (26.8)	13 (18.3)	2 (2.8)
Blood and lymphatic system disorders			
- Total	10 (14.1)	10 (14.1)	0
Febrile neutropenia	10 (14.1)	10 (14.1)	0
General disorders and administration site conditions			
- Total	6 (8.5)	2 (2.8)	0
Pyrexia	6 (8.5)	2 (2.8)	0
Respiratory, thoracic and mediastinal disorders			
- Total	4 (5.6)	2 (2.8)	0
Hypoxia	4 (5.6)	2 (2.8)	0
Vascular disorders			
- Total	4 (5.6)	2 (2.8)	2 (2.8)

Group term Preferred term	All patients N=71 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (5.6)	2 (2.8)	2 (2.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195q
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Sub group=Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (25.0)	6 (18.8)	0
Blood and lymphatic system disorders			
- Total	5 (15.6)	5 (15.6)	0
Febrile neutropenia	5 (15.6)	5 (15.6)	0
General disorders and administration site conditions			
- Total	2 (6.3)	1 (3.1)	0
Pyrexia	2 (6.3)	1 (3.1)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (6.3)	0	0
Hypoxia	2 (6.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195q
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Sub group=Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (21.9)	5 (15.6)	0
Blood and lymphatic system disorders			
- Total	5 (15.6)	5 (15.6)	0
Febrile neutropenia	5 (15.6)	5 (15.6)	0
General disorders and administration site conditions			
- Total	2 (6.3)	0	0
Pyrexia	2 (6.3)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.1)	0	0
Hypoxia	1 (3.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195q
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Sub group=Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (45.5)	3 (27.3)	2 (18.2)
Blood and lymphatic system disorders			
- Total	1 (9.1)	1 (9.1)	0
Febrile neutropenia	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
- Total	2 (18.2)	1 (9.1)	0
Pyrexia	2 (18.2)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (18.2)	2 (18.2)	0
Hypoxia	2 (18.2)	2 (18.2)	0
Vascular disorders			

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	4 (36.4)	2 (18.2)	2 (18.2)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195r
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Sub group=Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (25.0)	1 (12.5)	1 (12.5)
Blood and lymphatic system disorders			
- Total	1 (12.5)	1 (12.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
- Total	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (12.5)	1 (12.5)	0
Hypoxia	1 (12.5)	1 (12.5)	0
Vascular disorders			
- Total	1 (12.5)	0	1 (12.5)

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (12.5)	0	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195r
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Sub group=Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (30.4)	5 (21.7)	0
Blood and lymphatic system disorders			
- Total	4 (17.4)	4 (17.4)	0
Febrile neutropenia	4 (17.4)	4 (17.4)	0
General disorders and administration site conditions			
- Total	1 (4.3)	0	0
Pyrexia	1 (4.3)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (13.0)	1 (4.3)	0
Hypoxia	3 (13.0)	1 (4.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195r
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Sub group=Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (20.8)	4 (16.7)	1 (4.2)
Blood and lymphatic system disorders			
- Total	4 (16.7)	4 (16.7)	0
Febrile neutropenia	4 (16.7)	4 (16.7)	0
General disorders and administration site conditions			
- Total	1 (4.2)	1 (4.2)	0
Pyrexia	1 (4.2)	1 (4.2)	0
Vascular disorders			
- Total	1 (4.2)	0	1 (4.2)
Hypotension	1 (4.2)	0	1 (4.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 195r
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Sub group=Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (30.0)	4 (20.0)	0
Blood and lymphatic system disorders			
- Total	2 (10.0)	2 (10.0)	0
Febrile neutropenia	2 (10.0)	2 (10.0)	0
General disorders and administration site conditions			
- Total	3 (15.0)	0	0
Pyrexia	3 (15.0)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (5.0)	0	0
Hypoxia	1 (5.0)	0	0
Vascular disorders			

Group term Preferred term	All patients N=20 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	2 (10.0)	2 (10.0)	0
Hypotension	2 (10.0)	2 (10.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 196a
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (10.0)	2 (10.0)	0
Blood and lymphatic system disorders			
- Total	2 (10.0)	2 (10.0)	0
Febrile neutropenia	2 (10.0)	2 (10.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196a
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (12.1)	4 (12.1)	0
Blood and lymphatic system disorders			
- Total	4 (12.1)	4 (12.1)	0
Febrile neutropenia	4 (12.1)	4 (12.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196a
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Age: >=18

	All patients N=8		
Group term **Preferred term**	**All grades** **n (%)**	**Grade 3** **n (%)**	**Grade 4** **n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196b
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Gender: Male

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (10.3)	3 (10.3)	0
Blood and lymphatic system disorders			
- Total	3 (10.3)	3 (10.3)	0
Febrile neutropenia	3 (10.3)	3 (10.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196b
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (9.4)	3 (9.4)	0
Blood and lymphatic system disorders			
- Total	3 (9.4)	3 (9.4)	0
Febrile neutropenia	3 (9.4)	3 (9.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196c
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Race: White

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (10.0)	5 (10.0)	0
Blood and lymphatic system disorders			
- Total	5 (10.0)	5 (10.0)	0
Febrile neutropenia	5 (10.0)	5 (10.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196c
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196c
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Race: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (16.7)	1 (16.7)	0
Blood and lymphatic system disorders			
- Total	1 (16.7)	1 (16.7)	0
Febrile neutropenia	1 (16.7)	1 (16.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196d
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Ethnicity: Hispanic or Latino

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (17.4)	4 (17.4)	0
Blood and lymphatic system disorders			
- Total	4 (17.4)	4 (17.4)	0
Febrile neutropenia	4 (17.4)	4 (17.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196d
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Ethnicity: Other

	All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (5.3)	2 (5.3)	0
Blood and lymphatic system disorders			
- Total	2 (5.3)	2 (5.3)	0
Febrile neutropenia	2 (5.3)	2 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196e
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196e
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Response status at study entry: Relapsed disease

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (11.1)	6 (11.1)	0
Blood and lymphatic system disorders			
- Total	6 (11.1)	6 (11.1)	0
Febrile neutropenia	6 (11.1)	6 (11.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196f
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196f
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (10.2)	6 (10.2)	0
Blood and lymphatic system disorders			
- Total	6 (10.2)	6 (10.2)	0
Febrile neutropenia	6 (10.2)	6 (10.2)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196g
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196g
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Mixed-lineage leukemia rearrangement: No

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (10.3)	6 (10.3)	0
Blood and lymphatic system disorders			
- Total	6 (10.3)	6 (10.3)	0
Febrile neutropenia	6 (10.3)	6 (10.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196h
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196h
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Hypodiploidy: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (10.0)	6 (10.0)	0
Blood and lymphatic system disorders			
- Total	6 (10.0)	6 (10.0)	0
Febrile neutropenia	6 (10.0)	6 (10.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196i
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (25.0)	1 (25.0)	0
Blood and lymphatic system disorders			
- Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196i
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=BCR-ABL1-like: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (8.8)	5 (8.8)	0
Blood and lymphatic system disorders			
- Total	5 (8.8)	5 (8.8)	0
Febrile neutropenia	5 (8.8)	5 (8.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196j
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196j
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (14.0)	6 (14.0)	0
Blood and lymphatic system disorders			
- Total	6 (14.0)	6 (14.0)	0
Febrile neutropenia	6 (14.0)	6 (14.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196k
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Region: US

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (9.8)	6 (9.8)	0
Blood and lymphatic system disorders			
- Total	6 (9.8)	6 (9.8)	0
Febrile neutropenia	6 (9.8)	6 (9.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196l
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (14.3)	4 (14.3)	0
Blood and lymphatic system disorders			
- Total	4 (14.3)	4 (14.3)	0
Febrile neutropenia	4 (14.3)	4 (14.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196l
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Prior SCT therapy: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (6.1)	2 (6.1)	0
Blood and lymphatic system disorders			
- Total	2 (6.1)	2 (6.1)	0
Febrile neutropenia	2 (6.1)	2 (6.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196m
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (7.1)	1 (7.1)	0
Blood and lymphatic system disorders			
- Total	1 (7.1)	1 (7.1)	0
Febrile neutropenia	1 (7.1)	1 (7.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196m
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Eligibility for SCT: No

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (10.6)	5 (10.6)	0
Blood and lymphatic system disorders			
- Total	5 (10.6)	5 (10.6)	0
Febrile neutropenia	5 (10.6)	5 (10.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196n
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Baseline bone marrow tumor burden: Low

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (9.5)	2 (9.5)	0
Blood and lymphatic system disorders			
- Total	2 (9.5)	2 (9.5)	0
Febrile neutropenia	2 (9.5)	2 (9.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196n
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Baseline bone marrow tumor burden: High

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (10.0)	4 (10.0)	0
Blood and lymphatic system disorders			
- Total	4 (10.0)	4 (10.0)	0
Febrile neutropenia	4 (10.0)	4 (10.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196o
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Baseline extramedullary disease presence: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196o
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Baseline extramedullary disease presence: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (10.5)	6 (10.5)	0
Blood and lymphatic system disorders			
- Total	6 (10.5)	6 (10.5)	0
Febrile neutropenia	6 (10.5)	6 (10.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196p
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196p
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Down syndrome: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (10.5)	6 (10.5)	0
Blood and lymphatic system disorders			
- Total	6 (10.5)	6 (10.5)	0
Febrile neutropenia	6 (10.5)	6 (10.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196q
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Time since enrollment to CTL019 infusion: > Median

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (6.5)	2 (6.5)	0
Blood and lymphatic system disorders			
- Total	2 (6.5)	2 (6.5)	0
Febrile neutropenia	2 (6.5)	2 (6.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196q
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Time since enrollment to CTL019 infusion: <=Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (10.3)	3 (10.3)	0
Blood and lymphatic system disorders			
- Total	3 (10.3)	3 (10.3)	0
Febrile neutropenia	3 (10.3)	3 (10.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196q
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Time since enrollment to CTL019 infusion: Missing

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
- Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196r
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196r
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (5.3)	1 (5.3)	0
Blood and lymphatic system disorders			
- Total	1 (5.3)	1 (5.3)	0
Febrile neutropenia	1 (5.3)	1 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196r
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Number of previous relapses: 2

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (5.3)	1 (5.3)	0
Blood and lymphatic system disorders			
- Total	1 (5.3)	1 (5.3)	0
Febrile neutropenia	1 (5.3)	1 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 196r
Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Sub group=Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (25.0)	4 (25.0)	0
Blood and lymphatic system disorders			
- Total	4 (25.0)	4 (25.0)	0
Febrile neutropenia	4 (25.0)	4 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197a
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Sub group=Age: <10 years

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197a
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Sub group=Age: >=10 years to <18 years

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (80.0)	0	4 (80.0)
Blood and lymphatic system disorders			
- Total	2 (40.0)	1 (20.0)	1 (20.0)
Febrile neutropenia	2 (40.0)	2 (40.0)	0
Neutropenia	1 (20.0)	0	1 (20.0)
Thrombocytopenia	1 (20.0)	0	1 (20.0)
Gastrointestinal disorders			
- Total	3 (60.0)	3 (60.0)	0
Colitis	2 (40.0)	2 (40.0)	0
Abdominal pain	1 (20.0)	1 (20.0)	0
Ascites	1 (20.0)	1 (20.0)	0
Gastrointestinal haemorrhage	1 (20.0)	1 (20.0)	0

Group term Preferred term	All patients N=5 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Stomatitis	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
- Total	3 (60.0)	0	2 (40.0)
Multiple organ dysfunction syndrome	2 (40.0)	0	2 (40.0)
Chills	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	0
Hepatobiliary disorders			
- Total	1 (20.0)	0	1 (20.0)
Hepatic failure	1 (20.0)	0	1 (20.0)
Infections and infestations			
- Total	4 (80.0)	0	4 (80.0)
Bronchitis	1 (20.0)	0	0
Candida sepsis	1 (20.0)	0	1 (20.0)
Klebsiella sepsis	1 (20.0)	0	1 (20.0)
Pneumonia fungal	1 (20.0)	1 (20.0)	0
Sepsis	1 (20.0)	0	1 (20.0)
Staphylococcal bacteraemia	1 (20.0)	1 (20.0)	0
Staphylococcal infection	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
- Total	1 (20.0)	0	1 (20.0)

Group term Preferred term	All patients N=5 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypernatraemia	1 (20.0)	0	1 (20.0)
Renal and urinary disorders			
- Total	1 (20.0)	0	1 (20.0)
Acute kidney injury	1 (20.0)	0	1 (20.0)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (20.0)	0	1 (20.0)
Pulmonary oedema	1 (20.0)	0	1 (20.0)
Respiratory failure	1 (20.0)	0	1 (20.0)
Vascular disorders			
- Total	3 (60.0)	2 (40.0)	1 (20.0)
Hypotension	3 (60.0)	2 (40.0)	1 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197a
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Sub group=Age: >=18

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (75.0)	0	3 (75.0)
Cardiac disorders			
- Total	1 (25.0)	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	1 (25.0)
General disorders and administration site conditions			
- Total	2 (50.0)	1 (25.0)	1 (25.0)
Multiple organ dysfunction syndrome	1 (25.0)	0	1 (25.0)
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
- Total	2 (50.0)	0	2 (50.0)
Klebsiella sepsis	1 (25.0)	0	1 (25.0)

Group term Preferred term	All patients N=4 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	1 (25.0)	0	1 (25.0)
Nervous system disorders			
- Total	1 (25.0)	1 (25.0)	0
Headache	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (50.0)	0	2 (50.0)
Hypoxia	2 (50.0)	2 (50.0)	0
Aspiration	1 (25.0)	0	1 (25.0)
Respiratory distress	1 (25.0)	0	1 (25.0)
Vascular disorders			
- Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197b
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Sub group=Gender: Male

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (70.0)	0	7 (70.0)
Blood and lymphatic system disorders			
- Total	2 (20.0)	1 (10.0)	1 (10.0)
Febrile neutropenia	2 (20.0)	2 (20.0)	0
Neutropenia	1 (10.0)	0	1 (10.0)
Thrombocytopenia	1 (10.0)	0	1 (10.0)
Cardiac disorders			
- Total	1 (10.0)	0	1 (10.0)
Cardiovascular insufficiency	1 (10.0)	0	1 (10.0)
Gastrointestinal disorders			
- Total	3 (30.0)	3 (30.0)	0
Colitis	2 (20.0)	2 (20.0)	0

Group term Preferred term	All patients N=10 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (10.0)	1 (10.0)	0
Ascites	1 (10.0)	1 (10.0)	0
Gastrointestinal haemorrhage	1 (10.0)	1 (10.0)	0
Stomatitis	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			
- Total	5 (50.0)	1 (10.0)	3 (30.0)
Multiple organ dysfunction syndrome	3 (30.0)	0	3 (30.0)
Pyrexia	2 (20.0)	1 (10.0)	0
Chills	1 (10.0)	0	0
Hepatobiliary disorders			
- Total	1 (10.0)	0	1 (10.0)
Hepatic failure	1 (10.0)	0	1 (10.0)
Infections and infestations			
- Total	6 (60.0)	0	6 (60.0)
Klebsiella sepsis	2 (20.0)	0	2 (20.0)
Bronchitis	1 (10.0)	0	0
Candida sepsis	1 (10.0)	0	1 (10.0)
Pneumonia	1 (10.0)	0	1 (10.0)
Pneumonia fungal	1 (10.0)	1 (10.0)	0
Sepsis	1 (10.0)	0	1 (10.0)

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (10.0)	1 (10.0)	0
Staphylococcal infection	1 (10.0)	0	1 (10.0)
Metabolism and nutrition disorders			
- Total	1 (10.0)	0	1 (10.0)
Hypernatraemia	1 (10.0)	0	1 (10.0)
Nervous system disorders			
- Total	1 (10.0)	1 (10.0)	0
Headache	1 (10.0)	1 (10.0)	0
Renal and urinary disorders			
- Total	1 (10.0)	0	1 (10.0)
Acute kidney injury	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (30.0)	0	3 (30.0)
Hypoxia	2 (20.0)	2 (20.0)	0
Aspiration	1 (10.0)	0	1 (10.0)
Pulmonary oedema	1 (10.0)	0	1 (10.0)
Respiratory distress	1 (10.0)	0	1 (10.0)
Respiratory failure	1 (10.0)	0	1 (10.0)
Vascular disorders			
- Total	4 (40.0)	2 (20.0)	2 (20.0)

Group term Preferred term	All patients N=10 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (40.0)	2 (20.0)	2 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197b
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Sub group=Gender: Female

	All patients N=1		
Group term **Preferred term**	**All grades** **n (%)**	**Grade 3** **n (%)**	**Grade 4** **n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197c
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Sub group=Race: White

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (62.5)	0	5 (62.5)
Blood and lymphatic system disorders			
- Total	2 (25.0)	1 (12.5)	1 (12.5)
Febrile neutropenia	2 (25.0)	2 (25.0)	0
Neutropenia	1 (12.5)	0	1 (12.5)
Thrombocytopenia	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
- Total	3 (37.5)	3 (37.5)	0
Colitis	2 (25.0)	2 (25.0)	0
Abdominal pain	1 (12.5)	1 (12.5)	0
Ascites	1 (12.5)	1 (12.5)	0
Gastrointestinal haemorrhage	1 (12.5)	1 (12.5)	0

Group term Preferred term	All patients N=8 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Stomatitis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
- Total	4 (50.0)	1 (12.5)	2 (25.0)
Multiple organ dysfunction syndrome	2 (25.0)	0	2 (25.0)
Pyrexia	2 (25.0)	1 (12.5)	0
Chills	1 (12.5)	0	0
Hepatobiliary disorders			
- Total	1 (12.5)	0	1 (12.5)
Hepatic failure	1 (12.5)	0	1 (12.5)
Infections and infestations			
- Total	5 (62.5)	0	5 (62.5)
Bronchitis	1 (12.5)	0	0
Candida sepsis	1 (12.5)	0	1 (12.5)
Klebsiella sepsis	1 (12.5)	0	1 (12.5)
Pneumonia	1 (12.5)	0	1 (12.5)
Pneumonia fungal	1 (12.5)	1 (12.5)	0
Sepsis	1 (12.5)	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (12.5)	0	1 (12.5)
Hypernatraemia	1 (12.5)	0	1 (12.5)
Renal and urinary disorders			
- Total	1 (12.5)	0	1 (12.5)
Acute kidney injury	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (25.0)	0	2 (25.0)
Aspiration	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Respiratory failure	1 (12.5)	0	1 (12.5)
Vascular disorders			
- Total	4 (50.0)	2 (25.0)	2 (25.0)
Hypotension	4 (50.0)	2 (25.0)	2 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197c
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Sub group=Race: Asian

	All patients N=1		
Group term **Preferred term**	**All grades** **n (%)**	**Grade 3** **n (%)**	**Grade 4** **n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197c
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Sub group=Race: Other

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	0	2 (100)
Cardiac disorders			
- Total	1 (50.0)	0	1 (50.0)
Cardiovascular insufficiency	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
- Total	1 (50.0)	0	1 (50.0)
Multiple organ dysfunction syndrome	1 (50.0)	0	1 (50.0)
Infections and infestations			
- Total	1 (50.0)	0	1 (50.0)
Klebsiella sepsis	1 (50.0)	0	1 (50.0)
Nervous system disorders			

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (50.0)	1 (50.0)	0
Headache	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (50.0)	0	1 (50.0)
Hypoxia	1 (50.0)	1 (50.0)	0
Respiratory distress	1 (50.0)	0	1 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197d
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Sub group=Ethnicity: Hispanic or Latino

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (60.0)	0	3 (60.0)
Blood and lymphatic system disorders			
- Total	1 (20.0)	0	1 (20.0)
Febrile neutropenia	1 (20.0)	1 (20.0)	0
Neutropenia	1 (20.0)	0	1 (20.0)
Thrombocytopenia	1 (20.0)	0	1 (20.0)
Cardiac disorders			
- Total	1 (20.0)	0	1 (20.0)
Cardiovascular insufficiency	1 (20.0)	0	1 (20.0)
Gastrointestinal disorders			
- Total	1 (20.0)	1 (20.0)	0
Gastrointestinal haemorrhage	1 (20.0)	1 (20.0)	0

Group term Preferred term	All patients N=5 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
General disorders and administration site conditions			
- Total	2 (40.0)	0	1 (20.0)
Chills	1 (20.0)	0	0
Multiple organ dysfunction syndrome	1 (20.0)	0	1 (20.0)
Pyrexia	1 (20.0)	0	0
Infections and infestations			
- Total	3 (60.0)	0	3 (60.0)
Candida sepsis	1 (20.0)	0	1 (20.0)
Klebsiella sepsis	1 (20.0)	0	1 (20.0)
Pneumonia fungal	1 (20.0)	1 (20.0)	0
Sepsis	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
- Total	1 (20.0)	0	1 (20.0)
Hypernatraemia	1 (20.0)	0	1 (20.0)
Renal and urinary disorders			
- Total	1 (20.0)	0	1 (20.0)
Acute kidney injury	1 (20.0)	0	1 (20.0)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (20.0)	0	1 (20.0)
Pulmonary oedema	1 (20.0)	0	1 (20.0)

Group term Preferred term	All patients N=5 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (20.0)	0	1 (20.0)
Vascular disorders			
- Total	2 (40.0)	1 (20.0)	1 (20.0)
Hypotension	2 (40.0)	1 (20.0)	1 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197d
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Sub group=Ethnicity: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (66.7)	0	4 (66.7)
Blood and lymphatic system disorders			
- Total	1 (16.7)	1 (16.7)	0
Febrile neutropenia	1 (16.7)	1 (16.7)	0
Gastrointestinal disorders			
- Total	2 (33.3)	2 (33.3)	0
Colitis	2 (33.3)	2 (33.3)	0
Abdominal pain	1 (16.7)	1 (16.7)	0
Ascites	1 (16.7)	1 (16.7)	0
Stomatitis	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
- Total	3 (50.0)	1 (16.7)	2 (33.3)

Group term Preferred term	All patients N=6 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Multiple organ dysfunction syndrome	2 (33.3)	0	2 (33.3)
Pyrexia	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
- Total	1 (16.7)	0	1 (16.7)
Hepatic failure	1 (16.7)	0	1 (16.7)
Infections and infestations			
- Total	3 (50.0)	0	3 (50.0)
Bronchitis	1 (16.7)	0	0
Klebsiella sepsis	1 (16.7)	0	1 (16.7)
Pneumonia	1 (16.7)	0	1 (16.7)
Staphylococcal bacteraemia	1 (16.7)	1 (16.7)	0
Staphylococcal infection	1 (16.7)	0	1 (16.7)
Nervous system disorders			
- Total	1 (16.7)	1 (16.7)	0
Headache	1 (16.7)	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (33.3)	0	2 (33.3)
Hypoxia	2 (33.3)	2 (33.3)	0
Aspiration	1 (16.7)	0	1 (16.7)
Respiratory distress	1 (16.7)	0	1 (16.7)

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
- Total	2 (33.3)	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	1 (16.7)	1 (16.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197e
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Sub group=Response status at study entry: Primary refractory

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (100)	0	1 (100)
General disorders and administration site conditions			
- Total	1 (100)	1 (100)	0
Pyrexia	1 (100)	1 (100)	0
Infections and infestations			
- Total	1 (100)	0	1 (100)
Pneumonia	1 (100)	0	1 (100)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (100)	0	1 (100)
Aspiration	1 (100)	0	1 (100)
Hypoxia	1 (100)	1 (100)	0
Vascular disorders			

Group term Preferred term	All patients N=1 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (100)	0	1 (100)
Hypotension	1 (100)	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197e
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Sub group=Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (60.0)	0	6 (60.0)
Blood and lymphatic system disorders			
- Total	2 (20.0)	1 (10.0)	1 (10.0)
Febrile neutropenia	2 (20.0)	2 (20.0)	0
Neutropenia	1 (10.0)	0	1 (10.0)
Thrombocytopenia	1 (10.0)	0	1 (10.0)
Cardiac disorders			
- Total	1 (10.0)	0	1 (10.0)
Cardiovascular insufficiency	1 (10.0)	0	1 (10.0)
Gastrointestinal disorders			
- Total	3 (30.0)	3 (30.0)	0
Colitis	2 (20.0)	2 (20.0)	0

Group term Preferred term	All patients N=10 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (10.0)	1 (10.0)	0
Ascites	1 (10.0)	1 (10.0)	0
Gastrointestinal haemorrhage	1 (10.0)	1 (10.0)	0
Stomatitis	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			
- Total	4 (40.0)	0	3 (30.0)
Multiple organ dysfunction syndrome	3 (30.0)	0	3 (30.0)
Chills	1 (10.0)	0	0
Pyrexia	1 (10.0)	0	0
Hepatobiliary disorders			
- Total	1 (10.0)	0	1 (10.0)
Hepatic failure	1 (10.0)	0	1 (10.0)
Infections and infestations			
- Total	5 (50.0)	0	5 (50.0)
Klebsiella sepsis	2 (20.0)	0	2 (20.0)
Bronchitis	1 (10.0)	0	0
Candida sepsis	1 (10.0)	0	1 (10.0)
Pneumonia fungal	1 (10.0)	1 (10.0)	0
Sepsis	1 (10.0)	0	1 (10.0)
Staphylococcal bacteraemia	1 (10.0)	1 (10.0)	0

Group term Preferred term	All patients N=10 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Staphylococcal infection	1 (10.0)	0	1 (10.0)
Metabolism and nutrition disorders			
- Total	1 (10.0)	0	1 (10.0)
Hypernatraemia	1 (10.0)	0	1 (10.0)
Nervous system disorders			
- Total	1 (10.0)	1 (10.0)	0
Headache	1 (10.0)	1 (10.0)	0
Renal and urinary disorders			
- Total	1 (10.0)	0	1 (10.0)
Acute kidney injury	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (20.0)	0	2 (20.0)
Hypoxia	1 (10.0)	1 (10.0)	0
Pulmonary oedema	1 (10.0)	0	1 (10.0)
Respiratory distress	1 (10.0)	0	1 (10.0)
Respiratory failure	1 (10.0)	0	1 (10.0)
Vascular disorders			
- Total	3 (30.0)	2 (20.0)	1 (10.0)
Hypotension	3 (30.0)	2 (20.0)	1 (10.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197f
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set – non – infused patients

Sub group=Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
- Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
- Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
- Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
- Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
- Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
- Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
- Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
- Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
- Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
- Total	4 (36.4)	2 (18.2)	2 (18.2)

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197g
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set – non – infused patients

Sub group=Mixed-lineage leukemia rearrangement: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
- Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
- Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
- Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
- Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
- Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
- Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
- Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
- Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
- Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
- Total	4 (36.4)	2 (18.2)	2 (18.2)

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197h
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Sub group=Hypodiploidy: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
- Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
- Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
- Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
- Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
- Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
- Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
- Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
- Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
- Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
- Total	4 (36.4)	2 (18.2)	2 (18.2)

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197i
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

Sub group=BCR-ABL1-like: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
- Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
- Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
- Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
- Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
- Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
- Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
- Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
- Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
- Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
- Total	4 (36.4)	2 (18.2)	2 (18.2)

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197j
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (66.7)	0	2 (66.7)
Blood and lymphatic system disorders			
- Total	1 (33.3)	0	1 (33.3)
Febrile neutropenia	1 (33.3)	1 (33.3)	0
Neutropenia	1 (33.3)	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
- Total	1 (33.3)	1 (33.3)	0
Gastrointestinal haemorrhage	1 (33.3)	1 (33.3)	0
General disorders and administration site conditions			
- Total	1 (33.3)	0	0
Chills	1 (33.3)	0	0

Group term Preferred term	All patients N=3 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pyrexia	1 (33.3)	0	0
Infections and infestations			
- Total	2 (66.7)	0	2 (66.7)
Candida sepsis	1 (33.3)	0	1 (33.3)
Pneumonia fungal	1 (33.3)	1 (33.3)	0
Sepsis	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
- Total	1 (33.3)	0	1 (33.3)
Hypernatraemia	1 (33.3)	0	1 (33.3)
Renal and urinary disorders			
- Total	1 (33.3)	0	1 (33.3)
Acute kidney injury	1 (33.3)	0	1 (33.3)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)
Vascular disorders			
- Total	2 (66.7)	1 (33.3)	1 (33.3)
Hypotension	2 (66.7)	1 (33.3)	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197j
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (62.5)	0	5 (62.5)
Blood and lymphatic system disorders			
- Total	1 (12.5)	1 (12.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
Cardiac disorders			
- Total	1 (12.5)	0	1 (12.5)
Cardiovascular insufficiency	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
- Total	2 (25.0)	2 (25.0)	0
Colitis	2 (25.0)	2 (25.0)	0
Abdominal pain	1 (12.5)	1 (12.5)	0
Ascites	1 (12.5)	1 (12.5)	0

Group term Preferred term	All patients N=8 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Stomatitis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
- Total	4 (50.0)	1 (12.5)	3 (37.5)
Multiple organ dysfunction syndrome	3 (37.5)	0	3 (37.5)
Pyrexia	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
- Total	1 (12.5)	0	1 (12.5)
Hepatic failure	1 (12.5)	0	1 (12.5)
Infections and infestations			
- Total	4 (50.0)	0	4 (50.0)
Klebsiella sepsis	2 (25.0)	0	2 (25.0)
Bronchitis	1 (12.5)	0	0
Pneumonia	1 (12.5)	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Nervous system disorders			
- Total	1 (12.5)	1 (12.5)	0
Headache	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (25.0)	0	2 (25.0)

Group term Preferred term	All patients N=8 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypoxia	2 (25.0)	2 (25.0)	0
Aspiration	1 (12.5)	0	1 (12.5)
Respiratory distress	1 (12.5)	0	1 (12.5)
Vascular disorders			
- Total	2 (25.0)	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	1 (12.5)	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197k
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Sub group=Region: US

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
- Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
- Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
- Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
- Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
- Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
- Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
- Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
- Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
- Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
- Total	4 (36.4)	2 (18.2)	2 (18.2)

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197l
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Sub group=Prior SCT therapy: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (100)	0	4 (100)
Blood and lymphatic system disorders			
- Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Cardiac disorders			
- Total	1 (25.0)	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	1 (25.0)
Gastrointestinal disorders			
- Total	2 (50.0)	2 (50.0)	0
Colitis	2 (50.0)	2 (50.0)	0
Abdominal pain	1 (25.0)	1 (25.0)	0
Ascites	1 (25.0)	1 (25.0)	0

Group term Preferred term	All patients N=4 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Stomatitis	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
- Total	4 (100)	0	3 (75.0)
Multiple organ dysfunction syndrome	3 (75.0)	0	3 (75.0)
Chills	1 (25.0)	0	0
Pyrexia	1 (25.0)	0	0
Hepatobiliary disorders			
- Total	1 (25.0)	0	1 (25.0)
Hepatic failure	1 (25.0)	0	1 (25.0)
Infections and infestations			
- Total	4 (100)	0	4 (100)
Klebsiella sepsis	2 (50.0)	0	2 (50.0)
Bronchitis	1 (25.0)	0	0
Sepsis	1 (25.0)	0	1 (25.0)
Staphylococcal bacteraemia	1 (25.0)	1 (25.0)	0
Staphylococcal infection	1 (25.0)	0	1 (25.0)
Vascular disorders			
- Total	2 (50.0)	2 (50.0)	0
Hypotension	2 (50.0)	2 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197l
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Sub group=Prior SCT therapy: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (42.9)	0	3 (42.9)
Blood and lymphatic system disorders			
- Total	1 (14.3)	0	1 (14.3)
Febrile neutropenia	1 (14.3)	1 (14.3)	0
Neutropenia	1 (14.3)	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
- Total	1 (14.3)	1 (14.3)	0
Gastrointestinal haemorrhage	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
- Total	1 (14.3)	1 (14.3)	0
Pyrexia	1 (14.3)	1 (14.3)	0

Group term Preferred term	All patients N=7 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Infections and infestations			
- Total	2 (28.6)	0	2 (28.6)
Candida sepsis	1 (14.3)	0	1 (14.3)
Pneumonia	1 (14.3)	0	1 (14.3)
Pneumonia fungal	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
- Total	1 (14.3)	0	1 (14.3)
Hypernatraemia	1 (14.3)	0	1 (14.3)
Nervous system disorders			
- Total	1 (14.3)	1 (14.3)	0
Headache	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
- Total	1 (14.3)	0	1 (14.3)
Acute kidney injury	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (42.9)	0	3 (42.9)
Hypoxia	2 (28.6)	2 (28.6)	0
Aspiration	1 (14.3)	0	1 (14.3)
Pulmonary oedema	1 (14.3)	0	1 (14.3)
Respiratory distress	1 (14.3)	0	1 (14.3)

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
- Total	2 (28.6)	0	2 (28.6)
Hypotension	2 (28.6)	0	2 (28.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197m
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Sub group=Eligibility for SCT: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (25.0)	0	1 (25.0)
General disorders and administration site conditions			
- Total	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
- Total	1 (25.0)	0	1 (25.0)
Pneumonia	1 (25.0)	0	1 (25.0)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (25.0)	0	1 (25.0)
Aspiration	1 (25.0)	0	1 (25.0)
Hypoxia	1 (25.0)	1 (25.0)	0
Vascular disorders			

Group term Preferred term	All patients N=4 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197m
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Sub group=Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (85.7)	0	6 (85.7)
Blood and lymphatic system disorders			
- Total	2 (28.6)	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Neutropenia	1 (14.3)	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	1 (14.3)
Cardiac disorders			
- Total	1 (14.3)	0	1 (14.3)
Cardiovascular insufficiency	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
- Total	3 (42.9)	3 (42.9)	0
Colitis	2 (28.6)	2 (28.6)	0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (14.3)	1 (14.3)	0
Ascites	1 (14.3)	1 (14.3)	0
Gastrointestinal haemorrhage	1 (14.3)	1 (14.3)	0
Stomatitis	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
- Total	4 (57.1)	0	3 (42.9)
Multiple organ dysfunction syndrome	3 (42.9)	0	3 (42.9)
Chills	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	0
Hepatobiliary disorders			
- Total	1 (14.3)	0	1 (14.3)
Hepatic failure	1 (14.3)	0	1 (14.3)
Infections and infestations			
- Total	5 (71.4)	0	5 (71.4)
Klebsiella sepsis	2 (28.6)	0	2 (28.6)
Bronchitis	1 (14.3)	0	0
Candida sepsis	1 (14.3)	0	1 (14.3)
Pneumonia fungal	1 (14.3)	1 (14.3)	0
Sepsis	1 (14.3)	0	1 (14.3)
Staphylococcal bacteraemia	1 (14.3)	1 (14.3)	0

Group term Preferred term	All patients N=7 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Staphylococcal infection	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
- Total	1 (14.3)	0	1 (14.3)
Hypernatraemia	1 (14.3)	0	1 (14.3)
Nervous system disorders			
- Total	1 (14.3)	1 (14.3)	0
Headache	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
- Total	1 (14.3)	0	1 (14.3)
Acute kidney injury	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (28.6)	0	2 (28.6)
Hypoxia	1 (14.3)	1 (14.3)	0
Pulmonary oedema	1 (14.3)	0	1 (14.3)
Respiratory distress	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
- Total	3 (42.9)	2 (28.6)	1 (14.3)
Hypotension	3 (42.9)	2 (28.6)	1 (14.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197n
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Sub group=Baseline bone marrow tumor burden: Low

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
- Total	1 (50.0)	1 (50.0)	0
Febrile neutropenia	1 (50.0)	1 (50.0)	0
Gastrointestinal disorders			
- Total	1 (50.0)	1 (50.0)	0
Abdominal pain	1 (50.0)	1 (50.0)	0
Ascites	1 (50.0)	1 (50.0)	0
Colitis	1 (50.0)	1 (50.0)	0
Stomatitis	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
- Total	1 (50.0)	0	1 (50.0)

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Multiple organ dysfunction syndrome	1 (50.0)	0	1 (50.0)
Hepatobiliary disorders			
- Total	1 (50.0)	0	1 (50.0)
Hepatic failure	1 (50.0)	0	1 (50.0)
Infections and infestations			
- Total	1 (50.0)	0	1 (50.0)
Bronchitis	1 (50.0)	0	0
Staphylococcal bacteraemia	1 (50.0)	1 (50.0)	0
Staphylococcal infection	1 (50.0)	0	1 (50.0)
Nervous system disorders			
- Total	1 (50.0)	1 (50.0)	0
Headache	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (50.0)	0	1 (50.0)
Hypoxia	1 (50.0)	1 (50.0)	0
Respiratory distress	1 (50.0)	0	1 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197n
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Sub group=Baseline bone marrow tumor burden: High

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (55.6)	0	5 (55.6)
Blood and lymphatic system disorders			
- Total	1 (11.1)	0	1 (11.1)
Febrile neutropenia	1 (11.1)	1 (11.1)	0
Neutropenia	1 (11.1)	0	1 (11.1)
Thrombocytopenia	1 (11.1)	0	1 (11.1)
Cardiac disorders			
- Total	1 (11.1)	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	1 (11.1)
Gastrointestinal disorders			
- Total	2 (22.2)	2 (22.2)	0
Colitis	1 (11.1)	1 (11.1)	0

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
- Total	4 (44.4)	1 (11.1)	2 (22.2)
Multiple organ dysfunction syndrome	2 (22.2)	0	2 (22.2)
Pyrexia	2 (22.2)	1 (11.1)	0
Chills	1 (11.1)	0	0
Infections and infestations			
- Total	5 (55.6)	0	5 (55.6)
Klebsiella sepsis	2 (22.2)	0	2 (22.2)
Candida sepsis	1 (11.1)	0	1 (11.1)
Pneumonia	1 (11.1)	0	1 (11.1)
Pneumonia fungal	1 (11.1)	1 (11.1)	0
Sepsis	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
- Total	1 (11.1)	0	1 (11.1)
Hypernatraemia	1 (11.1)	0	1 (11.1)
Renal and urinary disorders			
- Total	1 (11.1)	0	1 (11.1)
Acute kidney injury	1 (11.1)	0	1 (11.1)
Respiratory, thoracic and mediastinal disorders			

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	2 (22.2)	0	2 (22.2)
Aspiration	1 (11.1)	0	1 (11.1)
Hypoxia	1 (11.1)	1 (11.1)	0
Pulmonary oedema	1 (11.1)	0	1 (11.1)
Respiratory failure	1 (11.1)	0	1 (11.1)
Vascular disorders			
- Total	4 (44.4)	2 (22.2)	2 (22.2)
Hypotension	4 (44.4)	2 (22.2)	2 (22.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197o
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Sub group=Baseline extramedullary disease presence: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197o
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Sub group=Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (77.8)	0	7 (77.8)
Blood and lymphatic system disorders			
- Total	2 (22.2)	1 (11.1)	1 (11.1)
Febrile neutropenia	2 (22.2)	2 (22.2)	0
Neutropenia	1 (11.1)	0	1 (11.1)
Thrombocytopenia	1 (11.1)	0	1 (11.1)
Cardiac disorders			
- Total	1 (11.1)	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	1 (11.1)
Gastrointestinal disorders			
- Total	3 (33.3)	3 (33.3)	0
Colitis	2 (22.2)	2 (22.2)	0

Group term Preferred term	All patients N=9 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (11.1)	1 (11.1)	0
Ascites	1 (11.1)	1 (11.1)	0
Gastrointestinal haemorrhage	1 (11.1)	1 (11.1)	0
Stomatitis	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
- Total	5 (55.6)	1 (11.1)	3 (33.3)
Multiple organ dysfunction syndrome	3 (33.3)	0	3 (33.3)
Pyrexia	2 (22.2)	1 (11.1)	0
Chills	1 (11.1)	0	0
Hepatobiliary disorders			
- Total	1 (11.1)	0	1 (11.1)
Hepatic failure	1 (11.1)	0	1 (11.1)
Infections and infestations			
- Total	6 (66.7)	0	6 (66.7)
Klebsiella sepsis	2 (22.2)	0	2 (22.2)
Bronchitis	1 (11.1)	0	0
Candida sepsis	1 (11.1)	0	1 (11.1)
Pneumonia	1 (11.1)	0	1 (11.1)
Pneumonia fungal	1 (11.1)	1 (11.1)	0
Sepsis	1 (11.1)	0	1 (11.1)

Group term Preferred term	All patients N=9 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Staphylococcal bacteraemia	1 (11.1)	1 (11.1)	0
Staphylococcal infection	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
- Total	1 (11.1)	0	1 (11.1)
Hypernatraemia	1 (11.1)	0	1 (11.1)
Nervous system disorders			
- Total	1 (11.1)	1 (11.1)	0
Headache	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
- Total	1 (11.1)	0	1 (11.1)
Acute kidney injury	1 (11.1)	0	1 (11.1)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (33.3)	0	3 (33.3)
Hypoxia	2 (22.2)	2 (22.2)	0
Aspiration	1 (11.1)	0	1 (11.1)
Pulmonary oedema	1 (11.1)	0	1 (11.1)
Respiratory distress	1 (11.1)	0	1 (11.1)
Respiratory failure	1 (11.1)	0	1 (11.1)
Vascular disorders			
- Total	4 (44.4)	2 (22.2)	2 (22.2)

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (44.4)	2 (22.2)	2 (22.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197p
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Sub group=Down syndrome: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
- Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
- Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
- Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
- Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
- Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
- Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
- Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
- Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
- Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
- Total	4 (36.4)	2 (18.2)	2 (18.2)

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197q
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set – non – infused patients

Sub group=Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
- Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
- Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
- Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
- Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
- Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
- Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
- Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
- Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
- Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
- Total	4 (36.4)	2 (18.2)	2 (18.2)

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Sub group=Number of previous relapses: 0

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (100)	0	1 (100)
General disorders and administration site conditions			
- Total	1 (100)	1 (100)	0
Pyrexia	1 (100)	1 (100)	0
Infections and infestations			
- Total	1 (100)	0	1 (100)
Pneumonia	1 (100)	0	1 (100)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (100)	0	1 (100)
Aspiration	1 (100)	0	1 (100)
Hypoxia	1 (100)	1 (100)	0
Vascular disorders			

Group term Preferred term	All patients N=1 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (100)	0	1 (100)
Hypotension	1 (100)	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Sub group=Number of previous relapses: 1

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (33.3)	0	1 (33.3)
Nervous system disorders			
- Total	1 (33.3)	1 (33.3)	0
Headache	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (33.3)	0	1 (33.3)
Hypoxia	1 (33.3)	1 (33.3)	0
Respiratory distress	1 (33.3)	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Sub group=Number of previous relapses: 2

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (33.3)	0	1 (33.3)
Blood and lymphatic system disorders			
- Total	1 (33.3)	0	1 (33.3)
Febrile neutropenia	1 (33.3)	1 (33.3)	0
Neutropenia	1 (33.3)	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
- Total	1 (33.3)	1 (33.3)	0
Gastrointestinal haemorrhage	1 (33.3)	1 (33.3)	0
Infections and infestations			
- Total	1 (33.3)	0	1 (33.3)

Group term Preferred term	All patients N=3 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Candida sepsis	1 (33.3)	0	1 (33.3)
Pneumonia fungal	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders			
- Total	1 (33.3)	0	1 (33.3)
Hypernatraemia	1 (33.3)	0	1 (33.3)
Renal and urinary disorders			
- Total	1 (33.3)	0	1 (33.3)
Acute kidney injury	1 (33.3)	0	1 (33.3)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)
Vascular disorders			
- Total	1 (33.3)	0	1 (33.3)
Hypotension	1 (33.3)	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 197r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Sub group=Number of previous relapses: >=3

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (100)	0	4 (100)
Blood and lymphatic system disorders			
- Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Cardiac disorders			
- Total	1 (25.0)	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	1 (25.0)
Gastrointestinal disorders			
- Total	2 (50.0)	2 (50.0)	0
Colitis	2 (50.0)	2 (50.0)	0
Abdominal pain	1 (25.0)	1 (25.0)	0

Group term Preferred term	All patients N=4 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Ascites	1 (25.0)	1 (25.0)	0
Stomatitis	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
- Total	4 (100)	0	3 (75.0)
Multiple organ dysfunction syndrome	3 (75.0)	0	3 (75.0)
Chills	1 (25.0)	0	0
Pyrexia	1 (25.0)	0	0
Hepatobiliary disorders			
- Total	1 (25.0)	0	1 (25.0)
Hepatic failure	1 (25.0)	0	1 (25.0)
Infections and infestations			
- Total	4 (100)	0	4 (100)
Klebsiella sepsis	2 (50.0)	0	2 (50.0)
Bronchitis	1 (25.0)	0	0
Sepsis	1 (25.0)	0	1 (25.0)
Staphylococcal bacteraemia	1 (25.0)	1 (25.0)	0
Staphylococcal infection	1 (25.0)	0	1 (25.0)
Vascular disorders			
- Total	2 (50.0)	2 (50.0)	0
Hypotension	2 (50.0)	2 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198a
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Sub group=Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (81.8)	10 (45.5)	4 (18.2)
Blood and lymphatic system disorders			
- Total	10 (45.5)	10 (45.5)	0
Febrile neutropenia	10 (45.5)	10 (45.5)	0
General disorders and administration site conditions			
- Total	3 (13.6)	0	0
Pyrexia	3 (13.6)	0	0
Immune system disorders			
- Total	12 (54.5)	3 (13.6)	2 (9.1)
Cytokine release syndrome	12 (54.5)	3 (13.6)	2 (9.1)
Infections and infestations			
- Total	1 (4.5)	1 (4.5)	0

Group term Preferred term	All patients N=22 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	1 (4.5)	1 (4.5)	0
Nervous system disorders			
- Total	2 (9.1)	2 (9.1)	0
Seizure	2 (9.1)	2 (9.1)	0
Renal and urinary disorders			
- Total	1 (4.5)	1 (4.5)	0
Acute kidney injury	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (9.1)	1 (4.5)	1 (4.5)
Hypoxia	1 (4.5)	1 (4.5)	0
Respiratory failure	1 (4.5)	0	1 (4.5)
Vascular disorders			
- Total	2 (9.1)	1 (4.5)	1 (4.5)
Hypotension	2 (9.1)	1 (4.5)	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198a
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Sub group=Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	31 (79.5)	19 (48.7)	9 (23.1)
Blood and lymphatic system disorders			
- Total	21 (53.8)	20 (51.3)	1 (2.6)
Febrile neutropenia	21 (53.8)	20 (51.3)	1 (2.6)
General disorders and administration site conditions			
- Total	4 (10.3)	1 (2.6)	0
Pyrexia	4 (10.3)	1 (2.6)	0
Immune system disorders			
- Total	23 (59.0)	5 (12.8)	5 (12.8)
Cytokine release syndrome	23 (59.0)	5 (12.8)	5 (12.8)
Infections and infestations			
- Total	2 (5.1)	0	0

Group term Preferred term	All patients N=39 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	2 (5.1)	0	0
Nervous system disorders			
- Total	6 (15.4)	2 (5.1)	0
Encephalopathy	4 (10.3)	2 (5.1)	0
Seizure	2 (5.1)	0	0
Renal and urinary disorders			
- Total	3 (7.7)	2 (5.1)	1 (2.6)
Acute kidney injury	3 (7.7)	2 (5.1)	1 (2.6)
Respiratory, thoracic and mediastinal disorders			
- Total	6 (15.4)	0	3 (7.7)
Hypoxia	3 (7.7)	0	0
Respiratory failure	3 (7.7)	0	3 (7.7)
Vascular disorders			
- Total	8 (20.5)	5 (12.8)	3 (7.7)
Hypotension	8 (20.5)	5 (12.8)	3 (7.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198a
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Sub group=Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (71.4)	2 (14.3)	4 (28.6)
Blood and lymphatic system disorders			
- Total	2 (14.3)	2 (14.3)	0
Febrile neutropenia	2 (14.3)	2 (14.3)	0
General disorders and administration site conditions			
- Total	3 (21.4)	1 (7.1)	0
Pyrexia	3 (21.4)	1 (7.1)	0
Immune system disorders			
- Total	6 (42.9)	0	3 (21.4)
Cytokine release syndrome	6 (42.9)	0	3 (21.4)
Infections and infestations			

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (7.1)	0	1 (7.1)
Pneumonia	1 (7.1)	0	1 (7.1)
Renal and urinary disorders			
- Total	2 (14.3)	0	1 (7.1)
Acute kidney injury	2 (14.3)	0	1 (7.1)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (14.3)	1 (7.1)	1 (7.1)
Hypoxia	2 (14.3)	1 (7.1)	1 (7.1)
Vascular disorders			
- Total	1 (7.1)	0	1 (7.1)
Hypotension	1 (7.1)	0	1 (7.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198b
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Sub group=Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (72.5)	18 (45.0)	7 (17.5)
Blood and lymphatic system disorders			
- Total	15 (37.5)	15 (37.5)	0
Febrile neutropenia	15 (37.5)	15 (37.5)	0
General disorders and administration site conditions			
- Total	4 (10.0)	1 (2.5)	0
Pyrexia	4 (10.0)	1 (2.5)	0
Immune system disorders			
- Total	19 (47.5)	3 (7.5)	5 (12.5)
Cytokine release syndrome	19 (47.5)	3 (7.5)	5 (12.5)
Infections and infestations			
- Total	1 (2.5)	0	1 (2.5)

Group term Preferred term	All patients N=40 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	1 (2.5)	0	1 (2.5)
Nervous system disorders			
- Total	4 (10.0)	2 (5.0)	0
Encephalopathy	2 (5.0)	1 (2.5)	0
Seizure	2 (5.0)	1 (2.5)	0
Renal and urinary disorders			
- Total	1 (2.5)	0	1 (2.5)
Acute kidney injury	1 (2.5)	0	1 (2.5)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (10.0)	1 (2.5)	1 (2.5)
Hypoxia	3 (7.5)	1 (2.5)	0
Respiratory failure	1 (2.5)	0	1 (2.5)
Vascular disorders			
- Total	7 (17.5)	5 (12.5)	2 (5.0)
Hypotension	7 (17.5)	5 (12.5)	2 (5.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198b
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Sub group=Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	30 (85.7)	13 (37.1)	10 (28.6)
Blood and lymphatic system disorders			
- Total	18 (51.4)	17 (48.6)	1 (2.9)
Febrile neutropenia	18 (51.4)	17 (48.6)	1 (2.9)
General disorders and administration site conditions			
- Total	6 (17.1)	1 (2.9)	0
Pyrexia	6 (17.1)	1 (2.9)	0
Immune system disorders			
- Total	22 (62.9)	5 (14.3)	5 (14.3)
Cytokine release syndrome	22 (62.9)	5 (14.3)	5 (14.3)
Infections and infestations			
- Total	3 (8.6)	1 (2.9)	0

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	3 (8.6)	1 (2.9)	0
Nervous system disorders			
- Total	4 (11.4)	2 (5.7)	0
Encephalopathy	2 (5.7)	1 (2.9)	0
Seizure	2 (5.7)	1 (2.9)	0
Renal and urinary disorders			
- Total	5 (14.3)	3 (8.6)	1 (2.9)
Acute kidney injury	5 (14.3)	3 (8.6)	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
- Total	6 (17.1)	1 (2.9)	4 (11.4)
Hypoxia	3 (8.6)	1 (2.9)	1 (2.9)
Respiratory failure	3 (8.6)	0	3 (8.6)
Vascular disorders			
- Total	4 (11.4)	1 (2.9)	3 (8.6)
Hypotension	4 (11.4)	1 (2.9)	3 (8.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198c
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Sub group=Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	48 (80.0)	27 (45.0)	14 (23.3)
Blood and lymphatic system disorders			
- Total	26 (43.3)	26 (43.3)	0
Febrile neutropenia	26 (43.3)	26 (43.3)	0
General disorders and administration site conditions			
- Total	8 (13.3)	2 (3.3)	0
Pyrexia	8 (13.3)	2 (3.3)	0
Immune system disorders			
- Total	33 (55.0)	7 (11.7)	9 (15.0)
Cytokine release syndrome	33 (55.0)	7 (11.7)	9 (15.0)
Infections and infestations			
- Total	4 (6.7)	1 (1.7)	1 (1.7)

Group term Preferred term	All patients N=60 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	4 (6.7)	1 (1.7)	1 (1.7)
Nervous system disorders			
- Total	6 (10.0)	4 (6.7)	0
Encephalopathy	3 (5.0)	2 (3.3)	0
Seizure	3 (5.0)	2 (3.3)	0
Renal and urinary disorders			
- Total	4 (6.7)	2 (3.3)	2 (3.3)
Acute kidney injury	4 (6.7)	2 (3.3)	2 (3.3)
Respiratory, thoracic and mediastinal disorders			
- Total	9 (15.0)	2 (3.3)	4 (6.7)
Hypoxia	6 (10.0)	2 (3.3)	1 (1.7)
Respiratory failure	3 (5.0)	0	3 (5.0)
Vascular disorders			
- Total	9 (15.0)	5 (8.3)	4 (6.7)
Hypotension	9 (15.0)	5 (8.3)	4 (6.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198c
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Sub group=Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (66.7)	1 (16.7)	0
Blood and lymphatic system disorders			
- Total	1 (16.7)	1 (16.7)	0
Febrile neutropenia	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
- Total	2 (33.3)	0	0
Pyrexia	2 (33.3)	0	0
Immune system disorders			
- Total	3 (50.0)	0	0
Cytokine release syndrome	3 (50.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198c
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Sub group=Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (77.8)	3 (33.3)	3 (33.3)
Blood and lymphatic system disorders			
- Total	6 (66.7)	5 (55.6)	1 (11.1)
Febrile neutropenia	6 (66.7)	5 (55.6)	1 (11.1)
Immune system disorders			
- Total	5 (55.6)	1 (11.1)	1 (11.1)
Cytokine release syndrome	5 (55.6)	1 (11.1)	1 (11.1)
Nervous system disorders			
- Total	2 (22.2)	0	0
Encephalopathy	1 (11.1)	0	0
Seizure	1 (11.1)	0	0

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal and urinary disorders			
- Total	2 (22.2)	1 (11.1)	0
Acute kidney injury	2 (22.2)	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (11.1)	0	1 (11.1)
Respiratory failure	1 (11.1)	0	1 (11.1)
Vascular disorders			
- Total	2 (22.2)	1 (11.1)	1 (11.1)
Hypotension	2 (22.2)	1 (11.1)	1 (11.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198d
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Sub group=Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	25 (83.3)	16 (53.3)	7 (23.3)
Blood and lymphatic system disorders			
- Total	20 (66.7)	19 (63.3)	1 (3.3)
Febrile neutropenia	20 (66.7)	19 (63.3)	1 (3.3)
General disorders and administration site conditions			
- Total	5 (16.7)	0	0
Pyrexia	5 (16.7)	0	0
Immune system disorders			
- Total	16 (53.3)	3 (10.0)	3 (10.0)
Cytokine release syndrome	16 (53.3)	3 (10.0)	3 (10.0)
Infections and infestations			
- Total	1 (3.3)	0	0

Group term Preferred term	All patients N=30 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	1 (3.3)	0	0
Nervous system disorders			
- Total	3 (10.0)	1 (3.3)	0
Seizure	2 (6.7)	0	0
Encephalopathy	1 (3.3)	1 (3.3)	0
Renal and urinary disorders			
- Total	4 (13.3)	3 (10.0)	1 (3.3)
Acute kidney injury	4 (13.3)	3 (10.0)	1 (3.3)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (16.7)	0	3 (10.0)
Respiratory failure	3 (10.0)	0	3 (10.0)
Hypoxia	2 (6.7)	0	0
Vascular disorders			
- Total	6 (20.0)	4 (13.3)	2 (6.7)
Hypotension	6 (20.0)	4 (13.3)	2 (6.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198d
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Sub group=Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	34 (75.6)	15 (33.3)	10 (22.2)
Blood and lymphatic system disorders			
- Total	13 (28.9)	13 (28.9)	0
Febrile neutropenia	13 (28.9)	13 (28.9)	0
General disorders and administration site conditions			
- Total	5 (11.1)	2 (4.4)	0
Pyrexia	5 (11.1)	2 (4.4)	0
Immune system disorders			
- Total	25 (55.6)	5 (11.1)	7 (15.6)
Cytokine release syndrome	25 (55.6)	5 (11.1)	7 (15.6)
Infections and infestations			
- Total	3 (6.7)	1 (2.2)	1 (2.2)

Group term Preferred term	All patients N=45 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	3 (6.7)	1 (2.2)	1 (2.2)
Nervous system disorders			
- Total	5 (11.1)	3 (6.7)	0
Encephalopathy	3 (6.7)	1 (2.2)	0
Seizure	2 (4.4)	2 (4.4)	0
Renal and urinary disorders			
- Total	2 (4.4)	0	1 (2.2)
Acute kidney injury	2 (4.4)	0	1 (2.2)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (11.1)	2 (4.4)	2 (4.4)
Hypoxia	4 (8.9)	2 (4.4)	1 (2.2)
Respiratory failure	1 (2.2)	0	1 (2.2)
Vascular disorders			
- Total	5 (11.1)	2 (4.4)	3 (6.7)
Hypotension	5 (11.1)	2 (4.4)	3 (6.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198e
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Sub group=Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (87.5)	3 (37.5)	4 (50.0)
Blood and lymphatic system disorders			
- Total	3 (37.5)	3 (37.5)	0
Febrile neutropenia	3 (37.5)	3 (37.5)	0
General disorders and administration site conditions			
- Total	2 (25.0)	1 (12.5)	0
Pyrexia	2 (25.0)	1 (12.5)	0
Immune system disorders			
- Total	5 (62.5)	0	3 (37.5)
Cytokine release syndrome	5 (62.5)	0	3 (37.5)
Infections and infestations			
- Total	1 (12.5)	0	1 (12.5)

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (25.0)	1 (12.5)	1 (12.5)
Hypoxia	1 (12.5)	1 (12.5)	0
Respiratory failure	1 (12.5)	0	1 (12.5)
Vascular disorders			
- Total	3 (37.5)	2 (25.0)	1 (12.5)
Hypotension	3 (37.5)	2 (25.0)	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198e
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Sub group=Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	52 (77.6)	28 (41.8)	13 (19.4)
Blood and lymphatic system disorders			
- Total	30 (44.8)	29 (43.3)	1 (1.5)
Febrile neutropenia	30 (44.8)	29 (43.3)	1 (1.5)
General disorders and administration site conditions			
- Total	8 (11.9)	1 (1.5)	0
Pyrexia	8 (11.9)	1 (1.5)	0
Immune system disorders			
- Total	36 (53.7)	8 (11.9)	7 (10.4)
Cytokine release syndrome	36 (53.7)	8 (11.9)	7 (10.4)
Infections and infestations			
- Total	3 (4.5)	1 (1.5)	0

Group term Preferred term	All patients N=67 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	3 (4.5)	1 (1.5)	0
Nervous system disorders			
- Total	8 (11.9)	4 (6.0)	0
Encephalopathy	4 (6.0)	2 (3.0)	0
Seizure	4 (6.0)	2 (3.0)	0
Renal and urinary disorders			
- Total	6 (9.0)	3 (4.5)	2 (3.0)
Acute kidney injury	6 (9.0)	3 (4.5)	2 (3.0)
Respiratory, thoracic and mediastinal disorders			
- Total	8 (11.9)	1 (1.5)	4 (6.0)
Hypoxia	5 (7.5)	1 (1.5)	1 (1.5)
Respiratory failure	3 (4.5)	0	3 (4.5)
Vascular disorders			
- Total	8 (11.9)	4 (6.0)	4 (6.0)
Hypotension	8 (11.9)	4 (6.0)	4 (6.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198f
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Sub group=Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	0	0
General disorders and administration site conditions			
- Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198f
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Sub group=Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	58 (79.5)	31 (42.5)	17 (23.3)
Blood and lymphatic system disorders			
- Total	33 (45.2)	32 (43.8)	1 (1.4)
Febrile neutropenia	33 (45.2)	32 (43.8)	1 (1.4)
General disorders and administration site conditions			
- Total	9 (12.3)	2 (2.7)	0
Pyrexia	9 (12.3)	2 (2.7)	0
Immune system disorders			
- Total	41 (56.2)	8 (11.0)	10 (13.7)
Cytokine release syndrome	41 (56.2)	8 (11.0)	10 (13.7)
Infections and infestations			
- Total	4 (5.5)	1 (1.4)	1 (1.4)

Group term Preferred term	All patients N=73 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	4 (5.5)	1 (1.4)	1 (1.4)
Nervous system disorders			
- Total	8 (11.0)	4 (5.5)	0
Encephalopathy	4 (5.5)	2 (2.7)	0
Seizure	4 (5.5)	2 (2.7)	0
Renal and urinary disorders			
- Total	6 (8.2)	3 (4.1)	2 (2.7)
Acute kidney injury	6 (8.2)	3 (4.1)	2 (2.7)
Respiratory, thoracic and mediastinal disorders			
- Total	10 (13.7)	2 (2.7)	5 (6.8)
Hypoxia	6 (8.2)	2 (2.7)	1 (1.4)
Respiratory failure	4 (5.5)	0	4 (5.5)
Vascular disorders			
- Total	11 (15.1)	6 (8.2)	5 (6.8)
Hypotension	11 (15.1)	6 (8.2)	5 (6.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198g
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Sub group=Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (66.7)	0	2 (66.7)
Immune system disorders			
- Total	2 (66.7)	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	2 (66.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198g
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Sub group=Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	57 (79.2)	31 (43.1)	15 (20.8)
Blood and lymphatic system disorders			
- Total	33 (45.8)	32 (44.4)	1 (1.4)
Febrile neutropenia	33 (45.8)	32 (44.4)	1 (1.4)
General disorders and administration site conditions			
- Total	10 (13.9)	2 (2.8)	0
Pyrexia	10 (13.9)	2 (2.8)	0
Immune system disorders			
- Total	39 (54.2)	8 (11.1)	8 (11.1)
Cytokine release syndrome	39 (54.2)	8 (11.1)	8 (11.1)
Infections and infestations			
- Total	4 (5.6)	1 (1.4)	1 (1.4)

Group term Preferred term	All patients N=72 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	4 (5.6)	1 (1.4)	1 (1.4)
Nervous system disorders			
- Total	8 (11.1)	4 (5.6)	0
Encephalopathy	4 (5.6)	2 (2.8)	0
Seizure	4 (5.6)	2 (2.8)	0
Renal and urinary disorders			
- Total	6 (8.3)	3 (4.2)	2 (2.8)
Acute kidney injury	6 (8.3)	3 (4.2)	2 (2.8)
Respiratory, thoracic and mediastinal disorders			
- Total	10 (13.9)	2 (2.8)	5 (6.9)
Hypoxia	6 (8.3)	2 (2.8)	1 (1.4)
Respiratory failure	4 (5.6)	0	4 (5.6)
Vascular disorders			
- Total	11 (15.3)	6 (8.3)	5 (6.9)
Hypotension	11 (15.3)	6 (8.3)	5 (6.9)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198h
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Sub group=Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
- Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Immune system disorders			
- Total	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	0
Nervous system disorders			
- Total	1 (100)	0	0
Encephalopathy	1 (100)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198h
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Sub group=Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	58 (78.4)	30 (40.5)	17 (23.0)
Blood and lymphatic system disorders			
- Total	32 (43.2)	31 (41.9)	1 (1.4)
Febrile neutropenia	32 (43.2)	31 (41.9)	1 (1.4)
General disorders and administration site conditions			
- Total	10 (13.5)	2 (2.7)	0
Pyrexia	10 (13.5)	2 (2.7)	0
Immune system disorders			
- Total	40 (54.1)	8 (10.8)	10 (13.5)
Cytokine release syndrome	40 (54.1)	8 (10.8)	10 (13.5)
Infections and infestations			
- Total	4 (5.4)	1 (1.4)	1 (1.4)

Group term Preferred term	All patients N=74 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	4 (5.4)	1 (1.4)	1 (1.4)
Nervous system disorders			
- Total	7 (9.5)	4 (5.4)	0
Seizure	4 (5.4)	2 (2.7)	0
Encephalopathy	3 (4.1)	2 (2.7)	0
Renal and urinary disorders			
- Total	6 (8.1)	3 (4.1)	2 (2.7)
Acute kidney injury	6 (8.1)	3 (4.1)	2 (2.7)
Respiratory, thoracic and mediastinal disorders			
- Total	10 (13.5)	2 (2.7)	5 (6.8)
Hypoxia	6 (8.1)	2 (2.7)	1 (1.4)
Respiratory failure	4 (5.4)	0	4 (5.4)
Vascular disorders			
- Total	11 (14.9)	6 (8.1)	5 (6.8)
Hypotension	11 (14.9)	6 (8.1)	5 (6.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198i
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

Sub group=BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (75.0)	2 (50.0)	1 (25.0)
Blood and lymphatic system disorders			
- Total	3 (75.0)	3 (75.0)	0
Febrile neutropenia	3 (75.0)	3 (75.0)	0
Immune system disorders			
- Total	2 (50.0)	1 (25.0)	0
Cytokine release syndrome	2 (50.0)	1 (25.0)	0
Vascular disorders			
- Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198i
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

Sub group=BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	56 (78.9)	29 (40.8)	16 (22.5)
Blood and lymphatic system disorders			
- Total	30 (42.3)	29 (40.8)	1 (1.4)
Febrile neutropenia	30 (42.3)	29 (40.8)	1 (1.4)
General disorders and administration site conditions			
- Total	10 (14.1)	2 (2.8)	0
Pyrexia	10 (14.1)	2 (2.8)	0
Immune system disorders			
- Total	39 (54.9)	7 (9.9)	10 (14.1)
Cytokine release syndrome	39 (54.9)	7 (9.9)	10 (14.1)
Infections and infestations			
- Total	4 (5.6)	1 (1.4)	1 (1.4)

Group term Preferred term	All patients N=71 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	4 (5.6)	1 (1.4)	1 (1.4)
Nervous system disorders			
- Total	8 (11.3)	4 (5.6)	0
Encephalopathy	4 (5.6)	2 (2.8)	0
Seizure	4 (5.6)	2 (2.8)	0
Renal and urinary disorders			
- Total	6 (8.5)	3 (4.2)	2 (2.8)
Acute kidney injury	6 (8.5)	3 (4.2)	2 (2.8)
Respiratory, thoracic and mediastinal disorders			
- Total	10 (14.1)	2 (2.8)	5 (7.0)
Hypoxia	6 (8.5)	2 (2.8)	1 (1.4)
Respiratory failure	4 (5.6)	0	4 (5.6)
Vascular disorders			
- Total	10 (14.1)	6 (8.5)	4 (5.6)
Hypotension	10 (14.1)	6 (8.5)	4 (5.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198j
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	21 (95.5)	9 (40.9)	8 (36.4)
Blood and lymphatic system disorders			
- Total	10 (45.5)	10 (45.5)	0
Febrile neutropenia	10 (45.5)	10 (45.5)	0
General disorders and administration site conditions			
- Total	4 (18.2)	0	0
Pyrexia	4 (18.2)	0	0
Immune system disorders			
- Total	16 (72.7)	3 (13.6)	5 (22.7)
Cytokine release syndrome	16 (72.7)	3 (13.6)	5 (22.7)
Nervous system disorders			
- Total	3 (13.6)	2 (9.1)	0

Group term Preferred term	All patients N=22 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Encephalopathy	2 (9.1)	1 (4.5)	0
Seizure	1 (4.5)	1 (4.5)	0
Renal and urinary disorders			
- Total	3 (13.6)	1 (4.5)	2 (9.1)
Acute kidney injury	3 (13.6)	1 (4.5)	2 (9.1)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (13.6)	0	2 (9.1)
Hypoxia	2 (9.1)	0	1 (4.5)
Respiratory failure	1 (4.5)	0	1 (4.5)
Vascular disorders			
- Total	4 (18.2)	1 (4.5)	3 (13.6)
Hypotension	4 (18.2)	1 (4.5)	3 (13.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198j
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Sub group=Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	38 (71.7)	22 (41.5)	9 (17.0)
Blood and lymphatic system disorders			
- Total	23 (43.4)	22 (41.5)	1 (1.9)
Febrile neutropenia	23 (43.4)	22 (41.5)	1 (1.9)
General disorders and administration site conditions			
- Total	6 (11.3)	2 (3.8)	0
Pyrexia	6 (11.3)	2 (3.8)	0
Immune system disorders			
- Total	25 (47.2)	5 (9.4)	5 (9.4)
Cytokine release syndrome	25 (47.2)	5 (9.4)	5 (9.4)
Infections and infestations			
- Total	4 (7.5)	1 (1.9)	1 (1.9)

Group term Preferred term	All patients N=53 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	4 (7.5)	1 (1.9)	1 (1.9)
Nervous system disorders			
- Total	5 (9.4)	2 (3.8)	0
Seizure	3 (5.7)	1 (1.9)	0
Encephalopathy	2 (3.8)	1 (1.9)	0
Renal and urinary disorders			
- Total	3 (5.7)	2 (3.8)	0
Acute kidney injury	3 (5.7)	2 (3.8)	0
Respiratory, thoracic and mediastinal disorders			
- Total	7 (13.2)	2 (3.8)	3 (5.7)
Hypoxia	4 (7.5)	2 (3.8)	0
Respiratory failure	3 (5.7)	0	3 (5.7)
Vascular disorders			
- Total	7 (13.2)	5 (9.4)	2 (3.8)
Hypotension	7 (13.2)	5 (9.4)	2 (3.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198k
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Sub group=Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	59 (78.7)	31 (41.3)	17 (22.7)
Blood and lymphatic system disorders			
- Total	33 (44.0)	32 (42.7)	1 (1.3)
Febrile neutropenia	33 (44.0)	32 (42.7)	1 (1.3)
General disorders and administration site conditions			
- Total	10 (13.3)	2 (2.7)	0
Pyrexia	10 (13.3)	2 (2.7)	0
Immune system disorders			
- Total	41 (54.7)	8 (10.7)	10 (13.3)
Cytokine release syndrome	41 (54.7)	8 (10.7)	10 (13.3)
Infections and infestations			
- Total	4 (5.3)	1 (1.3)	1 (1.3)

Group term Preferred term	All patients N=75 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	4 (5.3)	1 (1.3)	1 (1.3)
Nervous system disorders			
- Total	8 (10.7)	4 (5.3)	0
Encephalopathy	4 (5.3)	2 (2.7)	0
Seizure	4 (5.3)	2 (2.7)	0
Renal and urinary disorders			
- Total	6 (8.0)	3 (4.0)	2 (2.7)
Acute kidney injury	6 (8.0)	3 (4.0)	2 (2.7)
Respiratory, thoracic and mediastinal disorders			
- Total	10 (13.3)	2 (2.7)	5 (6.7)
Hypoxia	6 (8.0)	2 (2.7)	1 (1.3)
Respiratory failure	4 (5.3)	0	4 (5.3)
Vascular disorders			
- Total	11 (14.7)	6 (8.0)	5 (6.7)
Hypotension	11 (14.7)	6 (8.0)	5 (6.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198l
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Sub group=Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	25 (78.1)	17 (53.1)	4 (12.5)
Blood and lymphatic system disorders			
- Total	16 (50.0)	16 (50.0)	0
Febrile neutropenia	16 (50.0)	16 (50.0)	0
General disorders and administration site conditions			
- Total	4 (12.5)	0	0
Pyrexia	4 (12.5)	0	0
Immune system disorders			
- Total	17 (53.1)	4 (12.5)	2 (6.3)
Cytokine release syndrome	17 (53.1)	4 (12.5)	2 (6.3)
Infections and infestations			
- Total	1 (3.1)	0	0

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (3.1)	0	0
Nervous system disorders			
- Total	4 (12.5)	3 (9.4)	0
Encephalopathy	2 (6.3)	1 (3.1)	0
Seizure	2 (6.3)	2 (6.3)	0
Renal and urinary disorders			
- Total	1 (3.1)	0	0
Acute kidney injury	1 (3.1)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (9.4)	0	0
Hypoxia	3 (9.4)	0	0
Vascular disorders			
- Total	5 (15.6)	3 (9.4)	2 (6.3)
Hypotension	5 (15.6)	3 (9.4)	2 (6.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198l
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Sub group=Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	34 (79.1)	14 (32.6)	13 (30.2)
Blood and lymphatic system disorders			
- Total	17 (39.5)	16 (37.2)	1 (2.3)
Febrile neutropenia	17 (39.5)	16 (37.2)	1 (2.3)
General disorders and administration site conditions			
- Total	6 (14.0)	2 (4.7)	0
Pyrexia	6 (14.0)	2 (4.7)	0
Immune system disorders			
- Total	24 (55.8)	4 (9.3)	8 (18.6)
Cytokine release syndrome	24 (55.8)	4 (9.3)	8 (18.6)
Infections and infestations			
- Total	3 (7.0)	1 (2.3)	1 (2.3)

Group term Preferred term	All patients N=43 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	3 (7.0)	1 (2.3)	1 (2.3)
Nervous system disorders			
- Total	4 (9.3)	1 (2.3)	0
Encephalopathy	2 (4.7)	1 (2.3)	0
Seizure	2 (4.7)	0	0
Renal and urinary disorders			
- Total	5 (11.6)	3 (7.0)	2 (4.7)
Acute kidney injury	5 (11.6)	3 (7.0)	2 (4.7)
Respiratory, thoracic and mediastinal disorders			
- Total	7 (16.3)	2 (4.7)	5 (11.6)
Respiratory failure	4 (9.3)	0	4 (9.3)
Hypoxia	3 (7.0)	2 (4.7)	1 (2.3)
Vascular disorders			
- Total	6 (14.0)	3 (7.0)	3 (7.0)
Hypotension	6 (14.0)	3 (7.0)	3 (7.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198m
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Sub group=Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (72.2)	8 (44.4)	3 (16.7)
Blood and lymphatic system disorders			
- Total	9 (50.0)	9 (50.0)	0
Febrile neutropenia	9 (50.0)	9 (50.0)	0
General disorders and administration site conditions			
- Total	2 (11.1)	1 (5.6)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Immune system disorders			
- Total	9 (50.0)	2 (11.1)	1 (5.6)
Cytokine release syndrome	9 (50.0)	2 (11.1)	1 (5.6)
Infections and infestations			
- Total	2 (11.1)	1 (5.6)	1 (5.6)

Group term Preferred term	All patients N=18 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	2 (11.1)	1 (5.6)	1 (5.6)
Renal and urinary disorders			
- Total	1 (5.6)	1 (5.6)	0
Acute kidney injury	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
- Total	4 (22.2)	2 (11.1)	1 (5.6)
Hypoxia	3 (16.7)	2 (11.1)	0
Respiratory failure	1 (5.6)	0	1 (5.6)
Vascular disorders			
- Total	2 (11.1)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198m
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Sub group=Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	46 (80.7)	23 (40.4)	14 (24.6)
Blood and lymphatic system disorders			
- Total	24 (42.1)	23 (40.4)	1 (1.8)
Febrile neutropenia	24 (42.1)	23 (40.4)	1 (1.8)
General disorders and administration site conditions			
- Total	8 (14.0)	1 (1.8)	0
Pyrexia	8 (14.0)	1 (1.8)	0
Immune system disorders			
- Total	32 (56.1)	6 (10.5)	9 (15.8)
Cytokine release syndrome	32 (56.1)	6 (10.5)	9 (15.8)
Infections and infestations			
- Total	2 (3.5)	0	0

Group term Preferred term	All patients N=57 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	2 (3.5)	0	0
Nervous system disorders			
- Total	8 (14.0)	4 (7.0)	0
Encephalopathy	4 (7.0)	2 (3.5)	0
Seizure	4 (7.0)	2 (3.5)	0
Renal and urinary disorders			
- Total	5 (8.8)	2 (3.5)	2 (3.5)
Acute kidney injury	5 (8.8)	2 (3.5)	2 (3.5)
Respiratory, thoracic and mediastinal disorders			
- Total	6 (10.5)	0	4 (7.0)
Hypoxia	3 (5.3)	0	1 (1.8)
Respiratory failure	3 (5.3)	0	3 (5.3)
Vascular disorders			
- Total	9 (15.8)	5 (8.8)	4 (7.0)
Hypotension	9 (15.8)	5 (8.8)	4 (7.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198n
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Sub group=Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (81.8)	12 (54.5)	3 (13.6)
Blood and lymphatic system disorders			
- Total	10 (45.5)	10 (45.5)	0
Febrile neutropenia	10 (45.5)	10 (45.5)	0
General disorders and administration site conditions			
- Total	3 (13.6)	1 (4.5)	0
Pyrexia	3 (13.6)	1 (4.5)	0
Immune system disorders			
- Total	14 (63.6)	3 (13.6)	2 (9.1)
Cytokine release syndrome	14 (63.6)	3 (13.6)	2 (9.1)
Nervous system disorders			
- Total	5 (22.7)	2 (9.1)	0

Group term Preferred term	All patients N=22 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	3 (13.6)	1 (4.5)	0
Seizure	2 (9.1)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (9.1)	0	0
Hypoxia	2 (9.1)	0	0
Vascular disorders			
- Total	4 (18.2)	3 (13.6)	1 (4.5)
Hypotension	4 (18.2)	3 (13.6)	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198n
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Sub group=Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	41 (77.4)	19 (35.8)	14 (26.4)
Blood and lymphatic system disorders			
- Total	23 (43.4)	22 (41.5)	1 (1.9)
Febrile neutropenia	23 (43.4)	22 (41.5)	1 (1.9)
General disorders and administration site conditions			
- Total	7 (13.2)	1 (1.9)	0
Pyrexia	7 (13.2)	1 (1.9)	0
Immune system disorders			
- Total	27 (50.9)	5 (9.4)	8 (15.1)
Cytokine release syndrome	27 (50.9)	5 (9.4)	8 (15.1)
Infections and infestations			
- Total	4 (7.5)	1 (1.9)	1 (1.9)

Group term Preferred term	All patients N=53 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	4 (7.5)	1 (1.9)	1 (1.9)
Nervous system disorders			
- Total	3 (5.7)	2 (3.8)	0
Seizure	2 (3.8)	1 (1.9)	0
Encephalopathy	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
- Total	6 (11.3)	3 (5.7)	2 (3.8)
Acute kidney injury	6 (11.3)	3 (5.7)	2 (3.8)
Respiratory, thoracic and mediastinal disorders			
- Total	8 (15.1)	2 (3.8)	5 (9.4)
Hypoxia	4 (7.5)	2 (3.8)	1 (1.9)
Respiratory failure	4 (7.5)	0	4 (7.5)
Vascular disorders			
- Total	7 (13.2)	3 (5.7)	4 (7.5)
Hypotension	7 (13.2)	3 (5.7)	4 (7.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198o
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Sub group=Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	3 (42.9)	2 (28.6)
Blood and lymphatic system disorders			
- Total	3 (42.9)	2 (28.6)	1 (14.3)
Febrile neutropenia	3 (42.9)	2 (28.6)	1 (14.3)
Immune system disorders			
- Total	3 (42.9)	0	1 (14.3)
Cytokine release syndrome	3 (42.9)	0	1 (14.3)
Nervous system disorders			
- Total	1 (14.3)	1 (14.3)	0
Seizure	1 (14.3)	1 (14.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198o
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Sub group=Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	54 (79.4)	28 (41.2)	15 (22.1)
Blood and lymphatic system disorders			
- Total	30 (44.1)	30 (44.1)	0
Febrile neutropenia	30 (44.1)	30 (44.1)	0
General disorders and administration site conditions			
- Total	10 (14.7)	2 (2.9)	0
Pyrexia	10 (14.7)	2 (2.9)	0
Immune system disorders			
- Total	38 (55.9)	8 (11.8)	9 (13.2)
Cytokine release syndrome	38 (55.9)	8 (11.8)	9 (13.2)
Infections and infestations			
- Total	4 (5.9)	1 (1.5)	1 (1.5)

Group term Preferred term	All patients N=68 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	4 (5.9)	1 (1.5)	1 (1.5)
Nervous system disorders			
- Total	7 (10.3)	3 (4.4)	0
Encephalopathy	4 (5.9)	2 (2.9)	0
Seizure	3 (4.4)	1 (1.5)	0
Renal and urinary disorders			
- Total	6 (8.8)	3 (4.4)	2 (2.9)
Acute kidney injury	6 (8.8)	3 (4.4)	2 (2.9)
Respiratory, thoracic and mediastinal disorders			
- Total	10 (14.7)	2 (2.9)	5 (7.4)
Hypoxia	6 (8.8)	2 (2.9)	1 (1.5)
Respiratory failure	4 (5.9)	0	4 (5.9)
Vascular disorders			
- Total	11 (16.2)	6 (8.8)	5 (7.4)
Hypotension	11 (16.2)	6 (8.8)	5 (7.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198p
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Sub group=Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (75.0)	3 (75.0)	0
Blood and lymphatic system disorders			
- Total	2 (50.0)	2 (50.0)	0
Febrile neutropenia	2 (50.0)	2 (50.0)	0
General disorders and administration site conditions			
- Total	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Immune system disorders			
- Total	2 (50.0)	0	0
Cytokine release syndrome	2 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (25.0)	0	0

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (25.0)	0	0
Vascular disorders			
- Total	1 (25.0)	1 (25.0)	0
Hypotension	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198p
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Sub group=Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	56 (78.9)	28 (39.4)	17 (23.9)
Blood and lymphatic system disorders			
- Total	31 (43.7)	30 (42.3)	1 (1.4)
Febrile neutropenia	31 (43.7)	30 (42.3)	1 (1.4)
General disorders and administration site conditions			
- Total	9 (12.7)	1 (1.4)	0
Pyrexia	9 (12.7)	1 (1.4)	0
Immune system disorders			
- Total	39 (54.9)	8 (11.3)	10 (14.1)
Cytokine release syndrome	39 (54.9)	8 (11.3)	10 (14.1)
Infections and infestations			
- Total	4 (5.6)	1 (1.4)	1 (1.4)

Group term Preferred term	All patients N=71 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	4 (5.6)	1 (1.4)	1 (1.4)
Nervous system disorders			
- Total	8 (11.3)	4 (5.6)	0
Encephalopathy	4 (5.6)	2 (2.8)	0
Seizure	4 (5.6)	2 (2.8)	0
Renal and urinary disorders			
- Total	6 (8.5)	3 (4.2)	2 (2.8)
Acute kidney injury	6 (8.5)	3 (4.2)	2 (2.8)
Respiratory, thoracic and mediastinal disorders			
- Total	9 (12.7)	2 (2.8)	5 (7.0)
Hypoxia	5 (7.0)	2 (2.8)	1 (1.4)
Respiratory failure	4 (5.6)	0	4 (5.6)
Vascular disorders			
- Total	10 (14.1)	5 (7.0)	5 (7.0)
Hypotension	10 (14.1)	5 (7.0)	5 (7.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198q
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Sub group=Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	28 (87.5)	17 (53.1)	5 (15.6)
Blood and lymphatic system disorders			
- Total	16 (50.0)	15 (46.9)	1 (3.1)
Febrile neutropenia	16 (50.0)	15 (46.9)	1 (3.1)
General disorders and administration site conditions			
- Total	4 (12.5)	1 (3.1)	0
Pyrexia	4 (12.5)	1 (3.1)	0
Immune system disorders			
- Total	19 (59.4)	2 (6.3)	4 (12.5)
Cytokine release syndrome	19 (59.4)	2 (6.3)	4 (12.5)
Infections and infestations			
- Total	2 (6.3)	0	0

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	2 (6.3)	0	0
Nervous system disorders			
- Total	2 (6.3)	2 (6.3)	0
Encephalopathy	1 (3.1)	1 (3.1)	0
Seizure	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			
- Total	2 (6.3)	1 (3.1)	0
Acute kidney injury	2 (6.3)	1 (3.1)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (6.3)	0	0
Hypoxia	2 (6.3)	0	0
Vascular disorders			
- Total	2 (6.3)	2 (6.3)	0
Hypotension	2 (6.3)	2 (6.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198q
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Sub group=Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	27 (84.4)	12 (37.5)	10 (31.3)
Blood and lymphatic system disorders			
- Total	15 (46.9)	15 (46.9)	0
Febrile neutropenia	15 (46.9)	15 (46.9)	0
General disorders and administration site conditions			
- Total	4 (12.5)	0	0
Pyrexia	4 (12.5)	0	0
Immune system disorders			
- Total	22 (68.8)	6 (18.8)	6 (18.8)
Cytokine release syndrome	22 (68.8)	6 (18.8)	6 (18.8)
Infections and infestations			
- Total	1 (3.1)	1 (3.1)	0

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (3.1)	1 (3.1)	0
Nervous system disorders			
- Total	6 (18.8)	2 (6.3)	0
Encephalopathy	3 (9.4)	1 (3.1)	0
Seizure	3 (9.4)	1 (3.1)	0
Renal and urinary disorders			
- Total	3 (9.4)	2 (6.3)	1 (3.1)
Acute kidney injury	3 (9.4)	2 (6.3)	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
- Total	6 (18.8)	1 (3.1)	4 (12.5)
Hypoxia	3 (9.4)	1 (3.1)	1 (3.1)
Respiratory failure	3 (9.4)	0	3 (9.4)
Vascular disorders			
- Total	6 (18.8)	3 (9.4)	3 (9.4)
Hypotension	6 (18.8)	3 (9.4)	3 (9.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198q
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Sub group=Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (36.4)	2 (18.2)	2 (18.2)
Blood and lymphatic system disorders			
- Total	2 (18.2)	2 (18.2)	0
Febrile neutropenia	2 (18.2)	2 (18.2)	0
General disorders and administration site conditions			
- Total	2 (18.2)	1 (9.1)	0
Pyrexia	2 (18.2)	1 (9.1)	0
Infections and infestations			
- Total	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)
Renal and urinary disorders			

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (18.2)	1 (9.1)	1 (9.1)
Hypoxia	1 (9.1)	1 (9.1)	0
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
- Total	3 (27.3)	1 (9.1)	2 (18.2)
Hypotension	3 (27.3)	1 (9.1)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Sub group=Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (87.5)	3 (37.5)	4 (50.0)
Blood and lymphatic system disorders			
- Total	3 (37.5)	3 (37.5)	0
Febrile neutropenia	3 (37.5)	3 (37.5)	0
General disorders and administration site conditions			
- Total	2 (25.0)	1 (12.5)	0
Pyrexia	2 (25.0)	1 (12.5)	0
Immune system disorders			
- Total	5 (62.5)	0	3 (37.5)
Cytokine release syndrome	5 (62.5)	0	3 (37.5)
Infections and infestations			
- Total	1 (12.5)	0	1 (12.5)

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (25.0)	1 (12.5)	1 (12.5)
Hypoxia	1 (12.5)	1 (12.5)	0
Respiratory failure	1 (12.5)	0	1 (12.5)
Vascular disorders			
- Total	3 (37.5)	2 (25.0)	1 (12.5)
Hypotension	3 (37.5)	2 (25.0)	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Sub group=Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (78.3)	10 (43.5)	5 (21.7)
Blood and lymphatic system disorders			
- Total	11 (47.8)	11 (47.8)	0
Febrile neutropenia	11 (47.8)	11 (47.8)	0
General disorders and administration site conditions			
- Total	2 (8.7)	1 (4.3)	0
Pyrexia	2 (8.7)	1 (4.3)	0
Immune system disorders			
- Total	14 (60.9)	2 (8.7)	4 (17.4)
Cytokine release syndrome	14 (60.9)	2 (8.7)	4 (17.4)
Infections and infestations			
- Total	2 (8.7)	1 (4.3)	0

Group term Preferred term	All patients N=23 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	2 (8.7)	1 (4.3)	0
Nervous system disorders			
- Total	4 (17.4)	2 (8.7)	0
Encephalopathy	2 (8.7)	1 (4.3)	0
Seizure	2 (8.7)	1 (4.3)	0
Renal and urinary disorders			
- Total	3 (13.0)	2 (8.7)	0
Acute kidney injury	3 (13.0)	2 (8.7)	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (13.0)	1 (4.3)	1 (4.3)
Hypoxia	2 (8.7)	1 (4.3)	0
Respiratory failure	1 (4.3)	0	1 (4.3)
Vascular disorders			
- Total	2 (8.7)	1 (4.3)	1 (4.3)
Hypotension	2 (8.7)	1 (4.3)	1 (4.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Sub group=Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (83.3)	9 (37.5)	5 (20.8)
Blood and lymphatic system disorders			
- Total	11 (45.8)	10 (41.7)	1 (4.2)
Febrile neutropenia	11 (45.8)	10 (41.7)	1 (4.2)
General disorders and administration site conditions			
- Total	3 (12.5)	0	0
Pyrexia	3 (12.5)	0	0
Immune system disorders			
- Total	14 (58.3)	4 (16.7)	1 (4.2)
Cytokine release syndrome	14 (58.3)	4 (16.7)	1 (4.2)
Infections and infestations			

Group term Preferred term	All patients N=24 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
- Total	1 (4.2)	0	0
Pneumonia	1 (4.2)	0	0
Nervous system disorders			
- Total	2 (8.3)	1 (4.2)	0
Encephalopathy	1 (4.2)	1 (4.2)	0
Seizure	1 (4.2)	0	0
Renal and urinary disorders			
- Total	3 (12.5)	1 (4.2)	2 (8.3)
Acute kidney injury	3 (12.5)	1 (4.2)	2 (8.3)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (16.7)	0	3 (12.5)
Hypoxia	2 (8.3)	0	1 (4.2)
Respiratory failure	2 (8.3)	0	2 (8.3)
Vascular disorders			
- Total	3 (12.5)	1 (4.2)	2 (8.3)
Hypotension	3 (12.5)	1 (4.2)	2 (8.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 198r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Sub group=Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (70.0)	9 (45.0)	3 (15.0)
Blood and lymphatic system disorders			
- Total	8 (40.0)	8 (40.0)	0
Febrile neutropenia	8 (40.0)	8 (40.0)	0
General disorders and administration site conditions			
- Total	3 (15.0)	0	0
Pyrexia	3 (15.0)	0	0
Immune system disorders			
- Total	8 (40.0)	2 (10.0)	2 (10.0)
Cytokine release syndrome	8 (40.0)	2 (10.0)	2 (10.0)
Nervous system disorders			

Group term Preferred term	All patients N=20 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	2 (10.0)	1 (5.0)	0
Encephalopathy	1 (5.0)	0	0
Seizure	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (5.0)	0	0
Hypoxia	1 (5.0)	0	0
Vascular disorders			
- Total	3 (15.0)	2 (10.0)	1 (5.0)
Hypotension	3 (15.0)	2 (10.0)	1 (5.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (95.0)	1 (5.0)	7 (35.0)	5 (25.0)	6 (30.0)
Cytokine Release Syndrome					
-Total	16 (80.0)	2 (10.0)	8 (40.0)	3 (15.0)	3 (15.0)
Cytokine release syndrome	16 (80.0)	2 (10.0)	8 (40.0)	3 (15.0)	3 (15.0)
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	1 (5.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (40.0)	1 (5.0)	0	3 (15.0)	4 (20.0)
White blood cell count decreased	4 (20.0)	1 (5.0)	0	1 (5.0)	2 (10.0)
Neutrophil count decreased	3 (15.0)	0	0	1 (5.0)	2 (10.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	2 (10.0)	0	0	0	2 (10.0)
Febrile neutropenia	1 (5.0)	0	0	1 (5.0)	0
Lymphocyte count decreased	1 (5.0)	0	0	1 (5.0)	0
Thrombocytopenia	1 (5.0)	0	0	0	1 (5.0)
Infections					
-Total	10 (50.0)	2 (10.0)	4 (20.0)	3 (15.0)	1 (5.0)
Clostridium difficile infection	3 (15.0)	0	3 (15.0)	0	0
Rhinovirus infection	3 (15.0)	3 (15.0)	0	0	0
Clostridium difficile colitis	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Catheter site infection	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis	1 (5.0)	0	1 (5.0)	0	0
Oral candidiasis	1 (5.0)	1 (5.0)	0	0	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Septic embolus	1 (5.0)	0	0	0	1 (5.0)
Skin papilloma	1 (5.0)	0	1 (5.0)	0	0
Staphylococcal infection	1 (5.0)	1 (5.0)	0	0	0
Viral infection	1 (5.0)	0	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (5.0)	0	1 (5.0)	0	0
Vulvovaginal candidiasis	1 (5.0)	1 (5.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	9 (45.0)	1 (5.0)	7 (35.0)	1 (5.0)	0
Hypogammaglobulinaemia	8 (40.0)	1 (5.0)	6 (30.0)	1 (5.0)	0
Blood immunoglobulin g decreased	1 (5.0)	0	1 (5.0)	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Serious neurological adverse reactions					
-Total	5 (25.0)	2 (10.0)	1 (5.0)	2 (10.0)	0
Confusional state	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Delirium	1 (5.0)	0	1 (5.0)	0	0
Depressed level of consciousness	1 (5.0)	1 (5.0)	0	0	0
Dysphagia	1 (5.0)	0	0	1 (5.0)	0

Timing: within 8 weeks post infusion, Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Irritability	1 (5.0)	1 (5.0)	0	0	0
Seizure	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (91.2)	0	8 (23.5)	13 (38.2)	10 (29.4)
Cytokine Release Syndrome					
-Total	26 (76.5)	4 (11.8)	12 (35.3)	5 (14.7)	5 (14.7)
Cytokine release syndrome	26 (76.5)	4 (11.8)	12 (35.3)	5 (14.7)	5 (14.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	14 (41.2)	1 (2.9)	1 (2.9)	7 (20.6)	5 (14.7)
White blood cell count decreased	7 (20.6)	0	1 (2.9)	5 (14.7)	1 (2.9)
Neutrophil count decreased	5 (14.7)	0	0	2 (5.9)	3 (8.8)
Platelet count decreased	4 (11.8)	1 (2.9)	0	1 (2.9)	2 (5.9)
Febrile neutropenia	2 (5.9)	0	0	2 (5.9)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Neutropenia	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Thrombocytopenia	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Anaemia	1 (2.9)	0	1 (2.9)	0	0
Lymphopenia	1 (2.9)	0	0	1 (2.9)	0
Infections					
-Total	13 (38.2)	3 (8.8)	8 (23.5)	2 (5.9)	0
Clostridium difficile colitis	2 (5.9)	0	2 (5.9)	0	0
Acute sinusitis	1 (2.9)	0	1 (2.9)	0	0
Body tinea	1 (2.9)	1 (2.9)	0	0	0
Catheter site cellulitis	1 (2.9)	1 (2.9)	0	0	0
Clostridium difficile infection	1 (2.9)	0	1 (2.9)	0	0
Cytomegalovirus infection	1 (2.9)	1 (2.9)	0	0	0
Enterococcal infection	1 (2.9)	1 (2.9)	0	0	0
Fungal skin infection	1 (2.9)	1 (2.9)	0	0	0
Gastroenteritis	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Herpes simplex	1 (2.9)	1 (2.9)	0	0	0
Hypopyon	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (2.9)	1 (2.9)	0	0	0
Orchitis	1 (2.9)	1 (2.9)	0	0	0
Pharyngitis	1 (2.9)	0	1 (2.9)	0	0
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal infection	1 (2.9)	0	0	1 (2.9)	0
Streptococcal infection	1 (2.9)	0	1 (2.9)	0	0
Upper respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	15 (44.1)	3 (8.8)	9 (26.5)	3 (8.8)	0
Hypogammaglobulinaemia	14 (41.2)	2 (5.9)	9 (26.5)	3 (8.8)	0
Blood immunoglobulin a decreased	3 (8.8)	3 (8.8)	0	0	0
Blood immunoglobulin m decreased	2 (5.9)	2 (5.9)	0	0	0
Serious neurological adverse reactions					
-Total	12 (35.3)	4 (11.8)	6 (17.6)	2 (5.9)	0
Encephalopathy	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Agitation	2 (5.9)	0	2 (5.9)	0	0
Delirium	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Dysarthria	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Hallucination	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Seizure	2 (5.9)	0	2 (5.9)	0	0
Tremor	2 (5.9)	2 (5.9)	0	0	0
Asterixis	1 (2.9)	1 (2.9)	0	0	0
Dysphagia	1 (2.9)	0	1 (2.9)	0	0
Irritability	1 (2.9)	1 (2.9)	0	0	0
Listless	1 (2.9)	1 (2.9)	0	0	0
Mental status changes	1 (2.9)	1 (2.9)	0	0	0
Muscular weakness	1 (2.9)	0	1 (2.9)	0	0
Somnolence	1 (2.9)	1 (2.9)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (90.0)	0	4 (40.0)	0	5 (50.0)
Cytokine Release Syndrome					
-Total	8 (80.0)	0	5 (50.0)	0	3 (30.0)
Cytokine release syndrome	8 (80.0)	0	5 (50.0)	0	3 (30.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (50.0)	0	2 (20.0)	0	3 (30.0)
Anaemia	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Platelet count decreased	2 (20.0)	0	1 (10.0)	0	1 (10.0)
Neutropenia	1 (10.0)	0	0	0	1 (10.0)
Thrombocytopenia	1 (10.0)	0	0	0	1 (10.0)

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Folliculitis	1 (10.0)	0	1 (10.0)	0	0
Human herpesvirus 6 infection	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	1 (10.0)	0	0
Urinary tract infection enterococcal	1 (10.0)	0	0	1 (10.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (30.0)	0	3 (30.0)	0	0
Hypogammaglobulinaemia	3 (30.0)	0	3 (30.0)	0	0
Blood immunoglobulin m decreased	1 (10.0)	1 (10.0)	0	0	0
Serious neurological adverse reactions					
-Total	2 (20.0)	2 (20.0)	0	0	0
Confusional state	1 (10.0)	1 (10.0)	0	0	0
Delirium	1 (10.0)	1 (10.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

			All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (66.7)	2 (11.1)	5 (27.8)	5 (27.8)	0
Infections					
-Total	11 (61.1)	3 (16.7)	5 (27.8)	3 (16.7)	0
Upper respiratory tract infection	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Ear infection	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Gastroenteritis	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Corona virus infection	1 (5.6)	0	0	1 (5.6)	0
Cytomegalovirus infection	1 (5.6)	1 (5.6)	0	0	0
Enterovirus infection	1 (5.6)	0	0	1 (5.6)	0
Gastroenteritis viral	1 (5.6)	1 (5.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (5.6)	1 (5.6)	0	0	0
Otitis externa	1 (5.6)	0	1 (5.6)	0	0
Otitis media acute	1 (5.6)	0	1 (5.6)	0	0
Parainfluenzae virus infection	1 (5.6)	0	0	1 (5.6)	0
Paronychia	1 (5.6)	1 (5.6)	0	0	0
Rash pustular	1 (5.6)	0	1 (5.6)	0	0
Respiratory syncytial virus infection	1 (5.6)	0	0	1 (5.6)	0
Rotavirus infection	1 (5.6)	0	0	1 (5.6)	0
Sinusitis	1 (5.6)	0	1 (5.6)	0	0
Tinea capitis	1 (5.6)	1 (5.6)	0	0	0
Urinary tract infection	1 (5.6)	0	1 (5.6)	0	0
Viral upper respiratory tract infection	1 (5.6)	1 (5.6)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Hypogammaglobulinaemia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Tumour Lysis Syndrome					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=18 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (5.6)	0	0	1 (5.6)	0
Tumour lysis syndrome	1 (5.6)	0	0	1 (5.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (58.1)	3 (9.7)	9 (29.0)	6 (19.4)	0
Infections					
-Total	17 (54.8)	3 (9.7)	8 (25.8)	6 (19.4)	0
Upper respiratory tract infection	4 (12.9)	1 (3.2)	2 (6.5)	1 (3.2)	0
Urinary tract infection	3 (9.7)	0	1 (3.2)	2 (6.5)	0
Rhinovirus infection	2 (6.5)	2 (6.5)	0	0	0
Cellulitis of male external genital organ	1 (3.2)	0	0	1 (3.2)	0
Escherichia urinary tract infection	1 (3.2)	0	0	1 (3.2)	0
Gastroenteritis	1 (3.2)	0	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (3.2)	0	1 (3.2)	0	0
Herpes zoster	1 (3.2)	0	0	1 (3.2)	0
Influenza	1 (3.2)	0	1 (3.2)	0	0
Oral herpes	1 (3.2)	0	1 (3.2)	0	0
Otitis media	1 (3.2)	0	1 (3.2)	0	0
Parainfluenzae virus infection	1 (3.2)	1 (3.2)	0	0	0
Rhinitis	1 (3.2)	1 (3.2)	0	0	0
Sinusitis	1 (3.2)	0	1 (3.2)	0	0
Subcutaneous abscess	1 (3.2)	0	1 (3.2)	0	0
Vascular device infection	1 (3.2)	0	0	1 (3.2)	0
Viral infection	1 (3.2)	1 (3.2)	0	0	0
Viral upper respiratory tract infection	1 (3.2)	0	0	1 (3.2)	0
Vulvovaginal mycotic infection	1 (3.2)	0	1 (3.2)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (16.1)	0	5 (16.1)	0	0
Hypogammaglobulinaemia	5 (16.1)	0	5 (16.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	2 (6.5)	2 (6.5)	0	0	0
Muscular weakness	2 (6.5)	2 (6.5)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	0	2 (28.6)	1 (14.3)	2 (28.6)
Infections					
-Total	5 (71.4)	0	2 (28.6)	1 (14.3)	2 (28.6)
Influenza	2 (28.6)	0	2 (28.6)	0	0
Bacterial sepsis	1 (14.3)	0	0	0	1 (14.3)
Cholecystitis infective	1 (14.3)	0	0	1 (14.3)	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hypogammaglobulinaemia	1 (14.3)	0	1 (14.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (45.5)	0	2 (18.2)	2 (18.2)	1 (9.1)
Infections					
-Total	5 (45.5)	0	2 (18.2)	2 (18.2)	1 (9.1)
Otitis media acute	2 (18.2)	0	2 (18.2)	0	0
Campylobacter infection	1 (9.1)	0	0	1 (9.1)	0
Clostridium difficile infection	1 (9.1)	0	0	1 (9.1)	0
Haemophilus infection	1 (9.1)	0	1 (9.1)	0	0
Otitis media	1 (9.1)	0	0	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Respiratory tract infection	1 (9.1)	0	0	0	1 (9.1)

Timing: >1 year post-CTL019 infusion, Age: <10 years

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection viral	1 (9.1)	0	0	1 (9.1)	0
Sinusitis	1 (9.1)	0	1 (9.1)	0	0
Skin infection	1 (9.1)	0	1 (9.1)	0	0
Urinary tract infection	1 (9.1)	0	1 (9.1)	0	0
Vulvovaginal candidiasis	1 (9.1)	0	1 (9.1)	0	0
Serious neurological adverse reactions					
-Total	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	1 (9.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (31.8)	3 (13.6)	3 (13.6)	1 (4.5)	0
Infections					
-Total	5 (22.7)	2 (9.1)	2 (9.1)	1 (4.5)	0
Otitis media	2 (9.1)	0	2 (9.1)	0	0
Cellulitis of male external genital organ	1 (4.5)	0	0	1 (4.5)	0
Gingivitis	1 (4.5)	1 (4.5)	0	0	0
Meningitis aseptic	1 (4.5)	0	1 (4.5)	0	0
Pneumonia	1 (4.5)	0	1 (4.5)	0	0
Sinusitis	1 (4.5)	0	1 (4.5)	0	0
Upper respiratory tract infection	1 (4.5)	1 (4.5)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (4.5)	0	0	1 (4.5)	0
Viral infection	1 (4.5)	1 (4.5)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (4.5)	0	1 (4.5)	0	0
Immunodeficiency	1 (4.5)	0	1 (4.5)	0	0
Serious neurological adverse reactions					
-Total	1 (4.5)	1 (4.5)	0	0	0
Disturbance in attention	1 (4.5)	1 (4.5)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Infections					
-Total	1 (100)	0	1 (100)	0	0
Sinusitis	1 (100)	0	1 (100)	0	0
Upper respiratory tract infection	1 (100)	0	1 (100)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (100)	0	6 (30.0)	7 (35.0)	7 (35.0)
Cytokine Release Syndrome					
-Total	16 (80.0)	2 (10.0)	8 (40.0)	3 (15.0)	3 (15.0)
Cytokine release syndrome	16 (80.0)	2 (10.0)	8 (40.0)	3 (15.0)	3 (15.0)
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	1 (5.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (40.0)	1 (5.0)	0	3 (15.0)	4 (20.0)
White blood cell count decreased	4 (20.0)	1 (5.0)	0	1 (5.0)	2 (10.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	3 (15.0)	0	0	1 (5.0)	2 (10.0)
Platelet count decreased	2 (10.0)	0	0	0	2 (10.0)
Febrile neutropenia	1 (5.0)	0	0	1 (5.0)	0
Lymphocyte count decreased	1 (5.0)	0	0	1 (5.0)	0
Thrombocytopenia	1 (5.0)	0	0	0	1 (5.0)
Infections					
-Total	17 (85.0)	3 (15.0)	6 (30.0)	6 (30.0)	2 (10.0)
Clostridium difficile infection	4 (20.0)	0	3 (15.0)	1 (5.0)	0
Gastroenteritis	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Rhinovirus infection	3 (15.0)	3 (15.0)	0	0	0
Upper respiratory tract infection	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Clostridium difficile colitis	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Ear infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Otitis media acute	2 (10.0)	0	2 (10.0)	0	0
Pneumonia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Sinusitis	2 (10.0)	0	2 (10.0)	0	0
Urinary tract infection	2 (10.0)	0	2 (10.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Vulvovaginal candidiasis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Campylobacter infection	1 (5.0)	0	0	1 (5.0)	0
Catheter site infection	1 (5.0)	0	0	1 (5.0)	0
Corona virus infection	1 (5.0)	0	0	1 (5.0)	0
Cytomegalovirus infection	1 (5.0)	1 (5.0)	0	0	0
Enterovirus infection	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis viral	1 (5.0)	1 (5.0)	0	0	0
Haemophilus infection	1 (5.0)	0	1 (5.0)	0	0
Molluscum contagiosum	1 (5.0)	1 (5.0)	0	0	0
Oral candidiasis	1 (5.0)	1 (5.0)	0	0	0
Otitis externa	1 (5.0)	0	1 (5.0)	0	0
Otitis media	1 (5.0)	0	0	1 (5.0)	0
Parainfluenzae virus infection	1 (5.0)	0	0	1 (5.0)	0
Paronychia	1 (5.0)	1 (5.0)	0	0	0
Rash pustular	1 (5.0)	0	1 (5.0)	0	0
Respiratory syncytial virus infection	1 (5.0)	0	0	1 (5.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	1 (5.0)	0	0	0	1 (5.0)
Respiratory tract infection viral	1 (5.0)	0	0	1 (5.0)	0
Rotavirus infection	1 (5.0)	0	0	1 (5.0)	0
Septic embolus	1 (5.0)	0	0	0	1 (5.0)
Skin infection	1 (5.0)	0	1 (5.0)	0	0
Skin papilloma	1 (5.0)	0	1 (5.0)	0	0
Staphylococcal infection	1 (5.0)	1 (5.0)	0	0	0
Tinea capitis	1 (5.0)	1 (5.0)	0	0	0
Viral infection	1 (5.0)	0	1 (5.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	11 (55.0)	1 (5.0)	8 (40.0)	2 (10.0)	0
Hypogammaglobulinaemia	10 (50.0)	1 (5.0)	7 (35.0)	2 (10.0)	0
Blood immunoglobulin g decreased	1 (5.0)	0	1 (5.0)	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Serious neurological adverse reactions					

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (30.0)	2 (10.0)	1 (5.0)	3 (15.0)	0
Confusional state	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Seizure	2 (10.0)	0	0	2 (10.0)	0
Delirium	1 (5.0)	0	1 (5.0)	0	0
Depressed level of consciousness	1 (5.0)	1 (5.0)	0	0	0
Dysphagia	1 (5.0)	0	0	1 (5.0)	0
Irritability	1 (5.0)	1 (5.0)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (5.0)	0	0	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (97.1)	0	8 (23.5)	15 (44.1)	10 (29.4)
Cytokine Release Syndrome					
-Total	26 (76.5)	4 (11.8)	12 (35.3)	5 (14.7)	5 (14.7)
Cytokine release syndrome	26 (76.5)	4 (11.8)	12 (35.3)	5 (14.7)	5 (14.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	14 (41.2)	1 (2.9)	1 (2.9)	7 (20.6)	5 (14.7)
White blood cell count decreased	7 (20.6)	0	1 (2.9)	5 (14.7)	1 (2.9)
Neutrophil count decreased	5 (14.7)	0	0	2 (5.9)	3 (8.8)
Platelet count decreased	4 (11.8)	1 (2.9)	0	1 (2.9)	2 (5.9)
Febrile neutropenia	2 (5.9)	0	0	2 (5.9)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Neutropenia	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Thrombocytopenia	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Anaemia	1 (2.9)	0	1 (2.9)	0	0
Lymphopenia	1 (2.9)	0	0	1 (2.9)	0
Infections					
-Total	22 (64.7)	4 (11.8)	11 (32.4)	7 (20.6)	0
Upper respiratory tract infection	5 (14.7)	2 (5.9)	2 (5.9)	1 (2.9)	0
Otitis media	3 (8.8)	0	3 (8.8)	0	0
Urinary tract infection	3 (8.8)	0	1 (2.9)	2 (5.9)	0
Clostridium difficile colitis	2 (5.9)	0	2 (5.9)	0	0
Gastroenteritis	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Influenza	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Rhinovirus infection	2 (5.9)	2 (5.9)	0	0	0
Viral infection	2 (5.9)	2 (5.9)	0	0	0
Acute sinusitis	1 (2.9)	0	1 (2.9)	0	0
Body tinea	1 (2.9)	1 (2.9)	0	0	0
Catheter site cellulitis	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (2.9)	0	0	1 (2.9)	0
Clostridium difficile infection	1 (2.9)	0	1 (2.9)	0	0
Cytomegalovirus infection	1 (2.9)	1 (2.9)	0	0	0
Enterococcal infection	1 (2.9)	1 (2.9)	0	0	0
Escherichia urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Fungal skin infection	1 (2.9)	1 (2.9)	0	0	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Gingivitis	1 (2.9)	1 (2.9)	0	0	0
Herpes simplex	1 (2.9)	1 (2.9)	0	0	0
Herpes zoster	1 (2.9)	0	0	1 (2.9)	0
Hypopyon	1 (2.9)	0	1 (2.9)	0	0
Meningitis aseptic	1 (2.9)	0	1 (2.9)	0	0
Oral herpes	1 (2.9)	0	1 (2.9)	0	0
Orchitis	1 (2.9)	1 (2.9)	0	0	0
Parainfluenzae virus infection	1 (2.9)	1 (2.9)	0	0	0
Pharyngitis	1 (2.9)	0	1 (2.9)	0	0
Pneumonia	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	1 (2.9)	1 (2.9)	0	0	0
Sinusitis	1 (2.9)	0	1 (2.9)	0	0
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal infection	1 (2.9)	0	0	1 (2.9)	0
Streptococcal infection	1 (2.9)	0	1 (2.9)	0	0
Subcutaneous abscess	1 (2.9)	0	1 (2.9)	0	0
Vascular device infection	1 (2.9)	0	0	1 (2.9)	0
Viral upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Vulvovaginal mycotic infection	1 (2.9)	0	1 (2.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	19 (55.9)	2 (5.9)	14 (41.2)	3 (8.8)	0
Hypogammaglobulinaemia	19 (55.9)	2 (5.9)	14 (41.2)	3 (8.8)	0
Blood immunoglobulin a decreased	3 (8.8)	3 (8.8)	0	0	0
Blood immunoglobulin m decreased	2 (5.9)	2 (5.9)	0	0	0
Immunodeficiency	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	13 (38.2)	5 (14.7)	6 (17.6)	2 (5.9)	0
Encephalopathy	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Confusional state	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Muscular weakness	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Agitation	2 (5.9)	0	2 (5.9)	0	0
Delirium	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Dysarthria	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Hallucination	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Seizure	2 (5.9)	0	2 (5.9)	0	0
Tremor	2 (5.9)	2 (5.9)	0	0	0
Asterixis	1 (2.9)	1 (2.9)	0	0	0
Disturbance in attention	1 (2.9)	1 (2.9)	0	0	0
Dysphagia	1 (2.9)	0	1 (2.9)	0	0
Irritability	1 (2.9)	1 (2.9)	0	0	0
Listless	1 (2.9)	1 (2.9)	0	0	0
Mental status changes	1 (2.9)	1 (2.9)	0	0	0
Somnolence	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=34 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	3 (30.0)	1 (10.0)	6 (60.0)
Cytokine Release Syndrome					
-Total	8 (80.0)	0	5 (50.0)	0	3 (30.0)
Cytokine release syndrome	8 (80.0)	0	5 (50.0)	0	3 (30.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (50.0)	0	2 (20.0)	0	3 (30.0)
Anaemia	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Platelet count decreased	2 (20.0)	0	1 (10.0)	0	1 (10.0)
Neutropenia	1 (10.0)	0	0	0	1 (10.0)
Thrombocytopenia	1 (10.0)	0	0	0	1 (10.0)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	7 (70.0)	0	4 (40.0)	1 (10.0)	2 (20.0)
Influenza	2 (20.0)	0	2 (20.0)	0	0
Bacterial sepsis	1 (10.0)	0	0	0	1 (10.0)
Cholecystitis infective	1 (10.0)	0	0	1 (10.0)	0
Folliculitis	1 (10.0)	0	1 (10.0)	0	0
Human herpesvirus 6 infection	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	1 (10.0)	0	0
Sepsis	1 (10.0)	0	0	0	1 (10.0)
Sinusitis	1 (10.0)	0	1 (10.0)	0	0
Upper respiratory tract infection	1 (10.0)	0	1 (10.0)	0	0
Urinary tract infection enterococcal	1 (10.0)	0	0	1 (10.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (30.0)	0	3 (30.0)	0	0
Hypogammaglobulinaemia	3 (30.0)	0	3 (30.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin m decreased	1 (10.0)	1 (10.0)	0	0	0
Serious neurological adverse reactions					
-Total	2 (20.0)	2 (20.0)	0	0	0
Confusional state	1 (10.0)	1 (10.0)	0	0	0
Delirium	1 (10.0)	1 (10.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (86.7)	1 (3.3)	8 (26.7)	7 (23.3)	10 (33.3)
Cytokine Release Syndrome					
-Total	23 (76.7)	4 (13.3)	10 (33.3)	3 (10.0)	6 (20.0)
Cytokine release syndrome	23 (76.7)	4 (13.3)	10 (33.3)	3 (10.0)	6 (20.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	14 (46.7)	2 (6.7)	1 (3.3)	5 (16.7)	6 (20.0)
White blood cell count decreased	5 (16.7)	1 (3.3)	0	3 (10.0)	1 (3.3)
Neutrophil count decreased	4 (13.3)	0	0	1 (3.3)	3 (10.0)
Platelet count decreased	4 (13.3)	1 (3.3)	1 (3.3)	0	2 (6.7)
Thrombocytopenia	3 (10.0)	1 (3.3)	0	1 (3.3)	1 (3.3)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Febrile neutropenia	2 (6.7)	0	0	2 (6.7)	0
Neutropenia	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Lymphopenia	1 (3.3)	0	0	1 (3.3)	0
Infections					
-Total	8 (26.7)	2 (6.7)	4 (13.3)	2 (6.7)	0
Acute sinusitis	1 (3.3)	0	1 (3.3)	0	0
Body tinea	1 (3.3)	1 (3.3)	0	0	0
Clostridium difficile colitis	1 (3.3)	0	0	1 (3.3)	0
Clostridium difficile infection	1 (3.3)	0	1 (3.3)	0	0
Fungal skin infection	1 (3.3)	1 (3.3)	0	0	0
Gastroenteritis	1 (3.3)	0	0	1 (3.3)	0
Orchitis	1 (3.3)	1 (3.3)	0	0	0
Pharyngitis	1 (3.3)	0	1 (3.3)	0	0
Skin infection	1 (3.3)	0	1 (3.3)	0	0
Streptococcal infection	1 (3.3)	0	1 (3.3)	0	0
Upper respiratory tract infection	1 (3.3)	0	1 (3.3)	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (3.3)	0	1 (3.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	12 (40.0)	1 (3.3)	10 (33.3)	1 (3.3)	0
Hypogammaglobulinaemia	12 (40.0)	1 (3.3)	10 (33.3)	1 (3.3)	0
Blood immunoglobulin m decreased	2 (6.7)	2 (6.7)	0	0	0
Blood immunoglobulin a decreased	1 (3.3)	1 (3.3)	0	0	0
Serious neurological adverse reactions					
-Total	10 (33.3)	4 (13.3)	4 (13.3)	2 (6.7)	0
Confusional state	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Delirium	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Encephalopathy	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Irritability	2 (6.7)	2 (6.7)	0	0	0
Agitation	1 (3.3)	0	1 (3.3)	0	0
Dysarthria	1 (3.3)	0	1 (3.3)	0	0
Dysphagia	1 (3.3)	0	0	1 (3.3)	0

Timing: within 8 weeks post infusion, Gender: Male

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hallucination	1 (3.3)	0	1 (3.3)	0	0
Listless	1 (3.3)	1 (3.3)	0	0	0
Mental status changes	1 (3.3)	1 (3.3)	0	0	0
Muscular weakness	1 (3.3)	0	1 (3.3)	0	0
Seizure	1 (3.3)	0	1 (3.3)	0	0
Somnolence	1 (3.3)	1 (3.3)	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (97.1)	0	11 (32.4)	11 (32.4)	11 (32.4)
Cytokine Release Syndrome					
-Total	27 (79.4)	2 (5.9)	15 (44.1)	5 (14.7)	5 (14.7)
Cytokine release syndrome	27 (79.4)	2 (5.9)	15 (44.1)	5 (14.7)	5 (14.7)
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	1 (2.9)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	13 (38.2)	0	2 (5.9)	5 (14.7)	6 (17.6)
White blood cell count decreased	6 (17.6)	0	1 (2.9)	3 (8.8)	2 (5.9)
Neutrophil count decreased	4 (11.8)	0	0	2 (5.9)	2 (5.9)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	4 (11.8)	0	0	1 (2.9)	3 (8.8)
Lymphocyte count decreased	3 (8.8)	0	0	2 (5.9)	1 (2.9)
Anaemia	1 (2.9)	0	1 (2.9)	0	0
Febrile neutropenia	1 (2.9)	0	0	1 (2.9)	0
Neutropenia	1 (2.9)	0	0	0	1 (2.9)
Thrombocytopenia	1 (2.9)	0	0	0	1 (2.9)
Infections					
-Total	18 (52.9)	3 (8.8)	10 (29.4)	4 (11.8)	1 (2.9)
Clostridium difficile colitis	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Clostridium difficile infection	3 (8.8)	0	3 (8.8)	0	0
Rhinovirus infection	3 (8.8)	3 (8.8)	0	0	0
Pneumonia	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Staphylococcal infection	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Catheter site cellulitis	1 (2.9)	1 (2.9)	0	0	0
Catheter site infection	1 (2.9)	0	0	1 (2.9)	0
Cytomegalovirus infection	1 (2.9)	1 (2.9)	0	0	0
Enterococcal infection	1 (2.9)	1 (2.9)	0	0	0
Folliculitis	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Herpes simplex	1 (2.9)	1 (2.9)	0	0	0
Human herpesvirus 6 infection	1 (2.9)	0	1 (2.9)	0	0
Hypopyon	1 (2.9)	0	1 (2.9)	0	0
Influenza	1 (2.9)	1 (2.9)	0	0	0
Oral candidiasis	1 (2.9)	1 (2.9)	0	0	0
Septic embolus	1 (2.9)	0	0	0	1 (2.9)
Skin papilloma	1 (2.9)	0	1 (2.9)	0	0
Urinary tract infection enterococcal	1 (2.9)	0	0	1 (2.9)	0
Viral upper respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Vulvovaginal candidiasis	1 (2.9)	1 (2.9)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	15 (44.1)	3 (8.8)	9 (26.5)	3 (8.8)	0
Hypogammaglobulinaemia	13 (38.2)	2 (5.9)	8 (23.5)	3 (8.8)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (5.9)	2 (5.9)	0	0	0
Blood immunoglobulin m decreased	2 (5.9)	2 (5.9)	0	0	0
Blood immunoglobulin g decreased	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					
-Total	9 (26.5)	4 (11.8)	3 (8.8)	2 (5.9)	0
Confusional state	2 (5.9)	0	2 (5.9)	0	0
Delirium	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Encephalopathy	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Seizure	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Tremor	2 (5.9)	2 (5.9)	0	0	0
Agitation	1 (2.9)	0	1 (2.9)	0	0
Asterixis	1 (2.9)	1 (2.9)	0	0	0
Depressed level of consciousness	1 (2.9)	1 (2.9)	0	0	0
Dysarthria	1 (2.9)	1 (2.9)	0	0	0
Dysphagia	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hallucination	1 (2.9)	1 (2.9)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (55.6)	1 (3.7)	8 (29.6)	6 (22.2)	0
Infections					
-Total	14 (51.9)	2 (7.4)	7 (25.9)	5 (18.5)	0
Upper respiratory tract infection	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Gastroenteritis	2 (7.4)	0	2 (7.4)	0	0
Influenza	2 (7.4)	0	2 (7.4)	0	0
Cellulitis of male external genital organ	1 (3.7)	0	0	1 (3.7)	0
Cholecystitis infective	1 (3.7)	0	0	1 (3.7)	0
Corona virus infection	1 (3.7)	0	0	1 (3.7)	0
Herpes zoster	1 (3.7)	0	0	1 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (3.7)	0	1 (3.7)	0	0
Rash pustular	1 (3.7)	0	1 (3.7)	0	0
Respiratory syncytial virus infection	1 (3.7)	0	0	1 (3.7)	0
Rhinovirus infection	1 (3.7)	1 (3.7)	0	0	0
Subcutaneous abscess	1 (3.7)	0	1 (3.7)	0	0
Urinary tract infection	1 (3.7)	0	0	1 (3.7)	0
Viral infection	1 (3.7)	1 (3.7)	0	0	0
Viral upper respiratory tract infection	1 (3.7)	0	0	1 (3.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Hypogammaglobulinaemia	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Serious neurological adverse reactions					
-Total	1 (3.7)	1 (3.7)	0	0	0
Muscular weakness	1 (3.7)	1 (3.7)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

			All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (69.0)	4 (13.8)	8 (27.6)	6 (20.7)	2 (6.9)
Infections					
-Total	19 (65.5)	4 (13.8)	8 (27.6)	5 (17.2)	2 (6.9)
Upper respiratory tract infection	3 (10.3)	1 (3.4)	1 (3.4)	1 (3.4)	0
Urinary tract infection	3 (10.3)	0	2 (6.9)	1 (3.4)	0
Ear infection	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Parainfluenzae virus infection	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Sinusitis	2 (6.9)	0	2 (6.9)	0	0
Bacterial sepsis	1 (3.4)	0	0	0	1 (3.4)
Cytomegalovirus infection	1 (3.4)	1 (3.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus infection	1 (3.4)	0	0	1 (3.4)	0
Escherichia urinary tract infection	1 (3.4)	0	0	1 (3.4)	0
Gastroenteritis	1 (3.4)	1 (3.4)	0	0	0
Gastroenteritis norovirus	1 (3.4)	0	1 (3.4)	0	0
Gastroenteritis viral	1 (3.4)	1 (3.4)	0	0	0
Influenza	1 (3.4)	0	1 (3.4)	0	0
Molluscum contagiosum	1 (3.4)	1 (3.4)	0	0	0
Oral herpes	1 (3.4)	0	1 (3.4)	0	0
Otitis externa	1 (3.4)	0	1 (3.4)	0	0
Otitis media acute	1 (3.4)	0	1 (3.4)	0	0
Paronychia	1 (3.4)	1 (3.4)	0	0	0
Rhinitis	1 (3.4)	1 (3.4)	0	0	0
Rhinovirus infection	1 (3.4)	1 (3.4)	0	0	0
Rotavirus infection	1 (3.4)	0	0	1 (3.4)	0
Sepsis	1 (3.4)	0	0	0	1 (3.4)
Tinea capitis	1 (3.4)	1 (3.4)	0	0	0
Vascular device infection	1 (3.4)	0	0	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (3.4)	1 (3.4)	0	0	0
Vulvovaginal mycotic infection	1 (3.4)	0	1 (3.4)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (13.8)	0	4 (13.8)	0	0
Hypogammaglobulinaemia	4 (13.8)	0	4 (13.8)	0	0
Serious neurological adverse reactions					
-Total	1 (3.4)	1 (3.4)	0	0	0
Muscular weakness	1 (3.4)	1 (3.4)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.4)	0	0	1 (3.4)	0
Tumour lysis syndrome	1 (3.4)	0	0	1 (3.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (25.0)	2 (10.0)	1 (5.0)	2 (10.0)	0
Infections					
-Total	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Otitis media	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Sinusitis	2 (10.0)	0	2 (10.0)	0	0
Cellulitis of male external genital organ	1 (5.0)	0	0	1 (5.0)	0
Gingivitis	1 (5.0)	1 (5.0)	0	0	0
Haemophilus infection	1 (5.0)	0	1 (5.0)	0	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Upper respiratory tract infection	1 (5.0)	0	1 (5.0)	0	0
Urinary tract infection	1 (5.0)	0	0	1 (5.0)	0
Viral infection	1 (5.0)	1 (5.0)	0	0	0
Serious neurological adverse reactions					
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Disturbance in attention	1 (5.0)	1 (5.0)	0	0	0
Seizure	1 (5.0)	0	0	1 (5.0)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (57.1)	1 (7.1)	5 (35.7)	1 (7.1)	1 (7.1)
Infections					
-Total	7 (50.0)	1 (7.1)	4 (28.6)	1 (7.1)	1 (7.1)
Campylobacter infection	1 (7.1)	0	0	1 (7.1)	0
Clostridium difficile infection	1 (7.1)	0	0	1 (7.1)	0
Meningitis aseptic	1 (7.1)	0	1 (7.1)	0	0
Otitis media	1 (7.1)	0	1 (7.1)	0	0
Otitis media acute	1 (7.1)	0	1 (7.1)	0	0
Pneumonia	1 (7.1)	0	1 (7.1)	0	0
Respiratory tract infection	1 (7.1)	0	0	0	1 (7.1)

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (7.1)	0	0	1 (7.1)	0
Sinusitis	1 (7.1)	0	1 (7.1)	0	0
Skin infection	1 (7.1)	0	1 (7.1)	0	0
Upper respiratory tract infection	1 (7.1)	1 (7.1)	0	0	0
Urinary tract infection	1 (7.1)	0	1 (7.1)	0	0
Vulvovaginal candidiasis	1 (7.1)	0	1 (7.1)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (7.1)	0	1 (7.1)	0	0
Immunodeficiency	1 (7.1)	0	1 (7.1)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (96.7)	0	8 (26.7)	11 (36.7)	10 (33.3)
Cytokine Release Syndrome					
-Total	23 (76.7)	4 (13.3)	10 (33.3)	3 (10.0)	6 (20.0)
Cytokine release syndrome	23 (76.7)	4 (13.3)	10 (33.3)	3 (10.0)	6 (20.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	14 (46.7)	2 (6.7)	1 (3.3)	5 (16.7)	6 (20.0)
White blood cell count decreased	5 (16.7)	1 (3.3)	0	3 (10.0)	1 (3.3)
Neutrophil count decreased	4 (13.3)	0	0	1 (3.3)	3 (10.0)
Platelet count decreased	4 (13.3)	1 (3.3)	1 (3.3)	0	2 (6.7)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	3 (10.0)	1 (3.3)	0	1 (3.3)	1 (3.3)
Anaemia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Febrile neutropenia	2 (6.7)	0	0	2 (6.7)	0
Neutropenia	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Lymphopenia	1 (3.3)	0	0	1 (3.3)	0
Infections					
-Total	20 (66.7)	4 (13.3)	9 (30.0)	7 (23.3)	0
Upper respiratory tract infection	5 (16.7)	2 (6.7)	3 (10.0)	0	0
Gastroenteritis	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Otitis media	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Viral infection	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Influenza	2 (6.7)	0	2 (6.7)	0	0
Sinusitis	2 (6.7)	0	2 (6.7)	0	0
Acute sinusitis	1 (3.3)	0	1 (3.3)	0	0
Body tinea	1 (3.3)	1 (3.3)	0	0	0
Cellulitis of male external genital organ	1 (3.3)	0	0	1 (3.3)	0
Cholecystitis infective	1 (3.3)	0	0	1 (3.3)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (3.3)	0	0	1 (3.3)	0
Clostridium difficile infection	1 (3.3)	0	1 (3.3)	0	0
Corona virus infection	1 (3.3)	0	0	1 (3.3)	0
Fungal skin infection	1 (3.3)	1 (3.3)	0	0	0
Gingivitis	1 (3.3)	1 (3.3)	0	0	0
Haemophilus infection	1 (3.3)	0	1 (3.3)	0	0
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Orchitis	1 (3.3)	1 (3.3)	0	0	0
Otitis media acute	1 (3.3)	0	1 (3.3)	0	0
Pharyngitis	1 (3.3)	0	1 (3.3)	0	0
Pneumonia	1 (3.3)	0	1 (3.3)	0	0
Rash pustular	1 (3.3)	0	1 (3.3)	0	0
Respiratory syncytial virus infection	1 (3.3)	0	0	1 (3.3)	0
Rhinovirus infection	1 (3.3)	1 (3.3)	0	0	0
Skin infection	1 (3.3)	0	1 (3.3)	0	0
Streptococcal infection	1 (3.3)	0	1 (3.3)	0	0
Subcutaneous abscess	1 (3.3)	0	1 (3.3)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (3.3)	0	0	1 (3.3)	0
Viral upper respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	16 (53.3)	1 (3.3)	13 (43.3)	2 (6.7)	0
Hypogammaglobulinaemia	16 (53.3)	1 (3.3)	13 (43.3)	2 (6.7)	0
Blood immunoglobulin m decreased	2 (6.7)	2 (6.7)	0	0	0
Blood immunoglobulin a decreased	1 (3.3)	1 (3.3)	0	0	0
Serious neurological adverse reactions					
-Total	11 (36.7)	4 (13.3)	4 (13.3)	3 (10.0)	0
Confusional state	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Delirium	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Encephalopathy	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Irritability	2 (6.7)	2 (6.7)	0	0	0
Muscular weakness	2 (6.7)	1 (3.3)	1 (3.3)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Seizure	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Agitation	1 (3.3)	0	1 (3.3)	0	0
Disturbance in attention	1 (3.3)	1 (3.3)	0	0	0
Dysarthria	1 (3.3)	0	1 (3.3)	0	0
Dysphagia	1 (3.3)	0	0	1 (3.3)	0
Hallucination	1 (3.3)	0	1 (3.3)	0	0
Listless	1 (3.3)	1 (3.3)	0	0	0
Mental status changes	1 (3.3)	1 (3.3)	0	0	0
Somnolence	1 (3.3)	1 (3.3)	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	0	9 (26.5)	12 (35.3)	13 (38.2)
Cytokine Release Syndrome					
-Total	27 (79.4)	2 (5.9)	15 (44.1)	5 (14.7)	5 (14.7)
Cytokine release syndrome	27 (79.4)	2 (5.9)	15 (44.1)	5 (14.7)	5 (14.7)
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	1 (2.9)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	13 (38.2)	0	2 (5.9)	5 (14.7)	6 (17.6)
White blood cell count decreased	6 (17.6)	0	1 (2.9)	3 (8.8)	2 (5.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	4 (11.8)	0	0	2 (5.9)	2 (5.9)
Platelet count decreased	4 (11.8)	0	0	1 (2.9)	3 (8.8)
Lymphocyte count decreased	3 (8.8)	0	0	2 (5.9)	1 (2.9)
Anaemia	1 (2.9)	0	1 (2.9)	0	0
Febrile neutropenia	1 (2.9)	0	0	1 (2.9)	0
Neutropenia	1 (2.9)	0	0	0	1 (2.9)
Thrombocytopenia	1 (2.9)	0	0	0	1 (2.9)
Infections					
-Total	26 (76.5)	3 (8.8)	12 (35.3)	7 (20.6)	4 (11.8)
Clostridium difficile infection	4 (11.8)	0	3 (8.8)	1 (2.9)	0
Rhinovirus infection	4 (11.8)	4 (11.8)	0	0	0
Upper respiratory tract infection	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Urinary tract infection	4 (11.8)	0	3 (8.8)	1 (2.9)	0
Clostridium difficile colitis	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Pneumonia	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Cytomegalovirus infection	2 (5.9)	2 (5.9)	0	0	0
Ear infection	2 (5.9)	1 (2.9)	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Influenza	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Parainfluenzae virus infection	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Sinusitis	2 (5.9)	0	2 (5.9)	0	0
Staphylococcal infection	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Viral upper respiratory tract infection	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Vulvovaginal candidiasis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Bacterial sepsis	1 (2.9)	0	0	0	1 (2.9)
Campylobacter infection	1 (2.9)	0	0	1 (2.9)	0
Catheter site cellulitis	1 (2.9)	1 (2.9)	0	0	0
Catheter site infection	1 (2.9)	0	0	1 (2.9)	0
Enterococcal infection	1 (2.9)	1 (2.9)	0	0	0
Enterovirus infection	1 (2.9)	0	0	1 (2.9)	0
Escherichia urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Folliculitis	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis viral	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes simplex	1 (2.9)	1 (2.9)	0	0	0
Human herpesvirus 6 infection	1 (2.9)	0	1 (2.9)	0	0
Hypopyon	1 (2.9)	0	1 (2.9)	0	0
Meningitis aseptic	1 (2.9)	0	1 (2.9)	0	0
Molluscum contagiosum	1 (2.9)	1 (2.9)	0	0	0
Oral candidiasis	1 (2.9)	1 (2.9)	0	0	0
Oral herpes	1 (2.9)	0	1 (2.9)	0	0
Otitis externa	1 (2.9)	0	1 (2.9)	0	0
Otitis media	1 (2.9)	0	1 (2.9)	0	0
Otitis media acute	1 (2.9)	0	1 (2.9)	0	0
Paronychia	1 (2.9)	1 (2.9)	0	0	0
Respiratory tract infection	1 (2.9)	0	0	0	1 (2.9)
Respiratory tract infection viral	1 (2.9)	0	0	1 (2.9)	0
Rhinitis	1 (2.9)	1 (2.9)	0	0	0
Rotavirus infection	1 (2.9)	0	0	1 (2.9)	0
Sepsis	1 (2.9)	0	0	0	1 (2.9)
Septic embolus	1 (2.9)	0	0	0	1 (2.9)
Skin infection	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin papilloma	1 (2.9)	0	1 (2.9)	0	0
Tinea capitis	1 (2.9)	1 (2.9)	0	0	0
Urinary tract infection enterococcal	1 (2.9)	0	0	1 (2.9)	0
Vascular device infection	1 (2.9)	0	0	1 (2.9)	0
Vulvovaginal mycotic infection	1 (2.9)	0	1 (2.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	17 (50.0)	2 (5.9)	12 (35.3)	3 (8.8)	0
Hypogammaglobulinaemia	16 (47.1)	2 (5.9)	11 (32.4)	3 (8.8)	0
Blood immunoglobulin a decreased	2 (5.9)	2 (5.9)	0	0	0
Blood immunoglobulin m decreased	2 (5.9)	2 (5.9)	0	0	0
Blood immunoglobulin g decreased	1 (2.9)	0	1 (2.9)	0	0
Immunodeficiency	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (29.4)	5 (14.7)	3 (8.8)	2 (5.9)	0
Confusional state	2 (5.9)	0	2 (5.9)	0	0
Delirium	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Encephalopathy	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Seizure	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Tremor	2 (5.9)	2 (5.9)	0	0	0
Agitation	1 (2.9)	0	1 (2.9)	0	0
Asterixis	1 (2.9)	1 (2.9)	0	0	0
Depressed level of consciousness	1 (2.9)	1 (2.9)	0	0	0
Dysarthria	1 (2.9)	1 (2.9)	0	0	0
Dysphagia	1 (2.9)	0	1 (2.9)	0	0
Hallucination	1 (2.9)	1 (2.9)	0	0	0
Muscular weakness	1 (2.9)	1 (2.9)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (5.9)	0	0	2 (5.9)	0
Tumour lysis syndrome	2 (5.9)	0	0	2 (5.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (92.3)	1 (1.9)	14 (26.9)	14 (26.9)	19 (36.5)
Cytokine Release Syndrome					
-Total	40 (76.9)	4 (7.7)	19 (36.5)	7 (13.5)	10 (19.2)
Cytokine release syndrome	40 (76.9)	4 (7.7)	19 (36.5)	7 (13.5)	10 (19.2)
Haemophagocytic lymphohistiocytosis	1 (1.9)	0	1 (1.9)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	24 (46.2)	2 (3.8)	3 (5.8)	8 (15.4)	11 (21.2)
Platelet count decreased	8 (15.4)	1 (1.9)	1 (1.9)	1 (1.9)	5 (9.6)
White blood cell count decreased	8 (15.4)	1 (1.9)	1 (1.9)	3 (5.8)	3 (5.8)

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	7 (13.5)	0	0	3 (5.8)	4 (7.7)
Thrombocytopenia	4 (7.7)	1 (1.9)	0	1 (1.9)	2 (3.8)
Anaemia	3 (5.8)	0	2 (3.8)	1 (1.9)	0
Febrile neutropenia	3 (5.8)	0	0	3 (5.8)	0
Lymphocyte count decreased	3 (5.8)	0	0	2 (3.8)	1 (1.9)
Neutropenia	3 (5.8)	0	0	1 (1.9)	2 (3.8)
Lymphopenia	1 (1.9)	0	0	1 (1.9)	0
Infections					
-Total	21 (40.4)	4 (7.7)	11 (21.2)	5 (9.6)	1 (1.9)
Clostridium difficile colitis	3 (5.8)	1 (1.9)	1 (1.9)	1 (1.9)	0
Clostridium difficile infection	3 (5.8)	0	3 (5.8)	0	0
Rhinovirus infection	3 (5.8)	3 (5.8)	0	0	0
Pneumonia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Staphylococcal infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Acute sinusitis	1 (1.9)	0	1 (1.9)	0	0
Body tinea	1 (1.9)	1 (1.9)	0	0	0
Catheter site infection	1 (1.9)	0	0	1 (1.9)	0
Enterococcal infection	1 (1.9)	1 (1.9)	0	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Folliculitis	1 (1.9)	0	1 (1.9)	0	0
Fungal skin infection	1 (1.9)	1 (1.9)	0	0	0
Gastroenteritis	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Human herpesvirus 6 infection	1 (1.9)	0	1 (1.9)	0	0
Hypopyon	1 (1.9)	0	1 (1.9)	0	0
Influenza	1 (1.9)	1 (1.9)	0	0	0
Oral candidiasis	1 (1.9)	1 (1.9)	0	0	0
Orchitis	1 (1.9)	1 (1.9)	0	0	0
Septic embolus	1 (1.9)	0	0	0	1 (1.9)
Skin infection	1 (1.9)	0	1 (1.9)	0	0
Skin papilloma	1 (1.9)	0	1 (1.9)	0	0
Upper respiratory tract infection	1 (1.9)	0	1 (1.9)	0	0
Urinary tract infection enterococcal	1 (1.9)	0	0	1 (1.9)	0
Viral infection	1 (1.9)	0	1 (1.9)	0	0
Vulvovaginal candidiasis	1 (1.9)	1 (1.9)	0	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	21 (40.4)	1 (1.9)	16 (30.8)	4 (7.7)	0
Hypogammaglobulinaemia	20 (38.5)	1 (1.9)	15 (28.8)	4 (7.7)	0
Blood immunoglobulin m decreased	3 (5.8)	3 (5.8)	0	0	0
Blood immunoglobulin a decreased	1 (1.9)	1 (1.9)	0	0	0
Blood immunoglobulin g decreased	1 (1.9)	0	1 (1.9)	0	0
Serious neurological adverse reactions					
-Total	17 (32.7)	7 (13.5)	6 (11.5)	4 (7.7)	0
Confusional state	6 (11.5)	3 (5.8)	3 (5.8)	0	0
Delirium	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Encephalopathy	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Hallucination	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Irritability	2 (3.8)	2 (3.8)	0	0	0
Seizure	2 (3.8)	0	1 (1.9)	1 (1.9)	0

Timing: within 8 weeks post infusion, Race: White

Group term Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Agitation	1 (1.9)	0	1 (1.9)	0	0
Depressed level of consciousness	1 (1.9)	1 (1.9)	0	0	0
Dysarthria	1 (1.9)	0	1 (1.9)	0	0
Dysphagia	1 (1.9)	0	0	1 (1.9)	0
Listless	1 (1.9)	1 (1.9)	0	0	0
Mental status changes	1 (1.9)	1 (1.9)	0	0	0
Muscular weakness	1 (1.9)	0	1 (1.9)	0	0
Somnolence	1 (1.9)	1 (1.9)	0	0	0
Tremor	1 (1.9)	1 (1.9)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	3 (60.0)	1 (20.0)	1 (20.0)
Cytokine Release Syndrome					
-Total	4 (80.0)	0	4 (80.0)	0	0
Cytokine release syndrome	4 (80.0)	0	4 (80.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (20.0)	0	0	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	0	0	1 (20.0)
White blood cell count decreased	1 (20.0)	0	0	1 (20.0)	0
Infections					
-Total	2 (40.0)	0	1 (20.0)	1 (20.0)	0

Timing: within 8 weeks post infusion, Race: Asian

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	1 (20.0)	0	0	1 (20.0)	0
Pharyngitis	1 (20.0)	0	1 (20.0)	0	0
Streptococcal infection	1 (20.0)	0	1 (20.0)	0	0
Viral upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (60.0)	1 (20.0)	2 (40.0)	0	0
Hypogammaglobulinaemia	3 (60.0)	1 (20.0)	2 (40.0)	0	0
Blood immunoglobulin a decreased	1 (20.0)	1 (20.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	2 (28.6)	3 (42.9)	1 (14.3)
Cytokine Release Syndrome					
-Total	6 (85.7)	2 (28.6)	2 (28.6)	1 (14.3)	1 (14.3)
Cytokine release syndrome	6 (85.7)	2 (28.6)	2 (28.6)	1 (14.3)	1 (14.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (28.6)	0	0	2 (28.6)	0
White blood cell count decreased	2 (28.6)	0	0	2 (28.6)	0
Infections					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site cellulitis	1 (14.3)	1 (14.3)	0	0	0
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)	0	0
Clostridium difficile infection	1 (14.3)	0	1 (14.3)	0	0
Cytomegalovirus infection	1 (14.3)	1 (14.3)	0	0	0
Herpes simplex	1 (14.3)	1 (14.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Hypogammaglobulinaemia	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Blood immunoglobulin a decreased	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Serious neurological adverse reactions					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Agitation	1 (14.3)	0	1 (14.3)	0	0
Asterixis	1 (14.3)	1 (14.3)	0	0	0
Delirium	1 (14.3)	0	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysarthria	1 (14.3)	1 (14.3)	0	0	0
Dysphagia	1 (14.3)	0	1 (14.3)	0	0
Encephalopathy	1 (14.3)	1 (14.3)	0	0	0
Seizure	1 (14.3)	0	1 (14.3)	0	0
Tremor	1 (14.3)	1 (14.3)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (14.3)	0	0	1 (14.3)	0
Tumour lysis syndrome	1 (14.3)	0	0	1 (14.3)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (63.6)	4 (9.1)	13 (29.5)	10 (22.7)	1 (2.3)
Infections					
-Total	26 (59.1)	5 (11.4)	12 (27.3)	8 (18.2)	1 (2.3)
Upper respiratory tract infection	7 (15.9)	3 (6.8)	3 (6.8)	1 (2.3)	0
Gastroenteritis	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Influenza	3 (6.8)	0	3 (6.8)	0	0
Urinary tract infection	3 (6.8)	0	1 (2.3)	2 (4.5)	0
Ear infection	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Parainfluenzae virus infection	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Rhinovirus infection	2 (4.5)	2 (4.5)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	2 (4.5)	0	2 (4.5)	0	0
Viral upper respiratory tract infection	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Bacterial sepsis	1 (2.3)	0	0	0	1 (2.3)
Cellulitis of male external genital organ	1 (2.3)	0	0	1 (2.3)	0
Cholecystitis infective	1 (2.3)	0	0	1 (2.3)	0
Corona virus infection	1 (2.3)	0	0	1 (2.3)	0
Cytomegalovirus infection	1 (2.3)	1 (2.3)	0	0	0
Enterovirus infection	1 (2.3)	0	0	1 (2.3)	0
Escherichia urinary tract infection	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis norovirus	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis viral	1 (2.3)	1 (2.3)	0	0	0
Otitis externa	1 (2.3)	0	1 (2.3)	0	0
Otitis media	1 (2.3)	0	1 (2.3)	0	0
Otitis media acute	1 (2.3)	0	1 (2.3)	0	0
Paronychia	1 (2.3)	1 (2.3)	0	0	0
Rash pustular	1 (2.3)	0	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (2.3)	0	0	1 (2.3)	0
Rotavirus infection	1 (2.3)	0	0	1 (2.3)	0
Subcutaneous abscess	1 (2.3)	0	1 (2.3)	0	0
Tinea capitis	1 (2.3)	1 (2.3)	0	0	0
Viral infection	1 (2.3)	1 (2.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	7 (15.9)	0	6 (13.6)	1 (2.3)	0
Hypogammaglobulinaemia	7 (15.9)	0	6 (13.6)	1 (2.3)	0
Serious neurological adverse reactions					
-Total	1 (2.3)	1 (2.3)	0	0	0
Muscular weakness	1 (2.3)	1 (2.3)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.3)	0	0	1 (2.3)	0
Tumour lysis syndrome	1 (2.3)	0	0	1 (2.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Infections					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Herpes zoster	1 (20.0)	0	0	1 (20.0)	0
Molluscum contagiosum	1 (20.0)	1 (20.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	0	3 (42.9)	1 (14.3)	1 (14.3)
Infections					
-Total	5 (71.4)	0	3 (42.9)	1 (14.3)	1 (14.3)
Oral herpes	1 (14.3)	0	1 (14.3)	0	0
Rhinitis	1 (14.3)	1 (14.3)	0	0	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Urinary tract infection	1 (14.3)	0	1 (14.3)	0	0
Vascular device infection	1 (14.3)	0	0	1 (14.3)	0
Vulvovaginal mycotic infection	1 (14.3)	0	1 (14.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (14.3)	0	1 (14.3)	0	0
Hypogammaglobulinaemia	1 (14.3)	0	1 (14.3)	0	0
Serious neurological adverse reactions					
-Total	1 (14.3)	1 (14.3)	0	0	0
Muscular weakness	1 (14.3)	1 (14.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (28.6)	1 (3.6)	4 (14.3)	3 (10.7)	0
Infections					
-Total	7 (25.0)	0	4 (14.3)	3 (10.7)	0
Sinusitis	3 (10.7)	0	3 (10.7)	0	0
Otitis media	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Otitis media acute	2 (7.1)	0	2 (7.1)	0	0
Pneumonia	2 (7.1)	0	2 (7.1)	0	0
Urinary tract infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Campylobacter infection	1 (3.6)	0	0	1 (3.6)	0
Cellulitis of male external genital organ	1 (3.6)	0	0	1 (3.6)	0

Timing: >1 year post-CTL019 infusion, Race: White

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile infection	1 (3.6)	0	0	1 (3.6)	0
Haemophilus infection	1 (3.6)	0	1 (3.6)	0	0
Respiratory tract infection viral	1 (3.6)	0	0	1 (3.6)	0
Skin infection	1 (3.6)	0	1 (3.6)	0	0
Upper respiratory tract infection	1 (3.6)	0	1 (3.6)	0	0
Vulvovaginal candidiasis	1 (3.6)	0	1 (3.6)	0	0
Serious neurological adverse reactions					
-Total	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Disturbance in attention	1 (3.6)	1 (3.6)	0	0	0
Seizure	1 (3.6)	0	0	1 (3.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	0	0	1 (50.0)
Infections					
-Total	2 (100)	1 (50.0)	0	0	1 (50.0)
Gingivitis	1 (50.0)	1 (50.0)	0	0	0
Respiratory tract infection	1 (50.0)	0	0	0	1 (50.0)
Viral infection	1 (50.0)	1 (50.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Infections					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Meningitis aseptic	1 (25.0)	0	1 (25.0)	0	0
Otitis media	1 (25.0)	0	1 (25.0)	0	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (25.0)	0	1 (25.0)	0	0

Timing: >1 year post-CTL019 infusion, Race: Other

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Immunodeficiency	1 (25.0)	0	1 (25.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (98.1)	0	13 (25.0)	19 (36.5)	19 (36.5)
Cytokine Release Syndrome					
-Total	40 (76.9)	4 (7.7)	19 (36.5)	7 (13.5)	10 (19.2)
Cytokine release syndrome	40 (76.9)	4 (7.7)	19 (36.5)	7 (13.5)	10 (19.2)
Haemophagocytic lymphohistiocytosis	1 (1.9)	0	1 (1.9)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	24 (46.2)	2 (3.8)	3 (5.8)	8 (15.4)	11 (21.2)
Platelet count decreased	8 (15.4)	1 (1.9)	1 (1.9)	1 (1.9)	5 (9.6)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	8 (15.4)	1 (1.9)	1 (1.9)	3 (5.8)	3 (5.8)
Neutrophil count decreased	7 (13.5)	0	0	3 (5.8)	4 (7.7)
Thrombocytopenia	4 (7.7)	1 (1.9)	0	1 (1.9)	2 (3.8)
Anaemia	3 (5.8)	0	2 (3.8)	1 (1.9)	0
Febrile neutropenia	3 (5.8)	0	0	3 (5.8)	0
Lymphocyte count decreased	3 (5.8)	0	0	2 (3.8)	1 (1.9)
Neutropenia	3 (5.8)	0	0	1 (1.9)	2 (3.8)
Lymphopenia	1 (1.9)	0	0	1 (1.9)	0
Infections					
-Total	38 (73.1)	7 (13.5)	17 (32.7)	12 (23.1)	2 (3.8)
Upper respiratory tract infection	8 (15.4)	3 (5.8)	4 (7.7)	1 (1.9)	0
Rhinovirus infection	5 (9.6)	5 (9.6)	0	0	0
Clostridium difficile infection	4 (7.7)	0	3 (5.8)	1 (1.9)	0
Gastroenteritis	4 (7.7)	1 (1.9)	3 (5.8)	0	0
Influenza	4 (7.7)	1 (1.9)	3 (5.8)	0	0
Pneumonia	4 (7.7)	0	3 (5.8)	1 (1.9)	0
Sinusitis	4 (7.7)	0	4 (7.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	4 (7.7)	0	2 (3.8)	2 (3.8)	0
Clostridium difficile colitis	3 (5.8)	1 (1.9)	1 (1.9)	1 (1.9)	0
Otitis media	3 (5.8)	0	2 (3.8)	1 (1.9)	0
Ear infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Otitis media acute	2 (3.8)	0	2 (3.8)	0	0
Parainfluenzae virus infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Skin infection	2 (3.8)	0	2 (3.8)	0	0
Staphylococcal infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Viral infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Viral upper respiratory tract infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Vulvovaginal candidiasis	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Acute sinusitis	1 (1.9)	0	1 (1.9)	0	0
Bacterial sepsis	1 (1.9)	0	0	0	1 (1.9)
Body tinea	1 (1.9)	1 (1.9)	0	0	0
Campylobacter infection	1 (1.9)	0	0	1 (1.9)	0
Catheter site infection	1 (1.9)	0	0	1 (1.9)	0
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0
Cytomegalovirus infection	1 (1.9)	1 (1.9)	0	0	0
Enterococcal infection	1 (1.9)	1 (1.9)	0	0	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Folliculitis	1 (1.9)	0	1 (1.9)	0	0
Fungal skin infection	1 (1.9)	1 (1.9)	0	0	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0
Haemophilus infection	1 (1.9)	0	1 (1.9)	0	0
Human herpesvirus 6 infection	1 (1.9)	0	1 (1.9)	0	0
Hypopyon	1 (1.9)	0	1 (1.9)	0	0
Oral candidiasis	1 (1.9)	1 (1.9)	0	0	0
Orchitis	1 (1.9)	1 (1.9)	0	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash pustular	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus infection	1 (1.9)	0	0	1 (1.9)	0
Respiratory tract infection viral	1 (1.9)	0	0	1 (1.9)	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Septic embolus	1 (1.9)	0	0	0	1 (1.9)
Skin papilloma	1 (1.9)	0	1 (1.9)	0	0
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Tinea capitis	1 (1.9)	1 (1.9)	0	0	0
Urinary tract infection enterococcal	1 (1.9)	0	0	1 (1.9)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	27 (51.9)	1 (1.9)	21 (40.4)	5 (9.6)	0
Hypogammaglobulinaemia	26 (50.0)	1 (1.9)	20 (38.5)	5 (9.6)	0
Blood immunoglobulin m decreased	3 (5.8)	3 (5.8)	0	0	0
Blood immunoglobulin a decreased	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (1.9)	0	1 (1.9)	0	0
Serious neurological adverse reactions					
-Total	18 (34.6)	7 (13.5)	6 (11.5)	5 (9.6)	0
Confusional state	6 (11.5)	3 (5.8)	3 (5.8)	0	0
Delirium	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Encephalopathy	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Seizure	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Hallucination	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Irritability	2 (3.8)	2 (3.8)	0	0	0
Muscular weakness	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Agitation	1 (1.9)	0	1 (1.9)	0	0
Depressed level of consciousness	1 (1.9)	1 (1.9)	0	0	0
Disturbance in attention	1 (1.9)	1 (1.9)	0	0	0
Dysarthria	1 (1.9)	0	1 (1.9)	0	0
Dysphagia	1 (1.9)	0	0	1 (1.9)	0
Listless	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

Group term Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	1 (1.9)	1 (1.9)	0	0	0
Somnolence	1 (1.9)	1 (1.9)	0	0	0
Tremor	1 (1.9)	1 (1.9)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	2 (40.0)	1 (20.0)	2 (40.0)
Cytokine Release Syndrome					
-Total	4 (80.0)	0	4 (80.0)	0	0
Cytokine release syndrome	4 (80.0)	0	4 (80.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (20.0)	0	0	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	0	0	1 (20.0)
White blood cell count decreased	1 (20.0)	0	0	1 (20.0)	0
Infections					

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (60.0)	0	1 (20.0)	1 (20.0)	1 (20.0)
Gastroenteritis	1 (20.0)	0	0	1 (20.0)	0
Gingivitis	1 (20.0)	1 (20.0)	0	0	0
Herpes zoster	1 (20.0)	0	0	1 (20.0)	0
Molluscum contagiosum	1 (20.0)	1 (20.0)	0	0	0
Pharyngitis	1 (20.0)	0	1 (20.0)	0	0
Respiratory tract infection	1 (20.0)	0	0	0	1 (20.0)
Streptococcal infection	1 (20.0)	0	1 (20.0)	0	0
Viral infection	1 (20.0)	1 (20.0)	0	0	0
Viral upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (60.0)	1 (20.0)	2 (40.0)	0	0
Hypogammaglobulinaemia	3 (60.0)	1 (20.0)	2 (40.0)	0	0
Blood immunoglobulin a decreased	1 (20.0)	1 (20.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	2 (28.6)	3 (42.9)	2 (28.6)
Cytokine Release Syndrome					
-Total	6 (85.7)	2 (28.6)	2 (28.6)	1 (14.3)	1 (14.3)
Cytokine release syndrome	6 (85.7)	2 (28.6)	2 (28.6)	1 (14.3)	1 (14.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (28.6)	0	0	2 (28.6)	0
White blood cell count decreased	2 (28.6)	0	0	2 (28.6)	0
Infections					
-Total	5 (71.4)	0	3 (42.9)	1 (14.3)	1 (14.3)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site cellulitis	1 (14.3)	1 (14.3)	0	0	0
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)	0	0
Clostridium difficile infection	1 (14.3)	0	1 (14.3)	0	0
Cytomegalovirus infection	1 (14.3)	1 (14.3)	0	0	0
Herpes simplex	1 (14.3)	1 (14.3)	0	0	0
Meningitis aseptic	1 (14.3)	0	1 (14.3)	0	0
Oral herpes	1 (14.3)	0	1 (14.3)	0	0
Otitis media	1 (14.3)	0	1 (14.3)	0	0
Rhinitis	1 (14.3)	1 (14.3)	0	0	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Upper respiratory tract infection	1 (14.3)	1 (14.3)	0	0	0
Urinary tract infection	1 (14.3)	0	1 (14.3)	0	0
Vascular device infection	1 (14.3)	0	0	1 (14.3)	0
Vulvovaginal mycotic infection	1 (14.3)	0	1 (14.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Blood immunoglobulin a decreased	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Immunodeficiency	1 (14.3)	0	1 (14.3)	0	0
Serious neurological adverse reactions					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Agitation	1 (14.3)	0	1 (14.3)	0	0
Asterixis	1 (14.3)	1 (14.3)	0	0	0
Delirium	1 (14.3)	0	1 (14.3)	0	0
Dysarthria	1 (14.3)	1 (14.3)	0	0	0
Dysphagia	1 (14.3)	0	1 (14.3)	0	0
Encephalopathy	1 (14.3)	1 (14.3)	0	0	0
Muscular weakness	1 (14.3)	1 (14.3)	0	0	0
Seizure	1 (14.3)	0	1 (14.3)	0	0
Tremor	1 (14.3)	1 (14.3)	0	0	0
Tumour Lysis Syndrome					

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (14.3)	0	0	1 (14.3)	0
Tumour lysis syndrome	1 (14.3)	0	0	1 (14.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (92.0)	0	8 (32.0)	7 (28.0)	8 (32.0)
Cytokine Release Syndrome					
-Total	20 (80.0)	2 (8.0)	12 (48.0)	3 (12.0)	3 (12.0)
Cytokine release syndrome	20 (80.0)	2 (8.0)	12 (48.0)	3 (12.0)	3 (12.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	13 (52.0)	1 (4.0)	1 (4.0)	6 (24.0)	5 (20.0)
White blood cell count decreased	7 (28.0)	1 (4.0)	0	4 (16.0)	2 (8.0)
Neutrophil count decreased	6 (24.0)	0	0	2 (8.0)	4 (16.0)
Platelet count decreased	3 (12.0)	1 (4.0)	1 (4.0)	0	1 (4.0)
Thrombocytopenia	2 (8.0)	0	0	0	2 (8.0)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	1 (4.0)	0	1 (4.0)	0	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Lymphocyte count decreased	1 (4.0)	0	0	1 (4.0)	0
Lymphopenia	1 (4.0)	0	0	1 (4.0)	0
Neutropenia	1 (4.0)	0	0	1 (4.0)	0
Infections					
-Total	8 (32.0)	1 (4.0)	6 (24.0)	1 (4.0)	0
Clostridium difficile infection	2 (8.0)	0	2 (8.0)	0	0
Cytomegalovirus infection	1 (4.0)	1 (4.0)	0	0	0
Enterococcal infection	1 (4.0)	1 (4.0)	0	0	0
Fungal skin infection	1 (4.0)	1 (4.0)	0	0	0
Gastroenteritis	1 (4.0)	0	1 (4.0)	0	0
Gastroenteritis norovirus	1 (4.0)	0	1 (4.0)	0	0
Influenza	1 (4.0)	1 (4.0)	0	0	0
Skin infection	1 (4.0)	0	1 (4.0)	0	0
Skin papilloma	1 (4.0)	0	1 (4.0)	0	0
Staphylococcal infection	1 (4.0)	0	0	1 (4.0)	0
Viral infection	1 (4.0)	0	1 (4.0)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	13 (52.0)	0	12 (48.0)	1 (4.0)	0
Hypogammaglobulinaemia	12 (48.0)	0	11 (44.0)	1 (4.0)	0
Blood immunoglobulin m decreased	2 (8.0)	2 (8.0)	0	0	0
Blood immunoglobulin a decreased	1 (4.0)	1 (4.0)	0	0	0
Blood immunoglobulin g decreased	1 (4.0)	0	1 (4.0)	0	0
Serious neurological adverse reactions					
-Total	4 (16.0)	0	3 (12.0)	1 (4.0)	0
Dysarthria	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Seizure	2 (8.0)	0	2 (8.0)	0	0
Agitation	1 (4.0)	0	1 (4.0)	0	0
Asterixis	1 (4.0)	1 (4.0)	0	0	0
Confusional state	1 (4.0)	1 (4.0)	0	0	0
Delirium	1 (4.0)	0	1 (4.0)	0	0
Dysphagia	1 (4.0)	0	1 (4.0)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (4.0)	0	0	1 (4.0)	0
Hallucination	1 (4.0)	1 (4.0)	0	0	0
Muscular weakness	1 (4.0)	0	1 (4.0)	0	0
Somnolence	1 (4.0)	1 (4.0)	0	0	0
Tremor	1 (4.0)	1 (4.0)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (4.0)	0	0	1 (4.0)	0
Tumour lysis syndrome	1 (4.0)	0	0	1 (4.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (92.3)	1 (2.6)	11 (28.2)	11 (28.2)	13 (33.3)
Cytokine Release Syndrome					
-Total	30 (76.9)	4 (10.3)	13 (33.3)	5 (12.8)	8 (20.5)
Cytokine release syndrome	30 (76.9)	4 (10.3)	13 (33.3)	5 (12.8)	8 (20.5)
Haemophagocytic lymphohistiocytosis	1 (2.6)	0	1 (2.6)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	14 (35.9)	1 (2.6)	2 (5.1)	4 (10.3)	7 (17.9)
Platelet count decreased	5 (12.8)	0	0	1 (2.6)	4 (10.3)
White blood cell count decreased	4 (10.3)	0	1 (2.6)	2 (5.1)	1 (2.6)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Febrile neutropenia	2 (5.1)	0	0	2 (5.1)	0
Lymphocyte count decreased	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Neutropenia	2 (5.1)	0	0	0	2 (5.1)
Neutrophil count decreased	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Thrombocytopenia	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Infections					
-Total	18 (46.2)	4 (10.3)	8 (20.5)	5 (12.8)	1 (2.6)
Clostridium difficile colitis	4 (10.3)	1 (2.6)	2 (5.1)	1 (2.6)	0
Rhinovirus infection	3 (7.7)	3 (7.7)	0	0	0
Clostridium difficile infection	2 (5.1)	0	2 (5.1)	0	0
Pneumonia	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Acute sinusitis	1 (2.6)	0	1 (2.6)	0	0
Body tinea	1 (2.6)	1 (2.6)	0	0	0
Catheter site cellulitis	1 (2.6)	1 (2.6)	0	0	0
Catheter site infection	1 (2.6)	0	0	1 (2.6)	0
Folliculitis	1 (2.6)	0	1 (2.6)	0	0
Gastroenteritis	1 (2.6)	0	0	1 (2.6)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes simplex	1 (2.6)	1 (2.6)	0	0	0
Human herpesvirus 6 infection	1 (2.6)	0	1 (2.6)	0	0
Hypopyon	1 (2.6)	0	1 (2.6)	0	0
Oral candidiasis	1 (2.6)	1 (2.6)	0	0	0
Orchitis	1 (2.6)	1 (2.6)	0	0	0
Pharyngitis	1 (2.6)	0	1 (2.6)	0	0
Septic embolus	1 (2.6)	0	0	0	1 (2.6)
Staphylococcal infection	1 (2.6)	1 (2.6)	0	0	0
Streptococcal infection	1 (2.6)	0	1 (2.6)	0	0
Upper respiratory tract infection	1 (2.6)	0	1 (2.6)	0	0
Urinary tract infection enterococcal	1 (2.6)	0	0	1 (2.6)	0
Viral upper respiratory tract infection	1 (2.6)	0	1 (2.6)	0	0
Vulvovaginal candidiasis	1 (2.6)	1 (2.6)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	14 (35.9)	4 (10.3)	7 (17.9)	3 (7.7)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	13 (33.3)	3 (7.7)	7 (17.9)	3 (7.7)	0
Blood immunoglobulin a decreased	2 (5.1)	2 (5.1)	0	0	0
Blood immunoglobulin m decreased	2 (5.1)	2 (5.1)	0	0	0
Serious neurological adverse reactions					
-Total	15 (38.5)	8 (20.5)	4 (10.3)	3 (7.7)	0
Confusional state	5 (12.8)	2 (5.1)	3 (7.7)	0	0
Delirium	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Encephalopathy	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Irritability	2 (5.1)	2 (5.1)	0	0	0
Agitation	1 (2.6)	0	1 (2.6)	0	0
Depressed level of consciousness	1 (2.6)	1 (2.6)	0	0	0
Dysphagia	1 (2.6)	0	0	1 (2.6)	0
Hallucination	1 (2.6)	0	1 (2.6)	0	0
Listless	1 (2.6)	1 (2.6)	0	0	0
Mental status changes	1 (2.6)	1 (2.6)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

Group term Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Seizure	1 (2.6)	0	0	1 (2.6)	0
Tremor	1 (2.6)	1 (2.6)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (73.9)	2 (8.7)	10 (43.5)	5 (21.7)	0
Infections					
-Total	16 (69.6)	2 (8.7)	10 (43.5)	4 (17.4)	0
Upper respiratory tract infection	4 (17.4)	2 (8.7)	2 (8.7)	0	0
Urinary tract infection	4 (17.4)	0	2 (8.7)	2 (8.7)	0
Influenza	3 (13.0)	0	3 (13.0)	0	0
Cellulitis of male external genital organ	1 (4.3)	0	0	1 (4.3)	0
Corona virus infection	1 (4.3)	0	0	1 (4.3)	0
Cytomegalovirus infection	1 (4.3)	1 (4.3)	0	0	0
Ear infection	1 (4.3)	1 (4.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	1 (4.3)	0	0	1 (4.3)	0
Gastroenteritis	1 (4.3)	0	1 (4.3)	0	0
Gastroenteritis norovirus	1 (4.3)	0	1 (4.3)	0	0
Otitis externa	1 (4.3)	0	1 (4.3)	0	0
Otitis media	1 (4.3)	0	1 (4.3)	0	0
Otitis media acute	1 (4.3)	0	1 (4.3)	0	0
Parainfluenzae virus infection	1 (4.3)	1 (4.3)	0	0	0
Paronychia	1 (4.3)	1 (4.3)	0	0	0
Respiratory syncytial virus infection	1 (4.3)	0	0	1 (4.3)	0
Rhinovirus infection	1 (4.3)	1 (4.3)	0	0	0
Sinusitis	1 (4.3)	0	1 (4.3)	0	0
Subcutaneous abscess	1 (4.3)	0	1 (4.3)	0	0
Tinea capitis	1 (4.3)	1 (4.3)	0	0	0
Viral upper respiratory tract infection	1 (4.3)	0	0	1 (4.3)	0
Vulvovaginal mycotic infection	1 (4.3)	0	1 (4.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (17.4)	0	4 (17.4)	0	0
Hypogammaglobulinaemia	4 (17.4)	0	4 (17.4)	0	0
Serious neurological adverse reactions					
-Total	1 (4.3)	1 (4.3)	0	0	0
Muscular weakness	1 (4.3)	1 (4.3)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (4.3)	0	0	1 (4.3)	0
Tumour lysis syndrome	1 (4.3)	0	0	1 (4.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (54.5)	3 (9.1)	6 (18.2)	7 (21.2)	2 (6.1)
Infections					
-Total	17 (51.5)	4 (12.1)	5 (15.2)	6 (18.2)	2 (6.1)
Upper respiratory tract infection	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Gastroenteritis	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Bacterial sepsis	1 (3.0)	0	0	0	1 (3.0)
Cholecystitis infective	1 (3.0)	0	0	1 (3.0)	0
Ear infection	1 (3.0)	0	1 (3.0)	0	0
Enterovirus infection	1 (3.0)	0	0	1 (3.0)	0
Gastroenteritis viral	1 (3.0)	1 (3.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (3.0)	0	0	1 (3.0)	0
Molluscum contagiosum	1 (3.0)	1 (3.0)	0	0	0
Oral herpes	1 (3.0)	0	1 (3.0)	0	0
Parainfluenzae virus infection	1 (3.0)	0	0	1 (3.0)	0
Rash pustular	1 (3.0)	0	1 (3.0)	0	0
Rhinitis	1 (3.0)	1 (3.0)	0	0	0
Rhinovirus infection	1 (3.0)	1 (3.0)	0	0	0
Rotavirus infection	1 (3.0)	0	0	1 (3.0)	0
Sepsis	1 (3.0)	0	0	0	1 (3.0)
Sinusitis	1 (3.0)	0	1 (3.0)	0	0
Vascular device infection	1 (3.0)	0	0	1 (3.0)	0
Viral infection	1 (3.0)	1 (3.0)	0	0	0
Viral upper respiratory tract infection	1 (3.0)	1 (3.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Hypogammaglobulinaemia	4 (12.1)	0	3 (9.1)	1 (3.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	1 (3.0)	1 (3.0)	0	0	0
Muscular weakness	1 (3.0)	1 (3.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (29.4)	0	4 (23.5)	1 (5.9)	0
Infections					
-Total	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Otitis media	2 (11.8)	0	2 (11.8)	0	0
Cellulitis of male external genital organ	1 (5.9)	0	0	1 (5.9)	0
Meningitis aseptic	1 (5.9)	0	1 (5.9)	0	0
Otitis media acute	1 (5.9)	0	1 (5.9)	0	0
Skin infection	1 (5.9)	0	1 (5.9)	0	0
Urinary tract infection	1 (5.9)	0	0	1 (5.9)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (5.9)	0	1 (5.9)	0	0
Immunodeficiency	1 (5.9)	0	1 (5.9)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (47.1)	3 (17.6)	2 (11.8)	2 (11.8)	1 (5.9)
Infections					
-Total	7 (41.2)	2 (11.8)	2 (11.8)	2 (11.8)	1 (5.9)
Sinusitis	3 (17.6)	0	3 (17.6)	0	0
Pneumonia	2 (11.8)	0	2 (11.8)	0	0
Upper respiratory tract infection	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Campylobacter infection	1 (5.9)	0	0	1 (5.9)	0
Clostridium difficile infection	1 (5.9)	0	0	1 (5.9)	0
Gingivitis	1 (5.9)	1 (5.9)	0	0	0
Haemophilus infection	1 (5.9)	0	1 (5.9)	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (5.9)	0	0	1 (5.9)	0
Otitis media acute	1 (5.9)	0	1 (5.9)	0	0
Respiratory tract infection	1 (5.9)	0	0	0	1 (5.9)
Respiratory tract infection viral	1 (5.9)	0	0	1 (5.9)	0
Urinary tract infection	1 (5.9)	0	1 (5.9)	0	0
Viral infection	1 (5.9)	1 (5.9)	0	0	0
Vulvovaginal candidiasis	1 (5.9)	0	1 (5.9)	0	0
Serious neurological adverse reactions					
-Total	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Disturbance in attention	1 (5.9)	1 (5.9)	0	0	0
Seizure	1 (5.9)	0	0	1 (5.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (100)	0	7 (28.0)	10 (40.0)	8 (32.0)
Cytokine Release Syndrome					
-Total	20 (80.0)	2 (8.0)	12 (48.0)	3 (12.0)	3 (12.0)
Cytokine release syndrome	20 (80.0)	2 (8.0)	12 (48.0)	3 (12.0)	3 (12.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	13 (52.0)	1 (4.0)	1 (4.0)	6 (24.0)	5 (20.0)
White blood cell count decreased	7 (28.0)	1 (4.0)	0	4 (16.0)	2 (8.0)
Neutrophil count decreased	6 (24.0)	0	0	2 (8.0)	4 (16.0)
Platelet count decreased	3 (12.0)	1 (4.0)	1 (4.0)	0	1 (4.0)
Thrombocytopenia	2 (8.0)	0	0	0	2 (8.0)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	1 (4.0)	0	1 (4.0)	0	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Lymphocyte count decreased	1 (4.0)	0	0	1 (4.0)	0
Lymphopenia	1 (4.0)	0	0	1 (4.0)	0
Neutropenia	1 (4.0)	0	0	1 (4.0)	0
Infections					
-Total	18 (72.0)	2 (8.0)	11 (44.0)	5 (20.0)	0
Influenza	4 (16.0)	1 (4.0)	3 (12.0)	0	0
Upper respiratory tract infection	4 (16.0)	2 (8.0)	2 (8.0)	0	0
Urinary tract infection	4 (16.0)	0	2 (8.0)	2 (8.0)	0
Otitis media	3 (12.0)	0	3 (12.0)	0	0
Clostridium difficile infection	2 (8.0)	0	2 (8.0)	0	0
Cytomegalovirus infection	2 (8.0)	2 (8.0)	0	0	0
Gastroenteritis	2 (8.0)	0	2 (8.0)	0	0
Skin infection	2 (8.0)	0	2 (8.0)	0	0
Cellulitis of male external genital organ	1 (4.0)	0	0	1 (4.0)	0
Corona virus infection	1 (4.0)	0	0	1 (4.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (4.0)	1 (4.0)	0	0	0
Enterococcal infection	1 (4.0)	1 (4.0)	0	0	0
Escherichia urinary tract infection	1 (4.0)	0	0	1 (4.0)	0
Fungal skin infection	1 (4.0)	1 (4.0)	0	0	0
Gastroenteritis norovirus	1 (4.0)	0	1 (4.0)	0	0
Meningitis aseptic	1 (4.0)	0	1 (4.0)	0	0
Otitis externa	1 (4.0)	0	1 (4.0)	0	0
Otitis media acute	1 (4.0)	0	1 (4.0)	0	0
Parainfluenzae virus infection	1 (4.0)	1 (4.0)	0	0	0
Paronychia	1 (4.0)	1 (4.0)	0	0	0
Respiratory syncytial virus infection	1 (4.0)	0	0	1 (4.0)	0
Rhinovirus infection	1 (4.0)	1 (4.0)	0	0	0
Sinusitis	1 (4.0)	0	1 (4.0)	0	0
Skin papilloma	1 (4.0)	0	1 (4.0)	0	0
Staphylococcal infection	1 (4.0)	0	0	1 (4.0)	0
Subcutaneous abscess	1 (4.0)	0	1 (4.0)	0	0
Tinea capitis	1 (4.0)	1 (4.0)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (4.0)	0	1 (4.0)	0	0
Viral upper respiratory tract infection	1 (4.0)	0	0	1 (4.0)	0
Vulvovaginal mycotic infection	1 (4.0)	0	1 (4.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	16 (64.0)	0	15 (60.0)	1 (4.0)	0
Hypogammaglobulinaemia	15 (60.0)	0	14 (56.0)	1 (4.0)	0
Blood immunoglobulin m decreased	2 (8.0)	2 (8.0)	0	0	0
Blood immunoglobulin a decreased	1 (4.0)	1 (4.0)	0	0	0
Blood immunoglobulin g decreased	1 (4.0)	0	1 (4.0)	0	0
Immunodeficiency	1 (4.0)	0	1 (4.0)	0	0
Serious neurological adverse reactions					
-Total	5 (20.0)	1 (4.0)	3 (12.0)	1 (4.0)	0
Dysarthria	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Muscular weakness	2 (8.0)	1 (4.0)	1 (4.0)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	2 (8.0)	0	2 (8.0)	0	0
Agitation	1 (4.0)	0	1 (4.0)	0	0
Asterixis	1 (4.0)	1 (4.0)	0	0	0
Confusional state	1 (4.0)	1 (4.0)	0	0	0
Delirium	1 (4.0)	0	1 (4.0)	0	0
Dysphagia	1 (4.0)	0	1 (4.0)	0	0
Encephalopathy	1 (4.0)	0	0	1 (4.0)	0
Hallucination	1 (4.0)	1 (4.0)	0	0	0
Somnolence	1 (4.0)	1 (4.0)	0	0	0
Tremor	1 (4.0)	1 (4.0)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (8.0)	0	0	2 (8.0)	0
Tumour lysis syndrome	2 (8.0)	0	0	2 (8.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (97.4)	0	10 (25.6)	13 (33.3)	15 (38.5)
Cytokine Release Syndrome					
-Total	30 (76.9)	4 (10.3)	13 (33.3)	5 (12.8)	8 (20.5)
Cytokine release syndrome	30 (76.9)	4 (10.3)	13 (33.3)	5 (12.8)	8 (20.5)
Haemophagocytic lymphohistiocytosis	1 (2.6)	0	1 (2.6)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	14 (35.9)	1 (2.6)	2 (5.1)	4 (10.3)	7 (17.9)
Platelet count decreased	5 (12.8)	0	0	1 (2.6)	4 (10.3)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	4 (10.3)	0	1 (2.6)	2 (5.1)	1 (2.6)
Anaemia	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Febrile neutropenia	2 (5.1)	0	0	2 (5.1)	0
Lymphocyte count decreased	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Neutropenia	2 (5.1)	0	0	0	2 (5.1)
Neutrophil count decreased	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Thrombocytopenia	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Infections					
-Total	28 (71.8)	5 (12.8)	10 (25.6)	9 (23.1)	4 (10.3)
Upper respiratory tract infection	5 (12.8)	2 (5.1)	2 (5.1)	1 (2.6)	0
Clostridium difficile colitis	4 (10.3)	1 (2.6)	2 (5.1)	1 (2.6)	0
Pneumonia	4 (10.3)	0	3 (7.7)	1 (2.6)	0
Rhinovirus infection	4 (10.3)	4 (10.3)	0	0	0
Clostridium difficile infection	3 (7.7)	0	2 (5.1)	1 (2.6)	0
Gastroenteritis	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Sinusitis	3 (7.7)	0	3 (7.7)	0	0
Viral infection	2 (5.1)	2 (5.1)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Vulvovaginal candidiasis	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Acute sinusitis	1 (2.6)	0	1 (2.6)	0	0
Bacterial sepsis	1 (2.6)	0	0	0	1 (2.6)
Body tinea	1 (2.6)	1 (2.6)	0	0	0
Campylobacter infection	1 (2.6)	0	0	1 (2.6)	0
Catheter site cellulitis	1 (2.6)	1 (2.6)	0	0	0
Catheter site infection	1 (2.6)	0	0	1 (2.6)	0
Cholecystitis infective	1 (2.6)	0	0	1 (2.6)	0
Ear infection	1 (2.6)	0	1 (2.6)	0	0
Enterovirus infection	1 (2.6)	0	0	1 (2.6)	0
Folliculitis	1 (2.6)	0	1 (2.6)	0	0
Gastroenteritis viral	1 (2.6)	1 (2.6)	0	0	0
Gingivitis	1 (2.6)	1 (2.6)	0	0	0
Haemophilus infection	1 (2.6)	0	1 (2.6)	0	0
Herpes simplex	1 (2.6)	1 (2.6)	0	0	0
Herpes zoster	1 (2.6)	0	0	1 (2.6)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (2.6)	0	1 (2.6)	0	0
Hypopyon	1 (2.6)	0	1 (2.6)	0	0
Molluscum contagiosum	1 (2.6)	1 (2.6)	0	0	0
Oral candidiasis	1 (2.6)	1 (2.6)	0	0	0
Oral herpes	1 (2.6)	0	1 (2.6)	0	0
Orchitis	1 (2.6)	1 (2.6)	0	0	0
Otitis media	1 (2.6)	0	0	1 (2.6)	0
Otitis media acute	1 (2.6)	0	1 (2.6)	0	0
Parainfluenzae virus infection	1 (2.6)	0	0	1 (2.6)	0
Pharyngitis	1 (2.6)	0	1 (2.6)	0	0
Rash pustular	1 (2.6)	0	1 (2.6)	0	0
Respiratory tract infection	1 (2.6)	0	0	0	1 (2.6)
Respiratory tract infection viral	1 (2.6)	0	0	1 (2.6)	0
Rhinitis	1 (2.6)	1 (2.6)	0	0	0
Rotavirus infection	1 (2.6)	0	0	1 (2.6)	0
Sepsis	1 (2.6)	0	0	0	1 (2.6)
Septic embolus	1 (2.6)	0	0	0	1 (2.6)
Staphylococcal infection	1 (2.6)	1 (2.6)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (2.6)	0	1 (2.6)	0	0
Urinary tract infection	1 (2.6)	0	1 (2.6)	0	0
Urinary tract infection enterococcal	1 (2.6)	0	0	1 (2.6)	0
Vascular device infection	1 (2.6)	0	0	1 (2.6)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	17 (43.6)	3 (7.7)	10 (25.6)	4 (10.3)	0
Hypogammaglobulinaemia	17 (43.6)	3 (7.7)	10 (25.6)	4 (10.3)	0
Blood immunoglobulin a decreased	2 (5.1)	2 (5.1)	0	0	0
Blood immunoglobulin m decreased	2 (5.1)	2 (5.1)	0	0	0
Serious neurological adverse reactions					
-Total	16 (41.0)	8 (20.5)	4 (10.3)	4 (10.3)	0
Confusional state	5 (12.8)	2 (5.1)	3 (7.7)	0	0
Delirium	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Encephalopathy	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	2 (5.1)	2 (5.1)	0	0	0
Seizure	2 (5.1)	0	0	2 (5.1)	0
Agitation	1 (2.6)	0	1 (2.6)	0	0
Depressed level of consciousness	1 (2.6)	1 (2.6)	0	0	0
Disturbance in attention	1 (2.6)	1 (2.6)	0	0	0
Dysphagia	1 (2.6)	0	0	1 (2.6)	0
Hallucination	1 (2.6)	0	1 (2.6)	0	0
Listless	1 (2.6)	1 (2.6)	0	0	0
Mental status changes	1 (2.6)	1 (2.6)	0	0	0
Muscular weakness	1 (2.6)	1 (2.6)	0	0	0
Tremor	1 (2.6)	1 (2.6)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	3 (42.9)	1 (14.3)	3 (42.9)
Cytokine Release Syndrome					
-Total	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (42.9)	1 (14.3)	0	1 (14.3)	1 (14.3)
Anaemia	1 (14.3)	0	0	1 (14.3)	0
Neutropenia	1 (14.3)	0	0	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	0	1 (14.3)	0
White blood cell count decreased	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	2 (28.6)	0	2 (28.6)	0	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Viral infection	1 (14.3)	0	1 (14.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (57.1)	0	4 (57.1)	0	0
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Serious neurological adverse reactions					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Delirium	1 (14.3)	1 (14.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (91.2)	1 (1.8)	16 (28.1)	17 (29.8)	18 (31.6)
Cytokine Release Syndrome					
-Total	45 (78.9)	6 (10.5)	23 (40.4)	8 (14.0)	8 (14.0)
Cytokine release syndrome	45 (78.9)	6 (10.5)	23 (40.4)	8 (14.0)	8 (14.0)
Haemophagocytic lymphohistiocytosis	1 (1.8)	0	1 (1.8)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	24 (42.1)	1 (1.8)	3 (5.3)	9 (15.8)	11 (19.3)
White blood cell count decreased	10 (17.5)	0	1 (1.8)	6 (10.5)	3 (5.3)
Platelet count decreased	8 (14.0)	1 (1.8)	1 (1.8)	1 (1.8)	5 (8.8)
Neutrophil count decreased	7 (12.3)	0	0	2 (3.5)	5 (8.8)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	4 (7.0)	1 (1.8)	0	1 (1.8)	2 (3.5)
Febrile neutropenia	3 (5.3)	0	0	3 (5.3)	0
Lymphocyte count decreased	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Anaemia	2 (3.5)	0	2 (3.5)	0	0
Neutropenia	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Lymphopenia	1 (1.8)	0	0	1 (1.8)	0
Infections					
-Total	24 (42.1)	5 (8.8)	12 (21.1)	6 (10.5)	1 (1.8)
Clostridium difficile colitis	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Clostridium difficile infection	4 (7.0)	0	4 (7.0)	0	0
Rhinovirus infection	3 (5.3)	3 (5.3)	0	0	0
Pneumonia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Staphylococcal infection	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Acute sinusitis	1 (1.8)	0	1 (1.8)	0	0
Body tinea	1 (1.8)	1 (1.8)	0	0	0
Catheter site cellulitis	1 (1.8)	1 (1.8)	0	0	0
Catheter site infection	1 (1.8)	0	0	1 (1.8)	0
Cytomegalovirus infection	1 (1.8)	1 (1.8)	0	0	0
Enterococcal infection	1 (1.8)	1 (1.8)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Folliculitis	1 (1.8)	0	1 (1.8)	0	0
Fungal skin infection	1 (1.8)	1 (1.8)	0	0	0
Gastroenteritis	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Herpes simplex	1 (1.8)	1 (1.8)	0	0	0
Human herpesvirus 6 infection	1 (1.8)	0	1 (1.8)	0	0
Hypopyon	1 (1.8)	0	1 (1.8)	0	0
Influenza	1 (1.8)	1 (1.8)	0	0	0
Oral candidiasis	1 (1.8)	1 (1.8)	0	0	0
Orchitis	1 (1.8)	1 (1.8)	0	0	0
Pharyngitis	1 (1.8)	0	1 (1.8)	0	0
Septic embolus	1 (1.8)	0	0	0	1 (1.8)
Skin infection	1 (1.8)	0	1 (1.8)	0	0
Skin papilloma	1 (1.8)	0	1 (1.8)	0	0
Streptococcal infection	1 (1.8)	0	1 (1.8)	0	0
Upper respiratory tract infection	1 (1.8)	0	1 (1.8)	0	0
Urinary tract infection enterococcal	1 (1.8)	0	0	1 (1.8)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (1.8)	0	1 (1.8)	0	0
Vulvovaginal candidiasis	1 (1.8)	1 (1.8)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	23 (40.4)	4 (7.0)	15 (26.3)	4 (7.0)	0
Hypogammaglobulinaemia	21 (36.8)	3 (5.3)	14 (24.6)	4 (7.0)	0
Blood immunoglobulin a decreased	3 (5.3)	3 (5.3)	0	0	0
Blood immunoglobulin m decreased	3 (5.3)	3 (5.3)	0	0	0
Blood immunoglobulin g decreased	1 (1.8)	0	1 (1.8)	0	0
Serious neurological adverse reactions					
-Total	16 (28.1)	6 (10.5)	6 (10.5)	4 (7.0)	0
Confusional state	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Encephalopathy	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Delirium	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Seizure	3 (5.3)	0	2 (3.5)	1 (1.8)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	2 (3.5)	0	2 (3.5)	0	0
Dysarthria	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Dysphagia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Hallucination	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Irritability	2 (3.5)	2 (3.5)	0	0	0
Tremor	2 (3.5)	2 (3.5)	0	0	0
Asterixis	1 (1.8)	1 (1.8)	0	0	0
Depressed level of consciousness	1 (1.8)	1 (1.8)	0	0	0
Listless	1 (1.8)	1 (1.8)	0	0	0
Mental status changes	1 (1.8)	1 (1.8)	0	0	0
Muscular weakness	1 (1.8)	0	1 (1.8)	0	0
Somnolence	1 (1.8)	1 (1.8)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.8)	0	0	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=5			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Infections					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Upper respiratory tract infection	2 (40.0)	0	2 (40.0)	0	0
Corona virus infection	1 (20.0)	0	0	1 (20.0)	0
Ear infection	1 (20.0)	1 (20.0)	0	0	0
Respiratory syncytial virus infection	1 (20.0)	0	0	1 (20.0)	0
Rhinovirus infection	1 (20.0)	1 (20.0)	0	0	0
Tinea capitis	1 (20.0)	1 (20.0)	0	0	0
Viral infection	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	1 (20.0)	1 (20.0)	0	0	0
Muscular weakness	1 (20.0)	1 (20.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=51			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (60.8)	4 (7.8)	14 (27.5)	11 (21.6)	2 (3.9)
Infections					
-Total	29 (56.9)	5 (9.8)	13 (25.5)	9 (17.6)	2 (3.9)
Upper respiratory tract infection	5 (9.8)	3 (5.9)	1 (2.0)	1 (2.0)	0
Urinary tract infection	4 (7.8)	0	2 (3.9)	2 (3.9)	0
Gastroenteritis	3 (5.9)	1 (2.0)	2 (3.9)	0	0
Influenza	3 (5.9)	0	3 (5.9)	0	0
Parainfluenzae virus infection	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Sinusitis	2 (3.9)	0	2 (3.9)	0	0
Viral upper respiratory tract infection	2 (3.9)	1 (2.0)	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (2.0)	0	0	0	1 (2.0)
Cellulitis of male external genital organ	1 (2.0)	0	0	1 (2.0)	0
Cholecystitis infective	1 (2.0)	0	0	1 (2.0)	0
Cytomegalovirus infection	1 (2.0)	1 (2.0)	0	0	0
Ear infection	1 (2.0)	0	1 (2.0)	0	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0
Escherichia urinary tract infection	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis norovirus	1 (2.0)	0	1 (2.0)	0	0
Gastroenteritis viral	1 (2.0)	1 (2.0)	0	0	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Molluscum contagiosum	1 (2.0)	1 (2.0)	0	0	0
Oral herpes	1 (2.0)	0	1 (2.0)	0	0
Otitis externa	1 (2.0)	0	1 (2.0)	0	0
Otitis media	1 (2.0)	0	1 (2.0)	0	0
Otitis media acute	1 (2.0)	0	1 (2.0)	0	0
Paronychia	1 (2.0)	1 (2.0)	0	0	0
Rash pustular	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Rhinovirus infection	1 (2.0)	1 (2.0)	0	0	0
Rotavirus infection	1 (2.0)	0	0	1 (2.0)	0
Sepsis	1 (2.0)	0	0	0	1 (2.0)
Subcutaneous abscess	1 (2.0)	0	1 (2.0)	0	0
Vascular device infection	1 (2.0)	0	0	1 (2.0)	0
Vulvovaginal mycotic infection	1 (2.0)	0	1 (2.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (15.7)	0	7 (13.7)	1 (2.0)	0
Hypogammaglobulinaemia	8 (15.7)	0	7 (13.7)	1 (2.0)	0
Serious neurological adverse reactions					
-Total	1 (2.0)	1 (2.0)	0	0	0
Muscular weakness	1 (2.0)	1 (2.0)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.0)	0	0	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	0	0	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=5			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (20.0)	0	1 (20.0)	0	0
Infections					
-Total	1 (20.0)	0	1 (20.0)	0	0
Skin infection	1 (20.0)	0	1 (20.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (41.4)	3 (10.3)	5 (17.2)	3 (10.3)	1 (3.4)
Infections					
-Total	10 (34.5)	2 (6.9)	4 (13.8)	3 (10.3)	1 (3.4)
Otitis media	3 (10.3)	0	2 (6.9)	1 (3.4)	0
Sinusitis	3 (10.3)	0	3 (10.3)	0	0
Otitis media acute	2 (6.9)	0	2 (6.9)	0	0
Pneumonia	2 (6.9)	0	2 (6.9)	0	0
Upper respiratory tract infection	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Urinary tract infection	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Campylobacter infection	1 (3.4)	0	0	1 (3.4)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=29			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (3.4)	0	0	1 (3.4)	0
Clostridium difficile infection	1 (3.4)	0	0	1 (3.4)	0
Gingivitis	1 (3.4)	1 (3.4)	0	0	0
Haemophilus infection	1 (3.4)	0	1 (3.4)	0	0
Meningitis aseptic	1 (3.4)	0	1 (3.4)	0	0
Respiratory tract infection	1 (3.4)	0	0	0	1 (3.4)
Respiratory tract infection viral	1 (3.4)	0	0	1 (3.4)	0
Viral infection	1 (3.4)	1 (3.4)	0	0	0
Vulvovaginal candidiasis	1 (3.4)	0	1 (3.4)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.4)	0	1 (3.4)	0	0
Immunodeficiency	1 (3.4)	0	1 (3.4)	0	0
Serious neurological adverse reactions					
-Total	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Disturbance in attention	1 (3.4)	1 (3.4)	0	0	0
Seizure	1 (3.4)	0	0	1 (3.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=7			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	2 (28.6)	2 (28.6)	3 (42.9)
Cytokine Release Syndrome					
-Total	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (42.9)	1 (14.3)	0	1 (14.3)	1 (14.3)
Anaemia	1 (14.3)	0	0	1 (14.3)	0
Neutropenia	1 (14.3)	0	0	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	0	1 (14.3)	0
White blood cell count decreased	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Upper respiratory tract infection	2 (28.6)	0	2 (28.6)	0	0
Viral infection	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Corona virus infection	1 (14.3)	0	0	1 (14.3)	0
Ear infection	1 (14.3)	1 (14.3)	0	0	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	1 (14.3)	0	0	0
Skin infection	1 (14.3)	0	1 (14.3)	0	0
Tinea capitis	1 (14.3)	1 (14.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (57.1)	0	4 (57.1)	0	0
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Delirium	1 (14.3)	1 (14.3)	0	0	0
Muscular weakness	1 (14.3)	1 (14.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=57			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (98.2)	0	15 (26.3)	21 (36.8)	20 (35.1)
Cytokine Release Syndrome					
-Total	45 (78.9)	6 (10.5)	23 (40.4)	8 (14.0)	8 (14.0)
Cytokine release syndrome	45 (78.9)	6 (10.5)	23 (40.4)	8 (14.0)	8 (14.0)
Haemophagocytic lymphohistiocytosis	1 (1.8)	0	1 (1.8)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	24 (42.1)	1 (1.8)	3 (5.3)	9 (15.8)	11 (19.3)
White blood cell count decreased	10 (17.5)	0	1 (1.8)	6 (10.5)	3 (5.3)
Platelet count decreased	8 (14.0)	1 (1.8)	1 (1.8)	1 (1.8)	5 (8.8)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	7 (12.3)	0	0	2 (3.5)	5 (8.8)
Thrombocytopenia	4 (7.0)	1 (1.8)	0	1 (1.8)	2 (3.5)
Febrile neutropenia	3 (5.3)	0	0	3 (5.3)	0
Lymphocyte count decreased	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Anaemia	2 (3.5)	0	2 (3.5)	0	0
Neutropenia	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Lymphopenia	1 (1.8)	0	0	1 (1.8)	0
Infections					
-Total	42 (73.7)	6 (10.5)	19 (33.3)	13 (22.8)	4 (7.0)
Upper respiratory tract infection	7 (12.3)	4 (7.0)	2 (3.5)	1 (1.8)	0
Clostridium difficile infection	5 (8.8)	0	4 (7.0)	1 (1.8)	0
Urinary tract infection	5 (8.8)	0	3 (5.3)	2 (3.5)	0
Clostridium difficile colitis	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Gastroenteritis	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Influenza	4 (7.0)	1 (1.8)	3 (5.3)	0	0
Otitis media	4 (7.0)	0	3 (5.3)	1 (1.8)	0
Pneumonia	4 (7.0)	0	3 (5.3)	1 (1.8)	0
Rhinovirus infection	4 (7.0)	4 (7.0)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=57			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	4 (7.0)	0	4 (7.0)	0	0
Viral upper respiratory tract infection	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Cytomegalovirus infection	2 (3.5)	2 (3.5)	0	0	0
Otitis media acute	2 (3.5)	0	2 (3.5)	0	0
Parainfluenzae virus infection	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Staphylococcal infection	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Vulvovaginal candidiasis	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Acute sinusitis	1 (1.8)	0	1 (1.8)	0	0
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Body tinea	1 (1.8)	1 (1.8)	0	0	0
Campylobacter infection	1 (1.8)	0	0	1 (1.8)	0
Catheter site cellulitis	1 (1.8)	1 (1.8)	0	0	0
Catheter site infection	1 (1.8)	0	0	1 (1.8)	0
Cellulitis of male external genital organ	1 (1.8)	0	0	1 (1.8)	0
Cholecystitis infective	1 (1.8)	0	0	1 (1.8)	0
Ear infection	1 (1.8)	0	1 (1.8)	0	0
Enterococcal infection	1 (1.8)	1 (1.8)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=57			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Escherichia urinary tract infection	1 (1.8)	0	0	1 (1.8)	0
Folliculitis	1 (1.8)	0	1 (1.8)	0	0
Fungal skin infection	1 (1.8)	1 (1.8)	0	0	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis viral	1 (1.8)	1 (1.8)	0	0	0
Gingivitis	1 (1.8)	1 (1.8)	0	0	0
Haemophilus infection	1 (1.8)	0	1 (1.8)	0	0
Herpes simplex	1 (1.8)	1 (1.8)	0	0	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0
Human herpesvirus 6 infection	1 (1.8)	0	1 (1.8)	0	0
Hypopyon	1 (1.8)	0	1 (1.8)	0	0
Meningitis aseptic	1 (1.8)	0	1 (1.8)	0	0
Molluscum contagiosum	1 (1.8)	1 (1.8)	0	0	0
Oral candidiasis	1 (1.8)	1 (1.8)	0	0	0
Oral herpes	1 (1.8)	0	1 (1.8)	0	0
Orchitis	1 (1.8)	1 (1.8)	0	0	0
Otitis externa	1 (1.8)	0	1 (1.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=57			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (1.8)	1 (1.8)	0	0	0
Pharyngitis	1 (1.8)	0	1 (1.8)	0	0
Rash pustular	1 (1.8)	0	1 (1.8)	0	0
Respiratory tract infection	1 (1.8)	0	0	0	1 (1.8)
Respiratory tract infection viral	1 (1.8)	0	0	1 (1.8)	0
Rhinitis	1 (1.8)	1 (1.8)	0	0	0
Rotavirus infection	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Septic embolus	1 (1.8)	0	0	0	1 (1.8)
Skin infection	1 (1.8)	0	1 (1.8)	0	0
Skin papilloma	1 (1.8)	0	1 (1.8)	0	0
Streptococcal infection	1 (1.8)	0	1 (1.8)	0	0
Subcutaneous abscess	1 (1.8)	0	1 (1.8)	0	0
Urinary tract infection enterococcal	1 (1.8)	0	0	1 (1.8)	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral infection	1 (1.8)	1 (1.8)	0	0	0
Vulvovaginal mycotic infection	1 (1.8)	0	1 (1.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	29 (50.9)	3 (5.3)	21 (36.8)	5 (8.8)	0
Hypogammaglobulinaemia	28 (49.1)	3 (5.3)	20 (35.1)	5 (8.8)	0
Blood immunoglobulin a decreased	3 (5.3)	3 (5.3)	0	0	0
Blood immunoglobulin m decreased	3 (5.3)	3 (5.3)	0	0	0
Blood immunoglobulin g decreased	1 (1.8)	0	1 (1.8)	0	0
Immunodeficiency	1 (1.8)	0	1 (1.8)	0	0
Serious neurological adverse reactions					
-Total	18 (31.6)	7 (12.3)	6 (10.5)	5 (8.8)	0
Confusional state	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Encephalopathy	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Seizure	4 (7.0)	0	2 (3.5)	2 (3.5)	0
Delirium	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Agitation	2 (3.5)	0	2 (3.5)	0	0
Dysarthria	2 (3.5)	1 (1.8)	1 (1.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Hallucination	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Irritability	2 (3.5)	2 (3.5)	0	0	0
Muscular weakness	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Tremor	2 (3.5)	2 (3.5)	0	0	0
Asterixis	1 (1.8)	1 (1.8)	0	0	0
Depressed level of consciousness	1 (1.8)	1 (1.8)	0	0	0
Disturbance in attention	1 (1.8)	1 (1.8)	0	0	0
Listless	1 (1.8)	1 (1.8)	0	0	0
Mental status changes	1 (1.8)	1 (1.8)	0	0	0
Somnolence	1 (1.8)	1 (1.8)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (3.5)	0	0	2 (3.5)	0
Tumour lysis syndrome	2 (3.5)	0	0	2 (3.5)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (50.0)	0	1 (50.0)	0	0
Blood immunoglobulin a decreased	1 (50.0)	1 (50.0)	0	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (93.5)	1 (1.6)	18 (29.0)	18 (29.0)	21 (33.9)
Cytokine Release Syndrome					
-Total	50 (80.6)	6 (9.7)	25 (40.3)	8 (12.9)	11 (17.7)
Cytokine release syndrome	50 (80.6)	6 (9.7)	25 (40.3)	8 (12.9)	11 (17.7)
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	27 (43.5)	2 (3.2)	3 (4.8)	10 (16.1)	12 (19.4)
White blood cell count decreased	11 (17.7)	1 (1.6)	1 (1.6)	6 (9.7)	3 (4.8)
Neutrophil count decreased	8 (12.9)	0	0	3 (4.8)	5 (8.1)
Platelet count decreased	8 (12.9)	1 (1.6)	1 (1.6)	1 (1.6)	5 (8.1)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	4 (6.5)	1 (1.6)	0	1 (1.6)	2 (3.2)
Anaemia	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Febrile neutropenia	3 (4.8)	0	0	3 (4.8)	0
Lymphocyte count decreased	3 (4.8)	0	0	2 (3.2)	1 (1.6)
Neutropenia	3 (4.8)	0	0	1 (1.6)	2 (3.2)
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	26 (41.9)	5 (8.1)	14 (22.6)	6 (9.7)	1 (1.6)
Clostridium difficile colitis	4 (6.5)	1 (1.6)	2 (3.2)	1 (1.6)	0
Clostridium difficile infection	4 (6.5)	0	4 (6.5)	0	0
Rhinovirus infection	3 (4.8)	3 (4.8)	0	0	0
Gastroenteritis	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Pneumonia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Staphylococcal infection	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cytomegalovirus infection	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Influenza	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Skin infection	1 (1.6)	0	1 (1.6)	0	0
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (1.6)	0	1 (1.6)	0	0
Viral upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Vulvovaginal candidiasis	1 (1.6)	1 (1.6)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	26 (41.9)	4 (6.5)	18 (29.0)	4 (6.5)	0
Hypogammaglobulinaemia	24 (38.7)	3 (4.8)	17 (27.4)	4 (6.5)	0
Blood immunoglobulin m decreased	4 (6.5)	4 (6.5)	0	0	0
Blood immunoglobulin a decreased	2 (3.2)	2 (3.2)	0	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Serious neurological adverse reactions					
-Total	19 (30.6)	8 (12.9)	7 (11.3)	4 (6.5)	0
Confusional state	6 (9.7)	3 (4.8)	3 (4.8)	0	0
Delirium	4 (6.5)	2 (3.2)	2 (3.2)	0	0
Encephalopathy	4 (6.5)	1 (1.6)	1 (1.6)	2 (3.2)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Agitation	2 (3.2)	0	2 (3.2)	0	0
Dysarthria	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Dysphagia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Hallucination	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Irritability	2 (3.2)	2 (3.2)	0	0	0
Tremor	2 (3.2)	2 (3.2)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Muscular weakness	1 (1.6)	0	1 (1.6)	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	1 (50.0)	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0
Urinary tract infection	1 (50.0)	0	0	1 (50.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 199f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=54			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (63.0)	5 (9.3)	16 (29.6)	11 (20.4)	2 (3.7)
Infections					
-Total	32 (59.3)	6 (11.1)	15 (27.8)	9 (16.7)	2 (3.7)
Upper respiratory tract infection	7 (13.0)	3 (5.6)	3 (5.6)	1 (1.9)	0
Gastroenteritis	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Influenza	3 (5.6)	0	3 (5.6)	0	0
Urinary tract infection	3 (5.6)	0	2 (3.7)	1 (1.9)	0
Ear infection	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Parainfluenzae virus infection	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Rhinovirus infection	2 (3.7)	2 (3.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=54			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	2 (3.7)	0	2 (3.7)	0	0
Viral upper respiratory tract infection	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Bacterial sepsis	1 (1.9)	0	0	0	1 (1.9)
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0
Cytomegalovirus infection	1 (1.9)	1 (1.9)	0	0	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0
Herpes zoster	1 (1.9)	0	0	1 (1.9)	0
Molluscum contagiosum	1 (1.9)	1 (1.9)	0	0	0
Oral herpes	1 (1.9)	0	1 (1.9)	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Otitis media	1 (1.9)	0	1 (1.9)	0	0
Otitis media acute	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash pustular	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus infection	1 (1.9)	0	0	1 (1.9)	0
Rhinitis	1 (1.9)	1 (1.9)	0	0	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Tinea capitis	1 (1.9)	1 (1.9)	0	0	0
Vascular device infection	1 (1.9)	0	0	1 (1.9)	0
Viral infection	1 (1.9)	1 (1.9)	0	0	0
Vulvovaginal mycotic infection	1 (1.9)	0	1 (1.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (14.8)	0	7 (13.0)	1 (1.9)	0
Hypogammaglobulinaemia	8 (14.8)	0	7 (13.0)	1 (1.9)	0
Serious neurological adverse reactions					
-Total	2 (3.7)	2 (3.7)	0	0	0
Muscular weakness	2 (3.7)	2 (3.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour Lysis Syndrome					
-Total	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0

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Table 199f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Infections					
-Total	1 (100)	0	0	1 (100)	0
Cellulitis of male external genital organ	1 (100)	0	0	1 (100)	0
Otitis media	1 (100)	0	1 (100)	0	0
Urinary tract infection	1 (100)	0	0	1 (100)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 199f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=33			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (36.4)	3 (9.1)	6 (18.2)	2 (6.1)	1 (3.0)
Infections					
-Total	10 (30.3)	2 (6.1)	5 (15.2)	2 (6.1)	1 (3.0)
Sinusitis	3 (9.1)	0	3 (9.1)	0	0
Otitis media	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Otitis media acute	2 (6.1)	0	2 (6.1)	0	0
Pneumonia	2 (6.1)	0	2 (6.1)	0	0
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Campylobacter infection	1 (3.0)	0	0	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	0	0	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingivitis	1 (3.0)	1 (3.0)	0	0	0
Haemophilus infection	1 (3.0)	0	1 (3.0)	0	0
Meningitis aseptic	1 (3.0)	0	1 (3.0)	0	0
Respiratory tract infection	1 (3.0)	0	0	0	1 (3.0)
Respiratory tract infection viral	1 (3.0)	0	0	1 (3.0)	0
Skin infection	1 (3.0)	0	1 (3.0)	0	0
Urinary tract infection	1 (3.0)	0	1 (3.0)	0	0
Viral infection	1 (3.0)	1 (3.0)	0	0	0
Vulvovaginal candidiasis	1 (3.0)	0	1 (3.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.0)	0	1 (3.0)	0	0
Immunodeficiency	1 (3.0)	0	1 (3.0)	0	0
Serious neurological adverse reactions					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Disturbance in attention	1 (3.0)	1 (3.0)	0	0	0
Seizure	1 (3.0)	0	0	1 (3.0)	0

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Table 199f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	1 (50.0)	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0
Otitis media	1 (50.0)	0	1 (50.0)	0	0
Urinary tract infection	1 (50.0)	0	0	1 (50.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (50.0)	0	1 (50.0)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (50.0)	1 (50.0)	0	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 199f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (98.4)	0	16 (25.8)	22 (35.5)	23 (37.1)
Cytokine Release Syndrome					
-Total	50 (80.6)	6 (9.7)	25 (40.3)	8 (12.9)	11 (17.7)
Cytokine release syndrome	50 (80.6)	6 (9.7)	25 (40.3)	8 (12.9)	11 (17.7)
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	27 (43.5)	2 (3.2)	3 (4.8)	10 (16.1)	12 (19.4)
White blood cell count decreased	11 (17.7)	1 (1.6)	1 (1.6)	6 (9.7)	3 (4.8)
Neutrophil count decreased	8 (12.9)	0	0	3 (4.8)	5 (8.1)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (12.9)	1 (1.6)	1 (1.6)	1 (1.6)	5 (8.1)
Thrombocytopenia	4 (6.5)	1 (1.6)	0	1 (1.6)	2 (3.2)
Anaemia	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Febrile neutropenia	3 (4.8)	0	0	3 (4.8)	0
Lymphocyte count decreased	3 (4.8)	0	0	2 (3.2)	1 (1.6)
Neutropenia	3 (4.8)	0	0	1 (1.6)	2 (3.2)
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	45 (72.6)	7 (11.3)	21 (33.9)	13 (21.0)	4 (6.5)
Upper respiratory tract infection	9 (14.5)	4 (6.5)	4 (6.5)	1 (1.6)	0
Clostridium difficile infection	5 (8.1)	0	4 (6.5)	1 (1.6)	0
Gastroenteritis	5 (8.1)	1 (1.6)	3 (4.8)	1 (1.6)	0
Rhinovirus infection	5 (8.1)	5 (8.1)	0	0	0
Clostridium difficile colitis	4 (6.5)	1 (1.6)	2 (3.2)	1 (1.6)	0
Influenza	4 (6.5)	1 (1.6)	3 (4.8)	0	0
Pneumonia	4 (6.5)	0	3 (4.8)	1 (1.6)	0
Sinusitis	4 (6.5)	0	4 (6.5)	0	0
Urinary tract infection	4 (6.5)	0	3 (4.8)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Viral infection	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Viral upper respiratory tract infection	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Cytomegalovirus infection	2 (3.2)	2 (3.2)	0	0	0
Ear infection	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Otitis media acute	2 (3.2)	0	2 (3.2)	0	0
Parainfluenzae virus infection	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Skin infection	2 (3.2)	0	2 (3.2)	0	0
Staphylococcal infection	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Vulvovaginal candidiasis	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Escherichia urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0
Haemophilus infection	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Meningitis aseptic	1 (1.6)	0	1 (1.6)	0	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (1.6)	0	1 (1.6)	0	0
Paronychia	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Rash pustular	1 (1.6)	0	1 (1.6)	0	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Rhinitis	1 (1.6)	1 (1.6)	0	0	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Subcutaneous abscess	1 (1.6)	0	1 (1.6)	0	0
Tinea capitis	1 (1.6)	1 (1.6)	0	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal mycotic infection	1 (1.6)	0	1 (1.6)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	32 (51.6)	3 (4.8)	24 (38.7)	5 (8.1)	0
Hypogammaglobulinaemia	31 (50.0)	3 (4.8)	23 (37.1)	5 (8.1)	0
Blood immunoglobulin m decreased	4 (6.5)	4 (6.5)	0	0	0
Blood immunoglobulin a decreased	2 (3.2)	2 (3.2)	0	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Immunodeficiency	1 (1.6)	0	1 (1.6)	0	0
Serious neurological adverse reactions					
-Total	21 (33.9)	9 (14.5)	7 (11.3)	5 (8.1)	0
Confusional state	6 (9.7)	3 (4.8)	3 (4.8)	0	0
Delirium	4 (6.5)	2 (3.2)	2 (3.2)	0	0
Encephalopathy	4 (6.5)	1 (1.6)	1 (1.6)	2 (3.2)	0
Seizure	4 (6.5)	0	2 (3.2)	2 (3.2)	0
Muscular weakness	3 (4.8)	2 (3.2)	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	2 (3.2)	0	2 (3.2)	0	0
Dysarthria	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Dysphagia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Hallucination	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Irritability	2 (3.2)	2 (3.2)	0	0	0
Tremor	2 (3.2)	2 (3.2)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Disturbance in attention	1 (1.6)	1 (1.6)	0	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (3.2)	0	0	2 (3.2)	0
Tumour lysis syndrome	2 (3.2)	0	0	2 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Cytokine Release Syndrome					
-Total	2 (66.7)	0	0	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	0	0	2 (66.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Anaemia	1 (33.3)	0	0	1 (33.3)	0
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Neutrophil count decreased	1 (33.3)	0	0	1 (33.3)	0
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (33.3)	0	0	1 (33.3)	0
Serious neurological adverse reactions					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Confusional state	1 (33.3)	1 (33.3)	0	0	0
Delirium	1 (33.3)	0	1 (33.3)	0	0
Dysphagia	1 (33.3)	0	0	1 (33.3)	0
Irritability	1 (33.3)	1 (33.3)	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (91.8)	1 (1.6)	19 (31.1)	17 (27.9)	19 (31.1)
Cytokine Release Syndrome					
-Total	48 (78.7)	6 (9.8)	25 (41.0)	8 (13.1)	9 (14.8)
Cytokine release syndrome	48 (78.7)	6 (9.8)	25 (41.0)	8 (13.1)	9 (14.8)
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	25 (41.0)	2 (3.3)	3 (4.9)	9 (14.8)	11 (18.0)
White blood cell count decreased	10 (16.4)	1 (1.6)	1 (1.6)	5 (8.2)	3 (4.9)
Neutrophil count decreased	7 (11.5)	0	0	2 (3.3)	5 (8.2)
Platelet count decreased	7 (11.5)	1 (1.6)	1 (1.6)	0	5 (8.2)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	4 (6.6)	1 (1.6)	0	1 (1.6)	2 (3.3)
Febrile neutropenia	3 (4.9)	0	0	3 (4.9)	0
Lymphocyte count decreased	3 (4.9)	0	0	2 (3.3)	1 (1.6)
Anaemia	2 (3.3)	0	2 (3.3)	0	0
Neutropenia	2 (3.3)	0	0	1 (1.6)	1 (1.6)
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	26 (42.6)	5 (8.2)	14 (23.0)	6 (9.8)	1 (1.6)
Clostridium difficile colitis	4 (6.6)	1 (1.6)	2 (3.3)	1 (1.6)	0
Clostridium difficile infection	4 (6.6)	0	4 (6.6)	0	0
Rhinovirus infection	3 (4.9)	3 (4.9)	0	0	0
Gastroenteritis	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Pneumonia	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Staphylococcal infection	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cytomegalovirus infection	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Influenza	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Skin infection	1 (1.6)	0	1 (1.6)	0	0
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (1.6)	0	1 (1.6)	0	0
Viral upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Vulvovaginal candidiasis	1 (1.6)	1 (1.6)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	27 (44.3)	4 (6.6)	19 (31.1)	4 (6.6)	0
Hypogammaglobulinaemia	25 (41.0)	3 (4.9)	18 (29.5)	4 (6.6)	0
Blood immunoglobulin m decreased	4 (6.6)	4 (6.6)	0	0	0
Blood immunoglobulin a decreased	3 (4.9)	3 (4.9)	0	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Serious neurological adverse reactions					
-Total	17 (27.9)	7 (11.5)	7 (11.5)	3 (4.9)	0
Confusional state	5 (8.2)	2 (3.3)	3 (4.9)	0	0
Encephalopathy	4 (6.6)	1 (1.6)	1 (1.6)	2 (3.3)	0
Delirium	3 (4.9)	2 (3.3)	1 (1.6)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	3 (4.9)	0	2 (3.3)	1 (1.6)	0
Agitation	2 (3.3)	0	2 (3.3)	0	0
Dysarthria	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Hallucination	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Tremor	2 (3.3)	2 (3.3)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Dysphagia	1 (1.6)	0	1 (1.6)	0	0
Irritability	1 (1.6)	1 (1.6)	0	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Muscular weakness	1 (1.6)	0	1 (1.6)	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	1 (50.0)	0
Infections					
-Total	1 (50.0)	1 (50.0)	0	0	0
Upper respiratory tract infection	1 (50.0)	1 (50.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hypogammaglobulinaemia	1 (50.0)	0	0	1 (50.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (63.0)	5 (9.3)	16 (29.6)	11 (20.4)	2 (3.7)
Infections					
-Total	32 (59.3)	5 (9.3)	15 (27.8)	10 (18.5)	2 (3.7)
Upper respiratory tract infection	6 (11.1)	2 (3.7)	3 (5.6)	1 (1.9)	0
Urinary tract infection	4 (7.4)	0	2 (3.7)	2 (3.7)	0
Gastroenteritis	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Influenza	3 (5.6)	0	3 (5.6)	0	0
Ear infection	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Parainfluenzae virus infection	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Rhinovirus infection	2 (3.7)	2 (3.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	2 (3.7)	0	2 (3.7)	0	0
Viral upper respiratory tract infection	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Bacterial sepsis	1 (1.9)	0	0	0	1 (1.9)
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0
Cytomegalovirus infection	1 (1.9)	1 (1.9)	0	0	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0
Herpes zoster	1 (1.9)	0	0	1 (1.9)	0
Molluscum contagiosum	1 (1.9)	1 (1.9)	0	0	0
Oral herpes	1 (1.9)	0	1 (1.9)	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Otitis media	1 (1.9)	0	1 (1.9)	0	0
Otitis media acute	1 (1.9)	0	1 (1.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (1.9)	1 (1.9)	0	0	0
Rash pustular	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus infection	1 (1.9)	0	0	1 (1.9)	0
Rhinitis	1 (1.9)	1 (1.9)	0	0	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Tinea capitis	1 (1.9)	1 (1.9)	0	0	0
Vascular device infection	1 (1.9)	0	0	1 (1.9)	0
Viral infection	1 (1.9)	1 (1.9)	0	0	0
Vulvovaginal mycotic infection	1 (1.9)	0	1 (1.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	7 (13.0)	0	7 (13.0)	0	0
Hypogammaglobulinaemia	7 (13.0)	0	7 (13.0)	0	0
Serious neurological adverse reactions					
-Total	2 (3.7)	2 (3.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	2 (3.7)	2 (3.7)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0

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Table 199g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (39.4)	3 (9.1)	6 (18.2)	3 (9.1)	1 (3.0)
Infections					
-Total	11 (33.3)	2 (6.1)	5 (15.2)	3 (9.1)	1 (3.0)
Otitis media	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Sinusitis	3 (9.1)	0	3 (9.1)	0	0
Otitis media acute	2 (6.1)	0	2 (6.1)	0	0
Pneumonia	2 (6.1)	0	2 (6.1)	0	0
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Urinary tract infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Campylobacter infection	1 (3.0)	0	0	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (3.0)	0	0	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	0	0	1 (3.0)	0
Gingivitis	1 (3.0)	1 (3.0)	0	0	0
Haemophilus infection	1 (3.0)	0	1 (3.0)	0	0
Meningitis aseptic	1 (3.0)	0	1 (3.0)	0	0
Respiratory tract infection	1 (3.0)	0	0	0	1 (3.0)
Respiratory tract infection viral	1 (3.0)	0	0	1 (3.0)	0
Skin infection	1 (3.0)	0	1 (3.0)	0	0
Viral infection	1 (3.0)	1 (3.0)	0	0	0
Vulvovaginal candidiasis	1 (3.0)	0	1 (3.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.0)	0	1 (3.0)	0	0
Immunodeficiency	1 (3.0)	0	1 (3.0)	0	0
Serious neurological adverse reactions					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Disturbance in attention	1 (3.0)	1 (3.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (3.0)	0	0	1 (3.0)	0

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Table 199g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Cytokine Release Syndrome					
-Total	2 (66.7)	0	0	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	0	0	2 (66.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Anaemia	1 (33.3)	0	0	1 (33.3)	0
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Neutrophil count decreased	1 (33.3)	0	0	1 (33.3)	0
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (33.3)	0	0	1 (33.3)	0
Infections					
-Total	1 (33.3)	1 (33.3)	0	0	0
Upper respiratory tract infection	1 (33.3)	1 (33.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hypogammaglobulinaemia	1 (33.3)	0	0	1 (33.3)	0
Serious neurological adverse reactions					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Confusional state	1 (33.3)	1 (33.3)	0	0	0
Delirium	1 (33.3)	0	1 (33.3)	0	0
Dysphagia	1 (33.3)	0	0	1 (33.3)	0
Irritability	1 (33.3)	1 (33.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (98.4)	0	17 (27.9)	22 (36.1)	21 (34.4)
Cytokine Release Syndrome					
-Total	48 (78.7)	6 (9.8)	25 (41.0)	8 (13.1)	9 (14.8)
Cytokine release syndrome	48 (78.7)	6 (9.8)	25 (41.0)	8 (13.1)	9 (14.8)
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	25 (41.0)	2 (3.3)	3 (4.9)	9 (14.8)	11 (18.0)
White blood cell count decreased	10 (16.4)	1 (1.6)	1 (1.6)	5 (8.2)	3 (4.9)
Neutrophil count decreased	7 (11.5)	0	0	2 (3.3)	5 (8.2)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	7 (11.5)	1 (1.6)	1 (1.6)	0	5 (8.2)
Thrombocytopenia	4 (6.6)	1 (1.6)	0	1 (1.6)	2 (3.3)
Febrile neutropenia	3 (4.9)	0	0	3 (4.9)	0
Lymphocyte count decreased	3 (4.9)	0	0	2 (3.3)	1 (1.6)
Anaemia	2 (3.3)	0	2 (3.3)	0	0
Neutropenia	2 (3.3)	0	0	1 (1.6)	1 (1.6)
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	45 (73.8)	6 (9.8)	21 (34.4)	14 (23.0)	4 (6.6)
Upper respiratory tract infection	8 (13.1)	3 (4.9)	4 (6.6)	1 (1.6)	0
Clostridium difficile infection	5 (8.2)	0	4 (6.6)	1 (1.6)	0
Gastroenteritis	5 (8.2)	1 (1.6)	3 (4.9)	1 (1.6)	0
Rhinovirus infection	5 (8.2)	5 (8.2)	0	0	0
Urinary tract infection	5 (8.2)	0	3 (4.9)	2 (3.3)	0
Clostridium difficile colitis	4 (6.6)	1 (1.6)	2 (3.3)	1 (1.6)	0
Influenza	4 (6.6)	1 (1.6)	3 (4.9)	0	0
Otitis media	4 (6.6)	0	3 (4.9)	1 (1.6)	0
Pneumonia	4 (6.6)	0	3 (4.9)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	4 (6.6)	0	4 (6.6)	0	0
Viral infection	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Viral upper respiratory tract infection	3 (4.9)	1 (1.6)	1 (1.6)	1 (1.6)	0
Cytomegalovirus infection	2 (3.3)	2 (3.3)	0	0	0
Ear infection	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Otitis media acute	2 (3.3)	0	2 (3.3)	0	0
Parainfluenzae virus infection	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Skin infection	2 (3.3)	0	2 (3.3)	0	0
Staphylococcal infection	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Vulvovaginal candidiasis	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Escherichia urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0
Haemophilus infection	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Meningitis aseptic	1 (1.6)	0	1 (1.6)	0	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Otitis externa	1 (1.6)	0	1 (1.6)	0	0
Paronychia	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Rash pustular	1 (1.6)	0	1 (1.6)	0	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Rhinitis	1 (1.6)	1 (1.6)	0	0	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Subcutaneous abscess	1 (1.6)	0	1 (1.6)	0	0
Tinea capitis	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Vulvovaginal mycotic infection	1 (1.6)	0	1 (1.6)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	32 (52.5)	3 (4.9)	25 (41.0)	4 (6.6)	0
Hypogammaglobulinaemia	31 (50.8)	3 (4.9)	24 (39.3)	4 (6.6)	0
Blood immunoglobulin m decreased	4 (6.6)	4 (6.6)	0	0	0
Blood immunoglobulin a decreased	3 (4.9)	3 (4.9)	0	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Immunodeficiency	1 (1.6)	0	1 (1.6)	0	0
Serious neurological adverse reactions					
-Total	19 (31.1)	8 (13.1)	7 (11.5)	4 (6.6)	0
Confusional state	5 (8.2)	2 (3.3)	3 (4.9)	0	0
Encephalopathy	4 (6.6)	1 (1.6)	1 (1.6)	2 (3.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	4 (6.6)	0	2 (3.3)	2 (3.3)	0
Delirium	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Muscular weakness	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Agitation	2 (3.3)	0	2 (3.3)	0	0
Dysarthria	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Hallucination	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Tremor	2 (3.3)	2 (3.3)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Disturbance in attention	1 (1.6)	1 (1.6)	0	0	0
Dysphagia	1 (1.6)	0	1 (1.6)	0	0
Irritability	1 (1.6)	1 (1.6)	0	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (3.3)	0	0	2 (3.3)	0
Tumour lysis syndrome	2 (3.3)	0	0	2 (3.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Cytokine Release Syndrome					
-Total	1 (100)	0	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	1 (100)	0	0
Serious neurological adverse reactions					
-Total	1 (100)	0	1 (100)	0	0
Encephalopathy	1 (100)	0	1 (100)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (92.1)	1 (1.6)	18 (28.6)	18 (28.6)	21 (33.3)
Cytokine Release Syndrome					
-Total	49 (77.8)	6 (9.5)	24 (38.1)	8 (12.7)	11 (17.5)
Cytokine release syndrome	49 (77.8)	6 (9.5)	24 (38.1)	8 (12.7)	11 (17.5)
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	27 (42.9)	2 (3.2)	3 (4.8)	10 (15.9)	12 (19.0)
White blood cell count decreased	11 (17.5)	1 (1.6)	1 (1.6)	6 (9.5)	3 (4.8)
Neutrophil count decreased	8 (12.7)	0	0	3 (4.8)	5 (7.9)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (12.7)	1 (1.6)	1 (1.6)	1 (1.6)	5 (7.9)
Thrombocytopenia	4 (6.3)	1 (1.6)	0	1 (1.6)	2 (3.2)
Anaemia	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Febrile neutropenia	3 (4.8)	0	0	3 (4.8)	0
Lymphocyte count decreased	3 (4.8)	0	0	2 (3.2)	1 (1.6)
Neutropenia	3 (4.8)	0	0	1 (1.6)	2 (3.2)
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	26 (41.3)	5 (7.9)	14 (22.2)	6 (9.5)	1 (1.6)
Clostridium difficile colitis	4 (6.3)	1 (1.6)	2 (3.2)	1 (1.6)	0
Clostridium difficile infection	4 (6.3)	0	4 (6.3)	0	0
Rhinovirus infection	3 (4.8)	3 (4.8)	0	0	0
Gastroenteritis	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Pneumonia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Staphylococcal infection	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cytomegalovirus infection	1 (1.6)	1 (1.6)	0	0	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Influenza	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Skin infection	1 (1.6)	0	1 (1.6)	0	0
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Viral infection	1 (1.6)	0	1 (1.6)	0	0
Viral upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Vulvovaginal candidiasis	1 (1.6)	1 (1.6)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	27 (42.9)	4 (6.3)	19 (30.2)	4 (6.3)	0
Hypogammaglobulinaemia	25 (39.7)	3 (4.8)	18 (28.6)	4 (6.3)	0
Blood immunoglobulin m decreased	4 (6.3)	4 (6.3)	0	0	0
Blood immunoglobulin a decreased	3 (4.8)	3 (4.8)	0	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Serious neurological adverse reactions					

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	18 (28.6)	8 (12.7)	6 (9.5)	4 (6.3)	0
Confusional state	6 (9.5)	3 (4.8)	3 (4.8)	0	0
Delirium	4 (6.3)	2 (3.2)	2 (3.2)	0	0
Encephalopathy	3 (4.8)	1 (1.6)	0	2 (3.2)	0
Seizure	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Agitation	2 (3.2)	0	2 (3.2)	0	0
Dysarthria	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Dysphagia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Hallucination	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Irritability	2 (3.2)	2 (3.2)	0	0	0
Tremor	2 (3.2)	2 (3.2)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Muscular weakness	1 (1.6)	0	1 (1.6)	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

Group term Preferred term	All patients N=63 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (63.6)	5 (9.1)	16 (29.1)	12 (21.8)	2 (3.6)
Infections					
-Total	33 (60.0)	6 (10.9)	15 (27.3)	10 (18.2)	2 (3.6)
Upper respiratory tract infection	7 (12.7)	3 (5.5)	3 (5.5)	1 (1.8)	0
Urinary tract infection	4 (7.3)	0	2 (3.6)	2 (3.6)	0
Gastroenteritis	3 (5.5)	1 (1.8)	2 (3.6)	0	0
Influenza	3 (5.5)	0	3 (5.5)	0	0
Ear infection	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Parainfluenzae virus infection	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Rhinovirus infection	2 (3.6)	2 (3.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	2 (3.6)	0	2 (3.6)	0	0
Viral upper respiratory tract infection	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Cellulitis of male external genital organ	1 (1.8)	0	0	1 (1.8)	0
Cholecystitis infective	1 (1.8)	0	0	1 (1.8)	0
Corona virus infection	1 (1.8)	0	0	1 (1.8)	0
Cytomegalovirus infection	1 (1.8)	1 (1.8)	0	0	0
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Escherichia urinary tract infection	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis viral	1 (1.8)	1 (1.8)	0	0	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0
Molluscum contagiosum	1 (1.8)	1 (1.8)	0	0	0
Oral herpes	1 (1.8)	0	1 (1.8)	0	0
Otitis externa	1 (1.8)	0	1 (1.8)	0	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Otitis media acute	1 (1.8)	0	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (1.8)	1 (1.8)	0	0	0
Rash pustular	1 (1.8)	0	1 (1.8)	0	0
Respiratory syncytial virus infection	1 (1.8)	0	0	1 (1.8)	0
Rhinitis	1 (1.8)	1 (1.8)	0	0	0
Rotavirus infection	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Subcutaneous abscess	1 (1.8)	0	1 (1.8)	0	0
Tinea capitis	1 (1.8)	1 (1.8)	0	0	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral infection	1 (1.8)	1 (1.8)	0	0	0
Vulvovaginal mycotic infection	1 (1.8)	0	1 (1.8)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (14.5)	0	7 (12.7)	1 (1.8)	0
Hypogammaglobulinaemia	8 (14.5)	0	7 (12.7)	1 (1.8)	0
Serious neurological adverse reactions					
-Total	2 (3.6)	2 (3.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	2 (3.6)	2 (3.6)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.8)	0	0	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (39.4)	3 (9.1)	6 (18.2)	3 (9.1)	1 (3.0)
Infections					
-Total	11 (33.3)	2 (6.1)	5 (15.2)	3 (9.1)	1 (3.0)
Otitis media	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Sinusitis	3 (9.1)	0	3 (9.1)	0	0
Otitis media acute	2 (6.1)	0	2 (6.1)	0	0
Pneumonia	2 (6.1)	0	2 (6.1)	0	0
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Urinary tract infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Campylobacter infection	1 (3.0)	0	0	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (3.0)	0	0	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	0	0	1 (3.0)	0
Gingivitis	1 (3.0)	1 (3.0)	0	0	0
Haemophilus infection	1 (3.0)	0	1 (3.0)	0	0
Meningitis aseptic	1 (3.0)	0	1 (3.0)	0	0
Respiratory tract infection	1 (3.0)	0	0	0	1 (3.0)
Respiratory tract infection viral	1 (3.0)	0	0	1 (3.0)	0
Skin infection	1 (3.0)	0	1 (3.0)	0	0
Viral infection	1 (3.0)	1 (3.0)	0	0	0
Vulvovaginal candidiasis	1 (3.0)	0	1 (3.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.0)	0	1 (3.0)	0	0
Immunodeficiency	1 (3.0)	0	1 (3.0)	0	0
Serious neurological adverse reactions					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Group term Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Disturbance in attention	1 (3.0)	1 (3.0)	0	0	0
Seizure	1 (3.0)	0	0	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Cytokine Release Syndrome					
-Total	1 (100)	0	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	1 (100)	0	0
Serious neurological adverse reactions					
-Total	1 (100)	0	1 (100)	0	0
Encephalopathy	1 (100)	0	1 (100)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	62 (98.4)	0	16 (25.4)	23 (36.5)	23 (36.5)
Cytokine Release Syndrome					
-Total	49 (77.8)	6 (9.5)	24 (38.1)	8 (12.7)	11 (17.5)
Cytokine release syndrome	49 (77.8)	6 (9.5)	24 (38.1)	8 (12.7)	11 (17.5)
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	27 (42.9)	2 (3.2)	3 (4.8)	10 (15.9)	12 (19.0)
White blood cell count decreased	11 (17.5)	1 (1.6)	1 (1.6)	6 (9.5)	3 (4.8)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	8 (12.7)	0	0	3 (4.8)	5 (7.9)
Platelet count decreased	8 (12.7)	1 (1.6)	1 (1.6)	1 (1.6)	5 (7.9)
Thrombocytopenia	4 (6.3)	1 (1.6)	0	1 (1.6)	2 (3.2)
Anaemia	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Febrile neutropenia	3 (4.8)	0	0	3 (4.8)	0
Lymphocyte count decreased	3 (4.8)	0	0	2 (3.2)	1 (1.6)
Neutropenia	3 (4.8)	0	0	1 (1.6)	2 (3.2)
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	46 (73.0)	7 (11.1)	21 (33.3)	14 (22.2)	4 (6.3)
Upper respiratory tract infection	9 (14.3)	4 (6.3)	4 (6.3)	1 (1.6)	0
Clostridium difficile infection	5 (7.9)	0	4 (6.3)	1 (1.6)	0
Gastroenteritis	5 (7.9)	1 (1.6)	3 (4.8)	1 (1.6)	0
Rhinovirus infection	5 (7.9)	5 (7.9)	0	0	0
Urinary tract infection	5 (7.9)	0	3 (4.8)	2 (3.2)	0
Clostridium difficile colitis	4 (6.3)	1 (1.6)	2 (3.2)	1 (1.6)	0
Influenza	4 (6.3)	1 (1.6)	3 (4.8)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	4 (6.3)	0	3 (4.8)	1 (1.6)	0
Pneumonia	4 (6.3)	0	3 (4.8)	1 (1.6)	0
Sinusitis	4 (6.3)	0	4 (6.3)	0	0
Viral infection	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Viral upper respiratory tract infection	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Cytomegalovirus infection	2 (3.2)	2 (3.2)	0	0	0
Ear infection	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Otitis media acute	2 (3.2)	0	2 (3.2)	0	0
Parainfluenzae virus infection	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Skin infection	2 (3.2)	0	2 (3.2)	0	0
Staphylococcal infection	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Vulvovaginal candidiasis	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Escherichia urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0
Haemophilus infection	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis aseptic	1 (1.6)	0	1 (1.6)	0	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Otitis externa	1 (1.6)	0	1 (1.6)	0	0
Paronychia	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Rash pustular	1 (1.6)	0	1 (1.6)	0	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Rhinitis	1 (1.6)	1 (1.6)	0	0	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Subcutaneous abscess	1 (1.6)	0	1 (1.6)	0	0
Tinea capitis	1 (1.6)	1 (1.6)	0	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Vulvovaginal mycotic infection	1 (1.6)	0	1 (1.6)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	33 (52.4)	3 (4.8)	25 (39.7)	5 (7.9)	0
Hypogammaglobulinaemia	32 (50.8)	3 (4.8)	24 (38.1)	5 (7.9)	0
Blood immunoglobulin m decreased	4 (6.3)	4 (6.3)	0	0	0
Blood immunoglobulin a decreased	3 (4.8)	3 (4.8)	0	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Immunodeficiency	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	20 (31.7)	9 (14.3)	6 (9.5)	5 (7.9)	0
Confusional state	6 (9.5)	3 (4.8)	3 (4.8)	0	0
Delirium	4 (6.3)	2 (3.2)	2 (3.2)	0	0
Seizure	4 (6.3)	0	2 (3.2)	2 (3.2)	0
Encephalopathy	3 (4.8)	1 (1.6)	0	2 (3.2)	0
Muscular weakness	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Agitation	2 (3.2)	0	2 (3.2)	0	0
Dysarthria	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Dysphagia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Hallucination	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Irritability	2 (3.2)	2 (3.2)	0	0	0
Tremor	2 (3.2)	2 (3.2)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Disturbance in attention	1 (1.6)	1 (1.6)	0	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

Group term Preferred term	All patients N=63 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (3.2)	0	0	2 (3.2)	0
Tumour lysis syndrome	2 (3.2)	0	0	2 (3.2)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	2 (50.0)	2 (50.0)	0
Cytokine Release Syndrome					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Cytokine release syndrome	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Infections					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Clostridium difficile infection	1 (25.0)	0	1 (25.0)	0	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Pharyngitis	1 (25.0)	0	1 (25.0)	0	0
Skin papilloma	1 (25.0)	0	1 (25.0)	0	0
Streptococcal infection	1 (25.0)	0	1 (25.0)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (100)	0	4 (100)	0	0
Hypogammaglobulinaemia	4 (100)	0	4 (100)	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	55 (91.7)	1 (1.7)	17 (28.3)	16 (26.7)	21 (35.0)
Cytokine Release Syndrome					
-Total	48 (80.0)	6 (10.0)	24 (40.0)	7 (11.7)	11 (18.3)
Cytokine release syndrome	48 (80.0)	6 (10.0)	24 (40.0)	7 (11.7)	11 (18.3)
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	27 (45.0)	2 (3.3)	3 (5.0)	10 (16.7)	12 (20.0)
White blood cell count decreased	11 (18.3)	1 (1.7)	1 (1.7)	6 (10.0)	3 (5.0)
Neutrophil count decreased	8 (13.3)	0	0	3 (5.0)	5 (8.3)
Platelet count decreased	8 (13.3)	1 (1.7)	1 (1.7)	1 (1.7)	5 (8.3)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	4 (6.7)	1 (1.7)	0	1 (1.7)	2 (3.3)
Anaemia	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Febrile neutropenia	3 (5.0)	0	0	3 (5.0)	0
Lymphocyte count decreased	3 (5.0)	0	0	2 (3.3)	1 (1.7)
Neutropenia	3 (5.0)	0	0	1 (1.7)	2 (3.3)
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	24 (40.0)	5 (8.3)	13 (21.7)	5 (8.3)	1 (1.7)
Clostridium difficile colitis	4 (6.7)	1 (1.7)	2 (3.3)	1 (1.7)	0
Clostridium difficile infection	3 (5.0)	0	3 (5.0)	0	0
Rhinovirus infection	3 (5.0)	3 (5.0)	0	0	0
Pneumonia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Staphylococcal infection	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Catheter site cellulitis	1 (1.7)	1 (1.7)	0	0	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Fungal skin infection	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Herpes simplex	1 (1.7)	1 (1.7)	0	0	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Influenza	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Skin infection	1 (1.7)	0	1 (1.7)	0	0
Upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Viral infection	1 (1.7)	0	1 (1.7)	0	0
Viral upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Vulvovaginal candidiasis	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	23 (38.3)	4 (6.7)	15 (25.0)	4 (6.7)	0
Hypogammaglobulinaemia	21 (35.0)	3 (5.0)	14 (23.3)	4 (6.7)	0
Blood immunoglobulin m decreased	4 (6.7)	4 (6.7)	0	0	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	19 (31.7)	8 (13.3)	7 (11.7)	4 (6.7)	0
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Delirium	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Encephalopathy	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Seizure	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Agitation	2 (3.3)	0	2 (3.3)	0	0
Dysarthria	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Dysphagia	2 (3.3)	0	1 (1.7)	1 (1.7)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hallucination	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Irritability	2 (3.3)	2 (3.3)	0	0	0
Tremor	2 (3.3)	2 (3.3)	0	0	0
Asterixis	1 (1.7)	1 (1.7)	0	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Mental status changes	1 (1.7)	1 (1.7)	0	0	0
Muscular weakness	1 (1.7)	0	1 (1.7)	0	0
Somnolence	1 (1.7)	1 (1.7)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=4			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Infections					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Cytomegalovirus infection	1 (25.0)	1 (25.0)	0	0	0
Herpes zoster	1 (25.0)	0	0	1 (25.0)	0
Otitis media acute	1 (25.0)	0	1 (25.0)	0	0
Parainfluenzae virus infection	1 (25.0)	1 (25.0)	0	0	0
Sinusitis	1 (25.0)	0	1 (25.0)	0	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 199i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (61.5)	4 (7.7)	15 (28.8)	11 (21.2)	2 (3.8)
Infections					
-Total	30 (57.7)	5 (9.6)	14 (26.9)	9 (17.3)	2 (3.8)
Upper respiratory tract infection	6 (11.5)	2 (3.8)	3 (5.8)	1 (1.9)	0
Urinary tract infection	4 (7.7)	0	2 (3.8)	2 (3.8)	0
Gastroenteritis	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Influenza	3 (5.8)	0	3 (5.8)	0	0
Ear infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Rhinovirus infection	2 (3.8)	2 (3.8)	0	0	0
Viral upper respiratory tract infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (1.9)	0	0	0	1 (1.9)
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0
Molluscum contagiosum	1 (1.9)	1 (1.9)	0	0	0
Oral herpes	1 (1.9)	0	1 (1.9)	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Otitis media	1 (1.9)	0	1 (1.9)	0	0
Parainfluenzae virus infection	1 (1.9)	0	0	1 (1.9)	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0
Rash pustular	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus infection	1 (1.9)	0	0	1 (1.9)	0
Rhinitis	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Sinusitis	1 (1.9)	0	1 (1.9)	0	0
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Tinea capitis	1 (1.9)	1 (1.9)	0	0	0
Vascular device infection	1 (1.9)	0	0	1 (1.9)	0
Viral infection	1 (1.9)	1 (1.9)	0	0	0
Vulvovaginal mycotic infection	1 (1.9)	0	1 (1.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (15.4)	0	7 (13.5)	1 (1.9)	0
Hypogammaglobulinaemia	8 (15.4)	0	7 (13.5)	1 (1.9)	0
Serious neurological adverse reactions					
-Total	2 (3.8)	2 (3.8)	0	0	0
Muscular weakness	2 (3.8)	2 (3.8)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 199i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Infections					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Gingivitis	1 (33.3)	1 (33.3)	0	0	0
Otitis media acute	1 (33.3)	0	1 (33.3)	0	0
Viral infection	1 (33.3)	1 (33.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 199i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (35.5)	2 (6.5)	5 (16.1)	3 (9.7)	1 (3.2)
Infections					
-Total	9 (29.0)	1 (3.2)	4 (12.9)	3 (9.7)	1 (3.2)
Otitis media	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Sinusitis	3 (9.7)	0	3 (9.7)	0	0
Pneumonia	2 (6.5)	0	2 (6.5)	0	0
Upper respiratory tract infection	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Urinary tract infection	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Campylobacter infection	1 (3.2)	0	0	1 (3.2)	0
Cellulitis of male external genital organ	1 (3.2)	0	0	1 (3.2)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Group term Preferred term	All patients N=31 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile infection	1 (3.2)	0	0	1 (3.2)	0
Haemophilus infection	1 (3.2)	0	1 (3.2)	0	0
Meningitis aseptic	1 (3.2)	0	1 (3.2)	0	0
Otitis media acute	1 (3.2)	0	1 (3.2)	0	0
Respiratory tract infection	1 (3.2)	0	0	0	1 (3.2)
Respiratory tract infection viral	1 (3.2)	0	0	1 (3.2)	0
Skin infection	1 (3.2)	0	1 (3.2)	0	0
Vulvovaginal candidiasis	1 (3.2)	0	1 (3.2)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.2)	0	1 (3.2)	0	0
Immunodeficiency	1 (3.2)	0	1 (3.2)	0	0
Serious neurological adverse reactions					
-Total	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Disturbance in attention	1 (3.2)	1 (3.2)	0	0	0
Seizure	1 (3.2)	0	0	1 (3.2)	0

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Table 199i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	2 (50.0)	2 (50.0)	0
Cytokine Release Syndrome					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Cytokine release syndrome	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Infections					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Clostridium difficile infection	1 (25.0)	0	1 (25.0)	0	0
Cytomegalovirus infection	1 (25.0)	1 (25.0)	0	0	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Gingivitis	1 (25.0)	1 (25.0)	0	0	0
Herpes zoster	1 (25.0)	0	0	1 (25.0)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	1 (25.0)	0	1 (25.0)	0	0
Parainfluenzae virus infection	1 (25.0)	1 (25.0)	0	0	0
Pharyngitis	1 (25.0)	0	1 (25.0)	0	0
Sinusitis	1 (25.0)	0	1 (25.0)	0	0
Skin papilloma	1 (25.0)	0	1 (25.0)	0	0
Streptococcal infection	1 (25.0)	0	1 (25.0)	0	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Viral infection	1 (25.0)	1 (25.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (100)	0	4 (100)	0	0
Hypogammaglobulinaemia	4 (100)	0	4 (100)	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (98.3)	0	15 (25.0)	21 (35.0)	23 (38.3)
Cytokine Release Syndrome					
-Total	48 (80.0)	6 (10.0)	24 (40.0)	7 (11.7)	11 (18.3)
Cytokine release syndrome	48 (80.0)	6 (10.0)	24 (40.0)	7 (11.7)	11 (18.3)
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	27 (45.0)	2 (3.3)	3 (5.0)	10 (16.7)	12 (20.0)
White blood cell count decreased	11 (18.3)	1 (1.7)	1 (1.7)	6 (10.0)	3 (5.0)
Neutrophil count decreased	8 (13.3)	0	0	3 (5.0)	5 (8.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (13.3)	1 (1.7)	1 (1.7)	1 (1.7)	5 (8.3)
Thrombocytopenia	4 (6.7)	1 (1.7)	0	1 (1.7)	2 (3.3)
Anaemia	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Febrile neutropenia	3 (5.0)	0	0	3 (5.0)	0
Lymphocyte count decreased	3 (5.0)	0	0	2 (3.3)	1 (1.7)
Neutropenia	3 (5.0)	0	0	1 (1.7)	2 (3.3)
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	43 (71.7)	6 (10.0)	20 (33.3)	13 (21.7)	4 (6.7)
Upper respiratory tract infection	8 (13.3)	3 (5.0)	4 (6.7)	1 (1.7)	0
Rhinovirus infection	5 (8.3)	5 (8.3)	0	0	0
Urinary tract infection	5 (8.3)	0	3 (5.0)	2 (3.3)	0
Clostridium difficile colitis	4 (6.7)	1 (1.7)	2 (3.3)	1 (1.7)	0
Clostridium difficile infection	4 (6.7)	0	3 (5.0)	1 (1.7)	0
Gastroenteritis	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Influenza	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Otitis media	4 (6.7)	0	3 (5.0)	1 (1.7)	0
Pneumonia	4 (6.7)	0	3 (5.0)	1 (1.7)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	3 (5.0)	0	3 (5.0)	0	0
Viral upper respiratory tract infection	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Ear infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Skin infection	2 (3.3)	0	2 (3.3)	0	0
Staphylococcal infection	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Viral infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Vulvovaginal candidiasis	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Catheter site cellulitis	1 (1.7)	1 (1.7)	0	0	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Corona virus infection	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Escherichia urinary tract infection	1 (1.7)	0	0	1 (1.7)	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Fungal skin infection	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis viral	1 (1.7)	1 (1.7)	0	0	0
Haemophilus infection	1 (1.7)	0	1 (1.7)	0	0
Herpes simplex	1 (1.7)	1 (1.7)	0	0	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Meningitis aseptic	1 (1.7)	0	1 (1.7)	0	0
Molluscum contagiosum	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Oral herpes	1 (1.7)	0	1 (1.7)	0	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0
Otitis externa	1 (1.7)	0	1 (1.7)	0	0
Otitis media acute	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (1.7)	0	0	1 (1.7)	0
Paronychia	1 (1.7)	1 (1.7)	0	0	0
Rash pustular	1 (1.7)	0	1 (1.7)	0	0
Respiratory syncytial virus infection	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Rhinitis	1 (1.7)	1 (1.7)	0	0	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Subcutaneous abscess	1 (1.7)	0	1 (1.7)	0	0
Tinea capitis	1 (1.7)	1 (1.7)	0	0	0
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Vulvovaginal mycotic infection	1 (1.7)	0	1 (1.7)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	29 (48.3)	3 (5.0)	21 (35.0)	5 (8.3)	0
Hypogammaglobulinaemia	28 (46.7)	3 (5.0)	20 (33.3)	5 (8.3)	0
Blood immunoglobulin m decreased	4 (6.7)	4 (6.7)	0	0	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Immunodeficiency	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	21 (35.0)	9 (15.0)	7 (11.7)	5 (8.3)	0
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Delirium	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Encephalopathy	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Seizure	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Muscular weakness	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Agitation	2 (3.3)	0	2 (3.3)	0	0
Dysarthria	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Dysphagia	2 (3.3)	0	1 (1.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Irritability	2 (3.3)	2 (3.3)	0	0	0
Tremor	2 (3.3)	2 (3.3)	0	0	0
Asterixis	1 (1.7)	1 (1.7)	0	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Mental status changes	1 (1.7)	1 (1.7)	0	0	0
Somnolence	1 (1.7)	1 (1.7)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (3.3)	0	0	2 (3.3)	0
Tumour lysis syndrome	2 (3.3)	0	0	2 (3.3)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (94.7)	0	4 (21.1)	7 (36.8)	7 (36.8)
Cytokine Release Syndrome					
-Total	18 (94.7)	1 (5.3)	9 (47.4)	3 (15.8)	5 (26.3)
Cytokine release syndrome	18 (94.7)	1 (5.3)	9 (47.4)	3 (15.8)	5 (26.3)
Haemophagocytic lymphohistiocytosis	1 (5.3)	0	1 (5.3)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (36.8)	1 (5.3)	2 (10.5)	2 (10.5)	2 (10.5)
Platelet count decreased	2 (10.5)	0	0	0	2 (10.5)
White blood cell count decreased	2 (10.5)	0	1 (5.3)	0	1 (5.3)
Anaemia	1 (5.3)	0	1 (5.3)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (5.3)	0	0	1 (5.3)	0
Neutrophil count decreased	1 (5.3)	0	0	1 (5.3)	0
Thrombocytopenia	1 (5.3)	1 (5.3)	0	0	0
Infections					
-Total	11 (57.9)	3 (15.8)	4 (21.1)	3 (15.8)	1 (5.3)
Clostridium difficile colitis	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Gastroenteritis	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Rhinovirus infection	2 (10.5)	2 (10.5)	0	0	0
Catheter site cellulitis	1 (5.3)	1 (5.3)	0	0	0
Clostridium difficile infection	1 (5.3)	0	1 (5.3)	0	0
Folliculitis	1 (5.3)	0	1 (5.3)	0	0
Fungal skin infection	1 (5.3)	1 (5.3)	0	0	0
Herpes simplex	1 (5.3)	1 (5.3)	0	0	0
Orchitis	1 (5.3)	1 (5.3)	0	0	0
Pharyngitis	1 (5.3)	0	1 (5.3)	0	0
Pneumonia	1 (5.3)	0	1 (5.3)	0	0
Septic embolus	1 (5.3)	0	0	0	1 (5.3)
Staphylococcal infection	1 (5.3)	0	0	1 (5.3)	0
Streptococcal infection	1 (5.3)	0	1 (5.3)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (5.3)	0	1 (5.3)	0	0
Urinary tract infection enterococcal	1 (5.3)	0	0	1 (5.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (52.6)	3 (15.8)	5 (26.3)	2 (10.5)	0
Hypogammaglobulinaemia	9 (47.4)	2 (10.5)	5 (26.3)	2 (10.5)	0
Blood immunoglobulin a decreased	2 (10.5)	2 (10.5)	0	0	0
Blood immunoglobulin m decreased	2 (10.5)	2 (10.5)	0	0	0
Serious neurological adverse reactions					
-Total	8 (42.1)	3 (15.8)	2 (10.5)	3 (15.8)	0
Confusional state	2 (10.5)	0	2 (10.5)	0	0
Delirium	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Encephalopathy	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Hallucination	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Irritability	2 (10.5)	2 (10.5)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (5.3)	0	1 (5.3)	0	0
Dysphagia	1 (5.3)	0	0	1 (5.3)	0
Listless	1 (5.3)	1 (5.3)	0	0	0
Mental status changes	1 (5.3)	1 (5.3)	0	0	0
Seizure	1 (5.3)	0	0	1 (5.3)	0

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Table 199j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=45			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (91.1)	1 (2.2)	15 (33.3)	11 (24.4)	14 (31.1)
Cytokine Release Syndrome					
-Total	32 (71.1)	5 (11.1)	16 (35.6)	5 (11.1)	6 (13.3)
Cytokine release syndrome	32 (71.1)	5 (11.1)	16 (35.6)	5 (11.1)	6 (13.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	20 (44.4)	1 (2.2)	1 (2.2)	8 (17.8)	10 (22.2)
White blood cell count decreased	9 (20.0)	1 (2.2)	0	6 (13.3)	2 (4.4)
Neutrophil count decreased	7 (15.6)	0	0	2 (4.4)	5 (11.1)
Platelet count decreased	6 (13.3)	1 (2.2)	1 (2.2)	1 (2.2)	3 (6.7)
Febrile neutropenia	3 (6.7)	0	0	3 (6.7)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	3 (6.7)	0	0	1 (2.2)	2 (4.4)
Thrombocytopenia	3 (6.7)	0	0	1 (2.2)	2 (4.4)
Anaemia	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Lymphocyte count decreased	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Lymphopenia	1 (2.2)	0	0	1 (2.2)	0
Infections					
-Total	15 (33.3)	2 (4.4)	10 (22.2)	3 (6.7)	0
Clostridium difficile infection	3 (6.7)	0	3 (6.7)	0	0
Clostridium difficile colitis	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Acute sinusitis	1 (2.2)	0	1 (2.2)	0	0
Body tinea	1 (2.2)	1 (2.2)	0	0	0
Catheter site infection	1 (2.2)	0	0	1 (2.2)	0
Cytomegalovirus infection	1 (2.2)	1 (2.2)	0	0	0
Enterococcal infection	1 (2.2)	1 (2.2)	0	0	0
Gastroenteritis norovirus	1 (2.2)	0	1 (2.2)	0	0
Human herpesvirus 6 infection	1 (2.2)	0	1 (2.2)	0	0
Hypopyon	1 (2.2)	0	1 (2.2)	0	0
Influenza	1 (2.2)	1 (2.2)	0	0	0
Oral candidiasis	1 (2.2)	1 (2.2)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (2.2)	0	0	1 (2.2)	0
Rhinovirus infection	1 (2.2)	1 (2.2)	0	0	0
Skin infection	1 (2.2)	0	1 (2.2)	0	0
Skin papilloma	1 (2.2)	0	1 (2.2)	0	0
Staphylococcal infection	1 (2.2)	1 (2.2)	0	0	0
Viral infection	1 (2.2)	0	1 (2.2)	0	0
Viral upper respiratory tract infection	1 (2.2)	0	1 (2.2)	0	0
Vulvovaginal candidiasis	1 (2.2)	1 (2.2)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	17 (37.8)	1 (2.2)	14 (31.1)	2 (4.4)	0
Hypogammaglobulinaemia	16 (35.6)	1 (2.2)	13 (28.9)	2 (4.4)	0
Blood immunoglobulin m decreased	2 (4.4)	2 (4.4)	0	0	0
Blood immunoglobulin a decreased	1 (2.2)	1 (2.2)	0	0	0
Blood immunoglobulin g decreased	1 (2.2)	0	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	11 (24.4)	5 (11.1)	5 (11.1)	1 (2.2)	0
Confusional state	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Delirium	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Dysarthria	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Encephalopathy	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Seizure	2 (4.4)	0	2 (4.4)	0	0
Tremor	2 (4.4)	2 (4.4)	0	0	0
Agitation	1 (2.2)	0	1 (2.2)	0	0
Asterixis	1 (2.2)	1 (2.2)	0	0	0
Depressed level of consciousness	1 (2.2)	1 (2.2)	0	0	0
Dysphagia	1 (2.2)	0	1 (2.2)	0	0
Muscular weakness	1 (2.2)	0	1 (2.2)	0	0
Somnolence	1 (2.2)	1 (2.2)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.2)	0	0	1 (2.2)	0
Tumour lysis syndrome	1 (2.2)	0	0	1 (2.2)	0

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Table 199j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (72.2)	3 (16.7)	4 (22.2)	5 (27.8)	1 (5.6)
Infections					
-Total	13 (72.2)	4 (22.2)	4 (22.2)	4 (22.2)	1 (5.6)
Upper respiratory tract infection	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Ear infection	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Gastroenteritis	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Cellulitis of male external genital organ	1 (5.6)	0	0	1 (5.6)	0
Enterovirus infection	1 (5.6)	0	0	1 (5.6)	0
Herpes zoster	1 (5.6)	0	0	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (5.6)	1 (5.6)	0	0	0
Oral herpes	1 (5.6)	0	1 (5.6)	0	0
Rhinitis	1 (5.6)	1 (5.6)	0	0	0
Rhinovirus infection	1 (5.6)	1 (5.6)	0	0	0
Rotavirus infection	1 (5.6)	0	0	1 (5.6)	0
Tinea capitis	1 (5.6)	1 (5.6)	0	0	0
Urinary tract infection	1 (5.6)	0	0	1 (5.6)	0
Vascular device infection	1 (5.6)	0	0	1 (5.6)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Hypogammaglobulinaemia	3 (16.7)	0	2 (11.1)	1 (5.6)	0

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Table 199j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (57.9)	2 (5.3)	12 (31.6)	7 (18.4)	1 (2.6)
Infections					
-Total	20 (52.6)	2 (5.3)	11 (28.9)	6 (15.8)	1 (2.6)
Upper respiratory tract infection	4 (10.5)	2 (5.3)	1 (2.6)	1 (2.6)	0
Influenza	3 (7.9)	0	3 (7.9)	0	0
Urinary tract infection	3 (7.9)	0	2 (5.3)	1 (2.6)	0
Parainfluenzae virus infection	2 (5.3)	1 (2.6)	0	1 (2.6)	0
Sinusitis	2 (5.3)	0	2 (5.3)	0	0
Viral upper respiratory tract infection	2 (5.3)	1 (2.6)	0	1 (2.6)	0
Cholecystitis infective	1 (2.6)	0	0	1 (2.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (2.6)	0	0	1 (2.6)	0
Cytomegalovirus infection	1 (2.6)	1 (2.6)	0	0	0
Escherichia urinary tract infection	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis	1 (2.6)	0	1 (2.6)	0	0
Gastroenteritis norovirus	1 (2.6)	0	1 (2.6)	0	0
Gastroenteritis viral	1 (2.6)	1 (2.6)	0	0	0
Otitis externa	1 (2.6)	0	1 (2.6)	0	0
Otitis media	1 (2.6)	0	1 (2.6)	0	0
Otitis media acute	1 (2.6)	0	1 (2.6)	0	0
Paronychia	1 (2.6)	1 (2.6)	0	0	0
Rash pustular	1 (2.6)	0	1 (2.6)	0	0
Respiratory syncytial virus infection	1 (2.6)	0	0	1 (2.6)	0
Rhinovirus infection	1 (2.6)	1 (2.6)	0	0	0
Sepsis	1 (2.6)	0	0	0	1 (2.6)
Subcutaneous abscess	1 (2.6)	0	1 (2.6)	0	0
Viral infection	1 (2.6)	1 (2.6)	0	0	0
Vulvovaginal mycotic infection	1 (2.6)	0	1 (2.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (13.2)	0	5 (13.2)	0	0
Hypogammaglobulinaemia	5 (13.2)	0	5 (13.2)	0	0
Serious neurological adverse reactions					
-Total	2 (5.3)	2 (5.3)	0	0	0
Muscular weakness	2 (5.3)	2 (5.3)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.6)	0	0	1 (2.6)	0
Tumour lysis syndrome	1 (2.6)	0	0	1 (2.6)	0

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Table 199j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	3 (27.3)	1 (9.1)	2 (18.2)	1 (9.1)
Infections					
-Total	6 (54.5)	2 (18.2)	1 (9.1)	2 (18.2)	1 (9.1)
Urinary tract infection	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Campylobacter infection	1 (9.1)	0	0	1 (9.1)	0
Cellulitis of male external genital organ	1 (9.1)	0	0	1 (9.1)	0
Clostridium difficile infection	1 (9.1)	0	0	1 (9.1)	0
Gingivitis	1 (9.1)	1 (9.1)	0	0	0
Otitis media	1 (9.1)	0	1 (9.1)	0	0
Respiratory tract infection	1 (9.1)	0	0	0	1 (9.1)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (9.1)	0	0	1 (9.1)	0
Skin infection	1 (9.1)	0	1 (9.1)	0	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0	0	0
Viral infection	1 (9.1)	1 (9.1)	0	0	0
Vulvovaginal candidiasis	1 (9.1)	0	1 (9.1)	0	0
Serious neurological adverse reactions					
-Total	1 (9.1)	1 (9.1)	0	0	0
Disturbance in attention	1 (9.1)	1 (9.1)	0	0	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=23			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (26.1)	0	5 (21.7)	1 (4.3)	0
Infections					
-Total	5 (21.7)	0	4 (17.4)	1 (4.3)	0
Sinusitis	3 (13.0)	0	3 (13.0)	0	0
Otitis media	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Otitis media acute	2 (8.7)	0	2 (8.7)	0	0
Pneumonia	2 (8.7)	0	2 (8.7)	0	0
Haemophilus infection	1 (4.3)	0	1 (4.3)	0	0
Meningitis aseptic	1 (4.3)	0	1 (4.3)	0	0
Upper respiratory tract infection	1 (4.3)	0	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=23			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (4.3)	0	1 (4.3)	0	0
Immunodeficiency	1 (4.3)	0	1 (4.3)	0	0
Serious neurological adverse reactions					
-Total	1 (4.3)	0	0	1 (4.3)	0
Seizure	1 (4.3)	0	0	1 (4.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (100)	0	3 (15.8)	8 (42.1)	8 (42.1)
Cytokine Release Syndrome					
-Total	18 (94.7)	1 (5.3)	9 (47.4)	3 (15.8)	5 (26.3)
Cytokine release syndrome	18 (94.7)	1 (5.3)	9 (47.4)	3 (15.8)	5 (26.3)
Haemophagocytic lymphohistiocytosis	1 (5.3)	0	1 (5.3)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (36.8)	1 (5.3)	2 (10.5)	2 (10.5)	2 (10.5)
Platelet count decreased	2 (10.5)	0	0	0	2 (10.5)
White blood cell count decreased	2 (10.5)	0	1 (5.3)	0	1 (5.3)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	1 (5.3)	0	1 (5.3)	0	0
Lymphocyte count decreased	1 (5.3)	0	0	1 (5.3)	0
Neutrophil count decreased	1 (5.3)	0	0	1 (5.3)	0
Thrombocytopenia	1 (5.3)	1 (5.3)	0	0	0
Infections					
-Total	16 (84.2)	3 (15.8)	5 (26.3)	5 (26.3)	3 (15.8)
Gastroenteritis	4 (21.1)	1 (5.3)	2 (10.5)	1 (5.3)	0
Upper respiratory tract infection	4 (21.1)	2 (10.5)	2 (10.5)	0	0
Rhinovirus infection	3 (15.8)	3 (15.8)	0	0	0
Clostridium difficile colitis	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Clostridium difficile infection	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Ear infection	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Urinary tract infection	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Bacterial sepsis	1 (5.3)	0	0	0	1 (5.3)
Campylobacter infection	1 (5.3)	0	0	1 (5.3)	0
Catheter site cellulitis	1 (5.3)	1 (5.3)	0	0	0
Cellulitis of male external genital organ	1 (5.3)	0	0	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus infection	1 (5.3)	0	0	1 (5.3)	0
Folliculitis	1 (5.3)	0	1 (5.3)	0	0
Fungal skin infection	1 (5.3)	1 (5.3)	0	0	0
Gingivitis	1 (5.3)	1 (5.3)	0	0	0
Herpes simplex	1 (5.3)	1 (5.3)	0	0	0
Herpes zoster	1 (5.3)	0	0	1 (5.3)	0
Molluscum contagiosum	1 (5.3)	1 (5.3)	0	0	0
Oral herpes	1 (5.3)	0	1 (5.3)	0	0
Orchitis	1 (5.3)	1 (5.3)	0	0	0
Otitis media	1 (5.3)	0	1 (5.3)	0	0
Pharyngitis	1 (5.3)	0	1 (5.3)	0	0
Pneumonia	1 (5.3)	0	1 (5.3)	0	0
Respiratory tract infection	1 (5.3)	0	0	0	1 (5.3)
Respiratory tract infection viral	1 (5.3)	0	0	1 (5.3)	0
Rhinitis	1 (5.3)	1 (5.3)	0	0	0
Rotavirus infection	1 (5.3)	0	0	1 (5.3)	0
Septic embolus	1 (5.3)	0	0	0	1 (5.3)
Skin infection	1 (5.3)	0	1 (5.3)	0	0
Staphylococcal infection	1 (5.3)	0	0	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (5.3)	0	1 (5.3)	0	0
Tinea capitis	1 (5.3)	1 (5.3)	0	0	0
Urinary tract infection enterococcal	1 (5.3)	0	0	1 (5.3)	0
Vascular device infection	1 (5.3)	0	0	1 (5.3)	0
Viral infection	1 (5.3)	1 (5.3)	0	0	0
Vulvovaginal candidiasis	1 (5.3)	0	1 (5.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	12 (63.2)	2 (10.5)	7 (36.8)	3 (15.8)	0
Hypogammaglobulinaemia	12 (63.2)	2 (10.5)	7 (36.8)	3 (15.8)	0
Blood immunoglobulin a decreased	2 (10.5)	2 (10.5)	0	0	0
Blood immunoglobulin m decreased	2 (10.5)	2 (10.5)	0	0	0
Serious neurological adverse reactions					
-Total	8 (42.1)	3 (15.8)	2 (10.5)	3 (15.8)	0
Confusional state	2 (10.5)	0	2 (10.5)	0	0
Delirium	2 (10.5)	1 (5.3)	1 (5.3)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Hallucination	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Irritability	2 (10.5)	2 (10.5)	0	0	0
Agitation	1 (5.3)	0	1 (5.3)	0	0
Disturbance in attention	1 (5.3)	1 (5.3)	0	0	0
Dysphagia	1 (5.3)	0	0	1 (5.3)	0
Listless	1 (5.3)	1 (5.3)	0	0	0
Mental status changes	1 (5.3)	1 (5.3)	0	0	0
Seizure	1 (5.3)	0	0	1 (5.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=45			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (97.8)	0	14 (31.1)	15 (33.3)	15 (33.3)
Cytokine Release Syndrome					
-Total	32 (71.1)	5 (11.1)	16 (35.6)	5 (11.1)	6 (13.3)
Cytokine release syndrome	32 (71.1)	5 (11.1)	16 (35.6)	5 (11.1)	6 (13.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	20 (44.4)	1 (2.2)	1 (2.2)	8 (17.8)	10 (22.2)
White blood cell count decreased	9 (20.0)	1 (2.2)	0	6 (13.3)	2 (4.4)
Neutrophil count decreased	7 (15.6)	0	0	2 (4.4)	5 (11.1)
Platelet count decreased	6 (13.3)	1 (2.2)	1 (2.2)	1 (2.2)	3 (6.7)
Febrile neutropenia	3 (6.7)	0	0	3 (6.7)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	3 (6.7)	0	0	1 (2.2)	2 (4.4)
Thrombocytopenia	3 (6.7)	0	0	1 (2.2)	2 (4.4)
Anaemia	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Lymphocyte count decreased	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Lymphopenia	1 (2.2)	0	0	1 (2.2)	0
Infections					
-Total	30 (66.7)	4 (8.9)	16 (35.6)	9 (20.0)	1 (2.2)
Upper respiratory tract infection	5 (11.1)	2 (4.4)	2 (4.4)	1 (2.2)	0
Influenza	4 (8.9)	1 (2.2)	3 (6.7)	0	0
Sinusitis	4 (8.9)	0	4 (8.9)	0	0
Clostridium difficile infection	3 (6.7)	0	3 (6.7)	0	0
Otitis media	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Pneumonia	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Urinary tract infection	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Viral upper respiratory tract infection	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Clostridium difficile colitis	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Cytomegalovirus infection	2 (4.4)	2 (4.4)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=45			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	2 (4.4)	0	2 (4.4)	0	0
Parainfluenzae virus infection	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Rhinovirus infection	2 (4.4)	2 (4.4)	0	0	0
Viral infection	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Acute sinusitis	1 (2.2)	0	1 (2.2)	0	0
Body tinea	1 (2.2)	1 (2.2)	0	0	0
Catheter site infection	1 (2.2)	0	0	1 (2.2)	0
Cholecystitis infective	1 (2.2)	0	0	1 (2.2)	0
Corona virus infection	1 (2.2)	0	0	1 (2.2)	0
Enterococcal infection	1 (2.2)	1 (2.2)	0	0	0
Escherichia urinary tract infection	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis norovirus	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis viral	1 (2.2)	1 (2.2)	0	0	0
Haemophilus infection	1 (2.2)	0	1 (2.2)	0	0
Human herpesvirus 6 infection	1 (2.2)	0	1 (2.2)	0	0
Hypopyon	1 (2.2)	0	1 (2.2)	0	0
Meningitis aseptic	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=45			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (2.2)	1 (2.2)	0	0	0
Otitis externa	1 (2.2)	0	1 (2.2)	0	0
Paronychia	1 (2.2)	1 (2.2)	0	0	0
Rash pustular	1 (2.2)	0	1 (2.2)	0	0
Respiratory syncytial virus infection	1 (2.2)	0	0	1 (2.2)	0
Sepsis	1 (2.2)	0	0	0	1 (2.2)
Skin infection	1 (2.2)	0	1 (2.2)	0	0
Skin papilloma	1 (2.2)	0	1 (2.2)	0	0
Staphylococcal infection	1 (2.2)	1 (2.2)	0	0	0
Subcutaneous abscess	1 (2.2)	0	1 (2.2)	0	0
Vulvovaginal candidiasis	1 (2.2)	1 (2.2)	0	0	0
Vulvovaginal mycotic infection	1 (2.2)	0	1 (2.2)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	21 (46.7)	1 (2.2)	18 (40.0)	2 (4.4)	0
Hypogammaglobulinaemia	20 (44.4)	1 (2.2)	17 (37.8)	2 (4.4)	0
Blood immunoglobulin m decreased	2 (4.4)	2 (4.4)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (2.2)	1 (2.2)	0	0	0
Blood immunoglobulin g decreased	1 (2.2)	0	1 (2.2)	0	0
Immunodeficiency	1 (2.2)	0	1 (2.2)	0	0
Serious neurological adverse reactions					
-Total	13 (28.9)	6 (13.3)	5 (11.1)	2 (4.4)	0
Confusional state	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Muscular weakness	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Seizure	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Delirium	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Dysarthria	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Encephalopathy	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Tremor	2 (4.4)	2 (4.4)	0	0	0
Agitation	1 (2.2)	0	1 (2.2)	0	0
Asterixis	1 (2.2)	1 (2.2)	0	0	0
Depressed level of consciousness	1 (2.2)	1 (2.2)	0	0	0
Dysphagia	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=45			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	1 (2.2)	1 (2.2)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (4.4)	0	0	2 (4.4)	0
Tumour lysis syndrome	2 (4.4)	0	0	2 (4.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (92.2)	1 (1.6)	19 (29.7)	18 (28.1)	21 (32.8)
Cytokine Release Syndrome					
-Total	50 (78.1)	6 (9.4)	25 (39.1)	8 (12.5)	11 (17.2)
Cytokine release syndrome	50 (78.1)	6 (9.4)	25 (39.1)	8 (12.5)	11 (17.2)
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	27 (42.2)	2 (3.1)	3 (4.7)	10 (15.6)	12 (18.8)
White blood cell count decreased	11 (17.2)	1 (1.6)	1 (1.6)	6 (9.4)	3 (4.7)
Neutrophil count decreased	8 (12.5)	0	0	3 (4.7)	5 (7.8)

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (12.5)	1 (1.6)	1 (1.6)	1 (1.6)	5 (7.8)
Thrombocytopenia	4 (6.3)	1 (1.6)	0	1 (1.6)	2 (3.1)
Anaemia	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Febrile neutropenia	3 (4.7)	0	0	3 (4.7)	0
Lymphocyte count decreased	3 (4.7)	0	0	2 (3.1)	1 (1.6)
Neutropenia	3 (4.7)	0	0	1 (1.6)	2 (3.1)
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	26 (40.6)	5 (7.8)	14 (21.9)	6 (9.4)	1 (1.6)
Clostridium difficile colitis	4 (6.3)	1 (1.6)	2 (3.1)	1 (1.6)	0
Clostridium difficile infection	4 (6.3)	0	4 (6.3)	0	0
Rhinovirus infection	3 (4.7)	3 (4.7)	0	0	0
Gastroenteritis	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Pneumonia	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Staphylococcal infection	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cytomegalovirus infection	1 (1.6)	1 (1.6)	0	0	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Influenza	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Skin infection	1 (1.6)	0	1 (1.6)	0	0
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Viral infection	1 (1.6)	0	1 (1.6)	0	0
Viral upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Vulvovaginal candidiasis	1 (1.6)	1 (1.6)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	27 (42.2)	4 (6.3)	19 (29.7)	4 (6.3)	0
Hypogammaglobulinaemia	25 (39.1)	3 (4.7)	18 (28.1)	4 (6.3)	0
Blood immunoglobulin m decreased	4 (6.3)	4 (6.3)	0	0	0
Blood immunoglobulin a decreased	3 (4.7)	3 (4.7)	0	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Serious neurological adverse reactions					

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (29.7)	8 (12.5)	7 (10.9)	4 (6.3)	0
Confusional state	6 (9.4)	3 (4.7)	3 (4.7)	0	0
Delirium	4 (6.3)	2 (3.1)	2 (3.1)	0	0
Encephalopathy	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.1)	0
Seizure	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Agitation	2 (3.1)	0	2 (3.1)	0	0
Dysarthria	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Dysphagia	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Hallucination	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Irritability	2 (3.1)	2 (3.1)	0	0	0
Tremor	2 (3.1)	2 (3.1)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Muscular weakness	1 (1.6)	0	1 (1.6)	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Region: US

Group term Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (62.5)	5 (8.9)	16 (28.6)	12 (21.4)	2 (3.6)
Infections					
-Total	33 (58.9)	6 (10.7)	15 (26.8)	10 (17.9)	2 (3.6)
Upper respiratory tract infection	7 (12.5)	3 (5.4)	3 (5.4)	1 (1.8)	0
Urinary tract infection	4 (7.1)	0	2 (3.6)	2 (3.6)	0
Gastroenteritis	3 (5.4)	1 (1.8)	2 (3.6)	0	0
Influenza	3 (5.4)	0	3 (5.4)	0	0
Ear infection	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Parainfluenzae virus infection	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Rhinovirus infection	2 (3.6)	2 (3.6)	0	0	0
Sinusitis	2 (3.6)	0	2 (3.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Cellulitis of male external genital organ	1 (1.8)	0	0	1 (1.8)	0
Cholecystitis infective	1 (1.8)	0	0	1 (1.8)	0
Corona virus infection	1 (1.8)	0	0	1 (1.8)	0
Cytomegalovirus infection	1 (1.8)	1 (1.8)	0	0	0
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Escherichia urinary tract infection	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis viral	1 (1.8)	1 (1.8)	0	0	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0
Molluscum contagiosum	1 (1.8)	1 (1.8)	0	0	0
Oral herpes	1 (1.8)	0	1 (1.8)	0	0
Otitis externa	1 (1.8)	0	1 (1.8)	0	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Otitis media acute	1 (1.8)	0	1 (1.8)	0	0
Paronychia	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash pustular	1 (1.8)	0	1 (1.8)	0	0
Respiratory syncytial virus infection	1 (1.8)	0	0	1 (1.8)	0
Rhinitis	1 (1.8)	1 (1.8)	0	0	0
Rotavirus infection	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Subcutaneous abscess	1 (1.8)	0	1 (1.8)	0	0
Tinea capitis	1 (1.8)	1 (1.8)	0	0	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral infection	1 (1.8)	1 (1.8)	0	0	0
Vulvovaginal mycotic infection	1 (1.8)	0	1 (1.8)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (14.3)	0	7 (12.5)	1 (1.8)	0
Hypogammaglobulinaemia	8 (14.3)	0	7 (12.5)	1 (1.8)	0
Serious neurological adverse reactions					
-Total	2 (3.6)	2 (3.6)	0	0	0
Muscular weakness	2 (3.6)	2 (3.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour Lysis Syndrome					
-Total	1 (1.8)	0	0	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (38.2)	3 (8.8)	6 (17.6)	3 (8.8)	1 (2.9)
Infections					
-Total	11 (32.4)	2 (5.9)	5 (14.7)	3 (8.8)	1 (2.9)
Otitis media	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Sinusitis	3 (8.8)	0	3 (8.8)	0	0
Otitis media acute	2 (5.9)	0	2 (5.9)	0	0
Pneumonia	2 (5.9)	0	2 (5.9)	0	0
Upper respiratory tract infection	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Urinary tract infection	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Campylobacter infection	1 (2.9)	0	0	1 (2.9)	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (2.9)	0	0	1 (2.9)	0
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0
Gingivitis	1 (2.9)	1 (2.9)	0	0	0
Haemophilus infection	1 (2.9)	0	1 (2.9)	0	0
Meningitis aseptic	1 (2.9)	0	1 (2.9)	0	0
Respiratory tract infection	1 (2.9)	0	0	0	1 (2.9)
Respiratory tract infection viral	1 (2.9)	0	0	1 (2.9)	0
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Viral infection	1 (2.9)	1 (2.9)	0	0	0
Vulvovaginal candidiasis	1 (2.9)	0	1 (2.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (2.9)	0	1 (2.9)	0	0
Immunodeficiency	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					
-Total	2 (5.9)	1 (2.9)	0	1 (2.9)	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disturbance in attention	1 (2.9)	1 (2.9)	0	0	0
Seizure	1 (2.9)	0	0	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (98.4)	0	17 (26.6)	23 (35.9)	23 (35.9)
Cytokine Release Syndrome					
-Total	50 (78.1)	6 (9.4)	25 (39.1)	8 (12.5)	11 (17.2)
Cytokine release syndrome	50 (78.1)	6 (9.4)	25 (39.1)	8 (12.5)	11 (17.2)
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	27 (42.2)	2 (3.1)	3 (4.7)	10 (15.6)	12 (18.8)
White blood cell count decreased	11 (17.2)	1 (1.6)	1 (1.6)	6 (9.4)	3 (4.7)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	8 (12.5)	0	0	3 (4.7)	5 (7.8)
Platelet count decreased	8 (12.5)	1 (1.6)	1 (1.6)	1 (1.6)	5 (7.8)
Thrombocytopenia	4 (6.3)	1 (1.6)	0	1 (1.6)	2 (3.1)
Anaemia	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Febrile neutropenia	3 (4.7)	0	0	3 (4.7)	0
Lymphocyte count decreased	3 (4.7)	0	0	2 (3.1)	1 (1.6)
Neutropenia	3 (4.7)	0	0	1 (1.6)	2 (3.1)
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	46 (71.9)	7 (10.9)	21 (32.8)	14 (21.9)	4 (6.3)
Upper respiratory tract infection	9 (14.1)	4 (6.3)	4 (6.3)	1 (1.6)	0
Clostridium difficile infection	5 (7.8)	0	4 (6.3)	1 (1.6)	0
Gastroenteritis	5 (7.8)	1 (1.6)	3 (4.7)	1 (1.6)	0
Rhinovirus infection	5 (7.8)	5 (7.8)	0	0	0
Urinary tract infection	5 (7.8)	0	3 (4.7)	2 (3.1)	0
Clostridium difficile colitis	4 (6.3)	1 (1.6)	2 (3.1)	1 (1.6)	0
Influenza	4 (6.3)	1 (1.6)	3 (4.7)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	4 (6.3)	0	3 (4.7)	1 (1.6)	0
Pneumonia	4 (6.3)	0	3 (4.7)	1 (1.6)	0
Sinusitis	4 (6.3)	0	4 (6.3)	0	0
Viral infection	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Viral upper respiratory tract infection	3 (4.7)	1 (1.6)	1 (1.6)	1 (1.6)	0
Cytomegalovirus infection	2 (3.1)	2 (3.1)	0	0	0
Ear infection	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Otitis media acute	2 (3.1)	0	2 (3.1)	0	0
Parainfluenzae virus infection	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Skin infection	2 (3.1)	0	2 (3.1)	0	0
Staphylococcal infection	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Vulvovaginal candidiasis	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Escherichia urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0
Haemophilus infection	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis aseptic	1 (1.6)	0	1 (1.6)	0	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Otitis externa	1 (1.6)	0	1 (1.6)	0	0
Paronychia	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Rash pustular	1 (1.6)	0	1 (1.6)	0	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Rhinitis	1 (1.6)	1 (1.6)	0	0	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Subcutaneous abscess	1 (1.6)	0	1 (1.6)	0	0
Tinea capitis	1 (1.6)	1 (1.6)	0	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Vulvovaginal mycotic infection	1 (1.6)	0	1 (1.6)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	33 (51.6)	3 (4.7)	25 (39.1)	5 (7.8)	0
Hypogammaglobulinaemia	32 (50.0)	3 (4.7)	24 (37.5)	5 (7.8)	0
Blood immunoglobulin m decreased	4 (6.3)	4 (6.3)	0	0	0
Blood immunoglobulin a decreased	3 (4.7)	3 (4.7)	0	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Immunodeficiency	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	21 (32.8)	9 (14.1)	7 (10.9)	5 (7.8)	0
Confusional state	6 (9.4)	3 (4.7)	3 (4.7)	0	0
Delirium	4 (6.3)	2 (3.1)	2 (3.1)	0	0
Encephalopathy	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.1)	0
Seizure	4 (6.3)	0	2 (3.1)	2 (3.1)	0
Muscular weakness	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Agitation	2 (3.1)	0	2 (3.1)	0	0
Dysarthria	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Dysphagia	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Hallucination	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Irritability	2 (3.1)	2 (3.1)	0	0	0
Tremor	2 (3.1)	2 (3.1)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Disturbance in attention	1 (1.6)	1 (1.6)	0	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Region: US

Group term Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (3.1)	0	0	2 (3.1)	0
Tumour lysis syndrome	2 (3.1)	0	0	2 (3.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (82.1)	0	9 (32.1)	8 (28.6)	6 (21.4)
Cytokine Release Syndrome					
-Total	20 (71.4)	3 (10.7)	11 (39.3)	4 (14.3)	2 (7.1)
Cytokine release syndrome	20 (71.4)	3 (10.7)	11 (39.3)	4 (14.3)	2 (7.1)
Haemophagocytic lymphohistiocytosis	1 (3.6)	0	1 (3.6)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	11 (39.3)	1 (3.6)	1 (3.6)	5 (17.9)	4 (14.3)
White blood cell count decreased	7 (25.0)	0	1 (3.6)	5 (17.9)	1 (3.6)
Platelet count decreased	4 (14.3)	0	0	1 (3.6)	3 (10.7)
Neutrophil count decreased	3 (10.7)	0	0	1 (3.6)	2 (7.1)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Febrile neutropenia	1 (3.6)	0	0	1 (3.6)	0
Lymphocyte count decreased	1 (3.6)	0	0	1 (3.6)	0
Infections					
-Total	13 (46.4)	4 (14.3)	8 (28.6)	0	1 (3.6)
Clostridium difficile infection	3 (10.7)	0	3 (10.7)	0	0
Acute sinusitis	1 (3.6)	0	1 (3.6)	0	0
Body tinea	1 (3.6)	1 (3.6)	0	0	0
Catheter site cellulitis	1 (3.6)	1 (3.6)	0	0	0
Clostridium difficile colitis	1 (3.6)	0	1 (3.6)	0	0
Cytomegalovirus infection	1 (3.6)	1 (3.6)	0	0	0
Enterococcal infection	1 (3.6)	1 (3.6)	0	0	0
Fungal skin infection	1 (3.6)	1 (3.6)	0	0	0
Gastroenteritis norovirus	1 (3.6)	0	1 (3.6)	0	0
Herpes simplex	1 (3.6)	1 (3.6)	0	0	0
Human herpesvirus 6 infection	1 (3.6)	0	1 (3.6)	0	0
Hypopyon	1 (3.6)	0	1 (3.6)	0	0
Influenza	1 (3.6)	1 (3.6)	0	0	0
Oral candidiasis	1 (3.6)	1 (3.6)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (3.6)	1 (3.6)	0	0	0
Septic embolus	1 (3.6)	0	0	0	1 (3.6)
Skin infection	1 (3.6)	0	1 (3.6)	0	0
Skin papilloma	1 (3.6)	0	1 (3.6)	0	0
Vulvovaginal candidiasis	1 (3.6)	1 (3.6)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (35.7)	3 (10.7)	6 (21.4)	1 (3.6)	0
Hypogammaglobulinaemia	9 (32.1)	2 (7.1)	6 (21.4)	1 (3.6)	0
Blood immunoglobulin a decreased	3 (10.7)	3 (10.7)	0	0	0
Blood immunoglobulin m decreased	3 (10.7)	3 (10.7)	0	0	0
Serious neurological adverse reactions					
-Total	5 (17.9)	1 (3.6)	2 (7.1)	2 (7.1)	0
Confusional state	2 (7.1)	0	2 (7.1)	0	0
Encephalopathy	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Agitation	1 (3.6)	0	1 (3.6)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hallucination	1 (3.6)	0	1 (3.6)	0	0
Irritability	1 (3.6)	1 (3.6)	0	0	0
Listless	1 (3.6)	1 (3.6)	0	0	0
Seizure	1 (3.6)	0	0	1 (3.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (100)	1 (2.8)	10 (27.8)	10 (27.8)	15 (41.7)
Cytokine Release Syndrome					
-Total	30 (83.3)	3 (8.3)	14 (38.9)	4 (11.1)	9 (25.0)
Cytokine release syndrome	30 (83.3)	3 (8.3)	14 (38.9)	4 (11.1)	9 (25.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	16 (44.4)	1 (2.8)	2 (5.6)	5 (13.9)	8 (22.2)
Neutrophil count decreased	5 (13.9)	0	0	2 (5.6)	3 (8.3)
Platelet count decreased	4 (11.1)	1 (2.8)	1 (2.8)	0	2 (5.6)
White blood cell count decreased	4 (11.1)	1 (2.8)	0	1 (2.8)	2 (5.6)
Anaemia	3 (8.3)	0	2 (5.6)	1 (2.8)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	3 (8.3)	0	0	1 (2.8)	2 (5.6)
Febrile neutropenia	2 (5.6)	0	0	2 (5.6)	0
Lymphocyte count decreased	2 (5.6)	0	0	1 (2.8)	1 (2.8)
Thrombocytopenia	2 (5.6)	0	0	0	2 (5.6)
Lymphopenia	1 (2.8)	0	0	1 (2.8)	0
Infections					
-Total	13 (36.1)	1 (2.8)	6 (16.7)	6 (16.7)	0
Clostridium difficile colitis	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Gastroenteritis	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Pneumonia	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Rhinovirus infection	2 (5.6)	2 (5.6)	0	0	0
Staphylococcal infection	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Catheter site infection	1 (2.8)	0	0	1 (2.8)	0
Clostridium difficile infection	1 (2.8)	0	1 (2.8)	0	0
Folliculitis	1 (2.8)	0	1 (2.8)	0	0
Orchitis	1 (2.8)	1 (2.8)	0	0	0
Pharyngitis	1 (2.8)	0	1 (2.8)	0	0
Streptococcal infection	1 (2.8)	0	1 (2.8)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (2.8)	0	1 (2.8)	0	0
Urinary tract infection enterococcal	1 (2.8)	0	0	1 (2.8)	0
Viral infection	1 (2.8)	0	1 (2.8)	0	0
Viral upper respiratory tract infection	1 (2.8)	0	1 (2.8)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	17 (47.2)	1 (2.8)	13 (36.1)	3 (8.3)	0
Hypogammaglobulinaemia	16 (44.4)	1 (2.8)	12 (33.3)	3 (8.3)	0
Blood immunoglobulin g decreased	1 (2.8)	0	1 (2.8)	0	0
Blood immunoglobulin m decreased	1 (2.8)	1 (2.8)	0	0	0
Serious neurological adverse reactions					
-Total	14 (38.9)	7 (19.4)	5 (13.9)	2 (5.6)	0
Confusional state	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Delirium	4 (11.1)	2 (5.6)	2 (5.6)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysarthria	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Dysphagia	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Encephalopathy	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Seizure	2 (5.6)	0	2 (5.6)	0	0
Tremor	2 (5.6)	2 (5.6)	0	0	0
Agitation	1 (2.8)	0	1 (2.8)	0	0
Asterixis	1 (2.8)	1 (2.8)	0	0	0
Depressed level of consciousness	1 (2.8)	1 (2.8)	0	0	0
Hallucination	1 (2.8)	1 (2.8)	0	0	0
Irritability	1 (2.8)	1 (2.8)	0	0	0
Mental status changes	1 (2.8)	1 (2.8)	0	0	0
Muscular weakness	1 (2.8)	0	1 (2.8)	0	0
Somnolence	1 (2.8)	1 (2.8)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.8)	0	0	1 (2.8)	0
Tumour lysis syndrome	1 (2.8)	0	0	1 (2.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (56.0)	1 (4.0)	6 (24.0)	6 (24.0)	1 (4.0)
Infections					
-Total	13 (52.0)	1 (4.0)	5 (20.0)	6 (24.0)	1 (4.0)
Upper respiratory tract infection	3 (12.0)	2 (8.0)	0	1 (4.0)	0
Urinary tract infection	3 (12.0)	0	1 (4.0)	2 (8.0)	0
Cellulitis of male external genital organ	1 (4.0)	0	0	1 (4.0)	0
Cholecystitis infective	1 (4.0)	0	0	1 (4.0)	0
Cytomegalovirus infection	1 (4.0)	1 (4.0)	0	0	0
Ear infection	1 (4.0)	0	1 (4.0)	0	0
Enterovirus infection	1 (4.0)	0	0	1 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	1 (4.0)	0	0	1 (4.0)	0
Gastroenteritis norovirus	1 (4.0)	0	1 (4.0)	0	0
Influenza	1 (4.0)	0	1 (4.0)	0	0
Oral herpes	1 (4.0)	0	1 (4.0)	0	0
Otitis media	1 (4.0)	0	1 (4.0)	0	0
Otitis media acute	1 (4.0)	0	1 (4.0)	0	0
Parainfluenzae virus infection	1 (4.0)	1 (4.0)	0	0	0
Rhinitis	1 (4.0)	1 (4.0)	0	0	0
Rotavirus infection	1 (4.0)	0	0	1 (4.0)	0
Sepsis	1 (4.0)	0	0	0	1 (4.0)
Sinusitis	1 (4.0)	0	1 (4.0)	0	0
Vascular device infection	1 (4.0)	0	0	1 (4.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (20.0)	0	5 (20.0)	0	0
Hypogammaglobulinaemia	5 (20.0)	0	5 (20.0)	0	0
Serious neurological adverse reactions					

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=25 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (4.0)	1 (4.0)	0	0	0
Muscular weakness	1 (4.0)	1 (4.0)	0	0	0

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Table 199l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (67.7)	4 (12.9)	10 (32.3)	6 (19.4)	1 (3.2)
Infections					
-Total	20 (64.5)	5 (16.1)	10 (32.3)	4 (12.9)	1 (3.2)
Upper respiratory tract infection	4 (12.9)	1 (3.2)	3 (9.7)	0	0
Gastroenteritis	3 (9.7)	1 (3.2)	2 (6.5)	0	0
Influenza	2 (6.5)	0	2 (6.5)	0	0
Rhinovirus infection	2 (6.5)	2 (6.5)	0	0	0
Viral upper respiratory tract infection	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Bacterial sepsis	1 (3.2)	0	0	0	1 (3.2)
Corona virus infection	1 (3.2)	0	0	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (3.2)	1 (3.2)	0	0	0
Gastroenteritis viral	1 (3.2)	1 (3.2)	0	0	0
Herpes zoster	1 (3.2)	0	0	1 (3.2)	0
Molluscum contagiosum	1 (3.2)	1 (3.2)	0	0	0
Otitis externa	1 (3.2)	0	1 (3.2)	0	0
Parainfluenzae virus infection	1 (3.2)	0	0	1 (3.2)	0
Paronychia	1 (3.2)	1 (3.2)	0	0	0
Rash pustular	1 (3.2)	0	1 (3.2)	0	0
Respiratory syncytial virus infection	1 (3.2)	0	0	1 (3.2)	0
Sinusitis	1 (3.2)	0	1 (3.2)	0	0
Subcutaneous abscess	1 (3.2)	0	1 (3.2)	0	0
Tinea capitis	1 (3.2)	1 (3.2)	0	0	0
Urinary tract infection	1 (3.2)	0	1 (3.2)	0	0
Viral infection	1 (3.2)	1 (3.2)	0	0	0
Vulvovaginal mycotic infection	1 (3.2)	0	1 (3.2)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (9.7)	0	2 (6.5)	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Group term Preferred term	All patients N=31 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypogammaglobulinaemia	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Serious neurological adverse reactions					
-Total	1 (3.2)	1 (3.2)	0	0	0
Muscular weakness	1 (3.2)	1 (3.2)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.2)	0	0	1 (3.2)	0
Tumour lysis syndrome	1 (3.2)	0	0	1 (3.2)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 199l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (42.9)	1 (7.1)	2 (14.3)	3 (21.4)	0
Infections					
-Total	6 (42.9)	1 (7.1)	2 (14.3)	3 (21.4)	0
Otitis media	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Otitis media acute	2 (14.3)	0	2 (14.3)	0	0
Sinusitis	2 (14.3)	0	2 (14.3)	0	0
Upper respiratory tract infection	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Urinary tract infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Campylobacter infection	1 (7.1)	0	0	1 (7.1)	0
Cellulitis of male external genital organ	1 (7.1)	0	0	1 (7.1)	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (7.1)	0	0	1 (7.1)	0
Haemophilus infection	1 (7.1)	0	1 (7.1)	0	0
Pneumonia	1 (7.1)	0	1 (7.1)	0	0
Respiratory tract infection viral	1 (7.1)	0	0	1 (7.1)	0
Vulvovaginal candidiasis	1 (7.1)	0	1 (7.1)	0	0
Serious neurological adverse reactions					
-Total	1 (7.1)	0	0	1 (7.1)	0
Seizure	1 (7.1)	0	0	1 (7.1)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 199l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (35.0)	2 (10.0)	4 (20.0)	0	1 (5.0)
Infections					
-Total	5 (25.0)	1 (5.0)	3 (15.0)	0	1 (5.0)
Gingivitis	1 (5.0)	1 (5.0)	0	0	0
Meningitis aseptic	1 (5.0)	0	1 (5.0)	0	0
Otitis media	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	1 (5.0)	0	0
Respiratory tract infection	1 (5.0)	0	0	0	1 (5.0)
Sinusitis	1 (5.0)	0	1 (5.0)	0	0
Skin infection	1 (5.0)	0	1 (5.0)	0	0
Viral infection	1 (5.0)	1 (5.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (5.0)	0	1 (5.0)	0	0
Immunodeficiency	1 (5.0)	0	1 (5.0)	0	0
Serious neurological adverse reactions					
-Total	1 (5.0)	1 (5.0)	0	0	0
Disturbance in attention	1 (5.0)	1 (5.0)	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (96.4)	0	8 (28.6)	12 (42.9)	7 (25.0)
Cytokine Release Syndrome					
-Total	20 (71.4)	3 (10.7)	11 (39.3)	4 (14.3)	2 (7.1)
Cytokine release syndrome	20 (71.4)	3 (10.7)	11 (39.3)	4 (14.3)	2 (7.1)
Haemophagocytic lymphohistiocytosis	1 (3.6)	0	1 (3.6)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	11 (39.3)	1 (3.6)	1 (3.6)	5 (17.9)	4 (14.3)
White blood cell count decreased	7 (25.0)	0	1 (3.6)	5 (17.9)	1 (3.6)
Platelet count decreased	4 (14.3)	0	0	1 (3.6)	3 (10.7)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	3 (10.7)	0	0	1 (3.6)	2 (7.1)
Thrombocytopenia	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Febrile neutropenia	1 (3.6)	0	0	1 (3.6)	0
Lymphocyte count decreased	1 (3.6)	0	0	1 (3.6)	0
Infections					
-Total	21 (75.0)	4 (14.3)	8 (28.6)	7 (25.0)	2 (7.1)
Upper respiratory tract infection	5 (17.9)	3 (10.7)	1 (3.6)	1 (3.6)	0
Clostridium difficile infection	4 (14.3)	0	3 (10.7)	1 (3.6)	0
Urinary tract infection	4 (14.3)	0	2 (7.1)	2 (7.1)	0
Otitis media	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Sinusitis	3 (10.7)	0	3 (10.7)	0	0
Cytomegalovirus infection	2 (7.1)	2 (7.1)	0	0	0
Influenza	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Otitis media acute	2 (7.1)	0	2 (7.1)	0	0
Vulvovaginal candidiasis	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Acute sinusitis	1 (3.6)	0	1 (3.6)	0	0
Body tinea	1 (3.6)	1 (3.6)	0	0	0
Campylobacter infection	1 (3.6)	0	0	1 (3.6)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site cellulitis	1 (3.6)	1 (3.6)	0	0	0
Cellulitis of male external genital organ	1 (3.6)	0	0	1 (3.6)	0
Cholecystitis infective	1 (3.6)	0	0	1 (3.6)	0
Clostridium difficile colitis	1 (3.6)	0	1 (3.6)	0	0
Ear infection	1 (3.6)	0	1 (3.6)	0	0
Enterococcal infection	1 (3.6)	1 (3.6)	0	0	0
Enterovirus infection	1 (3.6)	0	0	1 (3.6)	0
Escherichia urinary tract infection	1 (3.6)	0	0	1 (3.6)	0
Fungal skin infection	1 (3.6)	1 (3.6)	0	0	0
Gastroenteritis norovirus	1 (3.6)	0	1 (3.6)	0	0
Haemophilus infection	1 (3.6)	0	1 (3.6)	0	0
Herpes simplex	1 (3.6)	1 (3.6)	0	0	0
Human herpesvirus 6 infection	1 (3.6)	0	1 (3.6)	0	0
Hypopyon	1 (3.6)	0	1 (3.6)	0	0
Oral candidiasis	1 (3.6)	1 (3.6)	0	0	0
Oral herpes	1 (3.6)	0	1 (3.6)	0	0
Parainfluenzae virus infection	1 (3.6)	1 (3.6)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (3.6)	0	1 (3.6)	0	0
Respiratory tract infection viral	1 (3.6)	0	0	1 (3.6)	0
Rhinitis	1 (3.6)	1 (3.6)	0	0	0
Rhinovirus infection	1 (3.6)	1 (3.6)	0	0	0
Rotavirus infection	1 (3.6)	0	0	1 (3.6)	0
Sepsis	1 (3.6)	0	0	0	1 (3.6)
Septic embolus	1 (3.6)	0	0	0	1 (3.6)
Skin infection	1 (3.6)	0	1 (3.6)	0	0
Skin papilloma	1 (3.6)	0	1 (3.6)	0	0
Vascular device infection	1 (3.6)	0	0	1 (3.6)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	13 (46.4)	2 (7.1)	10 (35.7)	1 (3.6)	0
Hypogammaglobulinaemia	13 (46.4)	2 (7.1)	10 (35.7)	1 (3.6)	0
Blood immunoglobulin a decreased	3 (10.7)	3 (10.7)	0	0	0
Blood immunoglobulin m decreased	3 (10.7)	3 (10.7)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	7 (25.0)	2 (7.1)	2 (7.1)	3 (10.7)	0
Confusional state	2 (7.1)	0	2 (7.1)	0	0
Encephalopathy	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Seizure	2 (7.1)	0	0	2 (7.1)	0
Agitation	1 (3.6)	0	1 (3.6)	0	0
Hallucination	1 (3.6)	0	1 (3.6)	0	0
Irritability	1 (3.6)	1 (3.6)	0	0	0
Listless	1 (3.6)	1 (3.6)	0	0	0
Muscular weakness	1 (3.6)	1 (3.6)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (100)	0	9 (25.0)	11 (30.6)	16 (44.4)
Cytokine Release Syndrome					
-Total	30 (83.3)	3 (8.3)	14 (38.9)	4 (11.1)	9 (25.0)
Cytokine release syndrome	30 (83.3)	3 (8.3)	14 (38.9)	4 (11.1)	9 (25.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	16 (44.4)	1 (2.8)	2 (5.6)	5 (13.9)	8 (22.2)
Neutrophil count decreased	5 (13.9)	0	0	2 (5.6)	3 (8.3)
Platelet count decreased	4 (11.1)	1 (2.8)	1 (2.8)	0	2 (5.6)
White blood cell count decreased	4 (11.1)	1 (2.8)	0	1 (2.8)	2 (5.6)
Anaemia	3 (8.3)	0	2 (5.6)	1 (2.8)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	3 (8.3)	0	0	1 (2.8)	2 (5.6)
Febrile neutropenia	2 (5.6)	0	0	2 (5.6)	0
Lymphocyte count decreased	2 (5.6)	0	0	1 (2.8)	1 (2.8)
Thrombocytopenia	2 (5.6)	0	0	0	2 (5.6)
Lymphopenia	1 (2.8)	0	0	1 (2.8)	0
Infections					
-Total	25 (69.4)	3 (8.3)	13 (36.1)	7 (19.4)	2 (5.6)
Gastroenteritis	5 (13.9)	1 (2.8)	3 (8.3)	1 (2.8)	0
Rhinovirus infection	4 (11.1)	4 (11.1)	0	0	0
Upper respiratory tract infection	4 (11.1)	1 (2.8)	3 (8.3)	0	0
Clostridium difficile colitis	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Pneumonia	3 (8.3)	0	2 (5.6)	1 (2.8)	0
Viral infection	3 (8.3)	2 (5.6)	1 (2.8)	0	0
Viral upper respiratory tract infection	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Influenza	2 (5.6)	0	2 (5.6)	0	0
Staphylococcal infection	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Bacterial sepsis	1 (2.8)	0	0	0	1 (2.8)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (2.8)	0	0	1 (2.8)	0
Clostridium difficile infection	1 (2.8)	0	1 (2.8)	0	0
Corona virus infection	1 (2.8)	0	0	1 (2.8)	0
Ear infection	1 (2.8)	1 (2.8)	0	0	0
Folliculitis	1 (2.8)	0	1 (2.8)	0	0
Gastroenteritis viral	1 (2.8)	1 (2.8)	0	0	0
Gingivitis	1 (2.8)	1 (2.8)	0	0	0
Herpes zoster	1 (2.8)	0	0	1 (2.8)	0
Meningitis aseptic	1 (2.8)	0	1 (2.8)	0	0
Molluscum contagiosum	1 (2.8)	1 (2.8)	0	0	0
Orchitis	1 (2.8)	1 (2.8)	0	0	0
Otitis externa	1 (2.8)	0	1 (2.8)	0	0
Otitis media	1 (2.8)	0	1 (2.8)	0	0
Parainfluenzae virus infection	1 (2.8)	0	0	1 (2.8)	0
Paronychia	1 (2.8)	1 (2.8)	0	0	0
Pharyngitis	1 (2.8)	0	1 (2.8)	0	0
Rash pustular	1 (2.8)	0	1 (2.8)	0	0
Respiratory syncytial virus infection	1 (2.8)	0	0	1 (2.8)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	1 (2.8)	0	0	0	1 (2.8)
Sinusitis	1 (2.8)	0	1 (2.8)	0	0
Skin infection	1 (2.8)	0	1 (2.8)	0	0
Streptococcal infection	1 (2.8)	0	1 (2.8)	0	0
Subcutaneous abscess	1 (2.8)	0	1 (2.8)	0	0
Tinea capitis	1 (2.8)	1 (2.8)	0	0	0
Urinary tract infection	1 (2.8)	0	1 (2.8)	0	0
Urinary tract infection enterococcal	1 (2.8)	0	0	1 (2.8)	0
Vulvovaginal mycotic infection	1 (2.8)	0	1 (2.8)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	20 (55.6)	1 (2.8)	15 (41.7)	4 (11.1)	0
Hypogammaglobulinaemia	19 (52.8)	1 (2.8)	14 (38.9)	4 (11.1)	0
Blood immunoglobulin g decreased	1 (2.8)	0	1 (2.8)	0	0
Blood immunoglobulin m decreased	1 (2.8)	1 (2.8)	0	0	0
Immunodeficiency	1 (2.8)	0	1 (2.8)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	14 (38.9)	7 (19.4)	5 (13.9)	2 (5.6)	0
Confusional state	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Delirium	4 (11.1)	2 (5.6)	2 (5.6)	0	0
Dysarthria	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Dysphagia	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Encephalopathy	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Muscular weakness	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Seizure	2 (5.6)	0	2 (5.6)	0	0
Tremor	2 (5.6)	2 (5.6)	0	0	0
Agitation	1 (2.8)	0	1 (2.8)	0	0
Asterixis	1 (2.8)	1 (2.8)	0	0	0
Depressed level of consciousness	1 (2.8)	1 (2.8)	0	0	0
Disturbance in attention	1 (2.8)	1 (2.8)	0	0	0
Hallucination	1 (2.8)	1 (2.8)	0	0	0
Irritability	1 (2.8)	1 (2.8)	0	0	0
Mental status changes	1 (2.8)	1 (2.8)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	1 (2.8)	1 (2.8)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (5.6)	0	0	2 (5.6)	0
Tumour lysis syndrome	2 (5.6)	0	0	2 (5.6)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	0	3 (21.4)	5 (35.7)	6 (42.9)
Cytokine Release Syndrome					
-Total	13 (92.9)	0	10 (71.4)	2 (14.3)	1 (7.1)
Cytokine release syndrome	13 (92.9)	0	10 (71.4)	2 (14.3)	1 (7.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	10 (71.4)	1 (7.1)	0	4 (28.6)	5 (35.7)
Neutrophil count decreased	4 (28.6)	0	0	1 (7.1)	3 (21.4)
White blood cell count decreased	4 (28.6)	1 (7.1)	0	1 (7.1)	2 (14.3)
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0
Thrombocytopenia	2 (14.3)	0	0	0	2 (14.3)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (7.1)	0	0	1 (7.1)	0
Platelet count decreased	1 (7.1)	0	0	0	1 (7.1)
Infections					
-Total	6 (42.9)	1 (7.1)	2 (14.3)	3 (21.4)	0
Catheter site infection	1 (7.1)	0	0	1 (7.1)	0
Clostridium difficile infection	1 (7.1)	0	1 (7.1)	0	0
Cytomegalovirus infection	1 (7.1)	1 (7.1)	0	0	0
Folliculitis	1 (7.1)	0	1 (7.1)	0	0
Fungal skin infection	1 (7.1)	1 (7.1)	0	0	0
Pneumonia	1 (7.1)	0	0	1 (7.1)	0
Rhinovirus infection	1 (7.1)	1 (7.1)	0	0	0
Staphylococcal infection	1 (7.1)	1 (7.1)	0	0	0
Urinary tract infection enterococcal	1 (7.1)	0	0	1 (7.1)	0
Viral infection	1 (7.1)	0	1 (7.1)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	9 (64.3)	1 (7.1)	7 (50.0)	1 (7.1)	0
Hypogammaglobulinaemia	8 (57.1)	1 (7.1)	6 (42.9)	1 (7.1)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (7.1)	1 (7.1)	0	0	0
Blood immunoglobulin g decreased	1 (7.1)	0	1 (7.1)	0	0
Blood immunoglobulin m decreased	1 (7.1)	1 (7.1)	0	0	0
Serious neurological adverse reactions					
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Depressed level of consciousness	1 (7.1)	1 (7.1)	0	0	0
Dysarthria	1 (7.1)	0	1 (7.1)	0	0
Muscular weakness	1 (7.1)	0	1 (7.1)	0	0
Somnolence	1 (7.1)	1 (7.1)	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (90.0)	1 (2.0)	16 (32.0)	13 (26.0)	15 (30.0)
Cytokine Release Syndrome					
-Total	37 (74.0)	6 (12.0)	15 (30.0)	6 (12.0)	10 (20.0)
Cytokine release syndrome	37 (74.0)	6 (12.0)	15 (30.0)	6 (12.0)	10 (20.0)
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	1 (2.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	17 (34.0)	1 (2.0)	3 (6.0)	6 (12.0)	7 (14.0)
Platelet count decreased	7 (14.0)	1 (2.0)	1 (2.0)	1 (2.0)	4 (8.0)
White blood cell count decreased	7 (14.0)	0	1 (2.0)	5 (10.0)	1 (2.0)
Neutrophil count decreased	4 (8.0)	0	0	2 (4.0)	2 (4.0)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Neutropenia	3 (6.0)	0	0	1 (2.0)	2 (4.0)
Lymphocyte count decreased	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Thrombocytopenia	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Febrile neutropenia	1 (2.0)	0	0	1 (2.0)	0
Lymphopenia	1 (2.0)	0	0	1 (2.0)	0
Infections					
-Total	20 (40.0)	4 (8.0)	12 (24.0)	3 (6.0)	1 (2.0)
Clostridium difficile colitis	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Clostridium difficile infection	3 (6.0)	0	3 (6.0)	0	0
Gastroenteritis	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Rhinovirus infection	2 (4.0)	2 (4.0)	0	0	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Body tinea	1 (2.0)	1 (2.0)	0	0	0
Catheter site cellulitis	1 (2.0)	1 (2.0)	0	0	0
Enterococcal infection	1 (2.0)	1 (2.0)	0	0	0
Gastroenteritis norovirus	1 (2.0)	0	1 (2.0)	0	0
Herpes simplex	1 (2.0)	1 (2.0)	0	0	0
Human herpesvirus 6 infection	1 (2.0)	0	1 (2.0)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypopyon	1 (2.0)	0	1 (2.0)	0	0
Influenza	1 (2.0)	1 (2.0)	0	0	0
Oral candidiasis	1 (2.0)	1 (2.0)	0	0	0
Orchitis	1 (2.0)	1 (2.0)	0	0	0
Pharyngitis	1 (2.0)	0	1 (2.0)	0	0
Pneumonia	1 (2.0)	0	1 (2.0)	0	0
Septic embolus	1 (2.0)	0	0	0	1 (2.0)
Skin infection	1 (2.0)	0	1 (2.0)	0	0
Skin papilloma	1 (2.0)	0	1 (2.0)	0	0
Staphylococcal infection	1 (2.0)	0	0	1 (2.0)	0
Streptococcal infection	1 (2.0)	0	1 (2.0)	0	0
Upper respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Viral upper respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Vulvovaginal candidiasis	1 (2.0)	1 (2.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	18 (36.0)	3 (6.0)	12 (24.0)	3 (6.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	17 (34.0)	2 (4.0)	12 (24.0)	3 (6.0)	0
Blood immunoglobulin m decreased	3 (6.0)	3 (6.0)	0	0	0
Blood immunoglobulin a decreased	2 (4.0)	2 (4.0)	0	0	0
Serious neurological adverse reactions					
-Total	17 (34.0)	7 (14.0)	6 (12.0)	4 (8.0)	0
Confusional state	6 (12.0)	3 (6.0)	3 (6.0)	0	0
Delirium	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Encephalopathy	4 (8.0)	1 (2.0)	1 (2.0)	2 (4.0)	0
Seizure	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Agitation	2 (4.0)	0	2 (4.0)	0	0
Dysphagia	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Hallucination	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Irritability	2 (4.0)	2 (4.0)	0	0	0
Tremor	2 (4.0)	2 (4.0)	0	0	0
Asterixis	1 (2.0)	1 (2.0)	0	0	0
Dysarthria	1 (2.0)	1 (2.0)	0	0	0
Listless	1 (2.0)	1 (2.0)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (2.0)	1 (2.0)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.0)	0	0	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	0	0	1 (2.0)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

			All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (75.0)	1 (8.3)	3 (25.0)	4 (33.3)	1 (8.3)
Infections					
-Total	9 (75.0)	1 (8.3)	4 (33.3)	3 (25.0)	1 (8.3)
Influenza	2 (16.7)	0	2 (16.7)	0	0
Urinary tract infection	2 (16.7)	0	2 (16.7)	0	0
Viral upper respiratory tract infection	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Bacterial sepsis	1 (8.3)	0	0	0	1 (8.3)
Corona virus infection	1 (8.3)	0	0	1 (8.3)	0
Gastroenteritis	1 (8.3)	0	1 (8.3)	0	0
Gastroenteritis viral	1 (8.3)	1 (8.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (8.3)	1 (8.3)	0	0	0
Otitis externa	1 (8.3)	0	1 (8.3)	0	0
Parainfluenzae virus infection	1 (8.3)	0	0	1 (8.3)	0
Paronychia	1 (8.3)	1 (8.3)	0	0	0
Respiratory syncytial virus infection	1 (8.3)	0	0	1 (8.3)	0
Subcutaneous abscess	1 (8.3)	0	1 (8.3)	0	0
Serious neurological adverse reactions					
-Total	1 (8.3)	1 (8.3)	0	0	0
Muscular weakness	1 (8.3)	1 (8.3)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (8.3)	0	0	1 (8.3)	0
Tumour lysis syndrome	1 (8.3)	0	0	1 (8.3)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (59.1)	4 (9.1)	13 (29.5)	8 (18.2)	1 (2.3)
Infections					
-Total	24 (54.5)	5 (11.4)	11 (25.0)	7 (15.9)	1 (2.3)
Upper respiratory tract infection	7 (15.9)	3 (6.8)	3 (6.8)	1 (2.3)	0
Ear infection	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Gastroenteritis	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Rhinovirus infection	2 (4.5)	2 (4.5)	0	0	0
Sinusitis	2 (4.5)	0	2 (4.5)	0	0
Urinary tract infection	2 (4.5)	0	0	2 (4.5)	0
Cellulitis of male external genital organ	1 (2.3)	0	0	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (2.3)	0	0	1 (2.3)	0
Cytomegalovirus infection	1 (2.3)	1 (2.3)	0	0	0
Enterovirus infection	1 (2.3)	0	0	1 (2.3)	0
Escherichia urinary tract infection	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis norovirus	1 (2.3)	0	1 (2.3)	0	0
Herpes zoster	1 (2.3)	0	0	1 (2.3)	0
Influenza	1 (2.3)	0	1 (2.3)	0	0
Oral herpes	1 (2.3)	0	1 (2.3)	0	0
Otitis media	1 (2.3)	0	1 (2.3)	0	0
Otitis media acute	1 (2.3)	0	1 (2.3)	0	0
Parainfluenzae virus infection	1 (2.3)	1 (2.3)	0	0	0
Rash pustular	1 (2.3)	0	1 (2.3)	0	0
Rhinitis	1 (2.3)	1 (2.3)	0	0	0
Rotavirus infection	1 (2.3)	0	0	1 (2.3)	0
Sepsis	1 (2.3)	0	0	0	1 (2.3)
Tinea capitis	1 (2.3)	1 (2.3)	0	0	0
Vascular device infection	1 (2.3)	0	0	1 (2.3)	0
Viral infection	1 (2.3)	1 (2.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal mycotic infection	1 (2.3)	0	1 (2.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (18.2)	0	7 (15.9)	1 (2.3)	0
Hypogammaglobulinaemia	8 (18.2)	0	7 (15.9)	1 (2.3)	0
Serious neurological adverse reactions					
-Total	1 (2.3)	1 (2.3)	0	0	0
Muscular weakness	1 (2.3)	1 (2.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (11.1)	0	0	0	1 (11.1)
Infections					
-Total	1 (11.1)	0	0	0	1 (11.1)
Respiratory tract infection	1 (11.1)	0	0	0	1 (11.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (48.0)	3 (12.0)	6 (24.0)	3 (12.0)	0
Infections					
-Total	10 (40.0)	2 (8.0)	5 (20.0)	3 (12.0)	0
Otitis media	3 (12.0)	0	2 (8.0)	1 (4.0)	0
Sinusitis	3 (12.0)	0	3 (12.0)	0	0
Otitis media acute	2 (8.0)	0	2 (8.0)	0	0
Pneumonia	2 (8.0)	0	2 (8.0)	0	0
Upper respiratory tract infection	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Urinary tract infection	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Campylobacter infection	1 (4.0)	0	0	1 (4.0)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (4.0)	0	0	1 (4.0)	0
Clostridium difficile infection	1 (4.0)	0	0	1 (4.0)	0
Gingivitis	1 (4.0)	1 (4.0)	0	0	0
Haemophilus infection	1 (4.0)	0	1 (4.0)	0	0
Meningitis aseptic	1 (4.0)	0	1 (4.0)	0	0
Respiratory tract infection viral	1 (4.0)	0	0	1 (4.0)	0
Skin infection	1 (4.0)	0	1 (4.0)	0	0
Viral infection	1 (4.0)	1 (4.0)	0	0	0
Vulvovaginal candidiasis	1 (4.0)	0	1 (4.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (4.0)	0	1 (4.0)	0	0
Immunodeficiency	1 (4.0)	0	1 (4.0)	0	0
Serious neurological adverse reactions					
-Total	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Disturbance in attention	1 (4.0)	1 (4.0)	0	0	0
Seizure	1 (4.0)	0	0	1 (4.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	0	1 (7.1)	6 (42.9)	7 (50.0)
Cytokine Release Syndrome					
-Total	13 (92.9)	0	10 (71.4)	2 (14.3)	1 (7.1)
Cytokine release syndrome	13 (92.9)	0	10 (71.4)	2 (14.3)	1 (7.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	10 (71.4)	1 (7.1)	0	4 (28.6)	5 (35.7)
Neutrophil count decreased	4 (28.6)	0	0	1 (7.1)	3 (21.4)
White blood cell count decreased	4 (28.6)	1 (7.1)	0	1 (7.1)	2 (14.3)
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0
Thrombocytopenia	2 (14.3)	0	0	0	2 (14.3)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (7.1)	0	0	1 (7.1)	0
Platelet count decreased	1 (7.1)	0	0	0	1 (7.1)
Infections					
-Total	11 (78.6)	1 (7.1)	4 (28.6)	4 (28.6)	2 (14.3)
Influenza	2 (14.3)	0	2 (14.3)	0	0
Urinary tract infection	2 (14.3)	0	2 (14.3)	0	0
Viral upper respiratory tract infection	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Bacterial sepsis	1 (7.1)	0	0	0	1 (7.1)
Catheter site infection	1 (7.1)	0	0	1 (7.1)	0
Clostridium difficile infection	1 (7.1)	0	1 (7.1)	0	0
Corona virus infection	1 (7.1)	0	0	1 (7.1)	0
Cytomegalovirus infection	1 (7.1)	1 (7.1)	0	0	0
Folliculitis	1 (7.1)	0	1 (7.1)	0	0
Fungal skin infection	1 (7.1)	1 (7.1)	0	0	0
Gastroenteritis	1 (7.1)	0	1 (7.1)	0	0
Gastroenteritis viral	1 (7.1)	1 (7.1)	0	0	0
Molluscum contagiosum	1 (7.1)	1 (7.1)	0	0	0
Otitis externa	1 (7.1)	0	1 (7.1)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (7.1)	0	0	1 (7.1)	0
Paronychia	1 (7.1)	1 (7.1)	0	0	0
Pneumonia	1 (7.1)	0	0	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	0	0	1 (7.1)	0
Respiratory tract infection	1 (7.1)	0	0	0	1 (7.1)
Rhinovirus infection	1 (7.1)	1 (7.1)	0	0	0
Staphylococcal infection	1 (7.1)	1 (7.1)	0	0	0
Subcutaneous abscess	1 (7.1)	0	1 (7.1)	0	0
Urinary tract infection enterococcal	1 (7.1)	0	0	1 (7.1)	0
Viral infection	1 (7.1)	0	1 (7.1)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	9 (64.3)	1 (7.1)	7 (50.0)	1 (7.1)	0
Hypogammaglobulinaemia	8 (57.1)	1 (7.1)	6 (42.9)	1 (7.1)	0
Blood immunoglobulin a decreased	1 (7.1)	1 (7.1)	0	0	0
Blood immunoglobulin g decreased	1 (7.1)	0	1 (7.1)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (7.1)	1 (7.1)	0	0	0
Serious neurological adverse reactions					
-Total	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Muscular weakness	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Depressed level of consciousness	1 (7.1)	1 (7.1)	0	0	0
Dysarthria	1 (7.1)	0	1 (7.1)	0	0
Somnolence	1 (7.1)	1 (7.1)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (7.1)	0	0	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (98.0)	0	16 (32.0)	17 (34.0)	16 (32.0)
Cytokine Release Syndrome					
-Total	37 (74.0)	6 (12.0)	15 (30.0)	6 (12.0)	10 (20.0)
Cytokine release syndrome	37 (74.0)	6 (12.0)	15 (30.0)	6 (12.0)	10 (20.0)
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	1 (2.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	17 (34.0)	1 (2.0)	3 (6.0)	6 (12.0)	7 (14.0)
Platelet count decreased	7 (14.0)	1 (2.0)	1 (2.0)	1 (2.0)	4 (8.0)
White blood cell count decreased	7 (14.0)	0	1 (2.0)	5 (10.0)	1 (2.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	4 (8.0)	0	0	2 (4.0)	2 (4.0)
Anaemia	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Neutropenia	3 (6.0)	0	0	1 (2.0)	2 (4.0)
Lymphocyte count decreased	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Thrombocytopenia	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Febrile neutropenia	1 (2.0)	0	0	1 (2.0)	0
Lymphopenia	1 (2.0)	0	0	1 (2.0)	0
Infections					
-Total	35 (70.0)	6 (12.0)	17 (34.0)	10 (20.0)	2 (4.0)
Upper respiratory tract infection	9 (18.0)	4 (8.0)	4 (8.0)	1 (2.0)	0
Clostridium difficile colitis	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Clostridium difficile infection	4 (8.0)	0	3 (6.0)	1 (2.0)	0
Gastroenteritis	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Otitis media	4 (8.0)	0	3 (6.0)	1 (2.0)	0
Rhinovirus infection	4 (8.0)	4 (8.0)	0	0	0
Sinusitis	4 (8.0)	0	4 (8.0)	0	0
Pneumonia	3 (6.0)	0	3 (6.0)	0	0
Urinary tract infection	3 (6.0)	0	1 (2.0)	2 (4.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Influenza	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Otitis media acute	2 (4.0)	0	2 (4.0)	0	0
Skin infection	2 (4.0)	0	2 (4.0)	0	0
Viral infection	2 (4.0)	2 (4.0)	0	0	0
Vulvovaginal candidiasis	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Body tinea	1 (2.0)	1 (2.0)	0	0	0
Campylobacter infection	1 (2.0)	0	0	1 (2.0)	0
Catheter site cellulitis	1 (2.0)	1 (2.0)	0	0	0
Cellulitis of male external genital organ	1 (2.0)	0	0	1 (2.0)	0
Cholecystitis infective	1 (2.0)	0	0	1 (2.0)	0
Cytomegalovirus infection	1 (2.0)	1 (2.0)	0	0	0
Enterococcal infection	1 (2.0)	1 (2.0)	0	0	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0
Escherichia urinary tract infection	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis norovirus	1 (2.0)	0	1 (2.0)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingivitis	1 (2.0)	1 (2.0)	0	0	0
Haemophilus infection	1 (2.0)	0	1 (2.0)	0	0
Herpes simplex	1 (2.0)	1 (2.0)	0	0	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Human herpesvirus 6 infection	1 (2.0)	0	1 (2.0)	0	0
Hypopyon	1 (2.0)	0	1 (2.0)	0	0
Meningitis aseptic	1 (2.0)	0	1 (2.0)	0	0
Oral candidiasis	1 (2.0)	1 (2.0)	0	0	0
Oral herpes	1 (2.0)	0	1 (2.0)	0	0
Orchitis	1 (2.0)	1 (2.0)	0	0	0
Parainfluenzae virus infection	1 (2.0)	1 (2.0)	0	0	0
Pharyngitis	1 (2.0)	0	1 (2.0)	0	0
Rash pustular	1 (2.0)	0	1 (2.0)	0	0
Respiratory tract infection viral	1 (2.0)	0	0	1 (2.0)	0
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Rotavirus infection	1 (2.0)	0	0	1 (2.0)	0
Sepsis	1 (2.0)	0	0	0	1 (2.0)
Septic embolus	1 (2.0)	0	0	0	1 (2.0)
Skin papilloma	1 (2.0)	0	1 (2.0)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (2.0)	0	0	1 (2.0)	0
Streptococcal infection	1 (2.0)	0	1 (2.0)	0	0
Tinea capitis	1 (2.0)	1 (2.0)	0	0	0
Vascular device infection	1 (2.0)	0	0	1 (2.0)	0
Viral upper respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Vulvovaginal mycotic infection	1 (2.0)	0	1 (2.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	24 (48.0)	2 (4.0)	18 (36.0)	4 (8.0)	0
Hypogammaglobulinaemia	24 (48.0)	2 (4.0)	18 (36.0)	4 (8.0)	0
Blood immunoglobulin m decreased	3 (6.0)	3 (6.0)	0	0	0
Blood immunoglobulin a decreased	2 (4.0)	2 (4.0)	0	0	0
Immunodeficiency	1 (2.0)	0	1 (2.0)	0	0
Serious neurological adverse reactions					
-Total	18 (36.0)	7 (14.0)	6 (12.0)	5 (10.0)	0
Confusional state	6 (12.0)	3 (6.0)	3 (6.0)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Encephalopathy	4 (8.0)	1 (2.0)	1 (2.0)	2 (4.0)	0
Seizure	4 (8.0)	0	2 (4.0)	2 (4.0)	0
Agitation	2 (4.0)	0	2 (4.0)	0	0
Dysphagia	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Hallucination	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Irritability	2 (4.0)	2 (4.0)	0	0	0
Tremor	2 (4.0)	2 (4.0)	0	0	0
Asterixis	1 (2.0)	1 (2.0)	0	0	0
Disturbance in attention	1 (2.0)	1 (2.0)	0	0	0
Dysarthria	1 (2.0)	1 (2.0)	0	0	0
Listless	1 (2.0)	1 (2.0)	0	0	0
Mental status changes	1 (2.0)	1 (2.0)	0	0	0
Muscular weakness	1 (2.0)	1 (2.0)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.0)	0	0	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	0	0	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

		All patients N=20			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (90.0)	0	6 (30.0)	7 (35.0)	5 (25.0)
Cytokine Release Syndrome					
-Total	16 (80.0)	0	11 (55.0)	3 (15.0)	2 (10.0)
Cytokine release syndrome	16 (80.0)	0	11 (55.0)	3 (15.0)	2 (10.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (40.0)	1 (5.0)	0	4 (20.0)	3 (15.0)
Neutrophil count decreased	3 (15.0)	0	0	2 (10.0)	1 (5.0)
White blood cell count decreased	3 (15.0)	1 (5.0)	0	2 (10.0)	0
Neutropenia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Platelet count decreased	2 (10.0)	1 (5.0)	0	0	1 (5.0)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	1 (5.0)	0	1 (5.0)	0	0
Febrile neutropenia	1 (5.0)	0	0	1 (5.0)	0
Lymphocyte count decreased	1 (5.0)	0	0	0	1 (5.0)
Lymphopenia	1 (5.0)	0	0	1 (5.0)	0
Infections					
-Total	9 (45.0)	2 (10.0)	5 (25.0)	2 (10.0)	0
Gastroenteritis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Acute sinusitis	1 (5.0)	0	1 (5.0)	0	0
Clostridium difficile colitis	1 (5.0)	0	1 (5.0)	0	0
Folliculitis	1 (5.0)	0	1 (5.0)	0	0
Fungal skin infection	1 (5.0)	1 (5.0)	0	0	0
Herpes simplex	1 (5.0)	1 (5.0)	0	0	0
Oral candidiasis	1 (5.0)	1 (5.0)	0	0	0
Orchitis	1 (5.0)	1 (5.0)	0	0	0
Pharyngitis	1 (5.0)	0	1 (5.0)	0	0
Streptococcal infection	1 (5.0)	0	1 (5.0)	0	0
Upper respiratory tract infection	1 (5.0)	0	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection enterococcal	1 (5.0)	0	0	1 (5.0)	0
Viral infection	1 (5.0)	0	1 (5.0)	0	0
Vulvovaginal candidiasis	1 (5.0)	1 (5.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	9 (45.0)	1 (5.0)	7 (35.0)	1 (5.0)	0
Hypogammaglobulinaemia	9 (45.0)	1 (5.0)	7 (35.0)	1 (5.0)	0
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Serious neurological adverse reactions					
-Total	7 (35.0)	4 (20.0)	2 (10.0)	1 (5.0)	0
Encephalopathy	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Confusional state	1 (5.0)	1 (5.0)	0	0	0
Delirium	1 (5.0)	1 (5.0)	0	0	0
Mental status changes	1 (5.0)	1 (5.0)	0	0	0
Seizure	1 (5.0)	0	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	1 (5.0)	1 (5.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

		All patients N=44			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (93.2)	1 (2.3)	13 (29.5)	11 (25.0)	16 (36.4)
Cytokine Release Syndrome					
-Total	34 (77.3)	6 (13.6)	14 (31.8)	5 (11.4)	9 (20.5)
Cytokine release syndrome	34 (77.3)	6 (13.6)	14 (31.8)	5 (11.4)	9 (20.5)
Haemophagocytic lymphohistiocytosis	1 (2.3)	0	1 (2.3)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	19 (43.2)	1 (2.3)	3 (6.8)	6 (13.6)	9 (20.5)
White blood cell count decreased	8 (18.2)	0	1 (2.3)	4 (9.1)	3 (6.8)
Platelet count decreased	6 (13.6)	0	1 (2.3)	1 (2.3)	4 (9.1)
Neutrophil count decreased	5 (11.4)	0	0	1 (2.3)	4 (9.1)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	4 (9.1)	1 (2.3)	0	1 (2.3)	2 (4.5)
Anaemia	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Febrile neutropenia	2 (4.5)	0	0	2 (4.5)	0
Lymphocyte count decreased	2 (4.5)	0	0	2 (4.5)	0
Neutropenia	1 (2.3)	0	0	0	1 (2.3)
Infections					
-Total	17 (38.6)	3 (6.8)	9 (20.5)	4 (9.1)	1 (2.3)
Clostridium difficile infection	4 (9.1)	0	4 (9.1)	0	0
Clostridium difficile colitis	3 (6.8)	1 (2.3)	1 (2.3)	1 (2.3)	0
Rhinovirus infection	3 (6.8)	3 (6.8)	0	0	0
Pneumonia	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Staphylococcal infection	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Body tinea	1 (2.3)	1 (2.3)	0	0	0
Catheter site cellulitis	1 (2.3)	1 (2.3)	0	0	0
Catheter site infection	1 (2.3)	0	0	1 (2.3)	0
Cytomegalovirus infection	1 (2.3)	1 (2.3)	0	0	0
Enterococcal infection	1 (2.3)	1 (2.3)	0	0	0
Gastroenteritis norovirus	1 (2.3)	0	1 (2.3)	0	0
Human herpesvirus 6 infection	1 (2.3)	0	1 (2.3)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypopyon	1 (2.3)	0	1 (2.3)	0	0
Influenza	1 (2.3)	1 (2.3)	0	0	0
Septic embolus	1 (2.3)	0	0	0	1 (2.3)
Skin infection	1 (2.3)	0	1 (2.3)	0	0
Skin papilloma	1 (2.3)	0	1 (2.3)	0	0
Viral upper respiratory tract infection	1 (2.3)	0	1 (2.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	18 (40.9)	3 (6.8)	12 (27.3)	3 (6.8)	0
Hypogammaglobulinaemia	16 (36.4)	2 (4.5)	11 (25.0)	3 (6.8)	0
Blood immunoglobulin m decreased	3 (6.8)	3 (6.8)	0	0	0
Blood immunoglobulin a decreased	2 (4.5)	2 (4.5)	0	0	0
Blood immunoglobulin g decreased	1 (2.3)	0	1 (2.3)	0	0
Serious neurological adverse reactions					
-Total	12 (27.3)	4 (9.1)	5 (11.4)	3 (6.8)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	5 (11.4)	2 (4.5)	3 (6.8)	0	0
Delirium	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Agitation	2 (4.5)	0	2 (4.5)	0	0
Dysarthria	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Dysphagia	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Hallucination	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Irritability	2 (4.5)	2 (4.5)	0	0	0
Seizure	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Asterixis	1 (2.3)	1 (2.3)	0	0	0
Depressed level of consciousness	1 (2.3)	1 (2.3)	0	0	0
Encephalopathy	1 (2.3)	0	0	1 (2.3)	0
Listless	1 (2.3)	1 (2.3)	0	0	0
Muscular weakness	1 (2.3)	0	1 (2.3)	0	0
Somnolence	1 (2.3)	1 (2.3)	0	0	0
Tremor	1 (2.3)	1 (2.3)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.3)	0	0	1 (2.3)	0
Tumour lysis syndrome	1 (2.3)	0	0	1 (2.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (65.0)	1 (5.0)	7 (35.0)	4 (20.0)	1 (5.0)
Infections					
-Total	11 (55.0)	1 (5.0)	5 (25.0)	4 (20.0)	1 (5.0)
Upper respiratory tract infection	3 (15.0)	0	3 (15.0)	0	0
Influenza	2 (10.0)	0	2 (10.0)	0	0
Bacterial sepsis	1 (5.0)	0	0	0	1 (5.0)
Cholecystitis infective	1 (5.0)	0	0	1 (5.0)	0
Corona virus infection	1 (5.0)	0	0	1 (5.0)	0
Ear infection	1 (5.0)	1 (5.0)	0	0	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (5.0)	0	0	1 (5.0)	0
Rhinovirus infection	1 (5.0)	1 (5.0)	0	0	0
Tinea capitis	1 (5.0)	1 (5.0)	0	0	0
Vascular device infection	1 (5.0)	0	0	1 (5.0)	0
Viral infection	1 (5.0)	1 (5.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (15.0)	0	3 (15.0)	0	0
Hypogammaglobulinaemia	3 (15.0)	0	3 (15.0)	0	0
Serious neurological adverse reactions					
-Total	1 (5.0)	1 (5.0)	0	0	0
Muscular weakness	1 (5.0)	1 (5.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (61.1)	4 (11.1)	9 (25.0)	8 (22.2)	1 (2.8)
Infections					
-Total	22 (61.1)	5 (13.9)	10 (27.8)	6 (16.7)	1 (2.8)
Upper respiratory tract infection	4 (11.1)	3 (8.3)	0	1 (2.8)	0
Urinary tract infection	4 (11.1)	0	2 (5.6)	2 (5.6)	0
Gastroenteritis	3 (8.3)	1 (2.8)	2 (5.6)	0	0
Parainfluenzae virus infection	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Sinusitis	2 (5.6)	0	2 (5.6)	0	0
Viral upper respiratory tract infection	2 (5.6)	1 (2.8)	0	1 (2.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (2.8)	0	0	1 (2.8)	0
Cytomegalovirus infection	1 (2.8)	1 (2.8)	0	0	0
Ear infection	1 (2.8)	0	1 (2.8)	0	0
Enterovirus infection	1 (2.8)	0	0	1 (2.8)	0
Escherichia urinary tract infection	1 (2.8)	0	0	1 (2.8)	0
Gastroenteritis norovirus	1 (2.8)	0	1 (2.8)	0	0
Gastroenteritis viral	1 (2.8)	1 (2.8)	0	0	0
Influenza	1 (2.8)	0	1 (2.8)	0	0
Molluscum contagiosum	1 (2.8)	1 (2.8)	0	0	0
Oral herpes	1 (2.8)	0	1 (2.8)	0	0
Otitis externa	1 (2.8)	0	1 (2.8)	0	0
Otitis media	1 (2.8)	0	1 (2.8)	0	0
Otitis media acute	1 (2.8)	0	1 (2.8)	0	0
Paronychia	1 (2.8)	1 (2.8)	0	0	0
Rash pustular	1 (2.8)	0	1 (2.8)	0	0
Rhinitis	1 (2.8)	1 (2.8)	0	0	0
Rhinovirus infection	1 (2.8)	1 (2.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	1 (2.8)	0	0	1 (2.8)	0
Sepsis	1 (2.8)	0	0	0	1 (2.8)
Subcutaneous abscess	1 (2.8)	0	1 (2.8)	0	0
Vulvovaginal mycotic infection	1 (2.8)	0	1 (2.8)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (13.9)	0	4 (11.1)	1 (2.8)	0
Hypogammaglobulinaemia	5 (13.9)	0	4 (11.1)	1 (2.8)	0
Serious neurological adverse reactions					
-Total	1 (2.8)	1 (2.8)	0	0	0
Muscular weakness	1 (2.8)	1 (2.8)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.8)	0	0	1 (2.8)	0
Tumour lysis syndrome	1 (2.8)	0	0	1 (2.8)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (42.9)	3 (21.4)	2 (14.3)	1 (7.1)	0
Infections					
-Total	5 (35.7)	2 (14.3)	2 (14.3)	1 (7.1)	0
Sinusitis	2 (14.3)	0	2 (14.3)	0	0
Upper respiratory tract infection	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Gingivitis	1 (7.1)	1 (7.1)	0	0	0
Haemophilus infection	1 (7.1)	0	1 (7.1)	0	0
Otitis media	1 (7.1)	0	0	1 (7.1)	0
Otitis media acute	1 (7.1)	0	1 (7.1)	0	0
Pneumonia	1 (7.1)	0	1 (7.1)	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=14 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin infection	1 (7.1)	0	1 (7.1)	0	0
Viral infection	1 (7.1)	1 (7.1)	0	0	0
Serious neurological adverse reactions					
-Total	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Disturbance in attention	1 (7.1)	1 (7.1)	0	0	0
Seizure	1 (7.1)	0	0	1 (7.1)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (35.0)	0	4 (20.0)	2 (10.0)	1 (5.0)
Infections					
-Total	6 (30.0)	0	3 (15.0)	2 (10.0)	1 (5.0)
Otitis media	2 (10.0)	0	2 (10.0)	0	0
Urinary tract infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Campylobacter infection	1 (5.0)	0	0	1 (5.0)	0
Cellulitis of male external genital organ	1 (5.0)	0	0	1 (5.0)	0
Clostridium difficile infection	1 (5.0)	0	0	1 (5.0)	0
Meningitis aseptic	1 (5.0)	0	1 (5.0)	0	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (5.0)	0	1 (5.0)	0	0
Respiratory tract infection	1 (5.0)	0	0	0	1 (5.0)
Respiratory tract infection viral	1 (5.0)	0	0	1 (5.0)	0
Sinusitis	1 (5.0)	0	1 (5.0)	0	0
Vulvovaginal candidiasis	1 (5.0)	0	1 (5.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (5.0)	0	1 (5.0)	0	0
Immunodeficiency	1 (5.0)	0	1 (5.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (95.0)	0	4 (20.0)	10 (50.0)	5 (25.0)
Cytokine Release Syndrome					
-Total	16 (80.0)	0	11 (55.0)	3 (15.0)	2 (10.0)
Cytokine release syndrome	16 (80.0)	0	11 (55.0)	3 (15.0)	2 (10.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (40.0)	1 (5.0)	0	4 (20.0)	3 (15.0)
Neutrophil count decreased	3 (15.0)	0	0	2 (10.0)	1 (5.0)
White blood cell count decreased	3 (15.0)	1 (5.0)	0	2 (10.0)	0
Neutropenia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Platelet count decreased	2 (10.0)	1 (5.0)	0	0	1 (5.0)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	1 (5.0)	0	1 (5.0)	0	0
Febrile neutropenia	1 (5.0)	0	0	1 (5.0)	0
Lymphocyte count decreased	1 (5.0)	0	0	0	1 (5.0)
Lymphopenia	1 (5.0)	0	0	1 (5.0)	0
Infections					
-Total	15 (75.0)	3 (15.0)	6 (30.0)	5 (25.0)	1 (5.0)
Upper respiratory tract infection	5 (25.0)	1 (5.0)	4 (20.0)	0	0
Viral infection	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Gastroenteritis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Influenza	2 (10.0)	0	2 (10.0)	0	0
Sinusitis	2 (10.0)	0	2 (10.0)	0	0
Acute sinusitis	1 (5.0)	0	1 (5.0)	0	0
Bacterial sepsis	1 (5.0)	0	0	0	1 (5.0)
Cholecystitis infective	1 (5.0)	0	0	1 (5.0)	0
Clostridium difficile colitis	1 (5.0)	0	1 (5.0)	0	0
Corona virus infection	1 (5.0)	0	0	1 (5.0)	0
Ear infection	1 (5.0)	1 (5.0)	0	0	0
Folliculitis	1 (5.0)	0	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (5.0)	1 (5.0)	0	0	0
Gingivitis	1 (5.0)	1 (5.0)	0	0	0
Haemophilus infection	1 (5.0)	0	1 (5.0)	0	0
Herpes simplex	1 (5.0)	1 (5.0)	0	0	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0
Oral candidiasis	1 (5.0)	1 (5.0)	0	0	0
Orchitis	1 (5.0)	1 (5.0)	0	0	0
Otitis media	1 (5.0)	0	0	1 (5.0)	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Pharyngitis	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	1 (5.0)	0	0
Respiratory syncytial virus infection	1 (5.0)	0	0	1 (5.0)	0
Rhinovirus infection	1 (5.0)	1 (5.0)	0	0	0
Skin infection	1 (5.0)	0	1 (5.0)	0	0
Streptococcal infection	1 (5.0)	0	1 (5.0)	0	0
Tinea capitis	1 (5.0)	1 (5.0)	0	0	0
Urinary tract infection enterococcal	1 (5.0)	0	0	1 (5.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (5.0)	0	0	1 (5.0)	0
Vulvovaginal candidiasis	1 (5.0)	1 (5.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	12 (60.0)	1 (5.0)	10 (50.0)	1 (5.0)	0
Hypogammaglobulinaemia	12 (60.0)	1 (5.0)	10 (50.0)	1 (5.0)	0
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Serious neurological adverse reactions					
-Total	8 (40.0)	4 (20.0)	2 (10.0)	2 (10.0)	0
Encephalopathy	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Seizure	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Confusional state	1 (5.0)	1 (5.0)	0	0	0
Delirium	1 (5.0)	1 (5.0)	0	0	0
Disturbance in attention	1 (5.0)	1 (5.0)	0	0	0
Mental status changes	1 (5.0)	1 (5.0)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	1 (5.0)	1 (5.0)	0	0	0
Tremor	1 (5.0)	1 (5.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (100)	0	13 (29.5)	13 (29.5)	18 (40.9)
Cytokine Release Syndrome					
-Total	34 (77.3)	6 (13.6)	14 (31.8)	5 (11.4)	9 (20.5)
Cytokine release syndrome	34 (77.3)	6 (13.6)	14 (31.8)	5 (11.4)	9 (20.5)
Haemophagocytic lymphohistiocytosis	1 (2.3)	0	1 (2.3)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	19 (43.2)	1 (2.3)	3 (6.8)	6 (13.6)	9 (20.5)
White blood cell count decreased	8 (18.2)	0	1 (2.3)	4 (9.1)	3 (6.8)
Platelet count decreased	6 (13.6)	0	1 (2.3)	1 (2.3)	4 (9.1)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	5 (11.4)	0	0	1 (2.3)	4 (9.1)
Thrombocytopenia	4 (9.1)	1 (2.3)	0	1 (2.3)	2 (4.5)
Anaemia	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Febrile neutropenia	2 (4.5)	0	0	2 (4.5)	0
Lymphocyte count decreased	2 (4.5)	0	0	2 (4.5)	0
Neutropenia	1 (2.3)	0	0	0	1 (2.3)
Infections					
-Total	31 (70.5)	4 (9.1)	15 (34.1)	9 (20.5)	3 (6.8)
Clostridium difficile infection	5 (11.4)	0	4 (9.1)	1 (2.3)	0
Urinary tract infection	5 (11.4)	0	3 (6.8)	2 (4.5)	0
Rhinovirus infection	4 (9.1)	4 (9.1)	0	0	0
Upper respiratory tract infection	4 (9.1)	3 (6.8)	0	1 (2.3)	0
Clostridium difficile colitis	3 (6.8)	1 (2.3)	1 (2.3)	1 (2.3)	0
Gastroenteritis	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Otitis media	3 (6.8)	0	3 (6.8)	0	0
Pneumonia	3 (6.8)	0	2 (4.5)	1 (2.3)	0
Viral upper respiratory tract infection	3 (6.8)	1 (2.3)	1 (2.3)	1 (2.3)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection	2 (4.5)	2 (4.5)	0	0	0
Influenza	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Parainfluenzae virus infection	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Sinusitis	2 (4.5)	0	2 (4.5)	0	0
Staphylococcal infection	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Body tinea	1 (2.3)	1 (2.3)	0	0	0
Campylobacter infection	1 (2.3)	0	0	1 (2.3)	0
Catheter site cellulitis	1 (2.3)	1 (2.3)	0	0	0
Catheter site infection	1 (2.3)	0	0	1 (2.3)	0
Cellulitis of male external genital organ	1 (2.3)	0	0	1 (2.3)	0
Ear infection	1 (2.3)	0	1 (2.3)	0	0
Enterococcal infection	1 (2.3)	1 (2.3)	0	0	0
Enterovirus infection	1 (2.3)	0	0	1 (2.3)	0
Escherichia urinary tract infection	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis norovirus	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis viral	1 (2.3)	1 (2.3)	0	0	0
Human herpesvirus 6 infection	1 (2.3)	0	1 (2.3)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypopyon	1 (2.3)	0	1 (2.3)	0	0
Meningitis aseptic	1 (2.3)	0	1 (2.3)	0	0
Molluscum contagiosum	1 (2.3)	1 (2.3)	0	0	0
Oral herpes	1 (2.3)	0	1 (2.3)	0	0
Otitis externa	1 (2.3)	0	1 (2.3)	0	0
Otitis media acute	1 (2.3)	0	1 (2.3)	0	0
Paronychia	1 (2.3)	1 (2.3)	0	0	0
Rash pustular	1 (2.3)	0	1 (2.3)	0	0
Respiratory tract infection	1 (2.3)	0	0	0	1 (2.3)
Respiratory tract infection viral	1 (2.3)	0	0	1 (2.3)	0
Rhinitis	1 (2.3)	1 (2.3)	0	0	0
Rotavirus infection	1 (2.3)	0	0	1 (2.3)	0
Sepsis	1 (2.3)	0	0	0	1 (2.3)
Septic embolus	1 (2.3)	0	0	0	1 (2.3)
Skin infection	1 (2.3)	0	1 (2.3)	0	0
Skin papilloma	1 (2.3)	0	1 (2.3)	0	0
Subcutaneous abscess	1 (2.3)	0	1 (2.3)	0	0
Vulvovaginal candidiasis	1 (2.3)	0	1 (2.3)	0	0
Vulvovaginal mycotic infection	1 (2.3)	0	1 (2.3)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	21 (47.7)	2 (4.5)	15 (34.1)	4 (9.1)	0
Hypogammaglobulinaemia	20 (45.5)	2 (4.5)	14 (31.8)	4 (9.1)	0
Blood immunoglobulin m decreased	3 (6.8)	3 (6.8)	0	0	0
Blood immunoglobulin a decreased	2 (4.5)	2 (4.5)	0	0	0
Blood immunoglobulin g decreased	1 (2.3)	0	1 (2.3)	0	0
Immunodeficiency	1 (2.3)	0	1 (2.3)	0	0
Serious neurological adverse reactions					
-Total	13 (29.5)	5 (11.4)	5 (11.4)	3 (6.8)	0
Confusional state	5 (11.4)	2 (4.5)	3 (6.8)	0	0
Delirium	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Agitation	2 (4.5)	0	2 (4.5)	0	0
Dysarthria	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Dysphagia	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Hallucination	2 (4.5)	1 (2.3)	1 (2.3)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	2 (4.5)	2 (4.5)	0	0	0
Muscular weakness	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Seizure	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Asterixis	1 (2.3)	1 (2.3)	0	0	0
Depressed level of consciousness	1 (2.3)	1 (2.3)	0	0	0
Encephalopathy	1 (2.3)	0	0	1 (2.3)	0
Listless	1 (2.3)	1 (2.3)	0	0	0
Somnolence	1 (2.3)	1 (2.3)	0	0	0
Tremor	1 (2.3)	1 (2.3)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (4.5)	0	0	2 (4.5)	0
Tumour lysis syndrome	2 (4.5)	0	0	2 (4.5)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=5			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	1 (20.0)	1 (20.0)	2 (40.0)
Cytokine Release Syndrome					
-Total	4 (80.0)	2 (40.0)	1 (20.0)	0	1 (20.0)
Cytokine release syndrome	4 (80.0)	2 (40.0)	1 (20.0)	0	1 (20.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (40.0)	0	0	1 (20.0)	1 (20.0)
White blood cell count decreased	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Neutrophil count decreased	1 (20.0)	0	0	0	1 (20.0)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (40.0)	0	2 (40.0)	0	0
Hypogammaglobulinaemia	2 (40.0)	0	2 (40.0)	0	0
Serious neurological adverse reactions					
-Total	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Delirium	1 (20.0)	0	1 (20.0)	0	0
Dysarthria	1 (20.0)	0	1 (20.0)	0	0
Dysphagia	1 (20.0)	0	0	1 (20.0)	0
Irritability	1 (20.0)	1 (20.0)	0	0	0
Muscular weakness	1 (20.0)	0	1 (20.0)	0	0
Somnolence	1 (20.0)	1 (20.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=59			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	55 (93.2)	1 (1.7)	18 (30.5)	17 (28.8)	19 (32.2)
Cytokine Release Syndrome					
-Total	46 (78.0)	4 (6.8)	24 (40.7)	8 (13.6)	10 (16.9)
Cytokine release syndrome	46 (78.0)	4 (6.8)	24 (40.7)	8 (13.6)	10 (16.9)
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	25 (42.4)	2 (3.4)	3 (5.1)	9 (15.3)	11 (18.6)
White blood cell count decreased	9 (15.3)	1 (1.7)	1 (1.7)	5 (8.5)	2 (3.4)
Platelet count decreased	8 (13.6)	1 (1.7)	1 (1.7)	1 (1.7)	5 (8.5)
Neutrophil count decreased	7 (11.9)	0	0	3 (5.1)	4 (6.8)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	4 (6.8)	1 (1.7)	0	1 (1.7)	2 (3.4)
Anaemia	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Lymphocyte count decreased	3 (5.1)	0	0	2 (3.4)	1 (1.7)
Neutropenia	3 (5.1)	0	0	1 (1.7)	2 (3.4)
Febrile neutropenia	2 (3.4)	0	0	2 (3.4)	0
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	26 (44.1)	5 (8.5)	14 (23.7)	6 (10.2)	1 (1.7)
Clostridium difficile colitis	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Clostridium difficile infection	4 (6.8)	0	4 (6.8)	0	0
Rhinovirus infection	3 (5.1)	3 (5.1)	0	0	0
Gastroenteritis	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Pneumonia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Staphylococcal infection	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Catheter site cellulitis	1 (1.7)	1 (1.7)	0	0	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=59			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Fungal skin infection	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Herpes simplex	1 (1.7)	1 (1.7)	0	0	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Influenza	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0
Pharyngitis	1 (1.7)	0	1 (1.7)	0	0
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Skin infection	1 (1.7)	0	1 (1.7)	0	0
Skin papilloma	1 (1.7)	0	1 (1.7)	0	0
Streptococcal infection	1 (1.7)	0	1 (1.7)	0	0
Upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=59			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (1.7)	0	1 (1.7)	0	0
Viral upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Vulvovaginal candidiasis	1 (1.7)	1 (1.7)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	25 (42.4)	4 (6.8)	17 (28.8)	4 (6.8)	0
Hypogammaglobulinaemia	23 (39.0)	3 (5.1)	16 (27.1)	4 (6.8)	0
Blood immunoglobulin m decreased	4 (6.8)	4 (6.8)	0	0	0
Blood immunoglobulin a decreased	3 (5.1)	3 (5.1)	0	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	17 (28.8)	8 (13.6)	6 (10.2)	3 (5.1)	0
Confusional state	6 (10.2)	3 (5.1)	3 (5.1)	0	0
Encephalopathy	4 (6.8)	1 (1.7)	1 (1.7)	2 (3.4)	0
Delirium	3 (5.1)	2 (3.4)	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Agitation	2 (3.4)	0	2 (3.4)	0	0
Hallucination	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Tremor	2 (3.4)	2 (3.4)	0	0	0
Asterixis	1 (1.7)	1 (1.7)	0	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Dysarthria	1 (1.7)	1 (1.7)	0	0	0
Dysphagia	1 (1.7)	0	1 (1.7)	0	0
Irritability	1 (1.7)	1 (1.7)	0	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Mental status changes	1 (1.7)	1 (1.7)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	0	0	2 (40.0)	0
Infections					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Gastroenteritis	1 (20.0)	0	1 (20.0)	0	0
Subcutaneous abscess	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0	0	0
Viral upper respiratory tract infection	1 (20.0)	0	0	1 (20.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (20.0)	0	0	1 (20.0)	0
Hypogammaglobulinaemia	1 (20.0)	0	0	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=51			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (64.7)	5 (9.8)	16 (31.4)	10 (19.6)	2 (3.9)
Infections					
-Total	31 (60.8)	5 (9.8)	15 (29.4)	9 (17.6)	2 (3.9)
Upper respiratory tract infection	6 (11.8)	2 (3.9)	3 (5.9)	1 (2.0)	0
Urinary tract infection	4 (7.8)	0	2 (3.9)	2 (3.9)	0
Influenza	3 (5.9)	0	3 (5.9)	0	0
Ear infection	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Gastroenteritis	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Parainfluenzae virus infection	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Rhinovirus infection	2 (3.9)	2 (3.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=51			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	2 (3.9)	0	2 (3.9)	0	0
Bacterial sepsis	1 (2.0)	0	0	0	1 (2.0)
Cellulitis of male external genital organ	1 (2.0)	0	0	1 (2.0)	0
Cholecystitis infective	1 (2.0)	0	0	1 (2.0)	0
Corona virus infection	1 (2.0)	0	0	1 (2.0)	0
Cytomegalovirus infection	1 (2.0)	1 (2.0)	0	0	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0
Escherichia urinary tract infection	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis norovirus	1 (2.0)	0	1 (2.0)	0	0
Gastroenteritis viral	1 (2.0)	1 (2.0)	0	0	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Molluscum contagiosum	1 (2.0)	1 (2.0)	0	0	0
Oral herpes	1 (2.0)	0	1 (2.0)	0	0
Otitis externa	1 (2.0)	0	1 (2.0)	0	0
Otitis media	1 (2.0)	0	1 (2.0)	0	0
Otitis media acute	1 (2.0)	0	1 (2.0)	0	0
Paronychia	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash pustular	1 (2.0)	0	1 (2.0)	0	0
Respiratory syncytial virus infection	1 (2.0)	0	0	1 (2.0)	0
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Rotavirus infection	1 (2.0)	0	0	1 (2.0)	0
Sepsis	1 (2.0)	0	0	0	1 (2.0)
Tinea capitis	1 (2.0)	1 (2.0)	0	0	0
Vascular device infection	1 (2.0)	0	0	1 (2.0)	0
Viral infection	1 (2.0)	1 (2.0)	0	0	0
Viral upper respiratory tract infection	1 (2.0)	1 (2.0)	0	0	0
Vulvovaginal mycotic infection	1 (2.0)	0	1 (2.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	7 (13.7)	0	7 (13.7)	0	0
Hypogammaglobulinaemia	7 (13.7)	0	7 (13.7)	0	0
Serious neurological adverse reactions					
-Total	2 (3.9)	2 (3.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=51			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	2 (3.9)	2 (3.9)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.0)	0	0	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	0	0	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=3			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Infections					
-Total	1 (33.3)	0	0	1 (33.3)	0
Haemophilus infection	1 (33.3)	0	1 (33.3)	0	0
Otitis media	1 (33.3)	0	0	1 (33.3)	0
Otitis media acute	1 (33.3)	0	1 (33.3)	0	0
Pneumonia	1 (33.3)	0	1 (33.3)	0	0
Sinusitis	1 (33.3)	0	1 (33.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (33.3)	0	1 (33.3)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=3 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Immunodeficiency	1 (33.3)	0	1 (33.3)	0	0
Serious neurological adverse reactions					
-Total	1 (33.3)	0	0	1 (33.3)	0
Seizure	1 (33.3)	0	0	1 (33.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=31			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (35.5)	3 (9.7)	5 (16.1)	2 (6.5)	1 (3.2)
Infections					
-Total	10 (32.3)	2 (6.5)	5 (16.1)	2 (6.5)	1 (3.2)
Otitis media	2 (6.5)	0	2 (6.5)	0	0
Sinusitis	2 (6.5)	0	2 (6.5)	0	0
Upper respiratory tract infection	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Urinary tract infection	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Campylobacter infection	1 (3.2)	0	0	1 (3.2)	0
Cellulitis of male external genital organ	1 (3.2)	0	0	1 (3.2)	0
Clostridium difficile infection	1 (3.2)	0	0	1 (3.2)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=31 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gingivitis	1 (3.2)	1 (3.2)	0	0	0
Meningitis aseptic	1 (3.2)	0	1 (3.2)	0	0
Otitis media acute	1 (3.2)	0	1 (3.2)	0	0
Pneumonia	1 (3.2)	0	1 (3.2)	0	0
Respiratory tract infection	1 (3.2)	0	0	0	1 (3.2)
Respiratory tract infection viral	1 (3.2)	0	0	1 (3.2)	0
Skin infection	1 (3.2)	0	1 (3.2)	0	0
Viral infection	1 (3.2)	1 (3.2)	0	0	0
Vulvovaginal candidiasis	1 (3.2)	0	1 (3.2)	0	0
Serious neurological adverse reactions					
-Total	1 (3.2)	1 (3.2)	0	0	0
Disturbance in attention	1 (3.2)	1 (3.2)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	1 (20.0)	2 (40.0)	2 (40.0)
Cytokine Release Syndrome					
-Total	4 (80.0)	2 (40.0)	1 (20.0)	0	1 (20.0)
Cytokine release syndrome	4 (80.0)	2 (40.0)	1 (20.0)	0	1 (20.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (40.0)	0	0	1 (20.0)	1 (20.0)
White blood cell count decreased	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Neutrophil count decreased	1 (20.0)	0	0	0	1 (20.0)
Infections					

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (60.0)	1 (20.0)	0	2 (40.0)	0
Gastroenteritis	1 (20.0)	0	1 (20.0)	0	0
Haemophilus infection	1 (20.0)	0	1 (20.0)	0	0
Otitis media	1 (20.0)	0	0	1 (20.0)	0
Otitis media acute	1 (20.0)	0	1 (20.0)	0	0
Pneumonia	1 (20.0)	0	1 (20.0)	0	0
Sinusitis	1 (20.0)	0	1 (20.0)	0	0
Subcutaneous abscess	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0	0	0
Viral upper respiratory tract infection	1 (20.0)	0	0	1 (20.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (60.0)	0	2 (40.0)	1 (20.0)	0
Hypogammaglobulinaemia	3 (60.0)	0	2 (40.0)	1 (20.0)	0
Immunodeficiency	1 (20.0)	0	1 (20.0)	0	0
Serious neurological adverse reactions					

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (60.0)	0	1 (20.0)	2 (40.0)	0
Delirium	1 (20.0)	0	1 (20.0)	0	0
Dysarthria	1 (20.0)	0	1 (20.0)	0	0
Dysphagia	1 (20.0)	0	0	1 (20.0)	0
Irritability	1 (20.0)	1 (20.0)	0	0	0
Muscular weakness	1 (20.0)	0	1 (20.0)	0	0
Seizure	1 (20.0)	0	0	1 (20.0)	0
Somnolence	1 (20.0)	1 (20.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=59			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (98.3)	0	16 (27.1)	21 (35.6)	21 (35.6)
Cytokine Release Syndrome					
-Total	46 (78.0)	4 (6.8)	24 (40.7)	8 (13.6)	10 (16.9)
Cytokine release syndrome	46 (78.0)	4 (6.8)	24 (40.7)	8 (13.6)	10 (16.9)
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	25 (42.4)	2 (3.4)	3 (5.1)	9 (15.3)	11 (18.6)
White blood cell count decreased	9 (15.3)	1 (1.7)	1 (1.7)	5 (8.5)	2 (3.4)
Platelet count decreased	8 (13.6)	1 (1.7)	1 (1.7)	1 (1.7)	5 (8.5)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	7 (11.9)	0	0	3 (5.1)	4 (6.8)
Thrombocytopenia	4 (6.8)	1 (1.7)	0	1 (1.7)	2 (3.4)
Anaemia	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Lymphocyte count decreased	3 (5.1)	0	0	2 (3.4)	1 (1.7)
Neutropenia	3 (5.1)	0	0	1 (1.7)	2 (3.4)
Febrile neutropenia	2 (3.4)	0	0	2 (3.4)	0
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	43 (72.9)	6 (10.2)	21 (35.6)	12 (20.3)	4 (6.8)
Upper respiratory tract infection	8 (13.6)	3 (5.1)	4 (6.8)	1 (1.7)	0
Clostridium difficile infection	5 (8.5)	0	4 (6.8)	1 (1.7)	0
Rhinovirus infection	5 (8.5)	5 (8.5)	0	0	0
Urinary tract infection	5 (8.5)	0	3 (5.1)	2 (3.4)	0
Clostridium difficile colitis	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Gastroenteritis	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Influenza	4 (6.8)	1 (1.7)	3 (5.1)	0	0
Otitis media	3 (5.1)	0	3 (5.1)	0	0
Pneumonia	3 (5.1)	0	2 (3.4)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	3 (5.1)	0	3 (5.1)	0	0
Viral infection	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Cytomegalovirus infection	2 (3.4)	2 (3.4)	0	0	0
Ear infection	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Parainfluenzae virus infection	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Skin infection	2 (3.4)	0	2 (3.4)	0	0
Staphylococcal infection	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Viral upper respiratory tract infection	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Vulvovaginal candidiasis	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Catheter site cellulitis	1 (1.7)	1 (1.7)	0	0	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (1.7)	0	0	1 (1.7)	0
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Escherichia urinary tract infection	1 (1.7)	0	0	1 (1.7)	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Fungal skin infection	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis viral	1 (1.7)	1 (1.7)	0	0	0
Gingivitis	1 (1.7)	1 (1.7)	0	0	0
Herpes simplex	1 (1.7)	1 (1.7)	0	0	0
Herpes zoster	1 (1.7)	0	0	1 (1.7)	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Meningitis aseptic	1 (1.7)	0	1 (1.7)	0	0
Molluscum contagiosum	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Oral herpes	1 (1.7)	0	1 (1.7)	0	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (1.7)	0	1 (1.7)	0	0
Otitis media acute	1 (1.7)	0	1 (1.7)	0	0
Paronychia	1 (1.7)	1 (1.7)	0	0	0
Pharyngitis	1 (1.7)	0	1 (1.7)	0	0
Rash pustular	1 (1.7)	0	1 (1.7)	0	0
Respiratory syncytial virus infection	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Rhinitis	1 (1.7)	1 (1.7)	0	0	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Skin papilloma	1 (1.7)	0	1 (1.7)	0	0
Streptococcal infection	1 (1.7)	0	1 (1.7)	0	0
Tinea capitis	1 (1.7)	1 (1.7)	0	0	0
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal mycotic infection	1 (1.7)	0	1 (1.7)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	30 (50.8)	3 (5.1)	23 (39.0)	4 (6.8)	0
Hypogammaglobulinaemia	29 (49.2)	3 (5.1)	22 (37.3)	4 (6.8)	0
Blood immunoglobulin m decreased	4 (6.8)	4 (6.8)	0	0	0
Blood immunoglobulin a decreased	3 (5.1)	3 (5.1)	0	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	18 (30.5)	9 (15.3)	6 (10.2)	3 (5.1)	0
Confusional state	6 (10.2)	3 (5.1)	3 (5.1)	0	0
Encephalopathy	4 (6.8)	1 (1.7)	1 (1.7)	2 (3.4)	0
Delirium	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Seizure	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Agitation	2 (3.4)	0	2 (3.4)	0	0
Hallucination	2 (3.4)	1 (1.7)	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	2 (3.4)	2 (3.4)	0	0	0
Tremor	2 (3.4)	2 (3.4)	0	0	0
Asterixis	1 (1.7)	1 (1.7)	0	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0
Dysarthria	1 (1.7)	1 (1.7)	0	0	0
Dysphagia	1 (1.7)	0	1 (1.7)	0	0
Irritability	1 (1.7)	1 (1.7)	0	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Mental status changes	1 (1.7)	1 (1.7)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (3.4)	0	0	2 (3.4)	0
Tumour lysis syndrome	2 (3.4)	0	0	2 (3.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	1 (25.0)	2 (50.0)	0	1 (25.0)
Cytokine Release Syndrome					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Cytokine release syndrome	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (50.0)	1 (25.0)	0	0	1 (25.0)
Lymphocyte count decreased	1 (25.0)	0	0	0	1 (25.0)
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
White blood cell count decreased	1 (25.0)	1 (25.0)	0	0	0
Infections					

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Fungal skin infection	1 (25.0)	1 (25.0)	0	0	0
Viral infection	1 (25.0)	0	1 (25.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (25.0)	0	1 (25.0)	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)	0	0
Serious neurological adverse reactions					
-Total	1 (25.0)	1 (25.0)	0	0	0
Tremor	1 (25.0)	1 (25.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	55 (91.7)	0	17 (28.3)	18 (30.0)	20 (33.3)
Cytokine Release Syndrome					
-Total	47 (78.3)	5 (8.3)	23 (38.3)	8 (13.3)	11 (18.3)
Cytokine release syndrome	47 (78.3)	5 (8.3)	23 (38.3)	8 (13.3)	11 (18.3)
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	25 (41.7)	1 (1.7)	3 (5.0)	10 (16.7)	11 (18.3)
White blood cell count decreased	10 (16.7)	0	1 (1.7)	6 (10.0)	3 (5.0)
Neutrophil count decreased	8 (13.3)	0	0	3 (5.0)	5 (8.3)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (13.3)	1 (1.7)	1 (1.7)	1 (1.7)	5 (8.3)
Thrombocytopenia	4 (6.7)	1 (1.7)	0	1 (1.7)	2 (3.3)
Anaemia	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Febrile neutropenia	3 (5.0)	0	0	3 (5.0)	0
Lymphocyte count decreased	2 (3.3)	0	0	2 (3.3)	0
Neutropenia	2 (3.3)	0	0	1 (1.7)	1 (1.7)
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	24 (40.0)	4 (6.7)	13 (21.7)	6 (10.0)	1 (1.7)
Clostridium difficile colitis	4 (6.7)	1 (1.7)	2 (3.3)	1 (1.7)	0
Clostridium difficile infection	4 (6.7)	0	4 (6.7)	0	0
Rhinovirus infection	3 (5.0)	3 (5.0)	0	0	0
Gastroenteritis	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Pneumonia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Staphylococcal infection	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Catheter site cellulitis	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Herpes simplex	1 (1.7)	1 (1.7)	0	0	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Influenza	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0
Pharyngitis	1 (1.7)	0	1 (1.7)	0	0
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Skin infection	1 (1.7)	0	1 (1.7)	0	0
Skin papilloma	1 (1.7)	0	1 (1.7)	0	0
Streptococcal infection	1 (1.7)	0	1 (1.7)	0	0
Upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Viral upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Vulvovaginal candidiasis	1 (1.7)	1 (1.7)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	26 (43.3)	4 (6.7)	18 (30.0)	4 (6.7)	0
Hypogammaglobulinaemia	24 (40.0)	3 (5.0)	17 (28.3)	4 (6.7)	0
Blood immunoglobulin m decreased	3 (5.0)	3 (5.0)	0	0	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	18 (30.0)	7 (11.7)	7 (11.7)	4 (6.7)	0
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Delirium	4 (6.7)	2 (3.3)	2 (3.3)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Seizure	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Agitation	2 (3.3)	0	2 (3.3)	0	0
Dysarthria	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Dysphagia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Hallucination	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Irritability	2 (3.3)	2 (3.3)	0	0	0
Asterixis	1 (1.7)	1 (1.7)	0	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Mental status changes	1 (1.7)	1 (1.7)	0	0	0
Muscular weakness	1 (1.7)	0	1 (1.7)	0	0
Somnolence	1 (1.7)	1 (1.7)	0	0	0
Tremor	1 (1.7)	1 (1.7)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

			All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Infections					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Corona virus infection	1 (25.0)	0	0	1 (25.0)	0
Rash pustular	1 (25.0)	0	1 (25.0)	0	0
Respiratory syncytial virus infection	1 (25.0)	0	0	1 (25.0)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (63.5)	5 (9.6)	15 (28.8)	11 (21.2)	2 (3.8)
Infections					
-Total	31 (59.6)	6 (11.5)	14 (26.9)	9 (17.3)	2 (3.8)
Upper respiratory tract infection	7 (13.5)	3 (5.8)	3 (5.8)	1 (1.9)	0
Urinary tract infection	4 (7.7)	0	2 (3.8)	2 (3.8)	0
Gastroenteritis	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Influenza	3 (5.8)	0	3 (5.8)	0	0
Ear infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Parainfluenzae virus infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Rhinovirus infection	2 (3.8)	2 (3.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	2 (3.8)	0	2 (3.8)	0	0
Viral upper respiratory tract infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Bacterial sepsis	1 (1.9)	0	0	0	1 (1.9)
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Cytomegalovirus infection	1 (1.9)	1 (1.9)	0	0	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0
Herpes zoster	1 (1.9)	0	0	1 (1.9)	0
Molluscum contagiosum	1 (1.9)	1 (1.9)	0	0	0
Oral herpes	1 (1.9)	0	1 (1.9)	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Otitis media	1 (1.9)	0	1 (1.9)	0	0
Otitis media acute	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	1 (1.9)	1 (1.9)	0	0	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Tinea capitis	1 (1.9)	1 (1.9)	0	0	0
Vascular device infection	1 (1.9)	0	0	1 (1.9)	0
Viral infection	1 (1.9)	1 (1.9)	0	0	0
Vulvovaginal mycotic infection	1 (1.9)	0	1 (1.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (15.4)	0	7 (13.5)	1 (1.9)	0
Hypogammaglobulinaemia	8 (15.4)	0	7 (13.5)	1 (1.9)	0
Serious neurological adverse reactions					
-Total	2 (3.8)	2 (3.8)	0	0	0
Muscular weakness	2 (3.8)	2 (3.8)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0

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Table 199p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (41.9)	3 (9.7)	6 (19.4)	3 (9.7)	1 (3.2)
Infections					
-Total	11 (35.5)	2 (6.5)	5 (16.1)	3 (9.7)	1 (3.2)
Otitis media	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Sinusitis	3 (9.7)	0	3 (9.7)	0	0
Otitis media acute	2 (6.5)	0	2 (6.5)	0	0
Pneumonia	2 (6.5)	0	2 (6.5)	0	0
Upper respiratory tract infection	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Urinary tract infection	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Campylobacter infection	1 (3.2)	0	0	1 (3.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (3.2)	0	0	1 (3.2)	0
Clostridium difficile infection	1 (3.2)	0	0	1 (3.2)	0
Gingivitis	1 (3.2)	1 (3.2)	0	0	0
Haemophilus infection	1 (3.2)	0	1 (3.2)	0	0
Meningitis aseptic	1 (3.2)	0	1 (3.2)	0	0
Respiratory tract infection	1 (3.2)	0	0	0	1 (3.2)
Respiratory tract infection viral	1 (3.2)	0	0	1 (3.2)	0
Skin infection	1 (3.2)	0	1 (3.2)	0	0
Viral infection	1 (3.2)	1 (3.2)	0	0	0
Vulvovaginal candidiasis	1 (3.2)	0	1 (3.2)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.2)	0	1 (3.2)	0	0
Immunodeficiency	1 (3.2)	0	1 (3.2)	0	0
Serious neurological adverse reactions					
-Total	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Disturbance in attention	1 (3.2)	1 (3.2)	0	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (3.2)	0	0	1 (3.2)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	2 (50.0)	1 (25.0)	1 (25.0)
Cytokine Release Syndrome					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Cytokine release syndrome	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (50.0)	1 (25.0)	0	0	1 (25.0)
Lymphocyte count decreased	1 (25.0)	0	0	0	1 (25.0)
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
White blood cell count decreased	1 (25.0)	1 (25.0)	0	0	0
Infections					

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Corona virus infection	1 (25.0)	0	0	1 (25.0)	0
Fungal skin infection	1 (25.0)	1 (25.0)	0	0	0
Rash pustular	1 (25.0)	0	1 (25.0)	0	0
Respiratory syncytial virus infection	1 (25.0)	0	0	1 (25.0)	0
Viral infection	1 (25.0)	0	1 (25.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (25.0)	0	1 (25.0)	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)	0	0
Serious neurological adverse reactions					
-Total	1 (25.0)	1 (25.0)	0	0	0
Tremor	1 (25.0)	1 (25.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 199p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

			All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (98.3)	0	15 (25.0)	22 (36.7)	22 (36.7)
Cytokine Release Syndrome					
-Total	47 (78.3)	5 (8.3)	23 (38.3)	8 (13.3)	11 (18.3)
Cytokine release syndrome	47 (78.3)	5 (8.3)	23 (38.3)	8 (13.3)	11 (18.3)
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	25 (41.7)	1 (1.7)	3 (5.0)	10 (16.7)	11 (18.3)
White blood cell count decreased	10 (16.7)	0	1 (1.7)	6 (10.0)	3 (5.0)
Neutrophil count decreased	8 (13.3)	0	0	3 (5.0)	5 (8.3)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (13.3)	1 (1.7)	1 (1.7)	1 (1.7)	5 (8.3)
Thrombocytopenia	4 (6.7)	1 (1.7)	0	1 (1.7)	2 (3.3)
Anaemia	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Febrile neutropenia	3 (5.0)	0	0	3 (5.0)	0
Lymphocyte count decreased	2 (3.3)	0	0	2 (3.3)	0
Neutropenia	2 (3.3)	0	0	1 (1.7)	1 (1.7)
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	43 (71.7)	6 (10.0)	20 (33.3)	13 (21.7)	4 (6.7)
Upper respiratory tract infection	9 (15.0)	4 (6.7)	4 (6.7)	1 (1.7)	0
Clostridium difficile infection	5 (8.3)	0	4 (6.7)	1 (1.7)	0
Gastroenteritis	5 (8.3)	1 (1.7)	3 (5.0)	1 (1.7)	0
Rhinovirus infection	5 (8.3)	5 (8.3)	0	0	0
Urinary tract infection	5 (8.3)	0	3 (5.0)	2 (3.3)	0
Clostridium difficile colitis	4 (6.7)	1 (1.7)	2 (3.3)	1 (1.7)	0
Influenza	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Otitis media	4 (6.7)	0	3 (5.0)	1 (1.7)	0
Pneumonia	4 (6.7)	0	3 (5.0)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	4 (6.7)	0	4 (6.7)	0	0
Viral upper respiratory tract infection	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Cytomegalovirus infection	2 (3.3)	2 (3.3)	0	0	0
Ear infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Otitis media acute	2 (3.3)	0	2 (3.3)	0	0
Parainfluenzae virus infection	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Skin infection	2 (3.3)	0	2 (3.3)	0	0
Staphylococcal infection	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Viral infection	2 (3.3)	2 (3.3)	0	0	0
Vulvovaginal candidiasis	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Catheter site cellulitis	1 (1.7)	1 (1.7)	0	0	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Escherichia urinary tract infection	1 (1.7)	0	0	1 (1.7)	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis viral	1 (1.7)	1 (1.7)	0	0	0
Gingivitis	1 (1.7)	1 (1.7)	0	0	0
Haemophilus infection	1 (1.7)	0	1 (1.7)	0	0
Herpes simplex	1 (1.7)	1 (1.7)	0	0	0
Herpes zoster	1 (1.7)	0	0	1 (1.7)	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Meningitis aseptic	1 (1.7)	0	1 (1.7)	0	0
Molluscum contagiosum	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Oral herpes	1 (1.7)	0	1 (1.7)	0	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (1.7)	0	1 (1.7)	0	0
Paronychia	1 (1.7)	1 (1.7)	0	0	0
Pharyngitis	1 (1.7)	0	1 (1.7)	0	0
Respiratory tract infection	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Rhinitis	1 (1.7)	1 (1.7)	0	0	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Skin papilloma	1 (1.7)	0	1 (1.7)	0	0
Streptococcal infection	1 (1.7)	0	1 (1.7)	0	0
Subcutaneous abscess	1 (1.7)	0	1 (1.7)	0	0
Tinea capitis	1 (1.7)	1 (1.7)	0	0	0
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Vulvovaginal mycotic infection	1 (1.7)	0	1 (1.7)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (53.3)	3 (5.0)	24 (40.0)	5 (8.3)	0
Hypogammaglobulinaemia	31 (51.7)	3 (5.0)	23 (38.3)	5 (8.3)	0
Blood immunoglobulin m decreased	3 (5.0)	3 (5.0)	0	0	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Immunodeficiency	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	20 (33.3)	8 (13.3)	7 (11.7)	5 (8.3)	0
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Delirium	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Encephalopathy	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Seizure	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Muscular weakness	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Agitation	2 (3.3)	0	2 (3.3)	0	0
Dysarthria	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Dysphagia	2 (3.3)	0	1 (1.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Irritability	2 (3.3)	2 (3.3)	0	0	0
Asterixis	1 (1.7)	1 (1.7)	0	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Mental status changes	1 (1.7)	1 (1.7)	0	0	0
Somnolence	1 (1.7)	1 (1.7)	0	0	0
Tremor	1 (1.7)	1 (1.7)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (3.3)	0	0	2 (3.3)	0
Tumour lysis syndrome	2 (3.3)	0	0	2 (3.3)	0

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Table 199q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (96.9)	0	9 (28.1)	10 (31.3)	12 (37.5)
Cytokine Release Syndrome					
-Total	25 (78.1)	3 (9.4)	15 (46.9)	2 (6.3)	5 (15.6)
Cytokine release syndrome	25 (78.1)	3 (9.4)	15 (46.9)	2 (6.3)	5 (15.6)
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	1 (3.1)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	15 (46.9)	0	1 (3.1)	6 (18.8)	8 (25.0)
White blood cell count decreased	8 (25.0)	0	1 (3.1)	5 (15.6)	2 (6.3)
Neutrophil count decreased	6 (18.8)	0	0	3 (9.4)	3 (9.4)
Platelet count decreased	5 (15.6)	0	0	1 (3.1)	4 (12.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Febrile neutropenia	1 (3.1)	0	0	1 (3.1)	0
Neutropenia	1 (3.1)	0	0	0	1 (3.1)
Thrombocytopenia	1 (3.1)	0	0	0	1 (3.1)
Infections					
-Total	14 (43.8)	3 (9.4)	6 (18.8)	4 (12.5)	1 (3.1)
Clostridium difficile infection	4 (12.5)	0	4 (12.5)	0	0
Rhinovirus infection	2 (6.3)	2 (6.3)	0	0	0
Catheter site cellulitis	1 (3.1)	1 (3.1)	0	0	0
Catheter site infection	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Cytomegalovirus infection	1 (3.1)	1 (3.1)	0	0	0
Enterococcal infection	1 (3.1)	1 (3.1)	0	0	0
Folliculitis	1 (3.1)	0	1 (3.1)	0	0
Fungal skin infection	1 (3.1)	1 (3.1)	0	0	0
Gastroenteritis	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Influenza	1 (3.1)	1 (3.1)	0	0	0
Oral candidiasis	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Orchitis	1 (3.1)	1 (3.1)	0	0	0
Septic embolus	1 (3.1)	0	0	0	1 (3.1)
Skin infection	1 (3.1)	0	1 (3.1)	0	0
Skin papilloma	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Upper respiratory tract infection	1 (3.1)	0	1 (3.1)	0	0
Urinary tract infection enterococcal	1 (3.1)	0	0	1 (3.1)	0
Vulvovaginal candidiasis	1 (3.1)	1 (3.1)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	16 (50.0)	2 (6.3)	11 (34.4)	3 (9.4)	0
Hypogammaglobulinaemia	15 (46.9)	1 (3.1)	11 (34.4)	3 (9.4)	0
Blood immunoglobulin a decreased	2 (6.3)	2 (6.3)	0	0	0
Blood immunoglobulin m decreased	2 (6.3)	2 (6.3)	0	0	0
Serious neurological adverse reactions					

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (25.0)	4 (12.5)	2 (6.3)	2 (6.3)	0
Confusional state	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Delirium	1 (3.1)	1 (3.1)	0	0	0
Dysarthria	1 (3.1)	0	1 (3.1)	0	0
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Hallucination	1 (3.1)	1 (3.1)	0	0	0
Mental status changes	1 (3.1)	1 (3.1)	0	0	0
Muscular weakness	1 (3.1)	0	1 (3.1)	0	0
Seizure	1 (3.1)	0	0	1 (3.1)	0
Somnolence	1 (3.1)	1 (3.1)	0	0	0
Tremor	1 (3.1)	1 (3.1)	0	0	0

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Table 199q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (87.5)	1 (3.1)	10 (31.3)	8 (25.0)	9 (28.1)
Cytokine Release Syndrome					
-Total	25 (78.1)	3 (9.4)	10 (31.3)	6 (18.8)	6 (18.8)
Cytokine release syndrome	25 (78.1)	3 (9.4)	10 (31.3)	6 (18.8)	6 (18.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	12 (37.5)	2 (6.3)	2 (6.3)	4 (12.5)	4 (12.5)
Anaemia	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Platelet count decreased	3 (9.4)	1 (3.1)	1 (3.1)	0	1 (3.1)
Thrombocytopenia	3 (9.4)	1 (3.1)	0	1 (3.1)	1 (3.1)
White blood cell count decreased	3 (9.4)	1 (3.1)	0	1 (3.1)	1 (3.1)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	2 (6.3)	0	0	2 (6.3)	0
Neutropenia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Neutrophil count decreased	2 (6.3)	0	0	0	2 (6.3)
Lymphocyte count decreased	1 (3.1)	0	0	1 (3.1)	0
Lymphopenia	1 (3.1)	0	0	1 (3.1)	0
Infections					
-Total	12 (37.5)	2 (6.3)	8 (25.0)	2 (6.3)	0
Clostridium difficile colitis	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Pneumonia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Acute sinusitis	1 (3.1)	0	1 (3.1)	0	0
Body tinea	1 (3.1)	1 (3.1)	0	0	0
Gastroenteritis	1 (3.1)	0	0	1 (3.1)	0
Herpes simplex	1 (3.1)	1 (3.1)	0	0	0
Human herpesvirus 6 infection	1 (3.1)	0	1 (3.1)	0	0
Hypopyon	1 (3.1)	0	1 (3.1)	0	0
Pharyngitis	1 (3.1)	0	1 (3.1)	0	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Staphylococcal infection	1 (3.1)	1 (3.1)	0	0	0
Streptococcal infection	1 (3.1)	0	1 (3.1)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (3.1)	0	1 (3.1)	0	0
Viral upper respiratory tract infection	1 (3.1)	0	1 (3.1)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	11 (34.4)	2 (6.3)	8 (25.0)	1 (3.1)	0
Hypogammaglobulinaemia	10 (31.3)	2 (6.3)	7 (21.9)	1 (3.1)	0
Blood immunoglobulin m decreased	2 (6.3)	2 (6.3)	0	0	0
Blood immunoglobulin a decreased	1 (3.1)	1 (3.1)	0	0	0
Blood immunoglobulin g decreased	1 (3.1)	0	1 (3.1)	0	0
Serious neurological adverse reactions					
-Total	11 (34.4)	4 (12.5)	5 (15.6)	2 (6.3)	0
Confusional state	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Delirium	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Encephalopathy	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Agitation	2 (6.3)	0	2 (6.3)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Irritability	2 (6.3)	2 (6.3)	0	0	0
Seizure	2 (6.3)	0	2 (6.3)	0	0
Asterixis	1 (3.1)	1 (3.1)	0	0	0
Depressed level of consciousness	1 (3.1)	1 (3.1)	0	0	0
Dysarthria	1 (3.1)	1 (3.1)	0	0	0
Hallucination	1 (3.1)	0	1 (3.1)	0	0
Listless	1 (3.1)	1 (3.1)	0	0	0
Tremor	1 (3.1)	1 (3.1)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.1)	0	0	1 (3.1)	0
Tumour lysis syndrome	1 (3.1)	0	0	1 (3.1)	0

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Table 199q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=29			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (69.0)	3 (10.3)	11 (37.9)	4 (13.8)	2 (6.9)
Infections					
-Total	19 (65.5)	3 (10.3)	10 (34.5)	4 (13.8)	2 (6.9)
Upper respiratory tract infection	4 (13.8)	1 (3.4)	3 (10.3)	0	0
Ear infection	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Gastroenteritis	2 (6.9)	0	2 (6.9)	0	0
Influenza	2 (6.9)	0	2 (6.9)	0	0
Rhinovirus infection	2 (6.9)	2 (6.9)	0	0	0
Sinusitis	2 (6.9)	0	2 (6.9)	0	0
Urinary tract infection	2 (6.9)	0	1 (3.4)	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Bacterial sepsis	1 (3.4)	0	0	0	1 (3.4)
Cytomegalovirus infection	1 (3.4)	1 (3.4)	0	0	0
Enterovirus infection	1 (3.4)	0	0	1 (3.4)	0
Escherichia urinary tract infection	1 (3.4)	0	0	1 (3.4)	0
Gastroenteritis norovirus	1 (3.4)	0	1 (3.4)	0	0
Gastroenteritis viral	1 (3.4)	1 (3.4)	0	0	0
Molluscum contagiosum	1 (3.4)	1 (3.4)	0	0	0
Oral herpes	1 (3.4)	0	1 (3.4)	0	0
Otitis media acute	1 (3.4)	0	1 (3.4)	0	0
Parainfluenzae virus infection	1 (3.4)	0	0	1 (3.4)	0
Rhinitis	1 (3.4)	1 (3.4)	0	0	0
Rotavirus infection	1 (3.4)	0	0	1 (3.4)	0
Sepsis	1 (3.4)	0	0	0	1 (3.4)
Subcutaneous abscess	1 (3.4)	0	1 (3.4)	0	0
Tinea capitis	1 (3.4)	1 (3.4)	0	0	0
Viral infection	1 (3.4)	1 (3.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (13.8)	0	4 (13.8)	0	0
Hypogammaglobulinaemia	4 (13.8)	0	4 (13.8)	0	0
Serious neurological adverse reactions					
-Total	2 (6.9)	2 (6.9)	0	0	0
Muscular weakness	2 (6.9)	2 (6.9)	0	0	0

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Table 199q
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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (55.6)	2 (7.4)	5 (18.5)	8 (29.6)	0
Infections					
-Total	14 (51.9)	3 (11.1)	5 (18.5)	6 (22.2)	0
Upper respiratory tract infection	3 (11.1)	2 (7.4)	0	1 (3.7)	0
Urinary tract infection	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Cellulitis of male external genital organ	1 (3.7)	0	0	1 (3.7)	0
Cholecystitis infective	1 (3.7)	0	0	1 (3.7)	0
Corona virus infection	1 (3.7)	0	0	1 (3.7)	0
Gastroenteritis	1 (3.7)	1 (3.7)	0	0	0
Herpes zoster	1 (3.7)	0	0	1 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (3.7)	0	1 (3.7)	0	0
Otitis externa	1 (3.7)	0	1 (3.7)	0	0
Otitis media	1 (3.7)	0	1 (3.7)	0	0
Parainfluenzae virus infection	1 (3.7)	1 (3.7)	0	0	0
Paronychia	1 (3.7)	1 (3.7)	0	0	0
Rash pustular	1 (3.7)	0	1 (3.7)	0	0
Respiratory syncytial virus infection	1 (3.7)	0	0	1 (3.7)	0
Vascular device infection	1 (3.7)	0	0	1 (3.7)	0
Vulvovaginal mycotic infection	1 (3.7)	0	1 (3.7)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Hypogammaglobulinaemia	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Tumour Lysis Syndrome					
-Total	1 (3.7)	0	0	1 (3.7)	0
Tumour lysis syndrome	1 (3.7)	0	0	1 (3.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=18			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (38.9)	1 (5.6)	4 (22.2)	1 (5.6)	1 (5.6)
Infections					
-Total	5 (27.8)	0	3 (16.7)	1 (5.6)	1 (5.6)
Campylobacter infection	1 (5.6)	0	0	1 (5.6)	0
Clostridium difficile infection	1 (5.6)	0	0	1 (5.6)	0
Otitis media acute	1 (5.6)	0	1 (5.6)	0	0
Pneumonia	1 (5.6)	0	1 (5.6)	0	0
Respiratory tract infection	1 (5.6)	0	0	0	1 (5.6)
Respiratory tract infection viral	1 (5.6)	0	0	1 (5.6)	0
Sinusitis	1 (5.6)	0	1 (5.6)	0	0
Skin infection	1 (5.6)	0	1 (5.6)	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (5.6)	0	1 (5.6)	0	0
Vulvovaginal candidiasis	1 (5.6)	0	1 (5.6)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (5.6)	0	1 (5.6)	0	0
Immunodeficiency	1 (5.6)	0	1 (5.6)	0	0
Serious neurological adverse reactions					
-Total	1 (5.6)	1 (5.6)	0	0	0
Disturbance in attention	1 (5.6)	1 (5.6)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (37.5)	2 (12.5)	2 (12.5)	2 (12.5)	0
Infections					
-Total	6 (37.5)	2 (12.5)	2 (12.5)	2 (12.5)	0
Otitis media	3 (18.8)	0	2 (12.5)	1 (6.3)	0
Sinusitis	2 (12.5)	0	2 (12.5)	0	0
Upper respiratory tract infection	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Cellulitis of male external genital organ	1 (6.3)	0	0	1 (6.3)	0
Gingivitis	1 (6.3)	1 (6.3)	0	0	0
Haemophilus infection	1 (6.3)	0	1 (6.3)	0	0
Meningitis aseptic	1 (6.3)	0	1 (6.3)	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	1 (6.3)	0	1 (6.3)	0	0
Pneumonia	1 (6.3)	0	1 (6.3)	0	0
Urinary tract infection	1 (6.3)	0	0	1 (6.3)	0
Viral infection	1 (6.3)	1 (6.3)	0	0	0
Serious neurological adverse reactions					
-Total	1 (6.3)	0	0	1 (6.3)	0
Seizure	1 (6.3)	0	0	1 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	7 (21.9)	11 (34.4)	14 (43.8)
Cytokine Release Syndrome					
-Total	25 (78.1)	3 (9.4)	15 (46.9)	2 (6.3)	5 (15.6)
Cytokine release syndrome	25 (78.1)	3 (9.4)	15 (46.9)	2 (6.3)	5 (15.6)
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	1 (3.1)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	15 (46.9)	0	1 (3.1)	6 (18.8)	8 (25.0)
White blood cell count decreased	8 (25.0)	0	1 (3.1)	5 (15.6)	2 (6.3)
Neutrophil count decreased	6 (18.8)	0	0	3 (9.4)	3 (9.4)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	5 (15.6)	0	0	1 (3.1)	4 (12.5)
Lymphocyte count decreased	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Febrile neutropenia	1 (3.1)	0	0	1 (3.1)	0
Neutropenia	1 (3.1)	0	0	0	1 (3.1)
Thrombocytopenia	1 (3.1)	0	0	0	1 (3.1)
Infections					
-Total	24 (75.0)	3 (9.4)	11 (34.4)	6 (18.8)	4 (12.5)
Clostridium difficile infection	5 (15.6)	0	4 (12.5)	1 (3.1)	0
Rhinovirus infection	4 (12.5)	4 (12.5)	0	0	0
Upper respiratory tract infection	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Gastroenteritis	3 (9.4)	0	3 (9.4)	0	0
Influenza	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Urinary tract infection	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Cytomegalovirus infection	2 (6.3)	2 (6.3)	0	0	0
Ear infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Sinusitis	2 (6.3)	0	2 (6.3)	0	0
Skin infection	2 (6.3)	0	2 (6.3)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Vulvovaginal candidiasis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Bacterial sepsis	1 (3.1)	0	0	0	1 (3.1)
Campylobacter infection	1 (3.1)	0	0	1 (3.1)	0
Catheter site cellulitis	1 (3.1)	1 (3.1)	0	0	0
Catheter site infection	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Enterococcal infection	1 (3.1)	1 (3.1)	0	0	0
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Escherichia urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Folliculitis	1 (3.1)	0	1 (3.1)	0	0
Fungal skin infection	1 (3.1)	1 (3.1)	0	0	0
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis viral	1 (3.1)	1 (3.1)	0	0	0
Molluscum contagiosum	1 (3.1)	1 (3.1)	0	0	0
Oral candidiasis	1 (3.1)	1 (3.1)	0	0	0
Oral herpes	1 (3.1)	0	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Orchitis	1 (3.1)	1 (3.1)	0	0	0
Otitis media acute	1 (3.1)	0	1 (3.1)	0	0
Parainfluenzae virus infection	1 (3.1)	0	0	1 (3.1)	0
Pneumonia	1 (3.1)	0	1 (3.1)	0	0
Respiratory tract infection	1 (3.1)	0	0	0	1 (3.1)
Respiratory tract infection viral	1 (3.1)	0	0	1 (3.1)	0
Rhinitis	1 (3.1)	1 (3.1)	0	0	0
Rotavirus infection	1 (3.1)	0	0	1 (3.1)	0
Sepsis	1 (3.1)	0	0	0	1 (3.1)
Septic embolus	1 (3.1)	0	0	0	1 (3.1)
Skin papilloma	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Subcutaneous abscess	1 (3.1)	0	1 (3.1)	0	0
Tinea capitis	1 (3.1)	1 (3.1)	0	0	0
Urinary tract infection enterococcal	1 (3.1)	0	0	1 (3.1)	0
Viral infection	1 (3.1)	1 (3.1)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (59.4)	1 (3.1)	15 (46.9)	3 (9.4)	0
Hypogammaglobulinaemia	19 (59.4)	1 (3.1)	15 (46.9)	3 (9.4)	0
Blood immunoglobulin a decreased	2 (6.3)	2 (6.3)	0	0	0
Blood immunoglobulin m decreased	2 (6.3)	2 (6.3)	0	0	0
Immunodeficiency	1 (3.1)	0	1 (3.1)	0	0
Serious neurological adverse reactions					
-Total	9 (28.1)	5 (15.6)	2 (6.3)	2 (6.3)	0
Muscular weakness	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Confusional state	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Delirium	1 (3.1)	1 (3.1)	0	0	0
Disturbance in attention	1 (3.1)	1 (3.1)	0	0	0
Dysarthria	1 (3.1)	0	1 (3.1)	0	0
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Hallucination	1 (3.1)	1 (3.1)	0	0	0
Mental status changes	1 (3.1)	1 (3.1)	0	0	0
Seizure	1 (3.1)	0	0	1 (3.1)	0
Somnolence	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
			All patients N=32		
Tremor	1 (3.1)	1 (3.1)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (96.9)	0	10 (31.3)	12 (37.5)	9 (28.1)
Cytokine Release Syndrome					
-Total	25 (78.1)	3 (9.4)	10 (31.3)	6 (18.8)	6 (18.8)
Cytokine release syndrome	25 (78.1)	3 (9.4)	10 (31.3)	6 (18.8)	6 (18.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	12 (37.5)	2 (6.3)	2 (6.3)	4 (12.5)	4 (12.5)
Anaemia	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Platelet count decreased	3 (9.4)	1 (3.1)	1 (3.1)	0	1 (3.1)
Thrombocytopenia	3 (9.4)	1 (3.1)	0	1 (3.1)	1 (3.1)
White blood cell count decreased	3 (9.4)	1 (3.1)	0	1 (3.1)	1 (3.1)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	2 (6.3)	0	0	2 (6.3)	0
Neutropenia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Neutrophil count decreased	2 (6.3)	0	0	0	2 (6.3)
Lymphocyte count decreased	1 (3.1)	0	0	1 (3.1)	0
Lymphopenia	1 (3.1)	0	0	1 (3.1)	0
Infections					
-Total	22 (68.8)	4 (12.5)	10 (31.3)	8 (25.0)	0
Upper respiratory tract infection	5 (15.6)	3 (9.4)	1 (3.1)	1 (3.1)	0
Otitis media	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Clostridium difficile colitis	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Pneumonia	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Gastroenteritis	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Sinusitis	2 (6.3)	0	2 (6.3)	0	0
Urinary tract infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Viral infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Acute sinusitis	1 (3.1)	0	1 (3.1)	0	0
Body tinea	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (3.1)	0	0	1 (3.1)	0
Cholecystitis infective	1 (3.1)	0	0	1 (3.1)	0
Corona virus infection	1 (3.1)	0	0	1 (3.1)	0
Gingivitis	1 (3.1)	1 (3.1)	0	0	0
Haemophilus infection	1 (3.1)	0	1 (3.1)	0	0
Herpes simplex	1 (3.1)	1 (3.1)	0	0	0
Herpes zoster	1 (3.1)	0	0	1 (3.1)	0
Human herpesvirus 6 infection	1 (3.1)	0	1 (3.1)	0	0
Hypopyon	1 (3.1)	0	1 (3.1)	0	0
Influenza	1 (3.1)	0	1 (3.1)	0	0
Meningitis aseptic	1 (3.1)	0	1 (3.1)	0	0
Otitis externa	1 (3.1)	0	1 (3.1)	0	0
Otitis media acute	1 (3.1)	0	1 (3.1)	0	0
Parainfluenzae virus infection	1 (3.1)	1 (3.1)	0	0	0
Paronychia	1 (3.1)	1 (3.1)	0	0	0
Pharyngitis	1 (3.1)	0	1 (3.1)	0	0
Rash pustular	1 (3.1)	0	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (3.1)	0	0	1 (3.1)	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Staphylococcal infection	1 (3.1)	1 (3.1)	0	0	0
Streptococcal infection	1 (3.1)	0	1 (3.1)	0	0
Vascular device infection	1 (3.1)	0	0	1 (3.1)	0
Viral upper respiratory tract infection	1 (3.1)	0	1 (3.1)	0	0
Vulvovaginal mycotic infection	1 (3.1)	0	1 (3.1)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	14 (43.8)	2 (6.3)	10 (31.3)	2 (6.3)	0
Hypogammaglobulinaemia	13 (40.6)	2 (6.3)	9 (28.1)	2 (6.3)	0
Blood immunoglobulin m decreased	2 (6.3)	2 (6.3)	0	0	0
Blood immunoglobulin a decreased	1 (3.1)	1 (3.1)	0	0	0
Blood immunoglobulin g decreased	1 (3.1)	0	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	12 (37.5)	4 (12.5)	5 (15.6)	3 (9.4)	0
Confusional state	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Delirium	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Encephalopathy	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Seizure	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Agitation	2 (6.3)	0	2 (6.3)	0	0
Dysphagia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Irritability	2 (6.3)	2 (6.3)	0	0	0
Asterixis	1 (3.1)	1 (3.1)	0	0	0
Depressed level of consciousness	1 (3.1)	1 (3.1)	0	0	0
Dysarthria	1 (3.1)	1 (3.1)	0	0	0
Hallucination	1 (3.1)	0	1 (3.1)	0	0
Listless	1 (3.1)	1 (3.1)	0	0	0
Tremor	1 (3.1)	1 (3.1)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (6.3)	0	0	2 (6.3)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	3 (42.9)	1 (14.3)	3 (42.9)
Cytokine Release Syndrome					
-Total	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (42.9)	1 (14.3)	0	1 (14.3)	1 (14.3)
Anaemia	1 (14.3)	0	0	1 (14.3)	0
Neutropenia	1 (14.3)	0	0	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	0	1 (14.3)	0
White blood cell count decreased	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=7 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections					
-Total	2 (28.6)	0	2 (28.6)	0	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Viral infection	1 (14.3)	0	1 (14.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (57.1)	0	4 (57.1)	0	0
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Serious neurological adverse reactions					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Delirium	1 (14.3)	1 (14.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (90.0)	1 (5.0)	5 (25.0)	5 (25.0)	7 (35.0)
Cytokine Release Syndrome					
-Total	16 (80.0)	2 (10.0)	7 (35.0)	2 (10.0)	5 (25.0)
Cytokine release syndrome	16 (80.0)	2 (10.0)	7 (35.0)	2 (10.0)	5 (25.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (35.0)	0	1 (5.0)	3 (15.0)	3 (15.0)
Febrile neutropenia	2 (10.0)	0	0	2 (10.0)	0
Neutrophil count decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Platelet count decreased	2 (10.0)	0	1 (5.0)	0	1 (5.0)
White blood cell count decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (5.0)	0	0	0	1 (5.0)
Neutropenia	1 (5.0)	0	0	0	1 (5.0)
Infections					
-Total	7 (35.0)	1 (5.0)	2 (10.0)	4 (20.0)	0
Clostridium difficile infection	2 (10.0)	0	2 (10.0)	0	0
Staphylococcal infection	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Catheter site cellulitis	1 (5.0)	1 (5.0)	0	0	0
Clostridium difficile colitis	1 (5.0)	0	0	1 (5.0)	0
Cytomegalovirus infection	1 (5.0)	1 (5.0)	0	0	0
Enterococcal infection	1 (5.0)	1 (5.0)	0	0	0
Gastroenteritis	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis norovirus	1 (5.0)	0	1 (5.0)	0	0
Influenza	1 (5.0)	1 (5.0)	0	0	0
Pharyngitis	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Streptococcal infection	1 (5.0)	0	1 (5.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (35.0)	1 (5.0)	5 (25.0)	1 (5.0)	0
Hypogammaglobulinaemia	6 (30.0)	0	5 (25.0)	1 (5.0)	0
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Serious neurological adverse reactions					
-Total	8 (40.0)	3 (15.0)	3 (15.0)	2 (10.0)	0
Delirium	2 (10.0)	0	2 (10.0)	0	0
Dysarthria	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Dysphagia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Encephalopathy	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Tremor	2 (10.0)	2 (10.0)	0	0	0
Agitation	1 (5.0)	0	1 (5.0)	0	0
Asterixis	1 (5.0)	1 (5.0)	0	0	0
Confusional state	1 (5.0)	1 (5.0)	0	0	0
Depressed level of consciousness	1 (5.0)	1 (5.0)	0	0	0
Hallucination	1 (5.0)	1 (5.0)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	1 (5.0)	1 (5.0)	0	0	0
Muscular weakness	1 (5.0)	0	1 (5.0)	0	0
Seizure	1 (5.0)	0	1 (5.0)	0	0
Somnolence	1 (5.0)	1 (5.0)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (5.0)	0	0	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (100)	0	6 (28.6)	9 (42.9)	6 (28.6)
Cytokine Release Syndrome					
-Total	18 (85.7)	1 (4.8)	12 (57.1)	4 (19.0)	1 (4.8)
Cytokine release syndrome	18 (85.7)	1 (4.8)	12 (57.1)	4 (19.0)	1 (4.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	10 (47.6)	0	2 (9.5)	4 (19.0)	4 (19.0)
White blood cell count decreased	4 (19.0)	0	1 (4.8)	2 (9.5)	1 (4.8)
Neutrophil count decreased	3 (14.3)	0	0	1 (4.8)	2 (9.5)
Platelet count decreased	3 (14.3)	1 (4.8)	0	1 (4.8)	1 (4.8)
Anaemia	2 (9.5)	0	2 (9.5)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (9.5)	0	0	0	2 (9.5)
Febrile neutropenia	1 (4.8)	0	0	1 (4.8)	0
Lymphocyte count decreased	1 (4.8)	0	0	1 (4.8)	0
Lymphopenia	1 (4.8)	0	0	1 (4.8)	0
Neutropenia	1 (4.8)	0	0	1 (4.8)	0
Infections					
-Total	9 (42.9)	1 (4.8)	5 (23.8)	2 (9.5)	1 (4.8)
Rhinovirus infection	3 (14.3)	3 (14.3)	0	0	0
Clostridium difficile colitis	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Acute sinusitis	1 (4.8)	0	1 (4.8)	0	0
Catheter site infection	1 (4.8)	0	0	1 (4.8)	0
Clostridium difficile infection	1 (4.8)	0	1 (4.8)	0	0
Folliculitis	1 (4.8)	0	1 (4.8)	0	0
Orchitis	1 (4.8)	1 (4.8)	0	0	0
Pneumonia	1 (4.8)	0	1 (4.8)	0	0
Septic embolus	1 (4.8)	0	0	0	1 (4.8)
Upper respiratory tract infection	1 (4.8)	0	1 (4.8)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection enterococcal	1 (4.8)	0	0	1 (4.8)	0
Viral upper respiratory tract infection	1 (4.8)	0	1 (4.8)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	11 (52.4)	1 (4.8)	7 (33.3)	3 (14.3)	0
Hypogammaglobulinaemia	10 (47.6)	1 (4.8)	6 (28.6)	3 (14.3)	0
Blood immunoglobulin g decreased	1 (4.8)	0	1 (4.8)	0	0
Blood immunoglobulin m decreased	1 (4.8)	1 (4.8)	0	0	0
Serious neurological adverse reactions					
-Total	5 (23.8)	2 (9.5)	2 (9.5)	1 (4.8)	0
Confusional state	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Delirium	1 (4.8)	1 (4.8)	0	0	0
Encephalopathy	1 (4.8)	0	0	1 (4.8)	0
Mental status changes	1 (4.8)	1 (4.8)	0	0	0
Seizure	1 (4.8)	0	1 (4.8)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (81.3)	0	5 (31.3)	3 (18.8)	5 (31.3)
Cytokine Release Syndrome					
-Total	11 (68.8)	3 (18.8)	4 (25.0)	2 (12.5)	2 (12.5)
Cytokine release syndrome	11 (68.8)	3 (18.8)	4 (25.0)	2 (12.5)	2 (12.5)
Haemophagocytic lymphohistiocytosis	1 (6.3)	0	1 (6.3)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (43.8)	1 (6.3)	0	2 (12.5)	4 (25.0)
White blood cell count decreased	4 (25.0)	0	0	3 (18.8)	1 (6.3)
Platelet count decreased	3 (18.8)	0	0	0	3 (18.8)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (12.5)	0	0	0	2 (12.5)
Thrombocytopenia	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Lymphocyte count decreased	1 (6.3)	0	0	1 (6.3)	0
Infections					
-Total	8 (50.0)	3 (18.8)	5 (31.3)	0	0
Body tinea	1 (6.3)	1 (6.3)	0	0	0
Clostridium difficile colitis	1 (6.3)	0	1 (6.3)	0	0
Clostridium difficile infection	1 (6.3)	0	1 (6.3)	0	0
Fungal skin infection	1 (6.3)	1 (6.3)	0	0	0
Herpes simplex	1 (6.3)	1 (6.3)	0	0	0
Human herpesvirus 6 infection	1 (6.3)	0	1 (6.3)	0	0
Hypopyon	1 (6.3)	0	1 (6.3)	0	0
Oral candidiasis	1 (6.3)	1 (6.3)	0	0	0
Skin infection	1 (6.3)	0	1 (6.3)	0	0
Skin papilloma	1 (6.3)	0	1 (6.3)	0	0
Vulvovaginal candidiasis	1 (6.3)	1 (6.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=16 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	5 (31.3)	2 (12.5)	3 (18.8)	0	0
Hypogammaglobulinaemia	5 (31.3)	2 (12.5)	3 (18.8)	0	0
Blood immunoglobulin a decreased	2 (12.5)	2 (12.5)	0	0	0
Blood immunoglobulin m decreased	1 (6.3)	1 (6.3)	0	0	0
Serious neurological adverse reactions					
-Total	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Agitation	1 (6.3)	0	1 (6.3)	0	0
Confusional state	1 (6.3)	0	1 (6.3)	0	0
Encephalopathy	1 (6.3)	1 (6.3)	0	0	0
Hallucination	1 (6.3)	0	1 (6.3)	0	0
Irritability	1 (6.3)	1 (6.3)	0	0	0
Listless	1 (6.3)	1 (6.3)	0	0	0
Seizure	1 (6.3)	0	0	1 (6.3)	0

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All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Infections					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Upper respiratory tract infection	2 (40.0)	0	2 (40.0)	0	0
Corona virus infection	1 (20.0)	0	0	1 (20.0)	0
Ear infection	1 (20.0)	1 (20.0)	0	0	0
Respiratory syncytial virus infection	1 (20.0)	0	0	1 (20.0)	0
Rhinovirus infection	1 (20.0)	1 (20.0)	0	0	0
Tinea capitis	1 (20.0)	1 (20.0)	0	0	0
Viral infection	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	1 (20.0)	1 (20.0)	0	0	0
Muscular weakness	1 (20.0)	1 (20.0)	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

			All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (73.7)	2 (10.5)	7 (36.8)	4 (21.1)	1 (5.3)
Infections					
-Total	14 (73.7)	3 (15.8)	7 (36.8)	3 (15.8)	1 (5.3)
Gastroenteritis	2 (10.5)	0	2 (10.5)	0	0
Influenza	2 (10.5)	0	2 (10.5)	0	0
Urinary tract infection	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Escherichia urinary tract infection	1 (5.3)	0	0	1 (5.3)	0
Gastroenteritis norovirus	1 (5.3)	0	1 (5.3)	0	0
Herpes zoster	1 (5.3)	0	0	1 (5.3)	0
Oral herpes	1 (5.3)	0	1 (5.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

			All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (5.3)	1 (5.3)	0	0	0
Rash pustular	1 (5.3)	0	1 (5.3)	0	0
Rhinitis	1 (5.3)	1 (5.3)	0	0	0
Rhinovirus infection	1 (5.3)	1 (5.3)	0	0	0
Sepsis	1 (5.3)	0	0	0	1 (5.3)
Subcutaneous abscess	1 (5.3)	0	1 (5.3)	0	0
Upper respiratory tract infection	1 (5.3)	1 (5.3)	0	0	0
Viral upper respiratory tract infection	1 (5.3)	0	0	1 (5.3)	0
Vulvovaginal mycotic infection	1 (5.3)	0	1 (5.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (15.8)	0	2 (10.5)	1 (5.3)	0
Hypogammaglobulinaemia	3 (15.8)	0	2 (10.5)	1 (5.3)	0
Serious neurological adverse reactions					
-Total	1 (5.3)	1 (5.3)	0	0	0
Muscular weakness	1 (5.3)	1 (5.3)	0	0	0

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Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

			All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (55.6)	2 (11.1)	4 (22.2)	3 (16.7)	1 (5.6)
Infections					
-Total	9 (50.0)	2 (11.1)	4 (22.2)	2 (11.1)	1 (5.6)
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Cholecystitis infective	1 (5.6)	0	0	1 (5.6)	0
Gastroenteritis	1 (5.6)	1 (5.6)	0	0	0
Gastroenteritis viral	1 (5.6)	1 (5.6)	0	0	0
Influenza	1 (5.6)	0	1 (5.6)	0	0
Molluscum contagiosum	1 (5.6)	1 (5.6)	0	0	0
Otitis externa	1 (5.6)	0	1 (5.6)	0	0
Parainfluenzae virus infection	1 (5.6)	0	0	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (5.6)	1 (5.6)	0	0	0
Sinusitis	1 (5.6)	0	1 (5.6)	0	0
Upper respiratory tract infection	1 (5.6)	0	1 (5.6)	0	0
Urinary tract infection	1 (5.6)	0	1 (5.6)	0	0
Viral upper respiratory tract infection	1 (5.6)	1 (5.6)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (16.7)	0	3 (16.7)	0	0
Hypogammaglobulinaemia	3 (16.7)	0	3 (16.7)	0	0
Tumour Lysis Syndrome					
-Total	1 (5.6)	0	0	1 (5.6)	0
Tumour lysis syndrome	1 (5.6)	0	0	1 (5.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (50.0)	0	3 (21.4)	4 (28.6)	0
Infections					
-Total	6 (42.9)	0	2 (14.3)	4 (28.6)	0
Upper respiratory tract infection	3 (21.4)	2 (14.3)	0	1 (7.1)	0
Cellulitis of male external genital organ	1 (7.1)	0	0	1 (7.1)	0
Cytomegalovirus infection	1 (7.1)	1 (7.1)	0	0	0
Ear infection	1 (7.1)	0	1 (7.1)	0	0
Enterovirus infection	1 (7.1)	0	0	1 (7.1)	0
Otitis media	1 (7.1)	0	1 (7.1)	0	0
Otitis media acute	1 (7.1)	0	1 (7.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	1 (7.1)	0	0	1 (7.1)	0
Sinusitis	1 (7.1)	0	1 (7.1)	0	0
Urinary tract infection	1 (7.1)	0	0	1 (7.1)	0
Vascular device infection	1 (7.1)	0	0	1 (7.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (14.3)	0	2 (14.3)	0	0
Hypogammaglobulinaemia	2 (14.3)	0	2 (14.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (20.0)	0	1 (20.0)	0	0
Infections					
-Total	1 (20.0)	0	1 (20.0)	0	0
Skin infection	1 (20.0)	0	1 (20.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

		All patients N=11			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Infections					
-Total	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Otitis media	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Gingivitis	1 (9.1)	1 (9.1)	0	0	0
Haemophilus infection	1 (9.1)	0	1 (9.1)	0	0
Meningitis aseptic	1 (9.1)	0	1 (9.1)	0	0
Otitis media acute	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Sinusitis	1 (9.1)	0	1 (9.1)	0	0
Viral infection	1 (9.1)	1 (9.1)	0	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

Group term Preferred term	All grades n (%)	All patients N=11 Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	1 (9.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

			All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (50.0)	1 (10.0)	3 (30.0)	0	1 (10.0)
Infections					
-Total	3 (30.0)	0	2 (20.0)	0	1 (10.0)
Sinusitis	2 (20.0)	0	2 (20.0)	0	0
Pneumonia	1 (10.0)	0	1 (10.0)	0	0
Respiratory tract infection	1 (10.0)	0	0	0	1 (10.0)
Upper respiratory tract infection	1 (10.0)	0	1 (10.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (10.0)	0	1 (10.0)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	1 (10.0)	0	1 (10.0)	0	0
Serious neurological adverse reactions					
-Total	1 (10.0)	1 (10.0)	0	0	0
Disturbance in attention	1 (10.0)	1 (10.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

			All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (50.0)	1 (12.5)	1 (12.5)	2 (25.0)	0
Infections					
-Total	4 (50.0)	1 (12.5)	1 (12.5)	2 (25.0)	0
Urinary tract infection	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Campylobacter infection	1 (12.5)	0	0	1 (12.5)	0
Cellulitis of male external genital organ	1 (12.5)	0	0	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	0	1 (12.5)	0
Otitis media	1 (12.5)	0	1 (12.5)	0	0
Otitis media acute	1 (12.5)	0	1 (12.5)	0	0
Respiratory tract infection viral	1 (12.5)	0	0	1 (12.5)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=8 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Upper respiratory tract infection	1 (12.5)	1 (12.5)	0	0	0
Vulvovaginal candidiasis	1 (12.5)	0	1 (12.5)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	2 (28.6)	2 (28.6)	3 (42.9)
Cytokine Release Syndrome					
-Total	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (42.9)	1 (14.3)	0	1 (14.3)	1 (14.3)
Anaemia	1 (14.3)	0	0	1 (14.3)	0
Neutropenia	1 (14.3)	0	0	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	0	1 (14.3)	0
White blood cell count decreased	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Upper respiratory tract infection	2 (28.6)	0	2 (28.6)	0	0
Viral infection	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Corona virus infection	1 (14.3)	0	0	1 (14.3)	0
Ear infection	1 (14.3)	1 (14.3)	0	0	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	1 (14.3)	0	0	0
Skin infection	1 (14.3)	0	1 (14.3)	0	0
Tinea capitis	1 (14.3)	1 (14.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (57.1)	0	4 (57.1)	0	0
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Delirium	1 (14.3)	1 (14.3)	0	0	0
Muscular weakness	1 (14.3)	1 (14.3)	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

		All patients N=20			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (100)	0	5 (25.0)	7 (35.0)	8 (40.0)
Cytokine Release Syndrome					
-Total	16 (80.0)	2 (10.0)	7 (35.0)	2 (10.0)	5 (25.0)
Cytokine release syndrome	16 (80.0)	2 (10.0)	7 (35.0)	2 (10.0)	5 (25.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (35.0)	0	1 (5.0)	3 (15.0)	3 (15.0)
Febrile neutropenia	2 (10.0)	0	0	2 (10.0)	0
Neutrophil count decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Platelet count decreased	2 (10.0)	0	1 (5.0)	0	1 (5.0)
White blood cell count decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (5.0)	0	0	0	1 (5.0)
Neutropenia	1 (5.0)	0	0	0	1 (5.0)
Infections					
-Total	17 (85.0)	2 (10.0)	7 (35.0)	7 (35.0)	1 (5.0)
Gastroenteritis	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Influenza	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Clostridium difficile infection	2 (10.0)	0	2 (10.0)	0	0
Otitis media	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Pneumonia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Staphylococcal infection	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Urinary tract infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Catheter site cellulitis	1 (5.0)	1 (5.0)	0	0	0
Clostridium difficile colitis	1 (5.0)	0	0	1 (5.0)	0
Cytomegalovirus infection	1 (5.0)	1 (5.0)	0	0	0
Enterococcal infection	1 (5.0)	1 (5.0)	0	0	0
Escherichia urinary tract infection	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis norovirus	1 (5.0)	0	1 (5.0)	0	0
Gingivitis	1 (5.0)	1 (5.0)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophilus infection	1 (5.0)	0	1 (5.0)	0	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0
Meningitis aseptic	1 (5.0)	0	1 (5.0)	0	0
Oral herpes	1 (5.0)	0	1 (5.0)	0	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Parainfluenzae virus infection	1 (5.0)	1 (5.0)	0	0	0
Pharyngitis	1 (5.0)	0	1 (5.0)	0	0
Rash pustular	1 (5.0)	0	1 (5.0)	0	0
Rhinitis	1 (5.0)	1 (5.0)	0	0	0
Rhinovirus infection	1 (5.0)	1 (5.0)	0	0	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Sinusitis	1 (5.0)	0	1 (5.0)	0	0
Streptococcal infection	1 (5.0)	0	1 (5.0)	0	0
Subcutaneous abscess	1 (5.0)	0	1 (5.0)	0	0
Upper respiratory tract infection	1 (5.0)	1 (5.0)	0	0	0
Viral infection	1 (5.0)	1 (5.0)	0	0	0
Viral upper respiratory tract infection	1 (5.0)	0	0	1 (5.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal mycotic infection	1 (5.0)	0	1 (5.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	9 (45.0)	0	7 (35.0)	2 (10.0)	0
Hypogammaglobulinaemia	9 (45.0)	0	7 (35.0)	2 (10.0)	0
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Serious neurological adverse reactions					
-Total	10 (50.0)	4 (20.0)	3 (15.0)	3 (15.0)	0
Delirium	2 (10.0)	0	2 (10.0)	0	0
Dysarthria	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Dysphagia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Encephalopathy	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Muscular weakness	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Seizure	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Tremor	2 (10.0)	2 (10.0)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (5.0)	0	1 (5.0)	0	0
Asterixis	1 (5.0)	1 (5.0)	0	0	0
Confusional state	1 (5.0)	1 (5.0)	0	0	0
Depressed level of consciousness	1 (5.0)	1 (5.0)	0	0	0
Hallucination	1 (5.0)	1 (5.0)	0	0	0
Irritability	1 (5.0)	1 (5.0)	0	0	0
Somnolence	1 (5.0)	1 (5.0)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (5.0)	0	0	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (100)	0	4 (19.0)	10 (47.6)	7 (33.3)
Cytokine Release Syndrome					
-Total	18 (85.7)	1 (4.8)	12 (57.1)	4 (19.0)	1 (4.8)
Cytokine release syndrome	18 (85.7)	1 (4.8)	12 (57.1)	4 (19.0)	1 (4.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	10 (47.6)	0	2 (9.5)	4 (19.0)	4 (19.0)
White blood cell count decreased	4 (19.0)	0	1 (4.8)	2 (9.5)	1 (4.8)
Neutrophil count decreased	3 (14.3)	0	0	1 (4.8)	2 (9.5)
Platelet count decreased	3 (14.3)	1 (4.8)	0	1 (4.8)	1 (4.8)
Anaemia	2 (9.5)	0	2 (9.5)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (9.5)	0	0	0	2 (9.5)
Febrile neutropenia	1 (4.8)	0	0	1 (4.8)	0
Lymphocyte count decreased	1 (4.8)	0	0	1 (4.8)	0
Lymphopenia	1 (4.8)	0	0	1 (4.8)	0
Neutropenia	1 (4.8)	0	0	1 (4.8)	0
Infections					
-Total	14 (66.7)	1 (4.8)	8 (38.1)	2 (9.5)	3 (14.3)
Rhinovirus infection	3 (14.3)	3 (14.3)	0	0	0
Clostridium difficile colitis	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Pneumonia	2 (9.5)	0	2 (9.5)	0	0
Sinusitis	2 (9.5)	0	2 (9.5)	0	0
Upper respiratory tract infection	2 (9.5)	0	2 (9.5)	0	0
Viral upper respiratory tract infection	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Acute sinusitis	1 (4.8)	0	1 (4.8)	0	0
Bacterial sepsis	1 (4.8)	0	0	0	1 (4.8)
Catheter site infection	1 (4.8)	0	0	1 (4.8)	0
Cholecystitis infective	1 (4.8)	0	0	1 (4.8)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (4.8)	0	1 (4.8)	0	0
Folliculitis	1 (4.8)	0	1 (4.8)	0	0
Gastroenteritis	1 (4.8)	1 (4.8)	0	0	0
Gastroenteritis viral	1 (4.8)	1 (4.8)	0	0	0
Influenza	1 (4.8)	0	1 (4.8)	0	0
Molluscum contagiosum	1 (4.8)	1 (4.8)	0	0	0
Orchitis	1 (4.8)	1 (4.8)	0	0	0
Otitis externa	1 (4.8)	0	1 (4.8)	0	0
Parainfluenzae virus infection	1 (4.8)	0	0	1 (4.8)	0
Paronychia	1 (4.8)	1 (4.8)	0	0	0
Respiratory tract infection	1 (4.8)	0	0	0	1 (4.8)
Septic embolus	1 (4.8)	0	0	0	1 (4.8)
Urinary tract infection	1 (4.8)	0	1 (4.8)	0	0
Urinary tract infection enterococcal	1 (4.8)	0	0	1 (4.8)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	13 (61.9)	1 (4.8)	9 (42.9)	3 (14.3)	0
Hypogammaglobulinaemia	12 (57.1)	1 (4.8)	8 (38.1)	3 (14.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (4.8)	0	1 (4.8)	0	0
Blood immunoglobulin m decreased	1 (4.8)	1 (4.8)	0	0	0
Immunodeficiency	1 (4.8)	0	1 (4.8)	0	0
Serious neurological adverse reactions					
-Total	5 (23.8)	2 (9.5)	2 (9.5)	1 (4.8)	0
Confusional state	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Delirium	1 (4.8)	1 (4.8)	0	0	0
Disturbance in attention	1 (4.8)	1 (4.8)	0	0	0
Encephalopathy	1 (4.8)	0	0	1 (4.8)	0
Mental status changes	1 (4.8)	1 (4.8)	0	0	0
Seizure	1 (4.8)	0	1 (4.8)	0	0
Tumour Lysis Syndrome					
-Total	1 (4.8)	0	0	1 (4.8)	0
Tumour lysis syndrome	1 (4.8)	0	0	1 (4.8)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 199r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

			All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (93.8)	0	6 (37.5)	4 (25.0)	5 (31.3)
Cytokine Release Syndrome					
-Total	11 (68.8)	3 (18.8)	4 (25.0)	2 (12.5)	2 (12.5)
Cytokine release syndrome	11 (68.8)	3 (18.8)	4 (25.0)	2 (12.5)	2 (12.5)
Haemophagocytic lymphohistiocytosis	1 (6.3)	0	1 (6.3)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (43.8)	1 (6.3)	0	2 (12.5)	4 (25.0)
White blood cell count decreased	4 (25.0)	0	0	3 (18.8)	1 (6.3)
Platelet count decreased	3 (18.8)	0	0	0	3 (18.8)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (12.5)	0	0	0	2 (12.5)
Thrombocytopenia	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Lymphocyte count decreased	1 (6.3)	0	0	1 (6.3)	0
Infections					
-Total	11 (68.8)	3 (18.8)	4 (25.0)	4 (25.0)	0
Upper respiratory tract infection	4 (25.0)	3 (18.8)	0	1 (6.3)	0
Clostridium difficile infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Otitis media	2 (12.5)	0	2 (12.5)	0	0
Urinary tract infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Vulvovaginal candidiasis	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Body tinea	1 (6.3)	1 (6.3)	0	0	0
Campylobacter infection	1 (6.3)	0	0	1 (6.3)	0
Cellulitis of male external genital organ	1 (6.3)	0	0	1 (6.3)	0
Clostridium difficile colitis	1 (6.3)	0	1 (6.3)	0	0
Cytomegalovirus infection	1 (6.3)	1 (6.3)	0	0	0
Ear infection	1 (6.3)	0	1 (6.3)	0	0
Enterovirus infection	1 (6.3)	0	0	1 (6.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (6.3)	1 (6.3)	0	0	0
Herpes simplex	1 (6.3)	1 (6.3)	0	0	0
Human herpesvirus 6 infection	1 (6.3)	0	1 (6.3)	0	0
Hypopyon	1 (6.3)	0	1 (6.3)	0	0
Oral candidiasis	1 (6.3)	1 (6.3)	0	0	0
Otitis media acute	1 (6.3)	0	1 (6.3)	0	0
Respiratory tract infection viral	1 (6.3)	0	0	1 (6.3)	0
Rotavirus infection	1 (6.3)	0	0	1 (6.3)	0
Sinusitis	1 (6.3)	0	1 (6.3)	0	0
Skin infection	1 (6.3)	0	1 (6.3)	0	0
Skin papilloma	1 (6.3)	0	1 (6.3)	0	0
Vascular device infection	1 (6.3)	0	0	1 (6.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	7 (43.8)	2 (12.5)	5 (31.3)	0	0
Hypogammaglobulinaemia	7 (43.8)	2 (12.5)	5 (31.3)	0	0
Blood immunoglobulin a decreased	2 (12.5)	2 (12.5)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

Group term Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin m decreased	1 (6.3)	1 (6.3)	0	0	0
Serious neurological adverse reactions					
-Total	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Agitation	1 (6.3)	0	1 (6.3)	0	0
Confusional state	1 (6.3)	0	1 (6.3)	0	0
Encephalopathy	1 (6.3)	1 (6.3)	0	0	0
Hallucination	1 (6.3)	0	1 (6.3)	0	0
Irritability	1 (6.3)	1 (6.3)	0	0	0
Listless	1 (6.3)	1 (6.3)	0	0	0
Seizure	1 (6.3)	0	0	1 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200a
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (63.6)	1 (4.5)	3 (13.6)	6 (27.3)	4 (18.2)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (22.7)	0	0	1 (4.5)	4 (18.2)
Anaemia	3 (13.6)	0	1 (4.5)	2 (9.1)	0
Neutropenia	2 (9.1)	0	0	0	2 (9.1)
Neutrophil count decreased	2 (9.1)	0	0	0	2 (9.1)
Leukopenia	1 (4.5)	0	0	0	1 (4.5)
Thrombocytopenia	1 (4.5)	0	0	1 (4.5)	0
White blood cell count decreased	1 (4.5)	0	0	0	1 (4.5)
Infections					
-Total	12 (54.5)	1 (4.5)	3 (13.6)	8 (36.4)	0

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Alpha haemolytic streptococcal infection	1 (4.5)	0	0	1 (4.5)	0
Bronchopulmonary aspergillosis	1 (4.5)	0	0	1 (4.5)	0
Clostridium difficile colitis	1 (4.5)	0	0	1 (4.5)	0
Conjunctivitis	1 (4.5)	0	1 (4.5)	0	0
Croup infectious	1 (4.5)	0	0	1 (4.5)	0
Cytomegalovirus viraemia	1 (4.5)	0	1 (4.5)	0	0
Device related infection	1 (4.5)	0	0	1 (4.5)	0
Enterococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Escherichia bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Escherichia infection	1 (4.5)	0	0	1 (4.5)	0
Metapneumovirus infection	1 (4.5)	0	1 (4.5)	0	0
Oral herpes	1 (4.5)	0	1 (4.5)	0	0
Respiratory syncytial virus infection	1 (4.5)	0	1 (4.5)	0	0
Sinusitis	1 (4.5)	1 (4.5)	0	0	0
Staphylococcal infection	1 (4.5)	0	0	1 (4.5)	0
Streptococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (4.5)	0	0	1 (4.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Hypogammaglobulinaemia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Serious neurological adverse reactions					
-Total	1 (4.5)	1 (4.5)	0	0	0
Irritability	1 (4.5)	1 (4.5)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (4.5)	0	0	1 (4.5)	0
Tumour lysis syndrome	1 (4.5)	0	0	1 (4.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200a
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (51.3)	2 (5.1)	5 (12.8)	8 (20.5)	5 (12.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Anaemia	1 (2.6)	0	0	1 (2.6)	0
Pancytopenia	1 (2.6)	0	0	0	1 (2.6)
Infections					
-Total	14 (35.9)	0	3 (7.7)	7 (17.9)	4 (10.3)
Device related infection	2 (5.1)	0	0	2 (5.1)	0
Oral herpes	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Staphylococcal bacteraemia	2 (5.1)	0	0	2 (5.1)	0
Bacteraemia	1 (2.6)	0	0	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida sepsis	1 (2.6)	0	0	0	1 (2.6)
Cellulitis	1 (2.6)	0	0	1 (2.6)	0
Clostridium difficile colitis	1 (2.6)	0	0	1 (2.6)	0
Clostridium difficile infection	1 (2.6)	0	1 (2.6)	0	0
Conjunctivitis	1 (2.6)	0	1 (2.6)	0	0
Escherichia bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Escherichia urinary tract infection	1 (2.6)	0	0	1 (2.6)	0
Fungal skin infection	1 (2.6)	0	1 (2.6)	0	0
Gastroenteritis	1 (2.6)	0	0	1 (2.6)	0
Human polyomavirus infection	1 (2.6)	0	0	0	1 (2.6)
Klebsiella infection	1 (2.6)	0	0	1 (2.6)	0
Klebsiella sepsis	1 (2.6)	0	0	0	1 (2.6)
Parainfluenzae virus infection	1 (2.6)	0	1 (2.6)	0	0
Pneumonia	1 (2.6)	0	1 (2.6)	0	0
Pneumonia fungal	1 (2.6)	0	0	1 (2.6)	0
Respiratory syncytial virus bronchitis	1 (2.6)	0	0	1 (2.6)	0
Sepsis	1 (2.6)	0	0	0	1 (2.6)

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Blood immunoglobulin m decreased	1 (2.6)	1 (2.6)	0	0	0
Hypogammaglobulinaemia	1 (2.6)	0	1 (2.6)	0	0
Serious neurological adverse reactions					
-Total	5 (12.8)	2 (5.1)	1 (2.6)	2 (5.1)	0
Mental status changes	3 (7.7)	2 (5.1)	0	1 (2.6)	0
Confusional state	1 (2.6)	0	1 (2.6)	0	0
Leukoencephalopathy	1 (2.6)	0	0	1 (2.6)	0
Tumour Lysis Syndrome					
-Total	1 (2.6)	0	0	1 (2.6)	0
Tumour lysis syndrome	1 (2.6)	0	0	1 (2.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200a
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (57.1)	0	1 (7.1)	2 (14.3)	5 (35.7)
Infections					
-Total	7 (50.0)	0	1 (7.1)	2 (14.3)	4 (28.6)
Abscess limb	1 (7.1)	0	0	1 (7.1)	0
Enterococcal bacteraemia	1 (7.1)	0	0	1 (7.1)	0
Escherichia sepsis	1 (7.1)	0	0	0	1 (7.1)
Escherichia urinary tract infection	1 (7.1)	0	1 (7.1)	0	0
Klebsiella sepsis	1 (7.1)	0	0	0	1 (7.1)
Pneumonia	1 (7.1)	0	0	0	1 (7.1)
Pneumonia fungal	1 (7.1)	0	1 (7.1)	0	0
Rhinovirus infection	1 (7.1)	0	1 (7.1)	0	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	1 (7.1)	0	0	1 (7.1)	0
Staphylococcal scalded skin syndrome	1 (7.1)	0	1 (7.1)	0	0
Staphylococcal sepsis	1 (7.1)	0	0	0	1 (7.1)
Serious neurological adverse reactions					
-Total	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Agitation	1 (7.1)	0	0	1 (7.1)	0
Confusional state	1 (7.1)	0	1 (7.1)	0	0
Hyporesponsive to stimuli	1 (7.1)	0	0	1 (7.1)	0
Seizure	1 (7.1)	0	0	0	1 (7.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200b
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (52.5)	1 (2.5)	5 (12.5)	8 (20.0)	7 (17.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Anaemia	1 (2.5)	0	0	1 (2.5)	0
Leukopenia	1 (2.5)	0	0	0	1 (2.5)
Neutropenia	1 (2.5)	0	0	0	1 (2.5)
Infections					
-Total	16 (40.0)	0	4 (10.0)	7 (17.5)	5 (12.5)
Klebsiella sepsis	2 (5.0)	0	0	0	2 (5.0)
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Candida sepsis	1 (2.5)	0	0	0	1 (2.5)

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Conjunctivitis	1 (2.5)	0	1 (2.5)	0	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Escherichia infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	1 (2.5)	0	0
Oral herpes	1 (2.5)	0	1 (2.5)	0	0
Pneumonia	1 (2.5)	0	0	0	1 (2.5)
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	1 (2.5)	0	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Serratia infection	1 (2.5)	0	0	1 (2.5)	0
Sinusitis	1 (2.5)	1 (2.5)	0	0	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Streptococcal infection	1 (2.5)	0	0	1 (2.5)	0
Upper respiratory tract infection	1 (2.5)	0	1 (2.5)	0	0

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Hypogammaglobulinaemia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Serious neurological adverse reactions					
-Total	6 (15.0)	2 (5.0)	1 (2.5)	2 (5.0)	1 (2.5)
Mental status changes	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Agitation	1 (2.5)	0	0	1 (2.5)	0
Confusional state	1 (2.5)	0	1 (2.5)	0	0
Hyporesponsive to stimuli	1 (2.5)	0	0	1 (2.5)	0
Irritability	1 (2.5)	1 (2.5)	0	0	0
Leukoencephalopathy	1 (2.5)	0	0	1 (2.5)	0
Seizure	1 (2.5)	0	0	0	1 (2.5)
Tumour Lysis Syndrome					
-Total	2 (5.0)	0	0	2 (5.0)	0
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200b
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (60.0)	2 (5.7)	4 (11.4)	8 (22.9)	7 (20.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (14.3)	0	0	1 (2.9)	4 (11.4)
Anaemia	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Neutrophil count decreased	2 (5.7)	0	0	0	2 (5.7)
Neutropenia	1 (2.9)	0	0	0	1 (2.9)
Pancytopenia	1 (2.9)	0	0	0	1 (2.9)
Thrombocytopenia	1 (2.9)	0	0	1 (2.9)	0
White blood cell count decreased	1 (2.9)	0	0	0	1 (2.9)
Infections					
-Total	17 (48.6)	1 (2.9)	3 (8.6)	10 (28.6)	3 (8.6)

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (5.7)	0	0	2 (5.7)	0
Enterococcal bacteraemia	2 (5.7)	0	0	2 (5.7)	0
Escherichia urinary tract infection	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Oral herpes	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Abscess limb	1 (2.9)	0	0	1 (2.9)	0
Alpha haemolytic streptococcal infection	1 (2.9)	0	0	1 (2.9)	0
Bronchopulmonary aspergillosis	1 (2.9)	0	0	1 (2.9)	0
Cellulitis	1 (2.9)	0	0	1 (2.9)	0
Clostridium difficile colitis	1 (2.9)	0	0	1 (2.9)	0
Clostridium difficile infection	1 (2.9)	0	1 (2.9)	0	0
Conjunctivitis	1 (2.9)	0	1 (2.9)	0	0
Croup infectious	1 (2.9)	0	0	1 (2.9)	0
Cytomegalovirus viraemia	1 (2.9)	0	1 (2.9)	0	0
Escherichia bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Escherichia sepsis	1 (2.9)	0	0	0	1 (2.9)
Fungal skin infection	1 (2.9)	0	1 (2.9)	0	0
Human polyomavirus infection	1 (2.9)	0	0	0	1 (2.9)

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (2.9)	0	1 (2.9)	0	0
Pneumonia	1 (2.9)	0	1 (2.9)	0	0
Pneumonia fungal	1 (2.9)	0	1 (2.9)	0	0
Respiratory syncytial virus bronchitis	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal infection	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal scalded skin syndrome	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Streptococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Upper respiratory tract infection	1 (2.9)	1 (2.9)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Blood immunoglobulin m decreased	1 (2.9)	1 (2.9)	0	0	0
Hypogammaglobulinaemia	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					
-Total	2 (5.7)	1 (2.9)	1 (2.9)	0	0

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Confusional state	1 (2.9)	0	1 (2.9)	0	0
Mental status changes	1 (2.9)	1 (2.9)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200c
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (50.0)	2 (3.3)	9 (15.0)	10 (16.7)	9 (15.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (6.7)	0	0	1 (1.7)	3 (5.0)
Anaemia	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Neutropenia	2 (3.3)	0	0	0	2 (3.3)
Leukopenia	1 (1.7)	0	0	0	1 (1.7)
Neutrophil count decreased	1 (1.7)	0	0	0	1 (1.7)
Thrombocytopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	25 (41.7)	1 (1.7)	7 (11.7)	11 (18.3)	6 (10.0)
Clostridium difficile colitis	2 (3.3)	0	0	2 (3.3)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterococcal bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Escherichia bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Oral herpes	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Pneumonia	2 (3.3)	0	1 (1.7)	0	1 (1.7)
Staphylococcal bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Upper respiratory tract infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bronchopulmonary aspergillosis	1 (1.7)	0	0	1 (1.7)	0
Candida sepsis	1 (1.7)	0	0	0	1 (1.7)
Cellulitis	1 (1.7)	0	0	1 (1.7)	0
Clostridium difficile infection	1 (1.7)	0	1 (1.7)	0	0
Conjunctivitis	1 (1.7)	0	1 (1.7)	0	0
Croup infectious	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus viraemia	1 (1.7)	0	1 (1.7)	0	0
Device related infection	1 (1.7)	0	0	1 (1.7)	0
Escherichia sepsis	1 (1.7)	0	0	0	1 (1.7)
Escherichia urinary tract infection	1 (1.7)	0	1 (1.7)	0	0
Fungal skin infection	1 (1.7)	0	1 (1.7)	0	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Human polyomavirus infection	1 (1.7)	0	0	0	1 (1.7)
Klebsiella infection	1 (1.7)	0	0	1 (1.7)	0
Klebsiella sepsis	1 (1.7)	0	0	0	1 (1.7)
Metapneumovirus infection	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	0	1 (1.7)	0	0
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Respiratory syncytial virus bronchitis	1 (1.7)	0	0	1 (1.7)	0
Respiratory syncytial virus infection	1 (1.7)	0	1 (1.7)	0	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Serratia infection	1 (1.7)	0	0	1 (1.7)	0
Sinusitis	1 (1.7)	1 (1.7)	0	0	0
Streptococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Hypogammaglobulinaemia	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Serious neurological adverse reactions					
-Total	6 (10.0)	3 (5.0)	2 (3.3)	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Confusional state	2 (3.3)	0	2 (3.3)	0	0
Mental status changes	2 (3.3)	2 (3.3)	0	0	0
Irritability	1 (1.7)	1 (1.7)	0	0	0
Leukoencephalopathy	1 (1.7)	0	0	1 (1.7)	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200c
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	1 (16.7)	0	3 (50.0)	1 (16.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (16.7)	0	0	0	1 (16.7)
Neutrophil count decreased	1 (16.7)	0	0	0	1 (16.7)
White blood cell count decreased	1 (16.7)	0	0	0	1 (16.7)
Infections					
-Total	4 (66.7)	0	0	4 (66.7)	0
Alpha haemolytic streptococcal infection	1 (16.7)	0	0	1 (16.7)	0
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Device related infection	1 (16.7)	0	0	1 (16.7)	0

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia infection	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis	1 (16.7)	0	0	1 (16.7)	0
Oral herpes	1 (16.7)	0	1 (16.7)	0	0
Staphylococcal infection	1 (16.7)	0	0	1 (16.7)	0
Streptococcal infection	1 (16.7)	0	0	1 (16.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin m decreased	1 (16.7)	1 (16.7)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200c
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (77.8)	0	0	3 (33.3)	4 (44.4)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Anaemia	1 (11.1)	0	0	1 (11.1)	0
Pancytopenia	1 (11.1)	0	0	0	1 (11.1)
Infections					
-Total	4 (44.4)	0	0	2 (22.2)	2 (22.2)
Abscess limb	1 (11.1)	0	0	1 (11.1)	0
Device related infection	1 (11.1)	0	0	1 (11.1)	0
Escherichia urinary tract infection	1 (11.1)	0	0	1 (11.1)	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	1 (11.1)	0	0	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	1 (11.1)	0	0
Rhinovirus infection	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal scalded skin syndrome	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal sepsis	1 (11.1)	0	0	0	1 (11.1)
Serious neurological adverse reactions					
-Total	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Agitation	1 (11.1)	0	0	1 (11.1)	0
Hyporesponsive to stimuli	1 (11.1)	0	0	1 (11.1)	0
Mental status changes	1 (11.1)	0	0	1 (11.1)	0
Seizure	1 (11.1)	0	0	0	1 (11.1)
Tumour Lysis Syndrome					
-Total	1 (11.1)	0	0	1 (11.1)	0
Tumour lysis syndrome	1 (11.1)	0	0	1 (11.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200d
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (56.7)	0	3 (10.0)	8 (26.7)	6 (20.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (10.0)	0	0	1 (3.3)	2 (6.7)
Anaemia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Neutropenia	1 (3.3)	0	0	0	1 (3.3)
Pancytopenia	1 (3.3)	0	0	0	1 (3.3)
Infections					
-Total	13 (43.3)	0	2 (6.7)	7 (23.3)	4 (13.3)
Bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Candida sepsis	1 (3.3)	0	0	0	1 (3.3)
Clostridium difficile colitis	1 (3.3)	0	0	1 (3.3)	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	1 (3.3)	0	1 (3.3)	0	0
Cytomegalovirus viraemia	1 (3.3)	0	1 (3.3)	0	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Enterococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Escherichia sepsis	1 (3.3)	0	0	0	1 (3.3)
Escherichia urinary tract infection	1 (3.3)	0	0	1 (3.3)	0
Klebsiella sepsis	1 (3.3)	0	0	0	1 (3.3)
Parainfluenzae virus infection	1 (3.3)	0	1 (3.3)	0	0
Pneumonia	1 (3.3)	0	1 (3.3)	0	0
Pneumonia fungal	1 (3.3)	0	0	1 (3.3)	0
Respiratory syncytial virus bronchitis	1 (3.3)	0	0	1 (3.3)	0
Sepsis	1 (3.3)	0	0	0	1 (3.3)
Serratia infection	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Streptococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (6.7)	0	2 (6.7)	0	0
Hypogammaglobulinaemia	2 (6.7)	0	2 (6.7)	0	0
Serious neurological adverse reactions					
-Total	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Mental status changes	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Tumour Lysis Syndrome					
-Total	1 (3.3)	0	0	1 (3.3)	0
Tumour lysis syndrome	1 (3.3)	0	0	1 (3.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200d
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (55.6)	3 (6.7)	6 (13.3)	8 (17.8)	8 (17.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (8.9)	0	0	1 (2.2)	3 (6.7)
Anaemia	2 (4.4)	0	0	2 (4.4)	0
Neutrophil count decreased	2 (4.4)	0	0	0	2 (4.4)
Leukopenia	1 (2.2)	0	0	0	1 (2.2)
Neutropenia	1 (2.2)	0	0	0	1 (2.2)
Thrombocytopenia	1 (2.2)	0	0	1 (2.2)	0
White blood cell count decreased	1 (2.2)	0	0	0	1 (2.2)
Infections					
-Total	20 (44.4)	1 (2.2)	5 (11.1)	10 (22.2)	4 (8.9)

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Device related infection	2 (4.4)	0	0	2 (4.4)	0
Upper respiratory tract infection	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Abscess limb	1 (2.2)	0	0	1 (2.2)	0
Alpha haemolytic streptococcal infection	1 (2.2)	0	0	1 (2.2)	0
Bronchopulmonary aspergillosis	1 (2.2)	0	0	1 (2.2)	0
Cellulitis	1 (2.2)	0	0	1 (2.2)	0
Clostridium difficile colitis	1 (2.2)	0	0	1 (2.2)	0
Clostridium difficile infection	1 (2.2)	0	1 (2.2)	0	0
Conjunctivitis	1 (2.2)	0	1 (2.2)	0	0
Croup infectious	1 (2.2)	0	0	1 (2.2)	0
Enterococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Escherichia bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Escherichia infection	1 (2.2)	0	0	1 (2.2)	0
Escherichia urinary tract infection	1 (2.2)	0	1 (2.2)	0	0
Fungal skin infection	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis	1 (2.2)	0	0	1 (2.2)	0

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human polyomavirus infection	1 (2.2)	0	0	0	1 (2.2)
Klebsiella infection	1 (2.2)	0	0	1 (2.2)	0
Klebsiella sepsis	1 (2.2)	0	0	0	1 (2.2)
Metapneumovirus infection	1 (2.2)	0	1 (2.2)	0	0
Pneumonia	1 (2.2)	0	0	0	1 (2.2)
Pneumonia fungal	1 (2.2)	0	1 (2.2)	0	0
Respiratory syncytial virus infection	1 (2.2)	0	1 (2.2)	0	0
Rhinovirus infection	1 (2.2)	0	1 (2.2)	0	0
Sinusitis	1 (2.2)	1 (2.2)	0	0	0
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal scalded skin syndrome	1 (2.2)	0	1 (2.2)	0	0
Staphylococcal sepsis	1 (2.2)	0	0	0	1 (2.2)
Streptococcal infection	1 (2.2)	0	0	1 (2.2)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (4.4)	2 (4.4)	0	0	0
Blood immunoglobulin m decreased	1 (2.2)	1 (2.2)	0	0	0

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypogammaglobulinaemia	1 (2.2)	1 (2.2)	0	0	0
Serious neurological adverse reactions					
-Total	6 (13.3)	2 (4.4)	2 (4.4)	1 (2.2)	1 (2.2)
Confusional state	2 (4.4)	0	2 (4.4)	0	0
Agitation	1 (2.2)	0	0	1 (2.2)	0
Hyporesponsive to stimuli	1 (2.2)	0	0	1 (2.2)	0
Irritability	1 (2.2)	1 (2.2)	0	0	0
Leukoencephalopathy	1 (2.2)	0	0	1 (2.2)	0
Mental status changes	1 (2.2)	1 (2.2)	0	0	0
Seizure	1 (2.2)	0	0	0	1 (2.2)
Tumour Lysis Syndrome					
-Total	1 (2.2)	0	0	1 (2.2)	0
Tumour lysis syndrome	1 (2.2)	0	0	1 (2.2)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200e
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (37.5)	0	1 (12.5)	0	2 (25.0)
Infections					
-Total	2 (25.0)	0	0	0	2 (25.0)
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	1 (12.5)	0	0
Human polyomavirus infection	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	1 (12.5)	0	1 (12.5)	0	0
Confusional state	1 (12.5)	0	1 (12.5)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200e
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (58.2)	3 (4.5)	8 (11.9)	16 (23.9)	12 (17.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (10.4)	0	0	2 (3.0)	5 (7.5)
Anaemia	4 (6.0)	0	1 (1.5)	3 (4.5)	0
Neutropenia	2 (3.0)	0	0	0	2 (3.0)
Neutrophil count decreased	2 (3.0)	0	0	0	2 (3.0)
Leukopenia	1 (1.5)	0	0	0	1 (1.5)
Pancytopenia	1 (1.5)	0	0	0	1 (1.5)
Thrombocytopenia	1 (1.5)	0	0	1 (1.5)	0
White blood cell count decreased	1 (1.5)	0	0	0	1 (1.5)
Infections					

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	31 (46.3)	1 (1.5)	7 (10.4)	17 (25.4)	6 (9.0)
Device related infection	3 (4.5)	0	0	3 (4.5)	0
Clostridium difficile colitis	2 (3.0)	0	0	2 (3.0)	0
Conjunctivitis	2 (3.0)	0	2 (3.0)	0	0
Enterococcal bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Escherichia bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Escherichia urinary tract infection	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Klebsiella sepsis	2 (3.0)	0	0	0	2 (3.0)
Oral herpes	2 (3.0)	0	2 (3.0)	0	0
Pneumonia fungal	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Staphylococcal bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Upper respiratory tract infection	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Alpha haemolytic streptococcal infection	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Candida sepsis	1 (1.5)	0	0	0	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Croup infectious	1 (1.5)	0	0	1 (1.5)	0
Cytomegalovirus viraemia	1 (1.5)	0	1 (1.5)	0	0
Escherichia infection	1 (1.5)	0	0	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	0	0	1 (1.5)
Fungal skin infection	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis	1 (1.5)	0	0	1 (1.5)	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Metapneumovirus infection	1 (1.5)	0	1 (1.5)	0	0
Parainfluenzae virus infection	1 (1.5)	0	1 (1.5)	0	0
Pneumonia	1 (1.5)	0	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	1 (1.5)	0	0
Rhinovirus infection	1 (1.5)	0	1 (1.5)	0	0
Sepsis	1 (1.5)	0	0	0	1 (1.5)
Serratia infection	1 (1.5)	0	0	1 (1.5)	0
Sinusitis	1 (1.5)	1 (1.5)	0	0	0
Staphylococcal infection	1 (1.5)	0	0	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (1.5)	0	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Streptococcal infection	1 (1.5)	0	0	1 (1.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Hypogammaglobulinaemia	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Blood immunoglobulin m decreased	1 (1.5)	1 (1.5)	0	0	0
Serious neurological adverse reactions					
-Total	7 (10.4)	3 (4.5)	1 (1.5)	2 (3.0)	1 (1.5)
Mental status changes	3 (4.5)	2 (3.0)	0	1 (1.5)	0
Agitation	1 (1.5)	0	0	1 (1.5)	0
Confusional state	1 (1.5)	0	1 (1.5)	0	0
Hyporesponsive to stimuli	1 (1.5)	0	0	1 (1.5)	0
Irritability	1 (1.5)	1 (1.5)	0	0	0
Leukoencephalopathy	1 (1.5)	0	0	1 (1.5)	0
Seizure	1 (1.5)	0	0	0	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour Lysis Syndrome					
-Total	2 (3.0)	0	0	2 (3.0)	0
Tumour lysis syndrome	2 (3.0)	0	0	2 (3.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200f
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	0	1 (50.0)	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Bacteraemia	1 (50.0)	0	0	1 (50.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (50.0)	1 (50.0)	0	0	0
Blood immunoglobulin m decreased	1 (50.0)	1 (50.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200f
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (54.8)	2 (2.7)	9 (12.3)	15 (20.5)	14 (19.2)
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (9.6)	0	0	2 (2.7)	5 (6.8)
Anaemia	4 (5.5)	0	1 (1.4)	3 (4.1)	0
Neutropenia	2 (2.7)	0	0	0	2 (2.7)
Neutrophil count decreased	2 (2.7)	0	0	0	2 (2.7)
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Pancytopenia	1 (1.4)	0	0	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	0	1 (1.4)	0
White blood cell count decreased	1 (1.4)	0	0	0	1 (1.4)
Infections					

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (43.8)	1 (1.4)	7 (9.6)	16 (21.9)	8 (11.0)
Device related infection	3 (4.1)	0	0	3 (4.1)	0
Oral herpes	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Clostridium difficile colitis	2 (2.7)	0	0	2 (2.7)	0
Conjunctivitis	2 (2.7)	0	2 (2.7)	0	0
Enterococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia urinary tract infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Pneumonia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Upper respiratory tract infection	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile infection	1 (1.4)	0	1 (1.4)	0	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus viraemia	1 (1.4)	0	1 (1.4)	0	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Sinusitis	1 (1.4)	1 (1.4)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Hypogammaglobulinaemia	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Serious neurological adverse reactions					
-Total	8 (11.0)	3 (4.1)	2 (2.7)	2 (2.7)	1 (1.4)
Mental status changes	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Confusional state	2 (2.7)	0	2 (2.7)	0	0
Agitation	1 (1.4)	0	0	1 (1.4)	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Irritability	1 (1.4)	1 (1.4)	0	0	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0
Seizure	1 (1.4)	0	0	0	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

Group term Preferred term	All patients N=73 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	2 (2.7)	0	0	2 (2.7)	0
Tumour lysis syndrome	2 (2.7)	0	0	2 (2.7)	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200g
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	0	0	0	1 (33.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (33.3)	0	0	0	1 (33.3)
Leukopenia	1 (33.3)	0	0	0	1 (33.3)
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Infections					
-Total	1 (33.3)	0	0	1 (33.3)	0
Escherichia bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Sinusitis	1 (33.3)	1 (33.3)	0	0	0
Serious neurological adverse reactions					
-Total	1 (33.3)	1 (33.3)	0	0	0

Mixed-lineage leukemia rearrangement: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Irritability	1 (33.3)	1 (33.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200g
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (56.9)	3 (4.2)	9 (12.5)	16 (22.2)	13 (18.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	6 (8.3)	0	0	2 (2.8)	4 (5.6)
Anaemia	4 (5.6)	0	1 (1.4)	3 (4.2)	0
Neutrophil count decreased	2 (2.8)	0	0	0	2 (2.8)
Neutropenia	1 (1.4)	0	0	0	1 (1.4)
Pancytopenia	1 (1.4)	0	0	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	0	1 (1.4)	0
White blood cell count decreased	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	32 (44.4)	1 (1.4)	7 (9.7)	16 (22.2)	8 (11.1)

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	3 (4.2)	0	0	3 (4.2)	0
Oral herpes	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Clostridium difficile colitis	2 (2.8)	0	0	2 (2.8)	0
Conjunctivitis	2 (2.8)	0	2 (2.8)	0	0
Enterococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Escherichia urinary tract infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Pneumonia	2 (2.8)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Upper respiratory tract infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (1.4)	0	1 (1.4)	0	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus viraemia	1 (1.4)	0	1 (1.4)	0	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Hypogammaglobulinaemia	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Blood immunoglobulin m decreased	1 (1.4)	1 (1.4)	0	0	0
Serious neurological adverse reactions					
-Total	7 (9.7)	2 (2.8)	2 (2.8)	2 (2.8)	1 (1.4)
Mental status changes	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Confusional state	2 (2.8)	0	2 (2.8)	0	0
Agitation	1 (1.4)	0	0	1 (1.4)	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0
Seizure	1 (1.4)	0	0	0	1 (1.4)
Tumour Lysis Syndrome					

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.8)	0	0	2 (2.8)	0
Tumour lysis syndrome	2 (2.8)	0	0	2 (2.8)	0

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- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200h
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0	0	0
Serious neurological adverse reactions					
-Total	1 (100)	1 (100)	0	0	0
Mental status changes	1 (100)	1 (100)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200h
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (55.4)	2 (2.7)	9 (12.2)	16 (21.6)	14 (18.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (9.5)	0	0	2 (2.7)	5 (6.8)
Anaemia	4 (5.4)	0	1 (1.4)	3 (4.1)	0
Neutropenia	2 (2.7)	0	0	0	2 (2.7)
Neutrophil count decreased	2 (2.7)	0	0	0	2 (2.7)
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Pancytopenia	1 (1.4)	0	0	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	0	1 (1.4)	0
White blood cell count decreased	1 (1.4)	0	0	0	1 (1.4)
Infections					

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	33 (44.6)	1 (1.4)	7 (9.5)	17 (23.0)	8 (10.8)
Device related infection	3 (4.1)	0	0	3 (4.1)	0
Oral herpes	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Clostridium difficile colitis	2 (2.7)	0	0	2 (2.7)	0
Conjunctivitis	2 (2.7)	0	2 (2.7)	0	0
Enterococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia urinary tract infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Pneumonia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Upper respiratory tract infection	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile infection	1 (1.4)	0	1 (1.4)	0	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus viraemia	1 (1.4)	0	1 (1.4)	0	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (1.4)	1 (1.4)	0	0	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Hypogammaglobulinaemia	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Blood immunoglobulin m decreased	1 (1.4)	1 (1.4)	0	0	0
Serious neurological adverse reactions					
-Total	7 (9.5)	2 (2.7)	2 (2.7)	2 (2.7)	1 (1.4)
Confusional state	2 (2.7)	0	2 (2.7)	0	0
Mental status changes	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Agitation	1 (1.4)	0	0	1 (1.4)	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Irritability	1 (1.4)	1 (1.4)	0	0	0

Hypodiploidy: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0
Seizure	1 (1.4)	0	0	0	1 (1.4)
Tumour Lysis Syndrome					
-Total	2 (2.7)	0	0	2 (2.7)	0
Tumour lysis syndrome	2 (2.7)	0	0	2 (2.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200i
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	0	2 (50.0)	0
Infections					
-Total	2 (50.0)	0	0	2 (50.0)	0
Cytomegalovirus viraemia	1 (25.0)	0	1 (25.0)	0	0
Enterococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Streptococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200i
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (54.9)	2 (2.8)	9 (12.7)	14 (19.7)	14 (19.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (9.9)	0	0	2 (2.8)	5 (7.0)
Anaemia	4 (5.6)	0	1 (1.4)	3 (4.2)	0
Neutropenia	2 (2.8)	0	0	0	2 (2.8)
Neutrophil count decreased	2 (2.8)	0	0	0	2 (2.8)
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Pancytopenia	1 (1.4)	0	0	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	0	1 (1.4)	0
White blood cell count decreased	1 (1.4)	0	0	0	1 (1.4)
Infections					

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	31 (43.7)	1 (1.4)	7 (9.9)	15 (21.1)	8 (11.3)
Device related infection	3 (4.2)	0	0	3 (4.2)	0
Oral herpes	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Clostridium difficile colitis	2 (2.8)	0	0	2 (2.8)	0
Conjunctivitis	2 (2.8)	0	2 (2.8)	0	0
Escherichia bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Escherichia urinary tract infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Pneumonia	2 (2.8)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Upper respiratory tract infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile infection	1 (1.4)	0	1 (1.4)	0	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Sinusitis	1 (1.4)	1 (1.4)	0	0	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Hypogammaglobulinaemia	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	8 (11.3)	3 (4.2)	2 (2.8)	2 (2.8)	1 (1.4)
Mental status changes	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Confusional state	2 (2.8)	0	2 (2.8)	0	0
Agitation	1 (1.4)	0	0	1 (1.4)	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Irritability	1 (1.4)	1 (1.4)	0	0	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0
Seizure	1 (1.4)	0	0	0	1 (1.4)
Tumour Lysis Syndrome					
-Total	2 (2.8)	0	0	2 (2.8)	0

BCR-ABL1-like: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (2.8)	0	0	2 (2.8)	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200j
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (59.1)	1 (4.5)	4 (18.2)	4 (18.2)	4 (18.2)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (9.1)	0	0	0	2 (9.1)
Neutropenia	2 (9.1)	0	0	0	2 (9.1)
Anaemia	1 (4.5)	0	1 (4.5)	0	0
Leukopenia	1 (4.5)	0	0	0	1 (4.5)
Infections					
-Total	12 (54.5)	1 (4.5)	4 (18.2)	5 (22.7)	2 (9.1)
Conjunctivitis	2 (9.1)	0	2 (9.1)	0	0
Device related infection	2 (9.1)	0	0	2 (9.1)	0
Upper respiratory tract infection	2 (9.1)	1 (4.5)	1 (4.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alpha haemolytic streptococcal infection	1 (4.5)	0	0	1 (4.5)	0
Bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Candida sepsis	1 (4.5)	0	0	0	1 (4.5)
Escherichia bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Escherichia urinary tract infection	1 (4.5)	0	1 (4.5)	0	0
Gastroenteritis	1 (4.5)	0	0	1 (4.5)	0
Parainfluenzae virus infection	1 (4.5)	0	1 (4.5)	0	0
Pneumonia fungal	1 (4.5)	0	0	1 (4.5)	0
Sepsis	1 (4.5)	0	0	0	1 (4.5)
Sinusitis	1 (4.5)	1 (4.5)	0	0	0
Serious neurological adverse reactions					
-Total	1 (4.5)	1 (4.5)	0	0	0
Irritability	1 (4.5)	1 (4.5)	0	0	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200j
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (54.7)	2 (3.8)	5 (9.4)	12 (22.6)	10 (18.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (9.4)	0	0	2 (3.8)	3 (5.7)
Anaemia	3 (5.7)	0	0	3 (5.7)	0
Neutrophil count decreased	2 (3.8)	0	0	0	2 (3.8)
Pancytopenia	1 (1.9)	0	0	0	1 (1.9)
Thrombocytopenia	1 (1.9)	0	0	1 (1.9)	0
White blood cell count decreased	1 (1.9)	0	0	0	1 (1.9)
Infections					
-Total	21 (39.6)	0	3 (5.7)	12 (22.6)	6 (11.3)
Oral herpes	3 (5.7)	0	2 (3.8)	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	2 (3.8)	0	0	2 (3.8)	0
Enterococcal bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Klebsiella sepsis	2 (3.8)	0	0	0	2 (3.8)
Pneumonia	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Staphylococcal bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Abscess limb	1 (1.9)	0	0	1 (1.9)	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Cellulitis	1 (1.9)	0	0	1 (1.9)	0
Clostridium difficile infection	1 (1.9)	0	1 (1.9)	0	0
Croup infectious	1 (1.9)	0	0	1 (1.9)	0
Cytomegalovirus viraemia	1 (1.9)	0	1 (1.9)	0	0
Device related infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	0	0	1 (1.9)
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Fungal skin infection	1 (1.9)	0	1 (1.9)	0	0
Human polyomavirus infection	1 (1.9)	0	0	0	1 (1.9)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Metapneumovirus infection	1 (1.9)	0	1 (1.9)	0	0
Pneumonia fungal	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	0	0	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	0	1 (1.9)	0	0
Rhinovirus infection	1 (1.9)	0	1 (1.9)	0	0
Serratia infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Streptococcal infection	1 (1.9)	0	0	1 (1.9)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (7.5)	2 (3.8)	2 (3.8)	0	0
Hypogammaglobulinaemia	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Blood immunoglobulin m decreased	1 (1.9)	1 (1.9)	0	0	0
Serious neurological adverse reactions					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (13.2)	2 (3.8)	2 (3.8)	2 (3.8)	1 (1.9)
Mental status changes	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Confusional state	2 (3.8)	0	2 (3.8)	0	0
Agitation	1 (1.9)	0	0	1 (1.9)	0
Hyporesponsive to stimuli	1 (1.9)	0	0	1 (1.9)	0
Leukoencephalopathy	1 (1.9)	0	0	1 (1.9)	0
Seizure	1 (1.9)	0	0	0	1 (1.9)
Tumour Lysis Syndrome					
-Total	2 (3.8)	0	0	2 (3.8)	0
Tumour lysis syndrome	2 (3.8)	0	0	2 (3.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200k
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (56.0)	3 (4.0)	9 (12.0)	16 (21.3)	14 (18.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (9.3)	0	0	2 (2.7)	5 (6.7)
Anaemia	4 (5.3)	0	1 (1.3)	3 (4.0)	0
Neutropenia	2 (2.7)	0	0	0	2 (2.7)
Neutrophil count decreased	2 (2.7)	0	0	0	2 (2.7)
Leukopenia	1 (1.3)	0	0	0	1 (1.3)
Pancytopenia	1 (1.3)	0	0	0	1 (1.3)
Thrombocytopenia	1 (1.3)	0	0	1 (1.3)	0
White blood cell count decreased	1 (1.3)	0	0	0	1 (1.3)
Infections					

Region: US

	All patients N=75				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	33 (44.0)	1 (1.3)	7 (9.3)	17 (22.7)	8 (10.7)
Device related infection	3 (4.0)	0	0	3 (4.0)	0
Oral herpes	3 (4.0)	0	2 (2.7)	1 (1.3)	0
Clostridium difficile colitis	2 (2.7)	0	0	2 (2.7)	0
Conjunctivitis	2 (2.7)	0	2 (2.7)	0	0
Enterococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia urinary tract infection	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Pneumonia	2 (2.7)	0	1 (1.3)	0	1 (1.3)
Pneumonia fungal	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Upper respiratory tract infection	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Abscess limb	1 (1.3)	0	0	1 (1.3)	0
Alpha haemolytic streptococcal infection	1 (1.3)	0	0	1 (1.3)	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Candida sepsis	1 (1.3)	0	0	0	1 (1.3)
Cellulitis	1 (1.3)	0	0	1 (1.3)	0
Clostridium difficile infection	1 (1.3)	0	1 (1.3)	0	0
Croup infectious	1 (1.3)	0	0	1 (1.3)	0
Cytomegalovirus viraemia	1 (1.3)	0	1 (1.3)	0	0
Escherichia infection	1 (1.3)	0	0	1 (1.3)	0
Escherichia sepsis	1 (1.3)	0	0	0	1 (1.3)
Fungal skin infection	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis	1 (1.3)	0	0	1 (1.3)	0
Human polyomavirus infection	1 (1.3)	0	0	0	1 (1.3)
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Metapneumovirus infection	1 (1.3)	0	1 (1.3)	0	0
Parainfluenzae virus infection	1 (1.3)	0	1 (1.3)	0	0
Respiratory syncytial virus bronchitis	1 (1.3)	0	0	1 (1.3)	0
Respiratory syncytial virus infection	1 (1.3)	0	1 (1.3)	0	0
Rhinovirus infection	1 (1.3)	0	1 (1.3)	0	0
Sepsis	1 (1.3)	0	0	0	1 (1.3)
Serratia infection	1 (1.3)	0	0	1 (1.3)	0

Region: US

	All patients N=75				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (1.3)	1 (1.3)	0	0	0
Staphylococcal infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal scalded skin syndrome	1 (1.3)	0	1 (1.3)	0	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Streptococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Streptococcal infection	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (5.3)	2 (2.7)	2 (2.7)	0	0
Hypogammaglobulinaemia	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Blood immunoglobulin m decreased	1 (1.3)	1 (1.3)	0	0	0
Serious neurological adverse reactions					
-Total	8 (10.7)	3 (4.0)	2 (2.7)	2 (2.7)	1 (1.3)
Mental status changes	3 (4.0)	2 (2.7)	0	1 (1.3)	0
Confusional state	2 (2.7)	0	2 (2.7)	0	0
Agitation	1 (1.3)	0	0	1 (1.3)	0
Hyporesponsive to stimuli	1 (1.3)	0	0	1 (1.3)	0
Irritability	1 (1.3)	1 (1.3)	0	0	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukoencephalopathy	1 (1.3)	0	0	1 (1.3)	0
Seizure	1 (1.3)	0	0	0	1 (1.3)
Tumour Lysis Syndrome					
-Total	2 (2.7)	0	0	2 (2.7)	0
Tumour lysis syndrome	2 (2.7)	0	0	2 (2.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200l
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (59.4)	2 (6.3)	2 (6.3)	9 (28.1)	6 (18.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (9.4)	0	0	2 (6.3)	1 (3.1)
Anaemia	3 (9.4)	0	0	3 (9.4)	0
Neutrophil count decreased	1 (3.1)	0	0	0	1 (3.1)
Thrombocytopenia	1 (3.1)	0	0	1 (3.1)	0
Infections					
-Total	16 (50.0)	1 (3.1)	2 (6.3)	8 (25.0)	5 (15.6)
Enterococcal bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Klebsiella sepsis	2 (6.3)	0	0	0	2 (6.3)
Staphylococcal bacteraemia	2 (6.3)	0	0	2 (6.3)	0

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Conjunctivitis	1 (3.1)	0	1 (3.1)	0	0
Croup infectious	1 (3.1)	0	0	1 (3.1)	0
Cytomegalovirus viraemia	1 (3.1)	0	1 (3.1)	0	0
Device related infection	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	0	0	1 (3.1)
Escherichia urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Fungal skin infection	1 (3.1)	0	1 (3.1)	0	0
Klebsiella infection	1 (3.1)	0	0	1 (3.1)	0
Oral herpes	1 (3.1)	0	1 (3.1)	0	0
Pneumonia	1 (3.1)	0	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	0	0	1 (3.1)	0
Rhinovirus infection	1 (3.1)	0	1 (3.1)	0	0
Sepsis	1 (3.1)	0	0	0	1 (3.1)

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Upper respiratory tract infection	1 (3.1)	1 (3.1)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Hypogammaglobulinaemia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Blood immunoglobulin m decreased	1 (3.1)	1 (3.1)	0	0	0
Serious neurological adverse reactions					
-Total	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Mental status changes	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Leukoencephalopathy	1 (3.1)	0	0	1 (3.1)	0
Tumour Lysis Syndrome					
-Total	2 (6.3)	0	0	2 (6.3)	0
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200l
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (53.5)	1 (2.3)	7 (16.3)	7 (16.3)	8 (18.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (9.3)	0	0	0	4 (9.3)
Neutropenia	2 (4.7)	0	0	0	2 (4.7)
Anaemia	1 (2.3)	0	1 (2.3)	0	0
Leukopenia	1 (2.3)	0	0	0	1 (2.3)
Neutrophil count decreased	1 (2.3)	0	0	0	1 (2.3)
Pancytopenia	1 (2.3)	0	0	0	1 (2.3)
White blood cell count decreased	1 (2.3)	0	0	0	1 (2.3)
Infections					
-Total	17 (39.5)	0	5 (11.6)	9 (20.9)	3 (7.0)

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (4.7)	0	0	2 (4.7)	0
Oral herpes	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Alpha haemolytic streptococcal infection	1 (2.3)	0	0	1 (2.3)	0
Bronchopulmonary aspergillosis	1 (2.3)	0	0	1 (2.3)	0
Candida sepsis	1 (2.3)	0	0	0	1 (2.3)
Cellulitis	1 (2.3)	0	0	1 (2.3)	0
Clostridium difficile colitis	1 (2.3)	0	0	1 (2.3)	0
Clostridium difficile infection	1 (2.3)	0	1 (2.3)	0	0
Conjunctivitis	1 (2.3)	0	1 (2.3)	0	0
Escherichia bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Escherichia infection	1 (2.3)	0	0	1 (2.3)	0
Escherichia urinary tract infection	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis	1 (2.3)	0	0	1 (2.3)	0
Human polyomavirus infection	1 (2.3)	0	0	0	1 (2.3)
Metapneumovirus infection	1 (2.3)	0	1 (2.3)	0	0
Parainfluenzae virus infection	1 (2.3)	0	1 (2.3)	0	0
Pneumonia	1 (2.3)	0	0	0	1 (2.3)

Prior SCT therapy: No

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	1 (2.3)	0	0	1 (2.3)	0
Respiratory syncytial virus infection	1 (2.3)	0	1 (2.3)	0	0
Serratia infection	1 (2.3)	0	0	1 (2.3)	0
Sinusitis	1 (2.3)	1 (2.3)	0	0	0
Staphylococcal infection	1 (2.3)	0	0	1 (2.3)	0
Streptococcal infection	1 (2.3)	0	0	1 (2.3)	0
Upper respiratory tract infection	1 (2.3)	0	1 (2.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (2.3)	0	1 (2.3)	0	0
Hypogammaglobulinaemia	1 (2.3)	0	1 (2.3)	0	0
Serious neurological adverse reactions					
-Total	5 (11.6)	2 (4.7)	2 (4.7)	0	1 (2.3)
Confusional state	2 (4.7)	0	2 (4.7)	0	0
Agitation	1 (2.3)	0	0	1 (2.3)	0
Hyporesponsive to stimuli	1 (2.3)	0	0	1 (2.3)	0
Irritability	1 (2.3)	1 (2.3)	0	0	0
Mental status changes	1 (2.3)	1 (2.3)	0	0	0

Prior SCT therapy: No

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Seizure	1 (2.3)	0	0	0	1 (2.3)

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200m
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (55.6)	0	2 (11.1)	6 (33.3)	2 (11.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Anaemia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Neutropenia	1 (5.6)	0	0	0	1 (5.6)
Infections					
-Total	9 (50.0)	0	2 (11.1)	6 (33.3)	1 (5.6)
Conjunctivitis	2 (11.1)	0	2 (11.1)	0	0
Device related infection	2 (11.1)	0	0	2 (11.1)	0
Escherichia urinary tract infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alpha haemolytic streptococcal infection	1 (5.6)	0	0	1 (5.6)	0
Bronchopulmonary aspergillosis	1 (5.6)	0	0	1 (5.6)	0
Clostridium difficile colitis	1 (5.6)	0	0	1 (5.6)	0
Escherichia infection	1 (5.6)	0	0	1 (5.6)	0
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Streptococcal infection	1 (5.6)	0	0	1 (5.6)	0
Serious neurological adverse reactions					
-Total	1 (5.6)	0	1 (5.6)	0	0
Confusional state	1 (5.6)	0	1 (5.6)	0	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200m
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (56.1)	3 (5.3)	7 (12.3)	10 (17.5)	12 (21.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (8.8)	0	0	1 (1.8)	4 (7.0)
Anaemia	2 (3.5)	0	0	2 (3.5)	0
Neutrophil count decreased	2 (3.5)	0	0	0	2 (3.5)
Leukopenia	1 (1.8)	0	0	0	1 (1.8)
Neutropenia	1 (1.8)	0	0	0	1 (1.8)
Pancytopenia	1 (1.8)	0	0	0	1 (1.8)
Thrombocytopenia	1 (1.8)	0	0	1 (1.8)	0
White blood cell count decreased	1 (1.8)	0	0	0	1 (1.8)
Infections					

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (42.1)	1 (1.8)	5 (8.8)	11 (19.3)	7 (12.3)
Oral herpes	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Enterococcal bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Escherichia bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Klebsiella sepsis	2 (3.5)	0	0	0	2 (3.5)
Pneumonia fungal	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Staphylococcal bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Upper respiratory tract infection	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Abscess limb	1 (1.8)	0	0	1 (1.8)	0
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Candida sepsis	1 (1.8)	0	0	0	1 (1.8)
Cellulitis	1 (1.8)	0	0	1 (1.8)	0
Clostridium difficile colitis	1 (1.8)	0	0	1 (1.8)	0
Clostridium difficile infection	1 (1.8)	0	1 (1.8)	0	0
Croup infectious	1 (1.8)	0	0	1 (1.8)	0
Cytomegalovirus viraemia	1 (1.8)	0	1 (1.8)	0	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Escherichia sepsis	1 (1.8)	0	0	0	1 (1.8)

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis	1 (1.8)	0	0	1 (1.8)	0
Human polyomavirus infection	1 (1.8)	0	0	0	1 (1.8)
Klebsiella infection	1 (1.8)	0	0	1 (1.8)	0
Metapneumovirus infection	1 (1.8)	0	1 (1.8)	0	0
Parainfluenzae virus infection	1 (1.8)	0	1 (1.8)	0	0
Pneumonia	1 (1.8)	0	1 (1.8)	0	0
Respiratory syncytial virus bronchitis	1 (1.8)	0	0	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	0	1 (1.8)	0	0
Rhinovirus infection	1 (1.8)	0	1 (1.8)	0	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Serratia infection	1 (1.8)	0	0	1 (1.8)	0
Sinusitis	1 (1.8)	1 (1.8)	0	0	0
Staphylococcal infection	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal scalded skin syndrome	1 (1.8)	0	1 (1.8)	0	0
Staphylococcal sepsis	1 (1.8)	0	0	0	1 (1.8)
Streptococcal bacteraemia	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Hypogammaglobulinaemia	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Blood immunoglobulin m decreased	1 (1.8)	1 (1.8)	0	0	0
Serious neurological adverse reactions					
-Total	7 (12.3)	3 (5.3)	1 (1.8)	2 (3.5)	1 (1.8)
Mental status changes	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Agitation	1 (1.8)	0	0	1 (1.8)	0
Confusional state	1 (1.8)	0	1 (1.8)	0	0
Hyporesponsive to stimuli	1 (1.8)	0	0	1 (1.8)	0
Irritability	1 (1.8)	1 (1.8)	0	0	0
Leukoencephalopathy	1 (1.8)	0	0	1 (1.8)	0
Seizure	1 (1.8)	0	0	0	1 (1.8)
Tumour Lysis Syndrome					
-Total	2 (3.5)	0	0	2 (3.5)	0
Tumour lysis syndrome	2 (3.5)	0	0	2 (3.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200n
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (40.9)	1 (4.5)	3 (13.6)	3 (13.6)	2 (9.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Anaemia	2 (9.1)	0	0	2 (9.1)	0
Neutrophil count decreased	1 (4.5)	0	0	0	1 (4.5)
Thrombocytopenia	1 (4.5)	0	0	1 (4.5)	0
Infections					
-Total	5 (22.7)	0	2 (9.1)	3 (13.6)	0
Conjunctivitis	1 (4.5)	0	1 (4.5)	0	0
Croup infectious	1 (4.5)	0	0	1 (4.5)	0
Escherichia urinary tract infection	1 (4.5)	0	1 (4.5)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (4.5)	0	0	1 (4.5)	0
Oral herpes	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Hypogammaglobulinaemia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Serious neurological adverse reactions					
-Total	2 (9.1)	1 (4.5)	0	0	1 (4.5)
Agitation	1 (4.5)	0	0	1 (4.5)	0
Hyporesponsive to stimuli	1 (4.5)	0	0	1 (4.5)	0
Mental status changes	1 (4.5)	1 (4.5)	0	0	0
Seizure	1 (4.5)	0	0	0	1 (4.5)
Tumour Lysis Syndrome					
-Total	1 (4.5)	0	0	1 (4.5)	0
Tumour lysis syndrome	1 (4.5)	0	0	1 (4.5)	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200n
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (62.3)	2 (3.8)	6 (11.3)	13 (24.5)	12 (22.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (9.4)	0	0	1 (1.9)	4 (7.5)
Anaemia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Neutropenia	2 (3.8)	0	0	0	2 (3.8)
Leukopenia	1 (1.9)	0	0	0	1 (1.9)
Neutrophil count decreased	1 (1.9)	0	0	0	1 (1.9)
Pancytopenia	1 (1.9)	0	0	0	1 (1.9)
White blood cell count decreased	1 (1.9)	0	0	0	1 (1.9)
Infections					
-Total	28 (52.8)	1 (1.9)	5 (9.4)	14 (26.4)	8 (15.1)

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	3 (5.7)	0	0	3 (5.7)	0
Clostridium difficile colitis	2 (3.8)	0	0	2 (3.8)	0
Enterococcal bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Escherichia bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Klebsiella sepsis	2 (3.8)	0	0	0	2 (3.8)
Oral herpes	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Pneumonia	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Pneumonia fungal	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Upper respiratory tract infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Abscess limb	1 (1.9)	0	0	1 (1.9)	0
Alpha haemolytic streptococcal infection	1 (1.9)	0	0	1 (1.9)	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Candida sepsis	1 (1.9)	0	0	0	1 (1.9)
Cellulitis	1 (1.9)	0	0	1 (1.9)	0
Clostridium difficile infection	1 (1.9)	0	1 (1.9)	0	0
Conjunctivitis	1 (1.9)	0	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus viraemia	1 (1.9)	0	1 (1.9)	0	0
Escherichia infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	0	0	1 (1.9)
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Fungal skin infection	1 (1.9)	0	1 (1.9)	0	0
Human polyomavirus infection	1 (1.9)	0	0	0	1 (1.9)
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Metapneumovirus infection	1 (1.9)	0	1 (1.9)	0	0
Parainfluenzae virus infection	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	0	0	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	0	1 (1.9)	0	0
Rhinovirus infection	1 (1.9)	0	1 (1.9)	0	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Serratia infection	1 (1.9)	0	0	1 (1.9)	0
Sinusitis	1 (1.9)	1 (1.9)	0	0	0
Staphylococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal infection	1 (1.9)	0	0	1 (1.9)	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Streptococcal infection	1 (1.9)	0	0	1 (1.9)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Blood immunoglobulin m decreased	1 (1.9)	1 (1.9)	0	0	0
Hypogammaglobulinaemia	1 (1.9)	0	1 (1.9)	0	0
Serious neurological adverse reactions					
-Total	6 (11.3)	2 (3.8)	2 (3.8)	2 (3.8)	0
Confusional state	2 (3.8)	0	2 (3.8)	0	0
Mental status changes	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Irritability	1 (1.9)	1 (1.9)	0	0	0
Leukoencephalopathy	1 (1.9)	0	0	1 (1.9)	0
Tumour Lysis Syndrome					
-Total	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200o
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	0	0	4 (57.1)	1 (14.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Anaemia	1 (14.3)	0	0	1 (14.3)	0
Leukopenia	1 (14.3)	0	0	0	1 (14.3)
Neutropenia	1 (14.3)	0	0	0	1 (14.3)
Infections					
-Total	3 (42.9)	0	0	3 (42.9)	0
Device related infection	1 (14.3)	0	0	1 (14.3)	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Escherichia infection	1 (14.3)	0	0	1 (14.3)	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (14.3)	1 (14.3)	0	0	0
Streptococcal infection	1 (14.3)	0	0	1 (14.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (14.3)	1 (14.3)	0	0	0
Hypogammaglobulinaemia	1 (14.3)	1 (14.3)	0	0	0
Serious neurological adverse reactions					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Irritability	1 (14.3)	1 (14.3)	0	0	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0
Tumour Lysis Syndrome					
-Total	2 (28.6)	0	0	2 (28.6)	0
Tumour lysis syndrome	2 (28.6)	0	0	2 (28.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200o
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (54.4)	3 (4.4)	9 (13.2)	12 (17.6)	13 (19.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (7.4)	0	0	1 (1.5)	4 (5.9)
Anaemia	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Neutrophil count decreased	2 (2.9)	0	0	0	2 (2.9)
Neutropenia	1 (1.5)	0	0	0	1 (1.5)
Pancytopenia	1 (1.5)	0	0	0	1 (1.5)
Thrombocytopenia	1 (1.5)	0	0	1 (1.5)	0
White blood cell count decreased	1 (1.5)	0	0	0	1 (1.5)
Infections					
-Total	30 (44.1)	1 (1.5)	7 (10.3)	14 (20.6)	8 (11.8)

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Clostridium difficile colitis	2 (2.9)	0	0	2 (2.9)	0
Conjunctivitis	2 (2.9)	0	2 (2.9)	0	0
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Enterococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Escherichia urinary tract infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Klebsiella sepsis	2 (2.9)	0	0	0	2 (2.9)
Pneumonia	2 (2.9)	0	1 (1.5)	0	1 (1.5)
Pneumonia fungal	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Upper respiratory tract infection	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Alpha haemolytic streptococcal infection	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Candida sepsis	1 (1.5)	0	0	0	1 (1.5)
Cellulitis	1 (1.5)	0	0	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (1.5)	0	1 (1.5)	0	0
Croup infectious	1 (1.5)	0	0	1 (1.5)	0
Cytomegalovirus viraemia	1 (1.5)	0	1 (1.5)	0	0
Escherichia bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	0	0	1 (1.5)
Fungal skin infection	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis	1 (1.5)	0	0	1 (1.5)	0
Human polyomavirus infection	1 (1.5)	0	0	0	1 (1.5)
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Metapneumovirus infection	1 (1.5)	0	1 (1.5)	0	0
Parainfluenzae virus infection	1 (1.5)	0	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	1 (1.5)	0	0
Rhinovirus infection	1 (1.5)	0	1 (1.5)	0	0
Sepsis	1 (1.5)	0	0	0	1 (1.5)
Serratia infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal infection	1 (1.5)	0	0	1 (1.5)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	1 (1.5)	0	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Hypogammaglobulinaemia	2 (2.9)	0	2 (2.9)	0	0
Blood immunoglobulin m decreased	1 (1.5)	1 (1.5)	0	0	0
Serious neurological adverse reactions					
-Total	6 (8.8)	2 (2.9)	2 (2.9)	1 (1.5)	1 (1.5)
Confusional state	2 (2.9)	0	2 (2.9)	0	0
Mental status changes	2 (2.9)	2 (2.9)	0	0	0
Agitation	1 (1.5)	0	0	1 (1.5)	0
Hyporesponsive to stimuli	1 (1.5)	0	0	1 (1.5)	0
Leukoencephalopathy	1 (1.5)	0	0	1 (1.5)	0
Seizure	1 (1.5)	0	0	0	1 (1.5)

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accepted by the manufacturing facility.
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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200p
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	0	2 (50.0)	0	0
Infections					
-Total	2 (50.0)	0	2 (50.0)	0	0
Conjunctivitis	1 (25.0)	0	1 (25.0)	0	0
Metapneumovirus infection	1 (25.0)	0	1 (25.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200p
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (56.3)	3 (4.2)	7 (9.9)	16 (22.5)	14 (19.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (9.9)	0	0	2 (2.8)	5 (7.0)
Anaemia	4 (5.6)	0	1 (1.4)	3 (4.2)	0
Neutropenia	2 (2.8)	0	0	0	2 (2.8)
Neutrophil count decreased	2 (2.8)	0	0	0	2 (2.8)
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Pancytopenia	1 (1.4)	0	0	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	0	1 (1.4)	0
White blood cell count decreased	1 (1.4)	0	0	0	1 (1.4)
Infections					

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	31 (43.7)	1 (1.4)	5 (7.0)	17 (23.9)	8 (11.3)
Device related infection	3 (4.2)	0	0	3 (4.2)	0
Oral herpes	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Clostridium difficile colitis	2 (2.8)	0	0	2 (2.8)	0
Enterococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Escherichia bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Escherichia urinary tract infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Pneumonia	2 (2.8)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Upper respiratory tract infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile infection	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus viraemia	1 (1.4)	0	1 (1.4)	0	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Sinusitis	1 (1.4)	1 (1.4)	0	0	0

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Hypogammaglobulinaemia	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Blood immunoglobulin m decreased	1 (1.4)	1 (1.4)	0	0	0
Serious neurological adverse reactions					
-Total	8 (11.3)	3 (4.2)	2 (2.8)	2 (2.8)	1 (1.4)
Mental status changes	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Confusional state	2 (2.8)	0	2 (2.8)	0	0
Agitation	1 (1.4)	0	0	1 (1.4)	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Irritability	1 (1.4)	1 (1.4)	0	0	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Seizure	1 (1.4)	0	0	0	1 (1.4)
Tumour Lysis Syndrome					
-Total	2 (2.8)	0	0	2 (2.8)	0
Tumour lysis syndrome	2 (2.8)	0	0	2 (2.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200q
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (56.3)	1 (3.1)	7 (21.9)	7 (21.9)	3 (9.4)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Anaemia	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Neutropenia	1 (3.1)	0	0	0	1 (3.1)
Neutrophil count decreased	1 (3.1)	0	0	0	1 (3.1)
Thrombocytopenia	1 (3.1)	0	0	1 (3.1)	0
Infections					
-Total	14 (43.8)	1 (3.1)	5 (15.6)	7 (21.9)	1 (3.1)
Device related infection	3 (9.4)	0	0	3 (9.4)	0
Conjunctivitis	2 (6.3)	0	2 (6.3)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Upper respiratory tract infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Alpha haemolytic streptococcal infection	1 (3.1)	0	0	1 (3.1)	0
Croup infectious	1 (3.1)	0	0	1 (3.1)	0
Cytomegalovirus viraemia	1 (3.1)	0	1 (3.1)	0	0
Enterococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Parainfluenzae virus infection	1 (3.1)	0	1 (3.1)	0	0
Pneumonia	1 (3.1)	0	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	0	0	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	0	1 (3.1)	0	0
Rhinovirus infection	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal scalded skin syndrome	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Streptococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (6.3)	0	2 (6.3)	0	0
Hypogammaglobulinaemia	2 (6.3)	0	2 (6.3)	0	0
Serious neurological adverse reactions					
-Total	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Mental status changes	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Confusional state	1 (3.1)	0	1 (3.1)	0	0
Tumour Lysis Syndrome					
-Total	1 (3.1)	0	0	1 (3.1)	0
Tumour lysis syndrome	1 (3.1)	0	0	1 (3.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200q
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (50.0)	2 (6.3)	2 (6.3)	7 (21.9)	5 (15.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (12.5)	0	0	1 (3.1)	3 (9.4)
Anaemia	1 (3.1)	0	0	1 (3.1)	0
Leukopenia	1 (3.1)	0	0	0	1 (3.1)
Neutropenia	1 (3.1)	0	0	0	1 (3.1)
Neutrophil count decreased	1 (3.1)	0	0	0	1 (3.1)
Pancytopenia	1 (3.1)	0	0	0	1 (3.1)
White blood cell count decreased	1 (3.1)	0	0	0	1 (3.1)
Infections					
-Total	12 (37.5)	0	2 (6.3)	8 (25.0)	2 (6.3)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Bronchopulmonary aspergillosis	1 (3.1)	0	0	1 (3.1)	0
Cellulitis	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile infection	1 (3.1)	0	1 (3.1)	0	0
Enterococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	0	0	1 (3.1)
Fungal skin infection	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis	1 (3.1)	0	0	1 (3.1)	0
Human polyomavirus infection	1 (3.1)	0	0	0	1 (3.1)
Metapneumovirus infection	1 (3.1)	0	1 (3.1)	0	0
Serratia infection	1 (3.1)	0	0	1 (3.1)	0
Sinusitis	1 (3.1)	1 (3.1)	0	0	0
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (6.3)	2 (6.3)	0	0	0
Blood immunoglobulin m decreased	1 (3.1)	1 (3.1)	0	0	0
Hypogammaglobulinaemia	1 (3.1)	1 (3.1)	0	0	0
Serious neurological adverse reactions					
-Total	2 (6.3)	2 (6.3)	0	0	0
Irritability	1 (3.1)	1 (3.1)	0	0	0
Mental status changes	1 (3.1)	1 (3.1)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.1)	0	0	1 (3.1)	0
Tumour lysis syndrome	1 (3.1)	0	0	1 (3.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200q
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	0	2 (18.2)	6 (54.5)
Infections					
-Total	7 (63.6)	0	0	2 (18.2)	5 (45.5)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	0	0	1 (9.1)	0
Escherichia infection	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Oral herpes	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Pneumonia fungal	1 (9.1)	0	0	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Streptococcal infection	1 (9.1)	0	0	1 (9.1)	0
Serious neurological adverse reactions					
-Total	3 (27.3)	0	1 (9.1)	1 (9.1)	1 (9.1)
Agitation	1 (9.1)	0	0	1 (9.1)	0
Confusional state	1 (9.1)	0	1 (9.1)	0	0
Hyporesponsive to stimuli	1 (9.1)	0	0	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	0	1 (9.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200r
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (37.5)	0	1 (12.5)	0	2 (25.0)
Infections					
-Total	2 (25.0)	0	0	0	2 (25.0)
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	1 (12.5)	0	0
Human polyomavirus infection	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (12.5)	0	1 (12.5)	0	0
Confusional state	1 (12.5)	0	1 (12.5)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200r
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (73.9)	1 (4.3)	4 (17.4)	8 (34.8)	4 (17.4)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (17.4)	0	0	2 (8.7)	2 (8.7)
Anaemia	2 (8.7)	0	0	2 (8.7)	0
Leukopenia	1 (4.3)	0	0	0	1 (4.3)
Neutropenia	1 (4.3)	0	0	0	1 (4.3)
Pancytopenia	1 (4.3)	0	0	0	1 (4.3)
Infections					
-Total	13 (56.5)	0	4 (17.4)	8 (34.8)	1 (4.3)
Device related infection	2 (8.7)	0	0	2 (8.7)	0
Escherichia bacteraemia	2 (8.7)	0	0	2 (8.7)	0

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (4.3)	0	0	1 (4.3)	0
Bronchopulmonary aspergillosis	1 (4.3)	0	0	1 (4.3)	0
Escherichia urinary tract infection	1 (4.3)	0	0	1 (4.3)	0
Gastroenteritis	1 (4.3)	0	0	1 (4.3)	0
Metapneumovirus infection	1 (4.3)	0	1 (4.3)	0	0
Parainfluenzae virus infection	1 (4.3)	0	1 (4.3)	0	0
Pneumonia	1 (4.3)	0	1 (4.3)	0	0
Pneumonia fungal	1 (4.3)	0	1 (4.3)	0	0
Respiratory syncytial virus bronchitis	1 (4.3)	0	0	1 (4.3)	0
Respiratory syncytial virus infection	1 (4.3)	0	1 (4.3)	0	0
Rhinovirus infection	1 (4.3)	0	1 (4.3)	0	0
Serratia infection	1 (4.3)	0	0	1 (4.3)	0
Sinusitis	1 (4.3)	1 (4.3)	0	0	0
Staphylococcal bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal scalded skin syndrome	1 (4.3)	0	1 (4.3)	0	0
Staphylococcal sepsis	1 (4.3)	0	0	0	1 (4.3)
Upper respiratory tract infection	1 (4.3)	0	1 (4.3)	0	0

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (4.3)	1 (4.3)	0	0	0
Hypogammaglobulinaemia	1 (4.3)	1 (4.3)	0	0	0
Serious neurological adverse reactions					
-Total	4 (17.4)	3 (13.0)	0	0	1 (4.3)
Mental status changes	2 (8.7)	2 (8.7)	0	0	0
Agitation	1 (4.3)	0	0	1 (4.3)	0
Hyporesponsive to stimuli	1 (4.3)	0	0	1 (4.3)	0
Irritability	1 (4.3)	1 (4.3)	0	0	0
Seizure	1 (4.3)	0	0	0	1 (4.3)
Tumour Lysis Syndrome					
-Total	1 (4.3)	0	0	1 (4.3)	0
Tumour lysis syndrome	1 (4.3)	0	0	1 (4.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200r
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (37.5)	0	2 (8.3)	3 (12.5)	4 (16.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (8.3)	0	0	0	2 (8.3)
Anaemia	1 (4.2)	0	1 (4.2)	0	0
Neutropenia	1 (4.2)	0	0	0	1 (4.2)
Neutrophil count decreased	1 (4.2)	0	0	0	1 (4.2)
White blood cell count decreased	1 (4.2)	0	0	0	1 (4.2)
Infections					
-Total	7 (29.2)	0	1 (4.2)	4 (16.7)	2 (8.3)
Alpha haemolytic streptococcal infection	1 (4.2)	0	0	1 (4.2)	0

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida sepsis	1 (4.2)	0	0	0	1 (4.2)
Clostridium difficile colitis	1 (4.2)	0	0	1 (4.2)	0
Conjunctivitis	1 (4.2)	0	1 (4.2)	0	0
Device related infection	1 (4.2)	0	0	1 (4.2)	0
Escherichia infection	1 (4.2)	0	0	1 (4.2)	0
Escherichia sepsis	1 (4.2)	0	0	0	1 (4.2)
Escherichia urinary tract infection	1 (4.2)	0	1 (4.2)	0	0
Oral herpes	1 (4.2)	0	1 (4.2)	0	0
Pneumonia fungal	1 (4.2)	0	0	1 (4.2)	0
Staphylococcal infection	1 (4.2)	0	0	1 (4.2)	0
Streptococcal infection	1 (4.2)	0	0	1 (4.2)	0
Serious neurological adverse reactions					
-Total	1 (4.2)	0	1 (4.2)	0	0
Confusional state	1 (4.2)	0	1 (4.2)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 200r
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (65.0)	2 (10.0)	2 (10.0)	5 (25.0)	4 (20.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (5.0)	0	0	0	1 (5.0)
Anaemia	1 (5.0)	0	0	1 (5.0)	0
Neutrophil count decreased	1 (5.0)	0	0	0	1 (5.0)
Thrombocytopenia	1 (5.0)	0	0	1 (5.0)	0
Infections					
-Total	11 (55.0)	1 (5.0)	2 (10.0)	5 (25.0)	3 (15.0)
Enterococcal bacteraemia	2 (10.0)	0	0	2 (10.0)	0
Klebsiella sepsis	2 (10.0)	0	0	0	2 (10.0)

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Clostridium difficile colitis	1 (5.0)	0	0	1 (5.0)	0
Conjunctivitis	1 (5.0)	0	1 (5.0)	0	0
Croup infectious	1 (5.0)	0	0	1 (5.0)	0
Cytomegalovirus viraemia	1 (5.0)	0	1 (5.0)	0	0
Fungal skin infection	1 (5.0)	0	1 (5.0)	0	0
Klebsiella infection	1 (5.0)	0	0	1 (5.0)	0
Oral herpes	1 (5.0)	0	1 (5.0)	0	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Streptococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Upper respiratory tract infection	1 (5.0)	1 (5.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)	0	0
Serious neurological adverse reactions					

Number of previous relapses: >=3

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (10.0)	0	0	2 (10.0)	0
Leukoencephalopathy	1 (5.0)	0	0	1 (5.0)	0
Mental status changes	1 (5.0)	0	0	1 (5.0)	0
Tumour Lysis Syndrome					
-Total	1 (5.0)	0	0	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201a
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (25.0)	0	1 (5.0)	2 (10.0)	2 (10.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (10.0)	0	0	0	2 (10.0)
Neutrophil count decreased	1 (5.0)	0	0	0	1 (5.0)
White blood cell count decreased	1 (5.0)	0	0	0	1 (5.0)
Infections					
-Total	3 (15.0)	0	1 (5.0)	2 (10.0)	0
Bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Device related infection	1 (5.0)	0	0	1 (5.0)	0
Pneumonia	1 (5.0)	0	1 (5.0)	0	0

Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (5.0)	1 (5.0)	0	0	0
Irritability	1 (5.0)	1 (5.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201a
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (21.2)	1 (3.0)	1 (3.0)	2 (6.1)	3 (9.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (12.1)	0	0	2 (6.1)	2 (6.1)
White blood cell count decreased	3 (9.1)	0	0	1 (3.0)	2 (6.1)
Neutrophil count decreased	2 (6.1)	0	0	0	2 (6.1)
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Infections					
-Total	3 (9.1)	1 (3.0)	1 (3.0)	0	1 (3.0)
Bronchitis	1 (3.0)	0	1 (3.0)	0	0
Otitis media	1 (3.0)	0	1 (3.0)	0	0

Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (3.0)	1 (3.0)	0	0	0
Staphylococcal infection	1 (3.0)	0	0	0	1 (3.0)
Viral upper respiratory tract infection	1 (3.0)	1 (3.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.0)	1 (3.0)	0	0	0
Hypogammaglobulinaemia	1 (3.0)	1 (3.0)	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.0)	0	0	1 (3.0)	0
Delirium	1 (3.0)	0	0	1 (3.0)	0
Somnolence	1 (3.0)	0	1 (3.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201a
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (25.0)	0	0	0	2 (25.0)
White blood cell count decreased	2 (25.0)	0	0	0	2 (25.0)
Anaemia	1 (12.5)	0	1 (12.5)	0	0
Neutropenia	1 (12.5)	0	0	0	1 (12.5)
Infections					
-Total	1 (12.5)	0	0	1 (12.5)	0
Device related infection	1 (12.5)	0	1 (12.5)	0	0
Necrotising fasciitis	1 (12.5)	0	0	1 (12.5)	0

Age: >=18

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	1 (12.5)	0	0	1 (12.5)	0
Tumour lysis syndrome	1 (12.5)	0	0	1 (12.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201b
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (27.6)	1 (3.4)	2 (6.9)	2 (6.9)	3 (10.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (13.8)	0	0	2 (6.9)	2 (6.9)
White blood cell count decreased	3 (10.3)	0	0	1 (3.4)	2 (6.9)
Anaemia	1 (3.4)	0	1 (3.4)	0	0
Pancytopenia	1 (3.4)	0	0	1 (3.4)	0
Infections					
-Total	4 (13.8)	1 (3.4)	2 (6.9)	0	1 (3.4)
Bronchitis	1 (3.4)	0	1 (3.4)	0	0
Otitis media	1 (3.4)	0	1 (3.4)	0	0

Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (3.4)	1 (3.4)	0	0	0
Pneumonia	1 (3.4)	0	1 (3.4)	0	0
Staphylococcal infection	1 (3.4)	0	0	0	1 (3.4)
Viral upper respiratory tract infection	1 (3.4)	1 (3.4)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.4)	1 (3.4)	0	0	0
Hypogammaglobulinaemia	1 (3.4)	1 (3.4)	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.4)	0	0	1 (3.4)	0
Delirium	1 (3.4)	0	0	1 (3.4)	0
Somnolence	1 (3.4)	0	1 (3.4)	0	0
Tumour Lysis Syndrome					
-Total	1 (3.4)	0	0	1 (3.4)	0
Tumour lysis syndrome	1 (3.4)	0	0	1 (3.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion

(for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201b
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (21.9)	0	0	3 (9.4)	4 (12.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (12.5)	0	0	0	4 (12.5)
Neutrophil count decreased	3 (9.4)	0	0	0	3 (9.4)
White blood cell count decreased	3 (9.4)	0	0	0	3 (9.4)
Neutropenia	1 (3.1)	0	0	0	1 (3.1)
Infections					
-Total	3 (9.4)	0	0	3 (9.4)	0
Device related infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0

Gender: Female

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Necrotising fasciitis	1 (3.1)	0	0	1 (3.1)	0
Serious neurological adverse reactions					
-Total	1 (3.1)	1 (3.1)	0	0	0
Irritability	1 (3.1)	1 (3.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201c
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (30.0)	1 (2.0)	2 (4.0)	5 (10.0)	7 (14.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (16.0)	0	0	2 (4.0)	6 (12.0)
White blood cell count decreased	6 (12.0)	0	0	1 (2.0)	5 (10.0)
Neutrophil count decreased	3 (6.0)	0	0	0	3 (6.0)
Anaemia	1 (2.0)	0	1 (2.0)	0	0
Neutropenia	1 (2.0)	0	0	0	1 (2.0)
Pancytopenia	1 (2.0)	0	0	1 (2.0)	0
Infections					
-Total	7 (14.0)	1 (2.0)	2 (4.0)	3 (6.0)	1 (2.0)

Race: White

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Bronchitis	1 (2.0)	0	1 (2.0)	0	0
Necrotising fasciitis	1 (2.0)	0	0	1 (2.0)	0
Otitis media	1 (2.0)	0	1 (2.0)	0	0
Parainfluenzae virus infection	1 (2.0)	1 (2.0)	0	0	0
Pneumonia	1 (2.0)	0	1 (2.0)	0	0
Staphylococcal infection	1 (2.0)	0	0	0	1 (2.0)
Viral upper respiratory tract infection	1 (2.0)	1 (2.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (2.0)	1 (2.0)	0	0	0
Hypogammaglobulinaemia	1 (2.0)	1 (2.0)	0	0	0
Serious neurological adverse reactions					
-Total	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Delirium	1 (2.0)	0	0	1 (2.0)	0
Irritability	1 (2.0)	1 (2.0)	0	0	0
Somnolence	1 (2.0)	0	1 (2.0)	0	0

Race: White

Group term Preferred term	All patients N=50 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	1 (2.0)	0	0	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	0	0	1 (2.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201d
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (26.1)	1 (4.3)	1 (4.3)	2 (8.7)	2 (8.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (13.0)	0	0	1 (4.3)	2 (8.7)
White blood cell count decreased	3 (13.0)	0	0	1 (4.3)	2 (8.7)
Anaemia	1 (4.3)	0	1 (4.3)	0	0
Neutrophil count decreased	1 (4.3)	0	0	0	1 (4.3)
Infections					
-Total	3 (13.0)	1 (4.3)	1 (4.3)	1 (4.3)	0
Bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Otitis media	1 (4.3)	0	1 (4.3)	0	0

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	1 (4.3)	1 (4.3)	0	0	0
Viral upper respiratory tract infection	1 (4.3)	1 (4.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (4.3)	1 (4.3)	0	0	0
Hypogammaglobulinaemia	1 (4.3)	1 (4.3)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (4.3)	0	0	1 (4.3)	0
Tumour lysis syndrome	1 (4.3)	0	0	1 (4.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201d
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=38				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (23.7)	0	1 (2.6)	3 (7.9)	5 (13.2)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (13.2)	0	0	1 (2.6)	4 (10.5)
White blood cell count decreased	3 (7.9)	0	0	0	3 (7.9)
Neutrophil count decreased	2 (5.3)	0	0	0	2 (5.3)
Neutropenia	1 (2.6)	0	0	0	1 (2.6)
Pancytopenia	1 (2.6)	0	0	1 (2.6)	0
Infections					
-Total	4 (10.5)	0	1 (2.6)	2 (5.3)	1 (2.6)
Device related infection	2 (5.3)	0	1 (2.6)	1 (2.6)	0

Ethnicity: Other

Group term Preferred term	All patients N=38 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchitis	1 (2.6)	0	1 (2.6)	0	0
Necrotising fasciitis	1 (2.6)	0	0	1 (2.6)	0
Pneumonia	1 (2.6)	0	1 (2.6)	0	0
Staphylococcal infection	1 (2.6)	0	0	0	1 (2.6)
Serious neurological adverse reactions					
-Total	2 (5.3)	1 (2.6)	0	1 (2.6)	0
Delirium	1 (2.6)	0	0	1 (2.6)	0
Irritability	1 (2.6)	1 (2.6)	0	0	0
Somnolence	1 (2.6)	0	1 (2.6)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201e
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (27.8)	1 (1.9)	2 (3.7)	5 (9.3)	7 (13.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (14.8)	0	0	2 (3.7)	6 (11.1)
White blood cell count decreased	6 (11.1)	0	0	1 (1.9)	5 (9.3)
Neutrophil count decreased	3 (5.6)	0	0	0	3 (5.6)
Anaemia	1 (1.9)	0	1 (1.9)	0	0
Neutropenia	1 (1.9)	0	0	0	1 (1.9)
Pancytopenia	1 (1.9)	0	0	1 (1.9)	0
Infections					
-Total	7 (13.0)	1 (1.9)	2 (3.7)	3 (5.6)	1 (1.9)

Response status at study entry: Relapsed disease

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Bronchitis	1 (1.9)	0	1 (1.9)	0	0
Necrotising fasciitis	1 (1.9)	0	0	1 (1.9)	0
Otitis media	1 (1.9)	0	1 (1.9)	0	0
Parainfluenzae virus infection	1 (1.9)	1 (1.9)	0	0	0
Pneumonia	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal infection	1 (1.9)	0	0	0	1 (1.9)
Viral upper respiratory tract infection	1 (1.9)	1 (1.9)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (1.9)	1 (1.9)	0	0	0
Hypogammaglobulinaemia	1 (1.9)	1 (1.9)	0	0	0
Serious neurological adverse reactions					
-Total	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Delirium	1 (1.9)	0	0	1 (1.9)	0
Irritability	1 (1.9)	1 (1.9)	0	0	0
Somnolence	1 (1.9)	0	1 (1.9)	0	0

Response status at study entry: Relapsed disease

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour Lysis Syndrome					
-Total	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201f
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (25.4)	1 (1.7)	2 (3.4)	5 (8.5)	7 (11.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (13.6)	0	0	2 (3.4)	6 (10.2)
White blood cell count decreased	6 (10.2)	0	0	1 (1.7)	5 (8.5)
Neutrophil count decreased	3 (5.1)	0	0	0	3 (5.1)
Anaemia	1 (1.7)	0	1 (1.7)	0	0
Neutropenia	1 (1.7)	0	0	0	1 (1.7)
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	7 (11.9)	1 (1.7)	2 (3.4)	3 (5.1)	1 (1.7)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Necrotising fasciitis	1 (1.7)	0	0	1 (1.7)	0
Otitis media	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	1 (1.7)	0	0	0
Pneumonia	1 (1.7)	0	1 (1.7)	0	0
Staphylococcal infection	1 (1.7)	0	0	0	1 (1.7)
Viral upper respiratory tract infection	1 (1.7)	1 (1.7)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (1.7)	1 (1.7)	0	0	0
Hypogammaglobulinaemia	1 (1.7)	1 (1.7)	0	0	0
Serious neurological adverse reactions					
-Total	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Delirium	1 (1.7)	0	0	1 (1.7)	0
Irritability	1 (1.7)	1 (1.7)	0	0	0
Somnolence	1 (1.7)	0	1 (1.7)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201g
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	0	1 (33.3)	0	0
Infections					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pneumonia	1 (33.3)	0	1 (33.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201g
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (24.1)	1 (1.7)	1 (1.7)	5 (8.6)	7 (12.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (13.8)	0	0	2 (3.4)	6 (10.3)
White blood cell count decreased	6 (10.3)	0	0	1 (1.7)	5 (8.6)
Neutrophil count decreased	3 (5.2)	0	0	0	3 (5.2)
Anaemia	1 (1.7)	0	1 (1.7)	0	0
Neutropenia	1 (1.7)	0	0	0	1 (1.7)
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	6 (10.3)	1 (1.7)	1 (1.7)	3 (5.2)	1 (1.7)

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Necrotising fasciitis	1 (1.7)	0	0	1 (1.7)	0
Otitis media	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	1 (1.7)	0	0	0
Staphylococcal infection	1 (1.7)	0	0	0	1 (1.7)
Viral upper respiratory tract infection	1 (1.7)	1 (1.7)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (1.7)	1 (1.7)	0	0	0
Hypogammaglobulinaemia	1 (1.7)	1 (1.7)	0	0	0
Serious neurological adverse reactions					
-Total	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Delirium	1 (1.7)	0	0	1 (1.7)	0
Irritability	1 (1.7)	1 (1.7)	0	0	0
Somnolence	1 (1.7)	0	1 (1.7)	0	0
Tumour Lysis Syndrome					

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201h
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (25.0)	1 (1.7)	2 (3.3)	5 (8.3)	7 (11.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (13.3)	0	0	2 (3.3)	6 (10.0)
White blood cell count decreased	6 (10.0)	0	0	1 (1.7)	5 (8.3)
Neutrophil count decreased	3 (5.0)	0	0	0	3 (5.0)
Anaemia	1 (1.7)	0	1 (1.7)	0	0
Neutropenia	1 (1.7)	0	0	0	1 (1.7)
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	7 (11.7)	1 (1.7)	2 (3.3)	3 (5.0)	1 (1.7)

Hypodiploidy: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Necrotising fasciitis	1 (1.7)	0	0	1 (1.7)	0
Otitis media	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	1 (1.7)	0	0	0
Pneumonia	1 (1.7)	0	1 (1.7)	0	0
Staphylococcal infection	1 (1.7)	0	0	0	1 (1.7)
Viral upper respiratory tract infection	1 (1.7)	1 (1.7)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (1.7)	1 (1.7)	0	0	0
Hypogammaglobulinaemia	1 (1.7)	1 (1.7)	0	0	0
Serious neurological adverse reactions					
-Total	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Delirium	1 (1.7)	0	0	1 (1.7)	0
Irritability	1 (1.7)	1 (1.7)	0	0	0
Somnolence	1 (1.7)	0	1 (1.7)	0	0

Hypodiploidy: No

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201i
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (25.0)	0	0	1 (25.0)	0
Infections					
-Total	1 (25.0)	0	0	1 (25.0)	0
Bacteraemia	1 (25.0)	0	0	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201i
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (24.6)	1 (1.8)	2 (3.5)	4 (7.0)	7 (12.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (14.0)	0	0	2 (3.5)	6 (10.5)
White blood cell count decreased	6 (10.5)	0	0	1 (1.8)	5 (8.8)
Neutrophil count decreased	3 (5.3)	0	0	0	3 (5.3)
Anaemia	1 (1.8)	0	1 (1.8)	0	0
Neutropenia	1 (1.8)	0	0	0	1 (1.8)
Pancytopenia	1 (1.8)	0	0	1 (1.8)	0
Infections					
-Total	6 (10.5)	1 (1.8)	2 (3.5)	2 (3.5)	1 (1.8)

BCR-ABL1-like: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Necrotising fasciitis	1 (1.8)	0	0	1 (1.8)	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Parainfluenzae virus infection	1 (1.8)	1 (1.8)	0	0	0
Pneumonia	1 (1.8)	0	1 (1.8)	0	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)
Viral upper respiratory tract infection	1 (1.8)	1 (1.8)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (1.8)	1 (1.8)	0	0	0
Hypogammaglobulinaemia	1 (1.8)	1 (1.8)	0	0	0
Serious neurological adverse reactions					
-Total	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Delirium	1 (1.8)	0	0	1 (1.8)	0
Irritability	1 (1.8)	1 (1.8)	0	0	0
Somnolence	1 (1.8)	0	1 (1.8)	0	0
Tumour Lysis Syndrome					

BCR-ABL1-like: No

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.8)	0	0	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201j
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (33.3)	1 (5.6)	1 (5.6)	1 (5.6)	3 (16.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (22.2)	0	0	1 (5.6)	3 (16.7)
Neutrophil count decreased	2 (11.1)	0	0	0	2 (11.1)
White blood cell count decreased	2 (11.1)	0	0	0	2 (11.1)
Neutropenia	1 (5.6)	0	0	0	1 (5.6)
Pancytopenia	1 (5.6)	0	0	1 (5.6)	0
Infections					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pneumonia	1 (5.6)	0	1 (5.6)	0	0
Viral upper respiratory tract infection	1 (5.6)	1 (5.6)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (5.6)	1 (5.6)	0	0	0
Hypogammaglobulinaemia	1 (5.6)	1 (5.6)	0	0	0
Serious neurological adverse reactions					
-Total	1 (5.6)	1 (5.6)	0	0	0
Irritability	1 (5.6)	1 (5.6)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201j
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (20.9)	0	1 (2.3)	4 (9.3)	4 (9.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (9.3)	0	0	1 (2.3)	3 (7.0)
White blood cell count decreased	4 (9.3)	0	0	1 (2.3)	3 (7.0)
Anaemia	1 (2.3)	0	1 (2.3)	0	0
Neutrophil count decreased	1 (2.3)	0	0	0	1 (2.3)
Infections					
-Total	5 (11.6)	0	1 (2.3)	3 (7.0)	1 (2.3)
Device related infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Bacteraemia	1 (2.3)	0	0	1 (2.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchitis	1 (2.3)	0	1 (2.3)	0	0
Necrotising fasciitis	1 (2.3)	0	0	1 (2.3)	0
Otitis media	1 (2.3)	0	1 (2.3)	0	0
Parainfluenzae virus infection	1 (2.3)	1 (2.3)	0	0	0
Staphylococcal infection	1 (2.3)	0	0	0	1 (2.3)
Serious neurological adverse reactions					
-Total	1 (2.3)	0	0	1 (2.3)	0
Delirium	1 (2.3)	0	0	1 (2.3)	0
Somnolence	1 (2.3)	0	1 (2.3)	0	0
Tumour Lysis Syndrome					
-Total	1 (2.3)	0	0	1 (2.3)	0
Tumour lysis syndrome	1 (2.3)	0	0	1 (2.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All

patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201k
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (24.6)	1 (1.6)	2 (3.3)	5 (8.2)	7 (11.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (13.1)	0	0	2 (3.3)	6 (9.8)
White blood cell count decreased	6 (9.8)	0	0	1 (1.6)	5 (8.2)
Neutrophil count decreased	3 (4.9)	0	0	0	3 (4.9)
Anaemia	1 (1.6)	0	1 (1.6)	0	0
Neutropenia	1 (1.6)	0	0	0	1 (1.6)
Pancytopenia	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	7 (11.5)	1 (1.6)	2 (3.3)	3 (4.9)	1 (1.6)

Region: US

Group term Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Bronchitis	1 (1.6)	0	1 (1.6)	0	0
Necrotising fasciitis	1 (1.6)	0	0	1 (1.6)	0
Otitis media	1 (1.6)	0	1 (1.6)	0	0
Parainfluenzae virus infection	1 (1.6)	1 (1.6)	0	0	0
Pneumonia	1 (1.6)	0	1 (1.6)	0	0
Staphylococcal infection	1 (1.6)	0	0	0	1 (1.6)
Viral upper respiratory tract infection	1 (1.6)	1 (1.6)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (1.6)	1 (1.6)	0	0	0
Hypogammaglobulinaemia	1 (1.6)	1 (1.6)	0	0	0
Serious neurological adverse reactions					
-Total	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Delirium	1 (1.6)	0	0	1 (1.6)	0
Irritability	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	0	1 (1.6)	0	0

Region: US

Group term Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201l
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (28.6)	1 (3.6)	1 (3.6)	3 (10.7)	3 (10.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (7.1)	0	0	0	2 (7.1)
Neutrophil count decreased	2 (7.1)	0	0	0	2 (7.1)
White blood cell count decreased	1 (3.6)	0	0	0	1 (3.6)
Infections					
-Total	6 (21.4)	1 (3.6)	1 (3.6)	3 (10.7)	1 (3.6)
Device related infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Bronchitis	1 (3.6)	0	1 (3.6)	0	0

Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Necrotising fasciitis	1 (3.6)	0	0	1 (3.6)	0
Otitis media	1 (3.6)	0	1 (3.6)	0	0
Parainfluenzae virus infection	1 (3.6)	1 (3.6)	0	0	0
Staphylococcal infection	1 (3.6)	0	0	0	1 (3.6)
Viral upper respiratory tract infection	1 (3.6)	1 (3.6)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.6)	1 (3.6)	0	0	0
Hypogammaglobulinaemia	1 (3.6)	1 (3.6)	0	0	0
Serious neurological adverse reactions					
-Total	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Delirium	1 (3.6)	0	0	1 (3.6)	0
Irritability	1 (3.6)	1 (3.6)	0	0	0
Somnolence	1 (3.6)	0	1 (3.6)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201l
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (21.2)	0	1 (3.0)	2 (6.1)	4 (12.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	6 (18.2)	0	0	2 (6.1)	4 (12.1)
White blood cell count decreased	5 (15.2)	0	0	1 (3.0)	4 (12.1)
Anaemia	1 (3.0)	0	1 (3.0)	0	0
Neutropenia	1 (3.0)	0	0	0	1 (3.0)
Neutrophil count decreased	1 (3.0)	0	0	0	1 (3.0)
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Infections					
-Total	1 (3.0)	0	1 (3.0)	0	0

Prior SCT therapy: No

Group term Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (3.0)	0	1 (3.0)	0	0
Tumour Lysis Syndrome					
-Total	1 (3.0)	0	0	1 (3.0)	0
Tumour lysis syndrome	1 (3.0)	0	0	1 (3.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201m
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (28.6)	1 (7.1)	0	1 (7.1)	2 (14.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (21.4)	0	0	1 (7.1)	2 (14.3)
White blood cell count decreased	3 (21.4)	0	0	1 (7.1)	2 (14.3)
Anaemia	1 (7.1)	0	1 (7.1)	0	0
Neutropenia	1 (7.1)	0	0	0	1 (7.1)
Infections					
-Total	1 (7.1)	1 (7.1)	0	0	0
Viral upper respiratory tract infection	1 (7.1)	1 (7.1)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Eligibility for SCT: Yes

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (7.1)	1 (7.1)	0	0	0
Hypogammaglobulinaemia	1 (7.1)	1 (7.1)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (7.1)	0	0	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201m
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=47				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (23.4)	0	2 (4.3)	4 (8.5)	5 (10.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (10.6)	0	0	1 (2.1)	4 (8.5)
Neutrophil count decreased	3 (6.4)	0	0	0	3 (6.4)
White blood cell count decreased	3 (6.4)	0	0	0	3 (6.4)
Pancytopenia	1 (2.1)	0	0	1 (2.1)	0
Infections					
-Total	6 (12.8)	0	2 (4.3)	3 (6.4)	1 (2.1)
Device related infection	2 (4.3)	0	1 (2.1)	1 (2.1)	0
Bacteraemia	1 (2.1)	0	0	1 (2.1)	0

Eligibility for SCT: No

Group term Preferred term	All patients N=47 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchitis	1 (2.1)	0	1 (2.1)	0	0
Necrotising fasciitis	1 (2.1)	0	0	1 (2.1)	0
Otitis media	1 (2.1)	0	1 (2.1)	0	0
Parainfluenzae virus infection	1 (2.1)	1 (2.1)	0	0	0
Pneumonia	1 (2.1)	0	1 (2.1)	0	0
Staphylococcal infection	1 (2.1)	0	0	0	1 (2.1)
Serious neurological adverse reactions					
-Total	2 (4.3)	1 (2.1)	0	1 (2.1)	0
Delirium	1 (2.1)	0	0	1 (2.1)	0
Irritability	1 (2.1)	1 (2.1)	0	0	0
Somnolence	1 (2.1)	0	1 (2.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201n
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (28.6)	1 (4.8)	0	3 (14.3)	2 (9.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (14.3)	0	0	2 (9.5)	1 (4.8)
White blood cell count decreased	2 (9.5)	0	0	1 (4.8)	1 (4.8)
Neutropenia	1 (4.8)	0	0	0	1 (4.8)
Pancytopenia	1 (4.8)	0	0	1 (4.8)	0
Infections					
-Total	3 (14.3)	1 (4.8)	0	1 (4.8)	1 (4.8)
Bronchitis	1 (4.8)	0	1 (4.8)	0	0
Device related infection	1 (4.8)	0	0	1 (4.8)	0

Baseline bone marrow tumor burden: Low

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (4.8)	0	0	0	1 (4.8)
Viral upper respiratory tract infection	1 (4.8)	1 (4.8)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (4.8)	1 (4.8)	0	0	0
Hypogammaglobulinaemia	1 (4.8)	1 (4.8)	0	0	0
Serious neurological adverse reactions					
-Total	1 (4.8)	0	0	1 (4.8)	0
Delirium	1 (4.8)	0	0	1 (4.8)	0
Somnolence	1 (4.8)	0	1 (4.8)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201n
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (22.5)	0	2 (5.0)	2 (5.0)	5 (12.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (12.5)	0	0	0	5 (12.5)
White blood cell count decreased	4 (10.0)	0	0	0	4 (10.0)
Neutrophil count decreased	3 (7.5)	0	0	0	3 (7.5)
Anaemia	1 (2.5)	0	1 (2.5)	0	0
Infections					
-Total	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Device related infection	1 (2.5)	0	1 (2.5)	0	0

Baseline bone marrow tumor burden: High

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Necrotising fasciitis	1 (2.5)	0	0	1 (2.5)	0
Otitis media	1 (2.5)	0	1 (2.5)	0	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0	0	0
Pneumonia	1 (2.5)	0	1 (2.5)	0	0
Serious neurological adverse reactions					
-Total	1 (2.5)	1 (2.5)	0	0	0
Irritability	1 (2.5)	1 (2.5)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.5)	0	0	1 (2.5)	0
Tumour lysis syndrome	1 (2.5)	0	0	1 (2.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201o
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (25.0)	0	1 (25.0)	0	0
Infections					
-Total	1 (25.0)	0	1 (25.0)	0	0
Pneumonia	1 (25.0)	0	1 (25.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201o
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (24.6)	1 (1.8)	1 (1.8)	5 (8.8)	7 (12.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (14.0)	0	0	2 (3.5)	6 (10.5)
White blood cell count decreased	6 (10.5)	0	0	1 (1.8)	5 (8.8)
Neutrophil count decreased	3 (5.3)	0	0	0	3 (5.3)
Anaemia	1 (1.8)	0	1 (1.8)	0	0
Neutropenia	1 (1.8)	0	0	0	1 (1.8)
Pancytopenia	1 (1.8)	0	0	1 (1.8)	0
Infections					
-Total	6 (10.5)	1 (1.8)	1 (1.8)	3 (5.3)	1 (1.8)

Baseline extramedullary disease presence: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Necrotising fasciitis	1 (1.8)	0	0	1 (1.8)	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Parainfluenzae virus infection	1 (1.8)	1 (1.8)	0	0	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)
Viral upper respiratory tract infection	1 (1.8)	1 (1.8)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (1.8)	1 (1.8)	0	0	0
Hypogammaglobulinaemia	1 (1.8)	1 (1.8)	0	0	0
Serious neurological adverse reactions					
-Total	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Delirium	1 (1.8)	0	0	1 (1.8)	0
Irritability	1 (1.8)	1 (1.8)	0	0	0
Somnolence	1 (1.8)	0	1 (1.8)	0	0
Tumour Lysis Syndrome					

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.8)	0	0	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201p
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (25.0)	1 (25.0)	0	0	0
Infections					
-Total	1 (25.0)	1 (25.0)	0	0	0
Viral upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (25.0)	1 (25.0)	0	0	0
Hypogammaglobulinaemia	1 (25.0)	1 (25.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion

(for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201p
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (24.6)	0	2 (3.5)	5 (8.8)	7 (12.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (14.0)	0	0	2 (3.5)	6 (10.5)
White blood cell count decreased	6 (10.5)	0	0	1 (1.8)	5 (8.8)
Neutrophil count decreased	3 (5.3)	0	0	0	3 (5.3)
Anaemia	1 (1.8)	0	1 (1.8)	0	0
Neutropenia	1 (1.8)	0	0	0	1 (1.8)
Pancytopenia	1 (1.8)	0	0	1 (1.8)	0
Infections					
-Total	6 (10.5)	0	2 (3.5)	3 (5.3)	1 (1.8)

Down syndrome: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Necrotising fasciitis	1 (1.8)	0	0	1 (1.8)	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Parainfluenzae virus infection	1 (1.8)	1 (1.8)	0	0	0
Pneumonia	1 (1.8)	0	1 (1.8)	0	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)
Serious neurological adverse reactions					
-Total	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Delirium	1 (1.8)	0	0	1 (1.8)	0
Irritability	1 (1.8)	1 (1.8)	0	0	0
Somnolence	1 (1.8)	0	1 (1.8)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.8)	0	0	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose

apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201q
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (32.3)	1 (3.2)	0	4 (12.9)	5 (16.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	7 (22.6)	0	0	2 (6.5)	5 (16.1)
White blood cell count decreased	5 (16.1)	0	0	1 (3.2)	4 (12.9)
Neutrophil count decreased	2 (6.5)	0	0	0	2 (6.5)
Anaemia	1 (3.2)	0	1 (3.2)	0	0
Neutropenia	1 (3.2)	0	0	0	1 (3.2)
Pancytopenia	1 (3.2)	0	0	1 (3.2)	0
Infections					
-Total	3 (9.7)	1 (3.2)	0	2 (6.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (3.2)	0	0	1 (3.2)	0
Device related infection	1 (3.2)	0	0	1 (3.2)	0
Viral upper respiratory tract infection	1 (3.2)	1 (3.2)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.2)	1 (3.2)	0	0	0
Hypogammaglobulinaemia	1 (3.2)	1 (3.2)	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.2)	1 (3.2)	0	0	0
Irritability	1 (3.2)	1 (3.2)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.2)	0	0	1 (3.2)	0
Tumour lysis syndrome	1 (3.2)	0	0	1 (3.2)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201q
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (13.8)	0	2 (6.9)	1 (3.4)	1 (3.4)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (3.4)	0	0	0	1 (3.4)
Neutrophil count decreased	1 (3.4)	0	0	0	1 (3.4)
White blood cell count decreased	1 (3.4)	0	0	0	1 (3.4)
Infections					
-Total	3 (10.3)	0	2 (6.9)	1 (3.4)	0
Device related infection	1 (3.4)	0	1 (3.4)	0	0
Necrotising fasciitis	1 (3.4)	0	0	1 (3.4)	0
Otitis media	1 (3.4)	0	1 (3.4)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (3.4)	1 (3.4)	0	0	0
Pneumonia	1 (3.4)	0	1 (3.4)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201q
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Infections					
-Total	1 (100)	0	0	0	1 (100)
Bronchitis	1 (100)	0	1 (100)	0	0
Staphylococcal infection	1 (100)	0	0	0	1 (100)
Serious neurological adverse reactions					
-Total	1 (100)	0	0	1 (100)	0
Delirium	1 (100)	0	0	1 (100)	0
Somnolence	1 (100)	0	1 (100)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201r
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (21.1)	0	1 (5.3)	1 (5.3)	2 (10.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (15.8)	0	0	1 (5.3)	2 (10.5)
White blood cell count decreased	3 (15.8)	0	0	1 (5.3)	2 (10.5)
Neutrophil count decreased	1 (5.3)	0	0	0	1 (5.3)
Infections					
-Total	1 (5.3)	0	1 (5.3)	0	0
Pneumonia	1 (5.3)	0	1 (5.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose

apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201r
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (15.8)	0	0	1 (5.3)	2 (10.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (15.8)	0	0	1 (5.3)	2 (10.5)
White blood cell count decreased	2 (10.5)	0	0	0	2 (10.5)
Anaemia	1 (5.3)	0	1 (5.3)	0	0
Neutropenia	1 (5.3)	0	0	0	1 (5.3)
Pancytopenia	1 (5.3)	0	0	1 (5.3)	0
Tumour Lysis Syndrome					
-Total	1 (5.3)	0	0	1 (5.3)	0
Tumour lysis syndrome	1 (5.3)	0	0	1 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 201r
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (50.0)	1 (6.3)	1 (6.3)	3 (18.8)	3 (18.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (12.5)	0	0	0	2 (12.5)
Neutrophil count decreased	2 (12.5)	0	0	0	2 (12.5)
White blood cell count decreased	1 (6.3)	0	0	0	1 (6.3)
Infections					
-Total	6 (37.5)	1 (6.3)	1 (6.3)	3 (18.8)	1 (6.3)
Device related infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Bacteraemia	1 (6.3)	0	0	1 (6.3)	0
Bronchitis	1 (6.3)	0	1 (6.3)	0	0

Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Necrotising fasciitis	1 (6.3)	0	0	1 (6.3)	0
Otitis media	1 (6.3)	0	1 (6.3)	0	0
Parainfluenzae virus infection	1 (6.3)	1 (6.3)	0	0	0
Staphylococcal infection	1 (6.3)	0	0	0	1 (6.3)
Viral upper respiratory tract infection	1 (6.3)	1 (6.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (6.3)	1 (6.3)	0	0	0
Hypogammaglobulinaemia	1 (6.3)	1 (6.3)	0	0	0
Serious neurological adverse reactions					
-Total	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Delirium	1 (6.3)	0	0	1 (6.3)	0
Irritability	1 (6.3)	1 (6.3)	0	0	0
Somnolence	1 (6.3)	0	1 (6.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202a
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (95.5)	0	3 (13.6)	8 (36.4)	10 (45.5)
Cytokine Release Syndrome					
-Total	16 (72.7)	2 (9.1)	8 (36.4)	3 (13.6)	3 (13.6)
Cytokine release syndrome	16 (72.7)	2 (9.1)	8 (36.4)	3 (13.6)	3 (13.6)
Haemophagocytic lymphohistiocytosis	1 (4.5)	0	1 (4.5)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	12 (54.5)	1 (4.5)	0	3 (13.6)	8 (36.4)
Neutrophil count decreased	6 (27.3)	0	0	1 (4.5)	5 (22.7)
White blood cell count decreased	6 (27.3)	1 (4.5)	0	1 (4.5)	4 (18.2)
Anaemia	3 (13.6)	0	1 (4.5)	2 (9.1)	0

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutropenia	2 (9.1)	0	0	0	2 (9.1)
Platelet count decreased	2 (9.1)	0	0	0	2 (9.1)
Thrombocytopenia	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Febrile neutropenia	1 (4.5)	0	0	1 (4.5)	0
Leukopenia	1 (4.5)	0	0	0	1 (4.5)
Lymphocyte count decreased	1 (4.5)	0	0	1 (4.5)	0
Infections					
-Total	18 (81.8)	1 (4.5)	3 (13.6)	12 (54.5)	2 (9.1)
Upper respiratory tract infection	5 (22.7)	3 (13.6)	2 (9.1)	0	0
Clostridium difficile infection	4 (18.2)	0	3 (13.6)	1 (4.5)	0
Clostridium difficile colitis	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Gastroenteritis	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Pneumonia	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Rhinovirus infection	3 (13.6)	3 (13.6)	0	0	0
Sinusitis	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Device related infection	2 (9.1)	0	0	2 (9.1)	0
Ear infection	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Otitis media acute	2 (9.1)	0	2 (9.1)	0	0

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Staphylococcal infection	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Urinary tract infection	2 (9.1)	0	2 (9.1)	0	0
Viral upper respiratory tract infection	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Vulvovaginal candidiasis	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Alpha haemolytic streptococcal infection	1 (4.5)	0	0	1 (4.5)	0
Bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Bronchopulmonary aspergillosis	1 (4.5)	0	0	1 (4.5)	0
Campylobacter infection	1 (4.5)	0	0	1 (4.5)	0
Catheter site infection	1 (4.5)	0	0	1 (4.5)	0
Conjunctivitis	1 (4.5)	0	1 (4.5)	0	0
Corona virus infection	1 (4.5)	0	0	1 (4.5)	0
Croup infectious	1 (4.5)	0	0	1 (4.5)	0
Cytomegalovirus infection	1 (4.5)	1 (4.5)	0	0	0
Cytomegalovirus viraemia	1 (4.5)	0	1 (4.5)	0	0
Enterococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Enterovirus infection	1 (4.5)	0	0	1 (4.5)	0

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Escherichia infection	1 (4.5)	0	0	1 (4.5)	0
Gastroenteritis viral	1 (4.5)	1 (4.5)	0	0	0
Haemophilus infection	1 (4.5)	0	1 (4.5)	0	0
Metapneumovirus infection	1 (4.5)	0	1 (4.5)	0	0
Molluscum contagiosum	1 (4.5)	1 (4.5)	0	0	0
Oral candidiasis	1 (4.5)	1 (4.5)	0	0	0
Oral herpes	1 (4.5)	0	1 (4.5)	0	0
Otitis externa	1 (4.5)	0	1 (4.5)	0	0
Otitis media	1 (4.5)	0	0	1 (4.5)	0
Parainfluenzae virus infection	1 (4.5)	0	0	1 (4.5)	0
Paronychia	1 (4.5)	1 (4.5)	0	0	0
Rash pustular	1 (4.5)	0	1 (4.5)	0	0
Respiratory tract infection	1 (4.5)	0	0	0	1 (4.5)
Respiratory tract infection viral	1 (4.5)	0	0	1 (4.5)	0
Rotavirus infection	1 (4.5)	0	0	1 (4.5)	0
Septic embolus	1 (4.5)	0	0	0	1 (4.5)
Skin infection	1 (4.5)	0	1 (4.5)	0	0

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin papilloma	1 (4.5)	0	1 (4.5)	0	0
Streptococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Streptococcal infection	1 (4.5)	0	0	1 (4.5)	0
Tinea capitis	1 (4.5)	1 (4.5)	0	0	0
Viral infection	1 (4.5)	0	1 (4.5)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	12 (54.5)	2 (9.1)	8 (36.4)	2 (9.1)	0
Hypogammaglobulinaemia	11 (50.0)	2 (9.1)	7 (31.8)	2 (9.1)	0
Blood immunoglobulin g decreased	1 (4.5)	0	1 (4.5)	0	0
Blood immunoglobulin m decreased	1 (4.5)	1 (4.5)	0	0	0
Serious neurological adverse reactions					
-Total	6 (27.3)	2 (9.1)	1 (4.5)	3 (13.6)	0
Confusional state	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Irritability	2 (9.1)	2 (9.1)	0	0	0
Seizure	2 (9.1)	0	0	2 (9.1)	0
Delirium	1 (4.5)	0	1 (4.5)	0	0
Depressed level of consciousness	1 (4.5)	1 (4.5)	0	0	0

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysphagia	1 (4.5)	0	0	1 (4.5)	0
Tumour Lysis Syndrome					
-Total	2 (9.1)	0	0	2 (9.1)	0
Tumour lysis syndrome	2 (9.1)	0	0	2 (9.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202a
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (94.9)	0	7 (17.9)	16 (41.0)	14 (35.9)
Cytokine Release Syndrome					
-Total	26 (66.7)	4 (10.3)	12 (30.8)	5 (12.8)	5 (12.8)
Cytokine release syndrome	26 (66.7)	4 (10.3)	12 (30.8)	5 (12.8)	5 (12.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	17 (43.6)	1 (2.6)	1 (2.6)	8 (20.5)	7 (17.9)
White blood cell count decreased	10 (25.6)	0	1 (2.6)	6 (15.4)	3 (7.7)
Neutrophil count decreased	7 (17.9)	0	0	2 (5.1)	5 (12.8)
Platelet count decreased	4 (10.3)	1 (2.6)	0	1 (2.6)	2 (5.1)
Anaemia	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Febrile neutropenia	2 (5.1)	0	0	2 (5.1)	0

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Neutropenia	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Pancytopenia	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Thrombocytopenia	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Lymphopenia	1 (2.6)	0	0	1 (2.6)	0
Infections					
-Total	27 (69.2)	3 (7.7)	10 (25.6)	9 (23.1)	5 (12.8)
Upper respiratory tract infection	5 (12.8)	2 (5.1)	2 (5.1)	1 (2.6)	0
Clostridium difficile colitis	3 (7.7)	0	2 (5.1)	1 (2.6)	0
Oral herpes	3 (7.7)	0	2 (5.1)	1 (2.6)	0
Otitis media	3 (7.7)	0	3 (7.7)	0	0
Parainfluenzae virus infection	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Urinary tract infection	3 (7.7)	0	1 (2.6)	2 (5.1)	0
Clostridium difficile infection	2 (5.1)	0	2 (5.1)	0	0
Device related infection	2 (5.1)	0	0	2 (5.1)	0
Escherichia urinary tract infection	2 (5.1)	0	0	2 (5.1)	0
Fungal skin infection	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Gastroenteritis	2 (5.1)	0	1 (2.6)	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Pneumonia	2 (5.1)	0	2 (5.1)	0	0
Rhinovirus infection	2 (5.1)	2 (5.1)	0	0	0
Staphylococcal bacteraemia	2 (5.1)	0	0	2 (5.1)	0
Staphylococcal infection	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Viral infection	2 (5.1)	2 (5.1)	0	0	0
Viral upper respiratory tract infection	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Acute sinusitis	1 (2.6)	0	1 (2.6)	0	0
Bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Body tinea	1 (2.6)	1 (2.6)	0	0	0
Bronchitis	1 (2.6)	0	1 (2.6)	0	0
Candida sepsis	1 (2.6)	0	0	0	1 (2.6)
Catheter site cellulitis	1 (2.6)	1 (2.6)	0	0	0
Cellulitis	1 (2.6)	0	0	1 (2.6)	0
Cellulitis of male external genital organ	1 (2.6)	0	0	1 (2.6)	0
Conjunctivitis	1 (2.6)	0	1 (2.6)	0	0
Cytomegalovirus infection	1 (2.6)	1 (2.6)	0	0	0

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal infection	1 (2.6)	1 (2.6)	0	0	0
Escherichia bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis norovirus	1 (2.6)	0	1 (2.6)	0	0
Gingivitis	1 (2.6)	1 (2.6)	0	0	0
Herpes simplex	1 (2.6)	1 (2.6)	0	0	0
Herpes zoster	1 (2.6)	0	0	1 (2.6)	0
Human polyomavirus infection	1 (2.6)	0	0	0	1 (2.6)
Hypopyon	1 (2.6)	0	1 (2.6)	0	0
Klebsiella infection	1 (2.6)	0	0	1 (2.6)	0
Klebsiella sepsis	1 (2.6)	0	0	0	1 (2.6)
Meningitis aseptic	1 (2.6)	0	1 (2.6)	0	0
Orchitis	1 (2.6)	1 (2.6)	0	0	0
Pharyngitis	1 (2.6)	0	1 (2.6)	0	0
Pneumonia fungal	1 (2.6)	0	0	1 (2.6)	0
Respiratory syncytial virus bronchitis	1 (2.6)	0	0	1 (2.6)	0
Rhinitis	1 (2.6)	1 (2.6)	0	0	0
Sepsis	1 (2.6)	0	0	0	1 (2.6)
Sinusitis	1 (2.6)	0	1 (2.6)	0	0

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	1 (2.6)	0	1 (2.6)	0	0
Streptococcal infection	1 (2.6)	0	1 (2.6)	0	0
Subcutaneous abscess	1 (2.6)	0	1 (2.6)	0	0
Vascular device infection	1 (2.6)	0	0	1 (2.6)	0
Vulvovaginal mycotic infection	1 (2.6)	0	1 (2.6)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	19 (48.7)	2 (5.1)	14 (35.9)	3 (7.7)	0
Hypogammaglobulinaemia	19 (48.7)	2 (5.1)	14 (35.9)	3 (7.7)	0
Blood immunoglobulin a decreased	3 (7.7)	3 (7.7)	0	0	0
Blood immunoglobulin m decreased	3 (7.7)	3 (7.7)	0	0	0
Immunodeficiency	1 (2.6)	0	1 (2.6)	0	0
Serious neurological adverse reactions					
-Total	18 (46.2)	6 (15.4)	7 (17.9)	5 (12.8)	0
Confusional state	4 (10.3)	1 (2.6)	3 (7.7)	0	0
Encephalopathy	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Mental status changes	4 (10.3)	3 (7.7)	0	1 (2.6)	0
Delirium	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Agitation	2 (5.1)	0	2 (5.1)	0	0
Dysarthria	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Hallucination	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Seizure	2 (5.1)	0	2 (5.1)	0	0
Somnolence	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Tremor	2 (5.1)	2 (5.1)	0	0	0
Asterixis	1 (2.6)	1 (2.6)	0	0	0
Disturbance in attention	1 (2.6)	1 (2.6)	0	0	0
Dysphagia	1 (2.6)	0	1 (2.6)	0	0
Irritability	1 (2.6)	1 (2.6)	0	0	0
Leukoencephalopathy	1 (2.6)	0	0	1 (2.6)	0
Listless	1 (2.6)	1 (2.6)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (5.1)	0	0	2 (5.1)	0
Tumour lysis syndrome	2 (5.1)	0	0	2 (5.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose

apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202a
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	0	0	3 (21.4)	10 (71.4)
Cytokine Release Syndrome					
-Total	8 (57.1)	0	5 (35.7)	0	3 (21.4)
Cytokine release syndrome	8 (57.1)	0	5 (35.7)	0	3 (21.4)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (35.7)	0	2 (14.3)	0	3 (21.4)
Anaemia	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Neutropenia	2 (14.3)	0	0	0	2 (14.3)
Platelet count decreased	2 (14.3)	0	1 (7.1)	0	1 (7.1)
White blood cell count decreased	2 (14.3)	0	0	0	2 (14.3)

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (7.1)	0	0	0	1 (7.1)
Infections					
-Total	10 (71.4)	0	2 (14.3)	3 (21.4)	5 (35.7)
Influenza	2 (14.3)	0	2 (14.3)	0	0
Pneumonia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Abscess limb	1 (7.1)	0	0	1 (7.1)	0
Bacterial sepsis	1 (7.1)	0	0	0	1 (7.1)
Cholecystitis infective	1 (7.1)	0	0	1 (7.1)	0
Device related infection	1 (7.1)	0	1 (7.1)	0	0
Enterococcal bacteraemia	1 (7.1)	0	0	1 (7.1)	0
Escherichia sepsis	1 (7.1)	0	0	0	1 (7.1)
Escherichia urinary tract infection	1 (7.1)	0	1 (7.1)	0	0
Folliculitis	1 (7.1)	0	1 (7.1)	0	0
Human herpesvirus 6 infection	1 (7.1)	0	1 (7.1)	0	0
Klebsiella sepsis	1 (7.1)	0	0	0	1 (7.1)
Necrotising fasciitis	1 (7.1)	0	0	1 (7.1)	0
Pneumonia fungal	1 (7.1)	0	1 (7.1)	0	0
Rhinovirus infection	1 (7.1)	0	1 (7.1)	0	0

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (7.1)	0	0	0	1 (7.1)
Serratia infection	1 (7.1)	0	0	1 (7.1)	0
Sinusitis	1 (7.1)	0	1 (7.1)	0	0
Staphylococcal scalded skin syndrome	1 (7.1)	0	1 (7.1)	0	0
Staphylococcal sepsis	1 (7.1)	0	0	0	1 (7.1)
Upper respiratory tract infection	1 (7.1)	0	1 (7.1)	0	0
Urinary tract infection enterococcal	1 (7.1)	0	0	1 (7.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (21.4)	0	3 (21.4)	0	0
Hypogammaglobulinaemia	3 (21.4)	0	3 (21.4)	0	0
Blood immunoglobulin m decreased	1 (7.1)	1 (7.1)	0	0	0
Serious neurological adverse reactions					
-Total	4 (28.6)	2 (14.3)	1 (7.1)	0	1 (7.1)
Confusional state	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Agitation	1 (7.1)	0	0	1 (7.1)	0
Delirium	1 (7.1)	1 (7.1)	0	0	0
Hyporesponsive to stimuli	1 (7.1)	0	0	1 (7.1)	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Seizure	1 (7.1)	0	0	0	1 (7.1)
Tumour Lysis Syndrome					
-Total	1 (7.1)	0	0	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202b
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (92.5)	0	7 (17.5)	13 (32.5)	17 (42.5)
Cytokine Release Syndrome					
-Total	23 (57.5)	4 (10.0)	10 (25.0)	3 (7.5)	6 (15.0)
Cytokine release syndrome	23 (57.5)	4 (10.0)	10 (25.0)	3 (7.5)	6 (15.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	17 (42.5)	2 (5.0)	1 (2.5)	7 (17.5)	7 (17.5)
White blood cell count decreased	8 (20.0)	1 (2.5)	0	4 (10.0)	3 (7.5)
Anaemia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Neutrophil count decreased	4 (10.0)	0	0	1 (2.5)	3 (7.5)
Platelet count decreased	4 (10.0)	1 (2.5)	1 (2.5)	0	2 (5.0)
Neutropenia	3 (7.5)	0	0	1 (2.5)	2 (5.0)

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Thrombocytopenia	3 (7.5)	1 (2.5)	0	1 (2.5)	1 (2.5)
Febrile neutropenia	2 (5.0)	0	0	2 (5.0)	0
Leukopenia	1 (2.5)	0	0	0	1 (2.5)
Lymphopenia	1 (2.5)	0	0	1 (2.5)	0
Pancytopenia	1 (2.5)	0	0	1 (2.5)	0
Infections					
-Total	28 (70.0)	2 (5.0)	10 (25.0)	10 (25.0)	6 (15.0)
Upper respiratory tract infection	6 (15.0)	2 (5.0)	4 (10.0)	0	0
Gastroenteritis	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Otitis media	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Pneumonia	3 (7.5)	0	2 (5.0)	0	1 (2.5)
Sinusitis	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Viral infection	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Clostridium difficile colitis	2 (5.0)	0	0	2 (5.0)	0
Influenza	2 (5.0)	0	2 (5.0)	0	0
Klebsiella sepsis	2 (5.0)	0	0	0	2 (5.0)
Respiratory syncytial virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Streptococcal infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Viral upper respiratory tract infection	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Body tinea	1 (2.5)	1 (2.5)	0	0	0
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Candida sepsis	1 (2.5)	0	0	0	1 (2.5)
Cellulitis of male external genital organ	1 (2.5)	0	0	1 (2.5)	0
Cholecystitis infective	1 (2.5)	0	0	1 (2.5)	0
Clostridium difficile infection	1 (2.5)	0	1 (2.5)	0	0
Conjunctivitis	1 (2.5)	0	1 (2.5)	0	0
Corona virus infection	1 (2.5)	0	0	1 (2.5)	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Escherichia infection	1 (2.5)	0	0	1 (2.5)	0
Fungal skin infection	1 (2.5)	1 (2.5)	0	0	0
Gingivitis	1 (2.5)	1 (2.5)	0	0	0
Haemophilus infection	1 (2.5)	0	1 (2.5)	0	0

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	1 (2.5)	0	0
Oral herpes	1 (2.5)	0	1 (2.5)	0	0
Orchitis	1 (2.5)	1 (2.5)	0	0	0
Otitis media acute	1 (2.5)	0	1 (2.5)	0	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0	0	0
Pharyngitis	1 (2.5)	0	1 (2.5)	0	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Rash pustular	1 (2.5)	0	1 (2.5)	0	0
Rhinovirus infection	1 (2.5)	1 (2.5)	0	0	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Serratia infection	1 (2.5)	0	0	1 (2.5)	0
Skin infection	1 (2.5)	0	1 (2.5)	0	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal infection	1 (2.5)	0	0	0	1 (2.5)
Subcutaneous abscess	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	17 (42.5)	2 (5.0)	13 (32.5)	2 (5.0)	0
Hypogammaglobulinaemia	17 (42.5)	2 (5.0)	13 (32.5)	2 (5.0)	0
Blood immunoglobulin m decreased	2 (5.0)	2 (5.0)	0	0	0
Blood immunoglobulin a decreased	1 (2.5)	1 (2.5)	0	0	0
Serious neurological adverse reactions					
-Total	16 (40.0)	4 (10.0)	5 (12.5)	6 (15.0)	1 (2.5)
Confusional state	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Delirium	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Mental status changes	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Seizure	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Agitation	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Encephalopathy	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Irritability	2 (5.0)	2 (5.0)	0	0	0
Muscular weakness	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Somnolence	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Disturbance in attention	1 (2.5)	1 (2.5)	0	0	0

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysarthria	1 (2.5)	0	1 (2.5)	0	0
Dysphagia	1 (2.5)	0	0	1 (2.5)	0
Hallucination	1 (2.5)	0	1 (2.5)	0	0
Hyporesponsive to stimuli	1 (2.5)	0	0	1 (2.5)	0
Leukoencephalopathy	1 (2.5)	0	0	1 (2.5)	0
Listless	1 (2.5)	1 (2.5)	0	0	0
Tumour Lysis Syndrome					
-Total	3 (7.5)	0	0	3 (7.5)	0
Tumour lysis syndrome	3 (7.5)	0	0	3 (7.5)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202b
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (97.1)	0	3 (8.6)	14 (40.0)	17 (48.6)
Cytokine Release Syndrome					
-Total	27 (77.1)	2 (5.7)	15 (42.9)	5 (14.3)	5 (14.3)
Cytokine release syndrome	27 (77.1)	2 (5.7)	15 (42.9)	5 (14.3)	5 (14.3)
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	1 (2.9)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	17 (48.6)	0	2 (5.7)	4 (11.4)	11 (31.4)
White blood cell count decreased	10 (28.6)	0	1 (2.9)	3 (8.6)	6 (17.1)
Neutrophil count decreased	9 (25.7)	0	0	2 (5.7)	7 (20.0)
Anaemia	4 (11.4)	0	2 (5.7)	2 (5.7)	0

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	4 (11.4)	0	0	1 (2.9)	3 (8.6)
Lymphocyte count decreased	3 (8.6)	0	0	2 (5.7)	1 (2.9)
Neutropenia	3 (8.6)	0	0	0	3 (8.6)
Thrombocytopenia	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Febrile neutropenia	1 (2.9)	0	0	1 (2.9)	0
Pancytopenia	1 (2.9)	0	0	0	1 (2.9)
Infections					
-Total	27 (77.1)	2 (5.7)	5 (14.3)	14 (40.0)	6 (17.1)
Clostridium difficile infection	5 (14.3)	0	4 (11.4)	1 (2.9)	0
Rhinovirus infection	5 (14.3)	4 (11.4)	1 (2.9)	0	0
Upper respiratory tract infection	5 (14.3)	3 (8.6)	1 (2.9)	1 (2.9)	0
Clostridium difficile colitis	4 (11.4)	1 (2.9)	2 (5.7)	1 (2.9)	0
Device related infection	4 (11.4)	0	1 (2.9)	3 (8.6)	0
Pneumonia	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Urinary tract infection	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Escherichia urinary tract infection	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Oral herpes	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Parainfluenzae virus infection	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	3 (8.6)	1 (2.9)	0	2 (5.7)	0
Cytomegalovirus infection	2 (5.7)	2 (5.7)	0	0	0
Ear infection	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Enterococcal bacteraemia	2 (5.7)	0	0	2 (5.7)	0
Gastroenteritis	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Influenza	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Sinusitis	2 (5.7)	0	2 (5.7)	0	0
Viral upper respiratory tract infection	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Vulvovaginal candidiasis	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Abscess limb	1 (2.9)	0	0	1 (2.9)	0
Alpha haemolytic streptococcal infection	1 (2.9)	0	0	1 (2.9)	0
Bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Bacterial sepsis	1 (2.9)	0	0	0	1 (2.9)
Bronchopulmonary aspergillosis	1 (2.9)	0	0	1 (2.9)	0
Campylobacter infection	1 (2.9)	0	0	1 (2.9)	0
Catheter site cellulitis	1 (2.9)	1 (2.9)	0	0	0
Catheter site infection	1 (2.9)	0	0	1 (2.9)	0

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (2.9)	0	0	1 (2.9)	0
Conjunctivitis	1 (2.9)	0	1 (2.9)	0	0
Croup infectious	1 (2.9)	0	0	1 (2.9)	0
Cytomegalovirus viraemia	1 (2.9)	0	1 (2.9)	0	0
Enterococcal infection	1 (2.9)	1 (2.9)	0	0	0
Enterovirus infection	1 (2.9)	0	0	1 (2.9)	0
Escherichia bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Escherichia sepsis	1 (2.9)	0	0	0	1 (2.9)
Folliculitis	1 (2.9)	0	1 (2.9)	0	0
Fungal skin infection	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis viral	1 (2.9)	1 (2.9)	0	0	0
Herpes simplex	1 (2.9)	1 (2.9)	0	0	0
Human herpesvirus 6 infection	1 (2.9)	0	1 (2.9)	0	0
Human polyomavirus infection	1 (2.9)	0	0	0	1 (2.9)
Hypopyon	1 (2.9)	0	1 (2.9)	0	0
Meningitis aseptic	1 (2.9)	0	1 (2.9)	0	0
Molluscum contagiosum	1 (2.9)	1 (2.9)	0	0	0

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Necrotising fasciitis	1 (2.9)	0	0	1 (2.9)	0
Oral candidiasis	1 (2.9)	1 (2.9)	0	0	0
Otitis externa	1 (2.9)	0	1 (2.9)	0	0
Otitis media	1 (2.9)	0	1 (2.9)	0	0
Otitis media acute	1 (2.9)	0	1 (2.9)	0	0
Paronychia	1 (2.9)	1 (2.9)	0	0	0
Pneumonia fungal	1 (2.9)	0	1 (2.9)	0	0
Respiratory syncytial virus bronchitis	1 (2.9)	0	0	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	0	0	1 (2.9)
Respiratory tract infection viral	1 (2.9)	0	0	1 (2.9)	0
Rhinitis	1 (2.9)	1 (2.9)	0	0	0
Rotavirus infection	1 (2.9)	0	0	1 (2.9)	0
Sepsis	1 (2.9)	0	0	0	1 (2.9)
Septic embolus	1 (2.9)	0	0	0	1 (2.9)
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Skin papilloma	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Streptococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Tinea capitis	1 (2.9)	1 (2.9)	0	0	0
Urinary tract infection enterococcal	1 (2.9)	0	0	1 (2.9)	0
Vascular device infection	1 (2.9)	0	0	1 (2.9)	0
Vulvovaginal mycotic infection	1 (2.9)	0	1 (2.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	17 (48.6)	2 (5.7)	12 (34.3)	3 (8.6)	0
Hypogammaglobulinaemia	16 (45.7)	2 (5.7)	11 (31.4)	3 (8.6)	0
Blood immunoglobulin m decreased	3 (8.6)	3 (8.6)	0	0	0
Blood immunoglobulin a decreased	2 (5.7)	2 (5.7)	0	0	0
Blood immunoglobulin g decreased	1 (2.9)	0	1 (2.9)	0	0
Immunodeficiency	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					
-Total	12 (34.3)	6 (17.1)	4 (11.4)	2 (5.7)	0
Confusional state	3 (8.6)	0	3 (8.6)	0	0

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Delirium	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Encephalopathy	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Seizure	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Tremor	2 (5.7)	2 (5.7)	0	0	0
Agitation	1 (2.9)	0	1 (2.9)	0	0
Asterixis	1 (2.9)	1 (2.9)	0	0	0
Depressed level of consciousness	1 (2.9)	1 (2.9)	0	0	0
Dysarthria	1 (2.9)	1 (2.9)	0	0	0
Dysphagia	1 (2.9)	0	1 (2.9)	0	0
Hallucination	1 (2.9)	1 (2.9)	0	0	0
Irritability	1 (2.9)	1 (2.9)	0	0	0
Mental status changes	1 (2.9)	1 (2.9)	0	0	0
Muscular weakness	1 (2.9)	1 (2.9)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (5.7)	0	0	2 (5.7)	0
Tumour lysis syndrome	2 (5.7)	0	0	2 (5.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose

apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202c
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (93.3)	0	8 (13.3)	21 (35.0)	27 (45.0)
Cytokine Release Syndrome					
-Total	40 (66.7)	4 (6.7)	19 (31.7)	7 (11.7)	10 (16.7)
Cytokine release syndrome	40 (66.7)	4 (6.7)	19 (31.7)	7 (11.7)	10 (16.7)
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	29 (48.3)	2 (3.3)	3 (5.0)	9 (15.0)	15 (25.0)
White blood cell count decreased	14 (23.3)	1 (1.7)	1 (1.7)	4 (6.7)	8 (13.3)
Neutrophil count decreased	11 (18.3)	0	0	3 (5.0)	8 (13.3)
Platelet count decreased	8 (13.3)	1 (1.7)	1 (1.7)	1 (1.7)	5 (8.3)

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Anaemia	7 (11.7)	0	4 (6.7)	3 (5.0)	0
Neutropenia	6 (10.0)	0	0	1 (1.7)	5 (8.3)
Thrombocytopenia	5 (8.3)	1 (1.7)	0	2 (3.3)	2 (3.3)
Febrile neutropenia	3 (5.0)	0	0	3 (5.0)	0
Lymphocyte count decreased	3 (5.0)	0	0	2 (3.3)	1 (1.7)
Leukopenia	1 (1.7)	0	0	0	1 (1.7)
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	45 (75.0)	4 (6.7)	14 (23.3)	18 (30.0)	9 (15.0)
Upper respiratory tract infection	10 (16.7)	4 (6.7)	5 (8.3)	1 (1.7)	0
Pneumonia	7 (11.7)	0	5 (8.3)	1 (1.7)	1 (1.7)
Clostridium difficile colitis	5 (8.3)	1 (1.7)	1 (1.7)	3 (5.0)	0
Clostridium difficile infection	5 (8.3)	0	4 (6.7)	1 (1.7)	0
Rhinovirus infection	5 (8.3)	5 (8.3)	0	0	0
Sinusitis	5 (8.3)	1 (1.7)	4 (6.7)	0	0
Gastroenteritis	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Influenza	4 (6.7)	1 (1.7)	3 (5.0)	0	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Urinary tract infection	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Device related infection	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Otitis media	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Staphylococcal infection	3 (5.0)	1 (1.7)	0	1 (1.7)	1 (1.7)
Viral upper respiratory tract infection	3 (5.0)	2 (3.3)	0	1 (1.7)	0
Bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Ear infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Enterococcal bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Escherichia bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Escherichia urinary tract infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Fungal skin infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Oral herpes	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Otitis media acute	2 (3.3)	0	2 (3.3)	0	0
Respiratory syncytial virus infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Skin infection	2 (3.3)	0	2 (3.3)	0	0
Staphylococcal bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Viral infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Bronchopulmonary aspergillosis	1 (1.7)	0	0	1 (1.7)	0
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Candida sepsis	1 (1.7)	0	0	0	1 (1.7)
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Conjunctivitis	1 (1.7)	0	1 (1.7)	0	0
Corona virus infection	1 (1.7)	0	0	1 (1.7)	0
Croup infectious	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0
Cytomegalovirus viraemia	1 (1.7)	0	1 (1.7)	0	0

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Escherichia sepsis	1 (1.7)	0	0	0	1 (1.7)
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis viral	1 (1.7)	1 (1.7)	0	0	0
Haemophilus infection	1 (1.7)	0	1 (1.7)	0	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Human polyomavirus infection	1 (1.7)	0	0	0	1 (1.7)
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Klebsiella infection	1 (1.7)	0	0	1 (1.7)	0
Klebsiella sepsis	1 (1.7)	0	0	0	1 (1.7)
Metapneumovirus infection	1 (1.7)	0	1 (1.7)	0	0
Necrotising fasciitis	1 (1.7)	0	0	1 (1.7)	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0
Otitis externa	1 (1.7)	0	1 (1.7)	0	0
Paronychia	1 (1.7)	1 (1.7)	0	0	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Rash pustular	1 (1.7)	0	1 (1.7)	0	0
Respiratory syncytial virus bronchitis	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Serratia infection	1 (1.7)	0	0	1 (1.7)	0
Skin papilloma	1 (1.7)	0	1 (1.7)	0	0
Streptococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Subcutaneous abscess	1 (1.7)	0	1 (1.7)	0	0
Tinea capitis	1 (1.7)	1 (1.7)	0	0	0
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	28 (46.7)	2 (3.3)	21 (35.0)	5 (8.3)	0
Hypogammaglobulinaemia	27 (45.0)	2 (3.3)	20 (33.3)	5 (8.3)	0
Blood immunoglobulin m decreased	3 (5.0)	3 (5.0)	0	0	0

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (1.7)	1 (1.7)	0	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	23 (38.3)	8 (13.3)	8 (13.3)	7 (11.7)	0
Confusional state	8 (13.3)	3 (5.0)	5 (8.3)	0	0
Delirium	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Encephalopathy	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Irritability	3 (5.0)	3 (5.0)	0	0	0
Mental status changes	3 (5.0)	3 (5.0)	0	0	0
Seizure	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Hallucination	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Muscular weakness	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Somnolence	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Agitation	1 (1.7)	0	1 (1.7)	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0
Dysarthria	1 (1.7)	0	1 (1.7)	0	0
Dysphagia	1 (1.7)	0	0	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukoencephalopathy	1 (1.7)	0	0	1 (1.7)	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Tremor	1 (1.7)	1 (1.7)	0	0	0
Tumour Lysis Syndrome					
-Total	3 (5.0)	0	0	3 (5.0)	0
Tumour lysis syndrome	3 (5.0)	0	0	3 (5.0)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202c
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	1 (16.7)	2 (33.3)	3 (50.0)
Cytokine Release Syndrome					
-Total	4 (66.7)	0	4 (66.7)	0	0
Cytokine release syndrome	4 (66.7)	0	4 (66.7)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (33.3)	0	0	0	2 (33.3)
Neutrophil count decreased	2 (33.3)	0	0	0	2 (33.3)
White blood cell count decreased	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Infections					
-Total	4 (66.7)	0	0	3 (50.0)	1 (16.7)
Streptococcal infection	2 (33.3)	0	1 (16.7)	1 (16.7)	0

Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alpha haemolytic streptococcal infection	1 (16.7)	0	0	1 (16.7)	0
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Device related infection	1 (16.7)	0	0	1 (16.7)	0
Escherichia infection	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis	1 (16.7)	0	0	1 (16.7)	0
Gingivitis	1 (16.7)	1 (16.7)	0	0	0
Herpes zoster	1 (16.7)	0	0	1 (16.7)	0
Molluscum contagiosum	1 (16.7)	1 (16.7)	0	0	0
Oral herpes	1 (16.7)	0	1 (16.7)	0	0
Pharyngitis	1 (16.7)	0	1 (16.7)	0	0
Respiratory tract infection	1 (16.7)	0	0	0	1 (16.7)
Staphylococcal infection	1 (16.7)	0	0	1 (16.7)	0
Viral infection	1 (16.7)	1 (16.7)	0	0	0
Viral upper respiratory tract infection	1 (16.7)	0	1 (16.7)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Hypogammaglobulinaemia	3 (50.0)	1 (16.7)	2 (33.3)	0	0

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin a decreased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin m decreased	1 (16.7)	1 (16.7)	0	0	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202c
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	0	1 (11.1)	4 (44.4)	4 (44.4)
Cytokine Release Syndrome					
-Total	6 (66.7)	2 (22.2)	2 (22.2)	1 (11.1)	1 (11.1)
Cytokine release syndrome	6 (66.7)	2 (22.2)	2 (22.2)	1 (11.1)	1 (11.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (33.3)	0	0	2 (22.2)	1 (11.1)
White blood cell count decreased	2 (22.2)	0	0	2 (22.2)	0
Anaemia	1 (11.1)	0	0	1 (11.1)	0
Pancytopenia	1 (11.1)	0	0	0	1 (11.1)
Infections					

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (66.7)	0	1 (11.1)	3 (33.3)	2 (22.2)
Abscess limb	1 (11.1)	0	0	1 (11.1)	0
Catheter site cellulitis	1 (11.1)	1 (11.1)	0	0	0
Clostridium difficile colitis	1 (11.1)	0	1 (11.1)	0	0
Clostridium difficile infection	1 (11.1)	0	1 (11.1)	0	0
Cytomegalovirus infection	1 (11.1)	1 (11.1)	0	0	0
Device related infection	1 (11.1)	0	0	1 (11.1)	0
Escherichia urinary tract infection	1 (11.1)	0	0	1 (11.1)	0
Herpes simplex	1 (11.1)	1 (11.1)	0	0	0
Klebsiella sepsis	1 (11.1)	0	0	0	1 (11.1)
Meningitis aseptic	1 (11.1)	0	1 (11.1)	0	0
Oral herpes	1 (11.1)	0	1 (11.1)	0	0
Otitis media	1 (11.1)	0	1 (11.1)	0	0
Pneumonia fungal	1 (11.1)	0	1 (11.1)	0	0
Rhinitis	1 (11.1)	1 (11.1)	0	0	0
Rhinovirus infection	1 (11.1)	0	1 (11.1)	0	0
Sepsis	1 (11.1)	0	0	0	1 (11.1)

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal sepsis	1 (11.1)	0	0	0	1 (11.1)
Upper respiratory tract infection	1 (11.1)	1 (11.1)	0	0	0
Urinary tract infection	1 (11.1)	0	1 (11.1)	0	0
Vascular device infection	1 (11.1)	0	0	1 (11.1)	0
Vulvovaginal mycotic infection	1 (11.1)	0	1 (11.1)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (33.3)	1 (11.1)	2 (22.2)	0	0
Hypogammaglobulinaemia	3 (33.3)	1 (11.1)	2 (22.2)	0	0
Blood immunoglobulin a decreased	1 (11.1)	1 (11.1)	0	0	0
Blood immunoglobulin m decreased	1 (11.1)	1 (11.1)	0	0	0
Immunodeficiency	1 (11.1)	0	1 (11.1)	0	0
Serious neurological adverse reactions					
-Total	5 (55.6)	2 (22.2)	1 (11.1)	1 (11.1)	1 (11.1)
Agitation	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Seizure	2 (22.2)	0	1 (11.1)	0	1 (11.1)
Asterixis	1 (11.1)	1 (11.1)	0	0	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (11.1)	0	1 (11.1)	0	0
Dysarthria	1 (11.1)	1 (11.1)	0	0	0
Dysphagia	1 (11.1)	0	1 (11.1)	0	0
Encephalopathy	1 (11.1)	1 (11.1)	0	0	0
Hyporesponsive to stimuli	1 (11.1)	0	0	1 (11.1)	0
Mental status changes	1 (11.1)	0	0	1 (11.1)	0
Muscular weakness	1 (11.1)	1 (11.1)	0	0	0
Tremor	1 (11.1)	1 (11.1)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (22.2)	0	0	2 (22.2)	0
Tumour lysis syndrome	2 (22.2)	0	0	2 (22.2)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202d
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (93.3)	0	4 (13.3)	11 (36.7)	13 (43.3)
Cytokine Release Syndrome					
-Total	20 (66.7)	2 (6.7)	12 (40.0)	3 (10.0)	3 (10.0)
Cytokine release syndrome	20 (66.7)	2 (6.7)	12 (40.0)	3 (10.0)	3 (10.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	15 (50.0)	1 (3.3)	1 (3.3)	5 (16.7)	8 (26.7)
White blood cell count decreased	10 (33.3)	1 (3.3)	0	5 (16.7)	4 (13.3)
Neutrophil count decreased	7 (23.3)	0	0	2 (6.7)	5 (16.7)
Anaemia	4 (13.3)	0	3 (10.0)	1 (3.3)	0
Platelet count decreased	3 (10.0)	1 (3.3)	1 (3.3)	0	1 (3.3)
Neutropenia	2 (6.7)	0	0	1 (3.3)	1 (3.3)

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (6.7)	0	0	0	2 (6.7)
Febrile neutropenia	1 (3.3)	0	0	1 (3.3)	0
Lymphocyte count decreased	1 (3.3)	0	0	1 (3.3)	0
Lymphopenia	1 (3.3)	0	0	1 (3.3)	0
Pancytopenia	1 (3.3)	0	0	0	1 (3.3)
Infections					
-Total	22 (73.3)	1 (3.3)	8 (26.7)	9 (30.0)	4 (13.3)
Influenza	4 (13.3)	1 (3.3)	3 (10.0)	0	0
Upper respiratory tract infection	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Urinary tract infection	4 (13.3)	0	2 (6.7)	2 (6.7)	0
Otitis media	3 (10.0)	0	3 (10.0)	0	0
Parainfluenzae virus infection	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Bacteraemia	2 (6.7)	0	0	2 (6.7)	0
Clostridium difficile infection	2 (6.7)	0	2 (6.7)	0	0
Cytomegalovirus infection	2 (6.7)	2 (6.7)	0	0	0
Escherichia urinary tract infection	2 (6.7)	0	0	2 (6.7)	0
Gastroenteritis	2 (6.7)	0	2 (6.7)	0	0
Skin infection	2 (6.7)	0	2 (6.7)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Candida sepsis	1 (3.3)	0	0	0	1 (3.3)
Cellulitis of male external genital organ	1 (3.3)	0	0	1 (3.3)	0
Clostridium difficile colitis	1 (3.3)	0	0	1 (3.3)	0
Conjunctivitis	1 (3.3)	0	1 (3.3)	0	0
Corona virus infection	1 (3.3)	0	0	1 (3.3)	0
Cytomegalovirus viraemia	1 (3.3)	0	1 (3.3)	0	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Ear infection	1 (3.3)	1 (3.3)	0	0	0
Enterococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Enterococcal infection	1 (3.3)	1 (3.3)	0	0	0
Escherichia bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Escherichia sepsis	1 (3.3)	0	0	0	1 (3.3)
Fungal skin infection	1 (3.3)	1 (3.3)	0	0	0
Gastroenteritis norovirus	1 (3.3)	0	1 (3.3)	0	0
Klebsiella sepsis	1 (3.3)	0	0	0	1 (3.3)
Meningitis aseptic	1 (3.3)	0	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (3.3)	0	1 (3.3)	0	0
Otitis media acute	1 (3.3)	0	1 (3.3)	0	0
Paronychia	1 (3.3)	1 (3.3)	0	0	0
Pneumonia	1 (3.3)	0	1 (3.3)	0	0
Pneumonia fungal	1 (3.3)	0	0	1 (3.3)	0
Respiratory syncytial virus bronchitis	1 (3.3)	0	0	1 (3.3)	0
Respiratory syncytial virus infection	1 (3.3)	0	0	1 (3.3)	0
Rhinovirus infection	1 (3.3)	1 (3.3)	0	0	0
Sepsis	1 (3.3)	0	0	0	1 (3.3)
Serratia infection	1 (3.3)	0	0	1 (3.3)	0
Sinusitis	1 (3.3)	0	1 (3.3)	0	0
Skin papilloma	1 (3.3)	0	1 (3.3)	0	0
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal infection	1 (3.3)	0	0	1 (3.3)	0
Streptococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Subcutaneous abscess	1 (3.3)	0	1 (3.3)	0	0
Tinea capitis	1 (3.3)	1 (3.3)	0	0	0
Viral infection	1 (3.3)	0	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal mycotic infection	1 (3.3)	0	1 (3.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	16 (53.3)	0	15 (50.0)	1 (3.3)	0
Hypogammaglobulinaemia	15 (50.0)	0	14 (46.7)	1 (3.3)	0
Blood immunoglobulin m decreased	2 (6.7)	2 (6.7)	0	0	0
Blood immunoglobulin a decreased	1 (3.3)	1 (3.3)	0	0	0
Blood immunoglobulin g decreased	1 (3.3)	0	1 (3.3)	0	0
Immunodeficiency	1 (3.3)	0	1 (3.3)	0	0
Serious neurological adverse reactions					
-Total	7 (23.3)	2 (6.7)	3 (10.0)	2 (6.7)	0
Dysarthria	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Mental status changes	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Muscular weakness	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Seizure	2 (6.7)	0	2 (6.7)	0	0
Agitation	1 (3.3)	0	1 (3.3)	0	0
Asterixis	1 (3.3)	1 (3.3)	0	0	0
Confusional state	1 (3.3)	1 (3.3)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (3.3)	0	1 (3.3)	0	0
Dysphagia	1 (3.3)	0	1 (3.3)	0	0
Encephalopathy	1 (3.3)	0	0	1 (3.3)	0
Hallucination	1 (3.3)	1 (3.3)	0	0	0
Somnolence	1 (3.3)	1 (3.3)	0	0	0
Tremor	1 (3.3)	1 (3.3)	0	0	0
Tumour Lysis Syndrome					
-Total	4 (13.3)	0	0	4 (13.3)	0
Tumour lysis syndrome	4 (13.3)	0	0	4 (13.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202d
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	43 (95.6)	0	6 (13.3)	16 (35.6)	21 (46.7)
Cytokine Release Syndrome					
-Total	30 (66.7)	4 (8.9)	13 (28.9)	5 (11.1)	8 (17.8)
Cytokine release syndrome	30 (66.7)	4 (8.9)	13 (28.9)	5 (11.1)	8 (17.8)
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	1 (2.2)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	19 (42.2)	1 (2.2)	2 (4.4)	6 (13.3)	10 (22.2)
White blood cell count decreased	8 (17.8)	0	1 (2.2)	2 (4.4)	5 (11.1)
Neutrophil count decreased	6 (13.3)	0	0	1 (2.2)	5 (11.1)
Platelet count decreased	5 (11.1)	0	0	1 (2.2)	4 (8.9)

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	4 (8.9)	0	1 (2.2)	3 (6.7)	0
Neutropenia	4 (8.9)	0	0	0	4 (8.9)
Thrombocytopenia	3 (6.7)	1 (2.2)	0	2 (4.4)	0
Febrile neutropenia	2 (4.4)	0	0	2 (4.4)	0
Lymphocyte count decreased	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Leukopenia	1 (2.2)	0	0	0	1 (2.2)
Pancytopenia	1 (2.2)	0	0	1 (2.2)	0
Infections					
-Total	33 (73.3)	3 (6.7)	7 (15.6)	15 (33.3)	8 (17.8)
Upper respiratory tract infection	7 (15.6)	3 (6.7)	3 (6.7)	1 (2.2)	0
Pneumonia	6 (13.3)	0	4 (8.9)	1 (2.2)	1 (2.2)
Clostridium difficile colitis	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Rhinovirus infection	5 (11.1)	4 (8.9)	1 (2.2)	0	0
Clostridium difficile infection	4 (8.9)	0	3 (6.7)	1 (2.2)	0
Device related infection	4 (8.9)	0	1 (2.2)	3 (6.7)	0
Oral herpes	4 (8.9)	0	3 (6.7)	1 (2.2)	0
Sinusitis	4 (8.9)	1 (2.2)	3 (6.7)	0	0
Gastroenteritis	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	3 (6.7)	1 (2.2)	0	1 (2.2)	1 (2.2)
Streptococcal infection	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Viral infection	2 (4.4)	2 (4.4)	0	0	0
Viral upper respiratory tract infection	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Vulvovaginal candidiasis	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Abscess limb	1 (2.2)	0	0	1 (2.2)	0
Acute sinusitis	1 (2.2)	0	1 (2.2)	0	0
Alpha haemolytic streptococcal infection	1 (2.2)	0	0	1 (2.2)	0
Bacterial sepsis	1 (2.2)	0	0	0	1 (2.2)
Body tinea	1 (2.2)	1 (2.2)	0	0	0
Bronchitis	1 (2.2)	0	1 (2.2)	0	0
Bronchopulmonary aspergillosis	1 (2.2)	0	0	1 (2.2)	0
Campylobacter infection	1 (2.2)	0	0	1 (2.2)	0
Catheter site cellulitis	1 (2.2)	1 (2.2)	0	0	0
Catheter site infection	1 (2.2)	0	0	1 (2.2)	0
Cellulitis	1 (2.2)	0	0	1 (2.2)	0
Cholecystitis infective	1 (2.2)	0	0	1 (2.2)	0

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Conjunctivitis	1 (2.2)	0	1 (2.2)	0	0
Croup infectious	1 (2.2)	0	0	1 (2.2)	0
Ear infection	1 (2.2)	0	1 (2.2)	0	0
Enterococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Enterovirus infection	1 (2.2)	0	0	1 (2.2)	0
Escherichia bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Escherichia infection	1 (2.2)	0	0	1 (2.2)	0
Escherichia urinary tract infection	1 (2.2)	0	1 (2.2)	0	0
Folliculitis	1 (2.2)	0	1 (2.2)	0	0
Fungal skin infection	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis viral	1 (2.2)	1 (2.2)	0	0	0
Gingivitis	1 (2.2)	1 (2.2)	0	0	0
Haemophilus infection	1 (2.2)	0	1 (2.2)	0	0
Herpes simplex	1 (2.2)	1 (2.2)	0	0	0
Herpes zoster	1 (2.2)	0	0	1 (2.2)	0
Human herpesvirus 6 infection	1 (2.2)	0	1 (2.2)	0	0
Human polyomavirus infection	1 (2.2)	0	0	0	1 (2.2)
Hypopyon	1 (2.2)	0	1 (2.2)	0	0

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (2.2)	0	0	1 (2.2)	0
Klebsiella sepsis	1 (2.2)	0	0	0	1 (2.2)
Metapneumovirus infection	1 (2.2)	0	1 (2.2)	0	0
Molluscum contagiosum	1 (2.2)	1 (2.2)	0	0	0
Necrotising fasciitis	1 (2.2)	0	0	1 (2.2)	0
Oral candidiasis	1 (2.2)	1 (2.2)	0	0	0
Orchitis	1 (2.2)	1 (2.2)	0	0	0
Otitis media	1 (2.2)	0	0	1 (2.2)	0
Otitis media acute	1 (2.2)	0	1 (2.2)	0	0
Parainfluenzae virus infection	1 (2.2)	0	0	1 (2.2)	0
Pharyngitis	1 (2.2)	0	1 (2.2)	0	0
Pneumonia fungal	1 (2.2)	0	1 (2.2)	0	0
Rash pustular	1 (2.2)	0	1 (2.2)	0	0
Respiratory syncytial virus infection	1 (2.2)	0	1 (2.2)	0	0
Respiratory tract infection	1 (2.2)	0	0	0	1 (2.2)
Respiratory tract infection viral	1 (2.2)	0	0	1 (2.2)	0
Rhinitis	1 (2.2)	1 (2.2)	0	0	0
Rotavirus infection	1 (2.2)	0	0	1 (2.2)	0

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (2.2)	0	0	0	1 (2.2)
Septic embolus	1 (2.2)	0	0	0	1 (2.2)
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal scalded skin syndrome	1 (2.2)	0	1 (2.2)	0	0
Staphylococcal sepsis	1 (2.2)	0	0	0	1 (2.2)
Urinary tract infection	1 (2.2)	0	1 (2.2)	0	0
Urinary tract infection enterococcal	1 (2.2)	0	0	1 (2.2)	0
Vascular device infection	1 (2.2)	0	0	1 (2.2)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	18 (40.0)	4 (8.9)	10 (22.2)	4 (8.9)	0
Hypogammaglobulinaemia	18 (40.0)	4 (8.9)	10 (22.2)	4 (8.9)	0
Blood immunoglobulin m decreased	3 (6.7)	3 (6.7)	0	0	0
Blood immunoglobulin a decreased	2 (4.4)	2 (4.4)	0	0	0
Serious neurological adverse reactions					
-Total	21 (46.7)	8 (17.8)	6 (13.3)	6 (13.3)	1 (2.2)
Confusional state	7 (15.6)	2 (4.4)	5 (11.1)	0	0
Delirium	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Irritability	3 (6.7)	3 (6.7)	0	0	0
Seizure	3 (6.7)	0	0	2 (4.4)	1 (2.2)
Agitation	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Mental status changes	2 (4.4)	2 (4.4)	0	0	0
Depressed level of consciousness	1 (2.2)	1 (2.2)	0	0	0
Disturbance in attention	1 (2.2)	1 (2.2)	0	0	0
Dysphagia	1 (2.2)	0	0	1 (2.2)	0
Hallucination	1 (2.2)	0	1 (2.2)	0	0
Hyporesponsive to stimuli	1 (2.2)	0	0	1 (2.2)	0
Leukoencephalopathy	1 (2.2)	0	0	1 (2.2)	0
Listless	1 (2.2)	1 (2.2)	0	0	0
Muscular weakness	1 (2.2)	1 (2.2)	0	0	0
Somnolence	1 (2.2)	0	1 (2.2)	0	0
Tremor	1 (2.2)	1 (2.2)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.2)	0	0	1 (2.2)	0
Tumour lysis syndrome	1 (2.2)	0	0	1 (2.2)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202e
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	2 (25.0)	2 (25.0)	4 (50.0)
Cytokine Release Syndrome					
-Total	5 (62.5)	0	2 (25.0)	0	3 (37.5)
Cytokine release syndrome	5 (62.5)	0	2 (25.0)	0	3 (37.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (37.5)	1 (12.5)	0	1 (12.5)	1 (12.5)
Anaemia	1 (12.5)	0	0	1 (12.5)	0
Neutropenia	1 (12.5)	0	0	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	0	1 (12.5)	0
White blood cell count decreased	1 (12.5)	1 (12.5)	0	0	0
Infections					

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (75.0)	1 (12.5)	2 (25.0)	1 (12.5)	2 (25.0)
Upper respiratory tract infection	2 (25.0)	0	2 (25.0)	0	0
Viral infection	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	1 (12.5)	0	0
Corona virus infection	1 (12.5)	0	0	1 (12.5)	0
Ear infection	1 (12.5)	1 (12.5)	0	0	0
Gastroenteritis	1 (12.5)	0	1 (12.5)	0	0
Human polyomavirus infection	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Respiratory syncytial virus infection	1 (12.5)	0	0	1 (12.5)	0
Rhinovirus infection	1 (12.5)	1 (12.5)	0	0	0
Skin infection	1 (12.5)	0	1 (12.5)	0	0
Tinea capitis	1 (12.5)	1 (12.5)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (50.0)	0	4 (50.0)	0	0

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypogammaglobulinaemia	4 (50.0)	0	4 (50.0)	0	0
Blood immunoglobulin m decreased	1 (12.5)	1 (12.5)	0	0	0
Serious neurological adverse reactions					
-Total	4 (50.0)	2 (25.0)	2 (25.0)	0	0
Confusional state	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Delirium	1 (12.5)	1 (12.5)	0	0	0
Muscular weakness	1 (12.5)	1 (12.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202e
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (94.0)	0	8 (11.9)	25 (37.3)	30 (44.8)
Cytokine Release Syndrome					
-Total	45 (67.2)	6 (9.0)	23 (34.3)	8 (11.9)	8 (11.9)
Cytokine release syndrome	45 (67.2)	6 (9.0)	23 (34.3)	8 (11.9)	8 (11.9)
Haemophagocytic lymphohistiocytosis	1 (1.5)	0	1 (1.5)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	31 (46.3)	1 (1.5)	3 (4.5)	10 (14.9)	17 (25.4)
White blood cell count decreased	17 (25.4)	0	1 (1.5)	7 (10.4)	9 (13.4)
Neutrophil count decreased	12 (17.9)	0	0	2 (3.0)	10 (14.9)
Platelet count decreased	8 (11.9)	1 (1.5)	1 (1.5)	1 (1.5)	5 (7.5)

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	7 (10.4)	0	4 (6.0)	3 (4.5)	0
Neutropenia	5 (7.5)	0	0	1 (1.5)	4 (6.0)
Thrombocytopenia	5 (7.5)	1 (1.5)	0	2 (3.0)	2 (3.0)
Febrile neutropenia	3 (4.5)	0	0	3 (4.5)	0
Lymphocyte count decreased	3 (4.5)	0	0	2 (3.0)	1 (1.5)
Pancytopenia	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Leukopenia	1 (1.5)	0	0	0	1 (1.5)
Lymphopenia	1 (1.5)	0	0	1 (1.5)	0
Infections					
-Total	49 (73.1)	3 (4.5)	13 (19.4)	23 (34.3)	10 (14.9)
Upper respiratory tract infection	9 (13.4)	5 (7.5)	3 (4.5)	1 (1.5)	0
Clostridium difficile colitis	6 (9.0)	1 (1.5)	2 (3.0)	3 (4.5)	0
Pneumonia	6 (9.0)	0	5 (7.5)	1 (1.5)	0
Clostridium difficile infection	5 (7.5)	0	4 (6.0)	1 (1.5)	0
Device related infection	5 (7.5)	0	1 (1.5)	4 (6.0)	0
Rhinovirus infection	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Sinusitis	5 (7.5)	1 (1.5)	4 (6.0)	0	0
Urinary tract infection	5 (7.5)	0	3 (4.5)	2 (3.0)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	4 (6.0)	1 (1.5)	2 (3.0)	1 (1.5)	0
Influenza	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Otitis media	4 (6.0)	0	3 (4.5)	1 (1.5)	0
Parainfluenzae virus infection	4 (6.0)	2 (3.0)	1 (1.5)	1 (1.5)	0
Staphylococcal infection	4 (6.0)	1 (1.5)	0	2 (3.0)	1 (1.5)
Viral upper respiratory tract infection	4 (6.0)	2 (3.0)	1 (1.5)	1 (1.5)	0
Escherichia urinary tract infection	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Oral herpes	3 (4.5)	0	3 (4.5)	0	0
Bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Conjunctivitis	2 (3.0)	0	2 (3.0)	0	0
Cytomegalovirus infection	2 (3.0)	2 (3.0)	0	0	0
Enterococcal bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Escherichia bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Fungal skin infection	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Klebsiella sepsis	2 (3.0)	0	0	0	2 (3.0)
Otitis media acute	2 (3.0)	0	2 (3.0)	0	0
Pneumonia fungal	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Sepsis	2 (3.0)	0	0	0	2 (3.0)

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Streptococcal infection	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Vulvovaginal candidiasis	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Acute sinusitis	1 (1.5)	0	1 (1.5)	0	0
Alpha haemolytic streptococcal infection	1 (1.5)	0	0	1 (1.5)	0
Bacterial sepsis	1 (1.5)	0	0	0	1 (1.5)
Body tinea	1 (1.5)	1 (1.5)	0	0	0
Bronchitis	1 (1.5)	0	1 (1.5)	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Campylobacter infection	1 (1.5)	0	0	1 (1.5)	0
Candida sepsis	1 (1.5)	0	0	0	1 (1.5)
Catheter site cellulitis	1 (1.5)	1 (1.5)	0	0	0
Catheter site infection	1 (1.5)	0	0	1 (1.5)	0
Cellulitis of male external genital organ	1 (1.5)	0	0	1 (1.5)	0
Cholecystitis infective	1 (1.5)	0	0	1 (1.5)	0
Croup infectious	1 (1.5)	0	0	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus viraemia	1 (1.5)	0	1 (1.5)	0	0
Ear infection	1 (1.5)	0	1 (1.5)	0	0
Enterococcal infection	1 (1.5)	1 (1.5)	0	0	0
Enterovirus infection	1 (1.5)	0	0	1 (1.5)	0
Escherichia infection	1 (1.5)	0	0	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	0	0	1 (1.5)
Folliculitis	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis norovirus	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis viral	1 (1.5)	1 (1.5)	0	0	0
Gingivitis	1 (1.5)	1 (1.5)	0	0	0
Haemophilus infection	1 (1.5)	0	1 (1.5)	0	0
Herpes simplex	1 (1.5)	1 (1.5)	0	0	0
Herpes zoster	1 (1.5)	0	0	1 (1.5)	0
Human herpesvirus 6 infection	1 (1.5)	0	1 (1.5)	0	0
Hypopyon	1 (1.5)	0	1 (1.5)	0	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Meningitis aseptic	1 (1.5)	0	1 (1.5)	0	0
Metapneumovirus infection	1 (1.5)	0	1 (1.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (1.5)	1 (1.5)	0	0	0
Necrotising fasciitis	1 (1.5)	0	0	1 (1.5)	0
Oral candidiasis	1 (1.5)	1 (1.5)	0	0	0
Orchitis	1 (1.5)	1 (1.5)	0	0	0
Otitis externa	1 (1.5)	0	1 (1.5)	0	0
Paronychia	1 (1.5)	1 (1.5)	0	0	0
Pharyngitis	1 (1.5)	0	1 (1.5)	0	0
Rash pustular	1 (1.5)	0	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	1 (1.5)	0	0
Respiratory tract infection	1 (1.5)	0	0	0	1 (1.5)
Respiratory tract infection viral	1 (1.5)	0	0	1 (1.5)	0
Rhinitis	1 (1.5)	1 (1.5)	0	0	0
Rotavirus infection	1 (1.5)	0	0	1 (1.5)	0
Septic embolus	1 (1.5)	0	0	0	1 (1.5)
Serratia infection	1 (1.5)	0	0	1 (1.5)	0
Skin infection	1 (1.5)	0	1 (1.5)	0	0
Skin papilloma	1 (1.5)	0	1 (1.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (1.5)	0	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Subcutaneous abscess	1 (1.5)	0	1 (1.5)	0	0
Urinary tract infection enterococcal	1 (1.5)	0	0	1 (1.5)	0
Vascular device infection	1 (1.5)	0	0	1 (1.5)	0
Viral infection	1 (1.5)	1 (1.5)	0	0	0
Vulvovaginal mycotic infection	1 (1.5)	0	1 (1.5)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	30 (44.8)	4 (6.0)	21 (31.3)	5 (7.5)	0
Hypogammaglobulinaemia	29 (43.3)	4 (6.0)	20 (29.9)	5 (7.5)	0
Blood immunoglobulin m decreased	4 (6.0)	4 (6.0)	0	0	0
Blood immunoglobulin a decreased	3 (4.5)	3 (4.5)	0	0	0
Blood immunoglobulin g decreased	1 (1.5)	0	1 (1.5)	0	0
Immunodeficiency	1 (1.5)	0	1 (1.5)	0	0
Serious neurological adverse reactions					
-Total	24 (35.8)	8 (11.9)	7 (10.4)	8 (11.9)	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	5 (7.5)	2 (3.0)	3 (4.5)	0	0
Seizure	5 (7.5)	0	2 (3.0)	2 (3.0)	1 (1.5)
Delirium	4 (6.0)	1 (1.5)	2 (3.0)	1 (1.5)	0
Encephalopathy	4 (6.0)	1 (1.5)	1 (1.5)	2 (3.0)	0
Mental status changes	4 (6.0)	3 (4.5)	0	1 (1.5)	0
Agitation	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Irritability	3 (4.5)	3 (4.5)	0	0	0
Dysarthria	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Dysphagia	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Hallucination	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Muscular weakness	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Somnolence	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Tremor	2 (3.0)	2 (3.0)	0	0	0
Asterixis	1 (1.5)	1 (1.5)	0	0	0
Depressed level of consciousness	1 (1.5)	1 (1.5)	0	0	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Hyporesponsive to stimuli	1 (1.5)	0	0	1 (1.5)	0
Leukoencephalopathy	1 (1.5)	0	0	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Listless	1 (1.5)	1 (1.5)	0	0	0
Tumour Lysis Syndrome					
-Total	5 (7.5)	0	0	5 (7.5)	0
Tumour lysis syndrome	5 (7.5)	0	0	5 (7.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202f
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	1 (50.0)	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Bacteraemia	1 (50.0)	0	0	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0
Otitis media	1 (50.0)	0	1 (50.0)	0	0
Urinary tract infection	1 (50.0)	0	0	1 (50.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (50.0)	0	1 (50.0)	0	0
Blood immunoglobulin a decreased	1 (50.0)	1 (50.0)	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin m decreased	1 (50.0)	1 (50.0)	0	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202f
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	69 (94.5)	0	9 (12.3)	26 (35.6)	34 (46.6)
Cytokine Release Syndrome					
-Total	50 (68.5)	6 (8.2)	25 (34.2)	8 (11.0)	11 (15.1)
Cytokine release syndrome	50 (68.5)	6 (8.2)	25 (34.2)	8 (11.0)	11 (15.1)
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	34 (46.6)	2 (2.7)	3 (4.1)	11 (15.1)	18 (24.7)
White blood cell count decreased	18 (24.7)	1 (1.4)	1 (1.4)	7 (9.6)	9 (12.3)
Neutrophil count decreased	13 (17.8)	0	0	3 (4.1)	10 (13.7)
Anaemia	8 (11.0)	0	4 (5.5)	4 (5.5)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (11.0)	1 (1.4)	1 (1.4)	1 (1.4)	5 (6.8)
Neutropenia	6 (8.2)	0	0	1 (1.4)	5 (6.8)
Thrombocytopenia	5 (6.8)	1 (1.4)	0	2 (2.7)	2 (2.7)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Lymphocyte count decreased	3 (4.1)	0	0	2 (2.7)	1 (1.4)
Pancytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	54 (74.0)	4 (5.5)	15 (20.5)	23 (31.5)	12 (16.4)
Upper respiratory tract infection	11 (15.1)	5 (6.8)	5 (6.8)	1 (1.4)	0
Pneumonia	7 (9.6)	0	5 (6.8)	1 (1.4)	1 (1.4)
Clostridium difficile colitis	6 (8.2)	1 (1.4)	2 (2.7)	3 (4.1)	0
Clostridium difficile infection	6 (8.2)	0	5 (6.8)	1 (1.4)	0
Rhinovirus infection	6 (8.2)	5 (6.8)	1 (1.4)	0	0
Device related infection	5 (6.8)	0	1 (1.4)	4 (5.5)	0
Gastroenteritis	5 (6.8)	1 (1.4)	3 (4.1)	1 (1.4)	0
Sinusitis	5 (6.8)	1 (1.4)	4 (5.5)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	4 (5.5)	1 (1.4)	3 (4.1)	0	0
Oral herpes	4 (5.5)	0	3 (4.1)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.5)	2 (2.7)	1 (1.4)	1 (1.4)	0
Staphylococcal infection	4 (5.5)	1 (1.4)	0	2 (2.7)	1 (1.4)
Urinary tract infection	4 (5.5)	0	3 (4.1)	1 (1.4)	0
Viral upper respiratory tract infection	4 (5.5)	2 (2.7)	1 (1.4)	1 (1.4)	0
Escherichia urinary tract infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Viral infection	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Conjunctivitis	2 (2.7)	0	2 (2.7)	0	0
Cytomegalovirus infection	2 (2.7)	2 (2.7)	0	0	0
Ear infection	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Enterococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Fungal skin infection	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Otitis media acute	2 (2.7)	0	2 (2.7)	0	0
Pneumonia fungal	2 (2.7)	0	1 (1.4)	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Sepsis	2 (2.7)	0	0	0	2 (2.7)
Skin infection	2 (2.7)	0	2 (2.7)	0	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Streptococcal infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Vulvovaginal candidiasis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Body tinea	1 (1.4)	1 (1.4)	0	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site cellulitis	1 (1.4)	1 (1.4)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Corona virus infection	1 (1.4)	0	0	1 (1.4)	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus viraemia	1 (1.4)	0	1 (1.4)	0	0
Enterococcal infection	1 (1.4)	1 (1.4)	0	0	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Haemophilus infection	1 (1.4)	0	1 (1.4)	0	0
Herpes simplex	1 (1.4)	1 (1.4)	0	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	1 (1.4)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Hypopyon	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Meningitis aseptic	1 (1.4)	0	1 (1.4)	0	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Oral candidiasis	1 (1.4)	1 (1.4)	0	0	0
Orchitis	1 (1.4)	1 (1.4)	0	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	1 (1.4)	0	0	0
Pharyngitis	1 (1.4)	0	1 (1.4)	0	0
Rash pustular	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinitis	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Skin papilloma	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Subcutaneous abscess	1 (1.4)	0	1 (1.4)	0	0
Tinea capitis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection enterococcal	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal mycotic infection	1 (1.4)	0	1 (1.4)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	33 (45.2)	4 (5.5)	24 (32.9)	5 (6.8)	0
Hypogammaglobulinaemia	32 (43.8)	4 (5.5)	23 (31.5)	5 (6.8)	0
Blood immunoglobulin m decreased	4 (5.5)	4 (5.5)	0	0	0
Blood immunoglobulin a decreased	2 (2.7)	2 (2.7)	0	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	28 (38.4)	10 (13.7)	9 (12.3)	8 (11.0)	1 (1.4)
Confusional state	8 (11.0)	3 (4.1)	5 (6.8)	0	0
Delirium	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Seizure	5 (6.8)	0	2 (2.7)	2 (2.7)	1 (1.4)
Encephalopathy	4 (5.5)	1 (1.4)	1 (1.4)	2 (2.7)	0
Mental status changes	4 (5.5)	3 (4.1)	0	1 (1.4)	0
Agitation	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Irritability	3 (4.1)	3 (4.1)	0	0	0
Muscular weakness	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Dysarthria	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Dysphagia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Hallucination	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Somnolence	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Tremor	2 (2.7)	2 (2.7)	0	0	0
Asterixis	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	1 (1.4)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0
Listless	1 (1.4)	1 (1.4)	0	0	0
Tumour Lysis Syndrome					
-Total	5 (6.8)	0	0	5 (6.8)	0
Tumour lysis syndrome	5 (6.8)	0	0	5 (6.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202g
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Cytokine Release Syndrome					
-Total	2 (66.7)	0	0	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	0	0	2 (66.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Neutropenia	2 (66.7)	0	0	0	2 (66.7)
Anaemia	1 (33.3)	0	0	1 (33.3)	0
Leukopenia	1 (33.3)	0	0	0	1 (33.3)
Neutrophil count decreased	1 (33.3)	0	0	1 (33.3)	0
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (33.3)	0	0	1 (33.3)	0
Infections					
-Total	1 (33.3)	0	0	1 (33.3)	0
Escherichia bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Pneumonia	1 (33.3)	0	1 (33.3)	0	0
Sinusitis	1 (33.3)	1 (33.3)	0	0	0
Upper respiratory tract infection	1 (33.3)	1 (33.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hypogammaglobulinaemia	1 (33.3)	0	0	1 (33.3)	0
Serious neurological adverse reactions					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Confusional state	1 (33.3)	1 (33.3)	0	0	0
Delirium	1 (33.3)	0	1 (33.3)	0	0
Dysphagia	1 (33.3)	0	0	1 (33.3)	0
Irritability	1 (33.3)	1 (33.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202g
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (94.4)	0	10 (13.9)	26 (36.1)	32 (44.4)
Cytokine Release Syndrome					
-Total	48 (66.7)	6 (8.3)	25 (34.7)	8 (11.1)	9 (12.5)
Cytokine release syndrome	48 (66.7)	6 (8.3)	25 (34.7)	8 (11.1)	9 (12.5)
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	31 (43.1)	2 (2.8)	3 (4.2)	10 (13.9)	16 (22.2)
White blood cell count decreased	17 (23.6)	1 (1.4)	1 (1.4)	6 (8.3)	9 (12.5)
Neutrophil count decreased	12 (16.7)	0	0	2 (2.8)	10 (13.9)
Anaemia	7 (9.7)	0	4 (5.6)	3 (4.2)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	7 (9.7)	1 (1.4)	1 (1.4)	0	5 (6.9)
Thrombocytopenia	5 (6.9)	1 (1.4)	0	2 (2.8)	2 (2.8)
Neutropenia	4 (5.6)	0	0	1 (1.4)	3 (4.2)
Febrile neutropenia	3 (4.2)	0	0	3 (4.2)	0
Lymphocyte count decreased	3 (4.2)	0	0	2 (2.8)	1 (1.4)
Pancytopenia	2 (2.8)	0	0	1 (1.4)	1 (1.4)
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	54 (75.0)	4 (5.6)	15 (20.8)	23 (31.9)	12 (16.7)
Upper respiratory tract infection	10 (13.9)	4 (5.6)	5 (6.9)	1 (1.4)	0
Clostridium difficile colitis	6 (8.3)	1 (1.4)	2 (2.8)	3 (4.2)	0
Clostridium difficile infection	6 (8.3)	0	5 (6.9)	1 (1.4)	0
Pneumonia	6 (8.3)	0	4 (5.6)	1 (1.4)	1 (1.4)
Rhinovirus infection	6 (8.3)	5 (6.9)	1 (1.4)	0	0
Device related infection	5 (6.9)	0	1 (1.4)	4 (5.6)	0
Gastroenteritis	5 (6.9)	1 (1.4)	3 (4.2)	1 (1.4)	0
Urinary tract infection	5 (6.9)	0	3 (4.2)	2 (2.8)	0
Influenza	4 (5.6)	1 (1.4)	3 (4.2)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	4 (5.6)	0	3 (4.2)	1 (1.4)	0
Otitis media	4 (5.6)	0	3 (4.2)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Sinusitis	4 (5.6)	0	4 (5.6)	0	0
Staphylococcal infection	4 (5.6)	1 (1.4)	0	2 (2.8)	1 (1.4)
Viral upper respiratory tract infection	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Escherichia urinary tract infection	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Viral infection	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Conjunctivitis	2 (2.8)	0	2 (2.8)	0	0
Cytomegalovirus infection	2 (2.8)	2 (2.8)	0	0	0
Ear infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Enterococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Fungal skin infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Otitis media acute	2 (2.8)	0	2 (2.8)	0	0
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	2 (2.8)	0	0	0	2 (2.8)
Skin infection	2 (2.8)	0	2 (2.8)	0	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Streptococcal infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Vulvovaginal candidiasis	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Body tinea	1 (1.4)	1 (1.4)	0	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site cellulitis	1 (1.4)	1 (1.4)	0	0	0
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Corona virus infection	1 (1.4)	0	0	1 (1.4)	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus viraemia	1 (1.4)	0	1 (1.4)	0	0
Enterococcal infection	1 (1.4)	1 (1.4)	0	0	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Haemophilus infection	1 (1.4)	0	1 (1.4)	0	0
Herpes simplex	1 (1.4)	1 (1.4)	0	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (1.4)	0	1 (1.4)	0	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Hypopyon	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Meningitis aseptic	1 (1.4)	0	1 (1.4)	0	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Oral candidiasis	1 (1.4)	1 (1.4)	0	0	0
Orchitis	1 (1.4)	1 (1.4)	0	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	1 (1.4)	0	0	0
Pharyngitis	1 (1.4)	0	1 (1.4)	0	0
Rash pustular	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinitis	1 (1.4)	1 (1.4)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Skin papilloma	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Subcutaneous abscess	1 (1.4)	0	1 (1.4)	0	0
Tinea capitis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection enterococcal	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal mycotic infection	1 (1.4)	0	1 (1.4)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	33 (45.8)	4 (5.6)	25 (34.7)	4 (5.6)	0
Hypogammaglobulinaemia	32 (44.4)	4 (5.6)	24 (33.3)	4 (5.6)	0
Blood immunoglobulin m decreased	5 (6.9)	5 (6.9)	0	0	0
Blood immunoglobulin a decreased	3 (4.2)	3 (4.2)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Immunodeficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	26 (36.1)	9 (12.5)	9 (12.5)	7 (9.7)	1 (1.4)
Confusional state	7 (9.7)	2 (2.8)	5 (6.9)	0	0
Seizure	5 (6.9)	0	2 (2.8)	2 (2.8)	1 (1.4)
Delirium	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Encephalopathy	4 (5.6)	1 (1.4)	1 (1.4)	2 (2.8)	0
Mental status changes	4 (5.6)	3 (4.2)	0	1 (1.4)	0
Agitation	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Muscular weakness	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Dysarthria	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Hallucination	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Irritability	2 (2.8)	2 (2.8)	0	0	0
Somnolence	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Tremor	2 (2.8)	2 (2.8)	0	0	0
Asterixis	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	1 (1.4)	0	0	0

Mixed-lineage leukemia rearrangement: No

Group term Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysphagia	1 (1.4)	0	1 (1.4)	0	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0
Listless	1 (1.4)	1 (1.4)	0	0	0
Tumour Lysis Syndrome					
-Total	5 (6.9)	0	0	5 (6.9)	0
Tumour lysis syndrome	5 (6.9)	0	0	5 (6.9)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202h
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Cytokine Release Syndrome					
-Total	1 (100)	0	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	1 (100)	0	0
Serious neurological adverse reactions					
-Total	1 (100)	0	1 (100)	0	0
Encephalopathy	1 (100)	0	1 (100)	0	0
Mental status changes	1 (100)	1 (100)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202h
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	70 (94.6)	0	9 (12.2)	27 (36.5)	34 (45.9)
Cytokine Release Syndrome					
-Total	49 (66.2)	6 (8.1)	24 (32.4)	8 (10.8)	11 (14.9)
Cytokine release syndrome	49 (66.2)	6 (8.1)	24 (32.4)	8 (10.8)	11 (14.9)
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	34 (45.9)	2 (2.7)	3 (4.1)	11 (14.9)	18 (24.3)
White blood cell count decreased	18 (24.3)	1 (1.4)	1 (1.4)	7 (9.5)	9 (12.2)
Neutrophil count decreased	13 (17.6)	0	0	3 (4.1)	10 (13.5)
Anaemia	8 (10.8)	0	4 (5.4)	4 (5.4)	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (10.8)	1 (1.4)	1 (1.4)	1 (1.4)	5 (6.8)
Neutropenia	6 (8.1)	0	0	1 (1.4)	5 (6.8)
Thrombocytopenia	5 (6.8)	1 (1.4)	0	2 (2.7)	2 (2.7)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Lymphocyte count decreased	3 (4.1)	0	0	2 (2.7)	1 (1.4)
Pancytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	55 (74.3)	4 (5.4)	15 (20.3)	24 (32.4)	12 (16.2)
Upper respiratory tract infection	11 (14.9)	5 (6.8)	5 (6.8)	1 (1.4)	0
Pneumonia	7 (9.5)	0	5 (6.8)	1 (1.4)	1 (1.4)
Clostridium difficile colitis	6 (8.1)	1 (1.4)	2 (2.7)	3 (4.1)	0
Clostridium difficile infection	6 (8.1)	0	5 (6.8)	1 (1.4)	0
Rhinovirus infection	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Device related infection	5 (6.8)	0	1 (1.4)	4 (5.4)	0
Gastroenteritis	5 (6.8)	1 (1.4)	3 (4.1)	1 (1.4)	0
Sinusitis	5 (6.8)	1 (1.4)	4 (5.4)	0	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	5 (6.8)	0	3 (4.1)	2 (2.7)	0
Influenza	4 (5.4)	1 (1.4)	3 (4.1)	0	0
Oral herpes	4 (5.4)	0	3 (4.1)	1 (1.4)	0
Otitis media	4 (5.4)	0	3 (4.1)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
Staphylococcal infection	4 (5.4)	1 (1.4)	0	2 (2.7)	1 (1.4)
Viral upper respiratory tract infection	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
Escherichia urinary tract infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Viral infection	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Conjunctivitis	2 (2.7)	0	2 (2.7)	0	0
Cytomegalovirus infection	2 (2.7)	2 (2.7)	0	0	0
Ear infection	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Enterococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Fungal skin infection	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Otitis media acute	2 (2.7)	0	2 (2.7)	0	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Sepsis	2 (2.7)	0	0	0	2 (2.7)
Skin infection	2 (2.7)	0	2 (2.7)	0	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Streptococcal infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Vulvovaginal candidiasis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Body tinea	1 (1.4)	1 (1.4)	0	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site cellulitis	1 (1.4)	1 (1.4)	0	0	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Corona virus infection	1 (1.4)	0	0	1 (1.4)	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus viraemia	1 (1.4)	0	1 (1.4)	0	0
Enterococcal infection	1 (1.4)	1 (1.4)	0	0	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Haemophilus infection	1 (1.4)	0	1 (1.4)	0	0
Herpes simplex	1 (1.4)	1 (1.4)	0	0	0

Hypodiploidy: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	1 (1.4)	0	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Hypopyon	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Meningitis aseptic	1 (1.4)	0	1 (1.4)	0	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Oral candidiasis	1 (1.4)	1 (1.4)	0	0	0
Orchitis	1 (1.4)	1 (1.4)	0	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	1 (1.4)	0	0	0
Pharyngitis	1 (1.4)	0	1 (1.4)	0	0
Rash pustular	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Skin papilloma	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Subcutaneous abscess	1 (1.4)	0	1 (1.4)	0	0
Tinea capitis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection enterococcal	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal mycotic infection	1 (1.4)	0	1 (1.4)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	34 (45.9)	4 (5.4)	25 (33.8)	5 (6.8)	0
Hypogammaglobulinaemia	33 (44.6)	4 (5.4)	24 (32.4)	5 (6.8)	0
Blood immunoglobulin m decreased	5 (6.8)	5 (6.8)	0	0	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	3 (4.1)	3 (4.1)	0	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Immunodeficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	27 (36.5)	10 (13.5)	8 (10.8)	8 (10.8)	1 (1.4)
Confusional state	8 (10.8)	3 (4.1)	5 (6.8)	0	0
Delirium	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Seizure	5 (6.8)	0	2 (2.7)	2 (2.7)	1 (1.4)
Agitation	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Encephalopathy	3 (4.1)	1 (1.4)	0	2 (2.7)	0
Irritability	3 (4.1)	3 (4.1)	0	0	0
Mental status changes	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Muscular weakness	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Dysarthria	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Dysphagia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Hallucination	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Somnolence	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Tremor	2 (2.7)	2 (2.7)	0	0	0

Hypodiploidy: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Asterixis	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	1 (1.4)	0	0	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0
Listless	1 (1.4)	1 (1.4)	0	0	0
Tumour Lysis Syndrome					
-Total	5 (6.8)	0	0	5 (6.8)	0
Tumour lysis syndrome	5 (6.8)	0	0	5 (6.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202i
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	1 (25.0)	3 (75.0)	0
Cytokine Release Syndrome					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Cytokine release syndrome	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Infections					
-Total	3 (75.0)	1 (25.0)	0	2 (50.0)	0
Bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Clostridium difficile infection	1 (25.0)	0	1 (25.0)	0	0
Cytomegalovirus infection	1 (25.0)	1 (25.0)	0	0	0
Cytomegalovirus viraemia	1 (25.0)	0	1 (25.0)	0	0
Enterococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingivitis	1 (25.0)	1 (25.0)	0	0	0
Herpes zoster	1 (25.0)	0	0	1 (25.0)	0
Otitis media acute	1 (25.0)	0	1 (25.0)	0	0
Parainfluenzae virus infection	1 (25.0)	1 (25.0)	0	0	0
Pharyngitis	1 (25.0)	0	1 (25.0)	0	0
Sinusitis	1 (25.0)	0	1 (25.0)	0	0
Skin papilloma	1 (25.0)	0	1 (25.0)	0	0
Streptococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Streptococcal infection	1 (25.0)	0	1 (25.0)	0	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Viral infection	1 (25.0)	1 (25.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (100)	0	4 (100)	0	0
Hypogammaglobulinaemia	4 (100)	0	4 (100)	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202i
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	67 (94.4)	0	9 (12.7)	24 (33.8)	34 (47.9)
Cytokine Release Syndrome					
-Total	48 (67.6)	6 (8.5)	24 (33.8)	7 (9.9)	11 (15.5)
Cytokine release syndrome	48 (67.6)	6 (8.5)	24 (33.8)	7 (9.9)	11 (15.5)
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	34 (47.9)	2 (2.8)	3 (4.2)	11 (15.5)	18 (25.4)
White blood cell count decreased	18 (25.4)	1 (1.4)	1 (1.4)	7 (9.9)	9 (12.7)
Neutrophil count decreased	13 (18.3)	0	0	3 (4.2)	10 (14.1)
Anaemia	8 (11.3)	0	4 (5.6)	4 (5.6)	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (11.3)	1 (1.4)	1 (1.4)	1 (1.4)	5 (7.0)
Neutropenia	6 (8.5)	0	0	1 (1.4)	5 (7.0)
Thrombocytopenia	5 (7.0)	1 (1.4)	0	2 (2.8)	2 (2.8)
Febrile neutropenia	3 (4.2)	0	0	3 (4.2)	0
Lymphocyte count decreased	3 (4.2)	0	0	2 (2.8)	1 (1.4)
Pancytopenia	2 (2.8)	0	0	1 (1.4)	1 (1.4)
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	52 (73.2)	3 (4.2)	15 (21.1)	22 (31.0)	12 (16.9)
Upper respiratory tract infection	10 (14.1)	4 (5.6)	5 (7.0)	1 (1.4)	0
Pneumonia	7 (9.9)	0	5 (7.0)	1 (1.4)	1 (1.4)
Clostridium difficile colitis	6 (8.5)	1 (1.4)	2 (2.8)	3 (4.2)	0
Rhinovirus infection	6 (8.5)	5 (7.0)	1 (1.4)	0	0
Clostridium difficile infection	5 (7.0)	0	4 (5.6)	1 (1.4)	0
Device related infection	5 (7.0)	0	1 (1.4)	4 (5.6)	0
Urinary tract infection	5 (7.0)	0	3 (4.2)	2 (2.8)	0
Gastroenteritis	4 (5.6)	1 (1.4)	3 (4.2)	0	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Oral herpes	4 (5.6)	0	3 (4.2)	1 (1.4)	0
Otitis media	4 (5.6)	0	3 (4.2)	1 (1.4)	0
Sinusitis	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Staphylococcal infection	4 (5.6)	1 (1.4)	0	2 (2.8)	1 (1.4)
Viral upper respiratory tract infection	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Escherichia urinary tract infection	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Parainfluenzae virus infection	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Conjunctivitis	2 (2.8)	0	2 (2.8)	0	0
Ear infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Escherichia bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Fungal skin infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Sepsis	2 (2.8)	0	0	0	2 (2.8)
Skin infection	2 (2.8)	0	2 (2.8)	0	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Vulvovaginal candidiasis	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Body tinea	1 (1.4)	1 (1.4)	0	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site cellulitis	1 (1.4)	1 (1.4)	0	0	0
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (1.4)	0	0	1 (1.4)	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus infection	1 (1.4)	1 (1.4)	0	0	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Enterococcal infection	1 (1.4)	1 (1.4)	0	0	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Haemophilus infection	1 (1.4)	0	1 (1.4)	0	0
Herpes simplex	1 (1.4)	1 (1.4)	0	0	0
Human herpesvirus 6 infection	1 (1.4)	0	1 (1.4)	0	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Hypopyon	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Meningitis aseptic	1 (1.4)	0	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Oral candidiasis	1 (1.4)	1 (1.4)	0	0	0
Orchitis	1 (1.4)	1 (1.4)	0	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Otitis media acute	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	1 (1.4)	0	0	0
Rash pustular	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinitis	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Subcutaneous abscess	1 (1.4)	0	1 (1.4)	0	0
Tinea capitis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection enterococcal	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal mycotic infection	1 (1.4)	0	1 (1.4)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	30 (42.3)	4 (5.6)	21 (29.6)	5 (7.0)	0
Hypogammaglobulinaemia	29 (40.8)	4 (5.6)	20 (28.2)	5 (7.0)	0
Blood immunoglobulin m decreased	4 (5.6)	4 (5.6)	0	0	0
Blood immunoglobulin a decreased	2 (2.8)	2 (2.8)	0	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Immunodeficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	28 (39.4)	10 (14.1)	9 (12.7)	8 (11.3)	1 (1.4)
Confusional state	8 (11.3)	3 (4.2)	5 (7.0)	0	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	5 (7.0)	2 (2.8)	2 (2.8)	1 (1.4)	0
Seizure	5 (7.0)	0	2 (2.8)	2 (2.8)	1 (1.4)
Encephalopathy	4 (5.6)	1 (1.4)	1 (1.4)	2 (2.8)	0
Mental status changes	4 (5.6)	3 (4.2)	0	1 (1.4)	0
Agitation	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Irritability	3 (4.2)	3 (4.2)	0	0	0
Muscular weakness	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Dysarthria	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Dysphagia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hallucination	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Somnolence	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Tremor	2 (2.8)	2 (2.8)	0	0	0
Asterixis	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	1 (1.4)	0	0	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0
Listless	1 (1.4)	1 (1.4)	0	0	0

BCR-ABL1-like: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	5 (7.0)	0	0	5 (7.0)	0
Tumour lysis syndrome	5 (7.0)	0	0	5 (7.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202j
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (95.5)	0	2 (9.1)	8 (36.4)	11 (50.0)
Cytokine Release Syndrome					
-Total	18 (81.8)	1 (4.5)	9 (40.9)	3 (13.6)	5 (22.7)
Cytokine release syndrome	18 (81.8)	1 (4.5)	9 (40.9)	3 (13.6)	5 (22.7)
Haemophagocytic lymphohistiocytosis	1 (4.5)	0	1 (4.5)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	10 (45.5)	1 (4.5)	2 (9.1)	2 (9.1)	5 (22.7)
White blood cell count decreased	4 (18.2)	0	1 (4.5)	0	3 (13.6)
Neutropenia	3 (13.6)	0	0	0	3 (13.6)
Neutrophil count decreased	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Anaemia	2 (9.1)	0	2 (9.1)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	2 (9.1)	0	0	0	2 (9.1)
Leukopenia	1 (4.5)	0	0	0	1 (4.5)
Lymphocyte count decreased	1 (4.5)	0	0	1 (4.5)	0
Pancytopenia	1 (4.5)	0	0	1 (4.5)	0
Thrombocytopenia	1 (4.5)	1 (4.5)	0	0	0
Infections					
-Total	18 (81.8)	1 (4.5)	5 (22.7)	7 (31.8)	5 (22.7)
Upper respiratory tract infection	6 (27.3)	3 (13.6)	3 (13.6)	0	0
Gastroenteritis	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0
Rhinovirus infection	3 (13.6)	3 (13.6)	0	0	0
Clostridium difficile colitis	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Clostridium difficile infection	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Conjunctivitis	2 (9.1)	0	2 (9.1)	0	0
Device related infection	2 (9.1)	0	0	2 (9.1)	0
Ear infection	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pneumonia	2 (9.1)	0	2 (9.1)	0	0
Urinary tract infection	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Alpha haemolytic streptococcal infection	1 (4.5)	0	0	1 (4.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Bacterial sepsis	1 (4.5)	0	0	0	1 (4.5)
Campylobacter infection	1 (4.5)	0	0	1 (4.5)	0
Candida sepsis	1 (4.5)	0	0	0	1 (4.5)
Catheter site cellulitis	1 (4.5)	1 (4.5)	0	0	0
Cellulitis of male external genital organ	1 (4.5)	0	0	1 (4.5)	0
Enterovirus infection	1 (4.5)	0	0	1 (4.5)	0
Escherichia bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Escherichia urinary tract infection	1 (4.5)	0	1 (4.5)	0	0
Folliculitis	1 (4.5)	0	1 (4.5)	0	0
Fungal skin infection	1 (4.5)	1 (4.5)	0	0	0
Gingivitis	1 (4.5)	1 (4.5)	0	0	0
Herpes simplex	1 (4.5)	1 (4.5)	0	0	0
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Molluscum contagiosum	1 (4.5)	1 (4.5)	0	0	0
Oral herpes	1 (4.5)	0	1 (4.5)	0	0
Orchitis	1 (4.5)	1 (4.5)	0	0	0
Otitis media	1 (4.5)	0	1 (4.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (4.5)	0	1 (4.5)	0	0
Pharyngitis	1 (4.5)	0	1 (4.5)	0	0
Pneumonia fungal	1 (4.5)	0	0	1 (4.5)	0
Respiratory tract infection	1 (4.5)	0	0	0	1 (4.5)
Respiratory tract infection viral	1 (4.5)	0	0	1 (4.5)	0
Rhinitis	1 (4.5)	1 (4.5)	0	0	0
Rotavirus infection	1 (4.5)	0	0	1 (4.5)	0
Sepsis	1 (4.5)	0	0	0	1 (4.5)
Septic embolus	1 (4.5)	0	0	0	1 (4.5)
Sinusitis	1 (4.5)	1 (4.5)	0	0	0
Skin infection	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal infection	1 (4.5)	0	0	1 (4.5)	0
Streptococcal infection	1 (4.5)	0	1 (4.5)	0	0
Tinea capitis	1 (4.5)	1 (4.5)	0	0	0
Urinary tract infection enterococcal	1 (4.5)	0	0	1 (4.5)	0
Vascular device infection	1 (4.5)	0	0	1 (4.5)	0
Viral infection	1 (4.5)	1 (4.5)	0	0	0
Viral upper respiratory tract infection	1 (4.5)	1 (4.5)	0	0	0
Vulvovaginal candidiasis	1 (4.5)	0	1 (4.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	12 (54.5)	2 (9.1)	7 (31.8)	3 (13.6)	0
Hypogammaglobulinaemia	12 (54.5)	2 (9.1)	7 (31.8)	3 (13.6)	0
Blood immunoglobulin a decreased	2 (9.1)	2 (9.1)	0	0	0
Blood immunoglobulin m decreased	2 (9.1)	2 (9.1)	0	0	0
Serious neurological adverse reactions					
-Total	8 (36.4)	3 (13.6)	2 (9.1)	3 (13.6)	0
Irritability	3 (13.6)	3 (13.6)	0	0	0
Confusional state	2 (9.1)	0	2 (9.1)	0	0
Delirium	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Encephalopathy	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Hallucination	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Agitation	1 (4.5)	0	1 (4.5)	0	0
Disturbance in attention	1 (4.5)	1 (4.5)	0	0	0
Dysphagia	1 (4.5)	0	0	1 (4.5)	0
Listless	1 (4.5)	1 (4.5)	0	0	0
Mental status changes	1 (4.5)	1 (4.5)	0	0	0
Seizure	1 (4.5)	0	0	1 (4.5)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202j
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (94.3)	0	8 (15.1)	19 (35.8)	23 (43.4)
Cytokine Release Syndrome					
-Total	32 (60.4)	5 (9.4)	16 (30.2)	5 (9.4)	6 (11.3)
Cytokine release syndrome	32 (60.4)	5 (9.4)	16 (30.2)	5 (9.4)	6 (11.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	24 (45.3)	1 (1.9)	1 (1.9)	9 (17.0)	13 (24.5)
White blood cell count decreased	14 (26.4)	1 (1.9)	0	7 (13.2)	6 (11.3)
Neutrophil count decreased	10 (18.9)	0	0	2 (3.8)	8 (15.1)
Anaemia	6 (11.3)	0	2 (3.8)	4 (7.5)	0
Platelet count decreased	6 (11.3)	1 (1.9)	1 (1.9)	1 (1.9)	3 (5.7)
Thrombocytopenia	4 (7.5)	0	0	2 (3.8)	2 (3.8)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	3 (5.7)	0	0	3 (5.7)	0
Neutropenia	3 (5.7)	0	0	1 (1.9)	2 (3.8)
Lymphocyte count decreased	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Lymphopenia	1 (1.9)	0	0	1 (1.9)	0
Pancytopenia	1 (1.9)	0	0	0	1 (1.9)
Infections					
-Total	37 (69.8)	3 (5.7)	10 (18.9)	17 (32.1)	7 (13.2)
Pneumonia	5 (9.4)	0	3 (5.7)	1 (1.9)	1 (1.9)
Upper respiratory tract infection	5 (9.4)	2 (3.8)	2 (3.8)	1 (1.9)	0
Clostridium difficile colitis	4 (7.5)	0	1 (1.9)	3 (5.7)	0
Clostridium difficile infection	4 (7.5)	0	4 (7.5)	0	0
Influenza	4 (7.5)	1 (1.9)	3 (5.7)	0	0
Sinusitis	4 (7.5)	0	4 (7.5)	0	0
Device related infection	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Oral herpes	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Otitis media	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Parainfluenzae virus infection	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Rhinovirus infection	3 (5.7)	2 (3.8)	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	3 (5.7)	1 (1.9)	0	1 (1.9)	1 (1.9)
Urinary tract infection	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Viral upper respiratory tract infection	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Cytomegalovirus infection	2 (3.8)	2 (3.8)	0	0	0
Enterococcal bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Escherichia urinary tract infection	2 (3.8)	0	0	2 (3.8)	0
Klebsiella sepsis	2 (3.8)	0	0	0	2 (3.8)
Otitis media acute	2 (3.8)	0	2 (3.8)	0	0
Respiratory syncytial virus infection	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Staphylococcal bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Viral infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Abscess limb	1 (1.9)	0	0	1 (1.9)	0
Acute sinusitis	1 (1.9)	0	1 (1.9)	0	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Body tinea	1 (1.9)	1 (1.9)	0	0	0
Bronchitis	1 (1.9)	0	1 (1.9)	0	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Catheter site infection	1 (1.9)	0	0	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0
Croup infectious	1 (1.9)	0	0	1 (1.9)	0
Cytomegalovirus viraemia	1 (1.9)	0	1 (1.9)	0	0
Enterococcal infection	1 (1.9)	1 (1.9)	0	0	0
Escherichia bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	0	0	1 (1.9)
Fungal skin infection	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0
Haemophilus infection	1 (1.9)	0	1 (1.9)	0	0
Human herpesvirus 6 infection	1 (1.9)	0	1 (1.9)	0	0
Human polyomavirus infection	1 (1.9)	0	0	0	1 (1.9)
Hypopyon	1 (1.9)	0	1 (1.9)	0	0
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis aseptic	1 (1.9)	0	1 (1.9)	0	0
Metapneumovirus infection	1 (1.9)	0	1 (1.9)	0	0
Necrotising fasciitis	1 (1.9)	0	0	1 (1.9)	0
Oral candidiasis	1 (1.9)	1 (1.9)	0	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0
Pneumonia fungal	1 (1.9)	0	1 (1.9)	0	0
Rash pustular	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	0	0	1 (1.9)	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Serratia infection	1 (1.9)	0	0	1 (1.9)	0
Skin infection	1 (1.9)	0	1 (1.9)	0	0
Skin papilloma	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Streptococcal infection	1 (1.9)	0	0	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Vulvovaginal candidiasis	1 (1.9)	1 (1.9)	0	0	0
Vulvovaginal mycotic infection	1 (1.9)	0	1 (1.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	22 (41.5)	2 (3.8)	18 (34.0)	2 (3.8)	0
Hypogammaglobulinaemia	21 (39.6)	2 (3.8)	17 (32.1)	2 (3.8)	0
Blood immunoglobulin m decreased	3 (5.7)	3 (5.7)	0	0	0
Blood immunoglobulin a decreased	1 (1.9)	1 (1.9)	0	0	0
Blood immunoglobulin g decreased	1 (1.9)	0	1 (1.9)	0	0
Immunodeficiency	1 (1.9)	0	1 (1.9)	0	0
Serious neurological adverse reactions					
-Total	20 (37.7)	7 (13.2)	7 (13.2)	5 (9.4)	1 (1.9)
Confusional state	6 (11.3)	3 (5.7)	3 (5.7)	0	0
Seizure	4 (7.5)	0	2 (3.8)	1 (1.9)	1 (1.9)
Delirium	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Mental status changes	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Muscular weakness	3 (5.7)	2 (3.8)	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Dysarthria	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Encephalopathy	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Somnolence	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Tremor	2 (3.8)	2 (3.8)	0	0	0
Asterixis	1 (1.9)	1 (1.9)	0	0	0
Depressed level of consciousness	1 (1.9)	1 (1.9)	0	0	0
Dysphagia	1 (1.9)	0	1 (1.9)	0	0
Hyporesponsive to stimuli	1 (1.9)	0	0	1 (1.9)	0
Leukoencephalopathy	1 (1.9)	0	0	1 (1.9)	0
Tumour Lysis Syndrome					
-Total	5 (9.4)	0	0	5 (9.4)	0
Tumour lysis syndrome	5 (9.4)	0	0	5 (9.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202k
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	71 (94.7)	0	10 (13.3)	27 (36.0)	34 (45.3)
Cytokine Release Syndrome					
-Total	50 (66.7)	6 (8.0)	25 (33.3)	8 (10.7)	11 (14.7)
Cytokine release syndrome	50 (66.7)	6 (8.0)	25 (33.3)	8 (10.7)	11 (14.7)
Haemophagocytic lymphohistiocytosis	1 (1.3)	0	1 (1.3)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	34 (45.3)	2 (2.7)	3 (4.0)	11 (14.7)	18 (24.0)
White blood cell count decreased	18 (24.0)	1 (1.3)	1 (1.3)	7 (9.3)	9 (12.0)
Neutrophil count decreased	13 (17.3)	0	0	3 (4.0)	10 (13.3)
Anaemia	8 (10.7)	0	4 (5.3)	4 (5.3)	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Platelet count decreased	8 (10.7)	1 (1.3)	1 (1.3)	1 (1.3)	5 (6.7)
Neutropenia	6 (8.0)	0	0	1 (1.3)	5 (6.7)
Thrombocytopenia	5 (6.7)	1 (1.3)	0	2 (2.7)	2 (2.7)
Febrile neutropenia	3 (4.0)	0	0	3 (4.0)	0
Lymphocyte count decreased	3 (4.0)	0	0	2 (2.7)	1 (1.3)
Pancytopenia	2 (2.7)	0	0	1 (1.3)	1 (1.3)
Leukopenia	1 (1.3)	0	0	0	1 (1.3)
Lymphopenia	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	55 (73.3)	4 (5.3)	15 (20.0)	24 (32.0)	12 (16.0)
Upper respiratory tract infection	11 (14.7)	5 (6.7)	5 (6.7)	1 (1.3)	0
Pneumonia	7 (9.3)	0	5 (6.7)	1 (1.3)	1 (1.3)
Clostridium difficile colitis	6 (8.0)	1 (1.3)	2 (2.7)	3 (4.0)	0
Clostridium difficile infection	6 (8.0)	0	5 (6.7)	1 (1.3)	0
Rhinovirus infection	6 (8.0)	5 (6.7)	1 (1.3)	0	0
Device related infection	5 (6.7)	0	1 (1.3)	4 (5.3)	0
Gastroenteritis	5 (6.7)	1 (1.3)	3 (4.0)	1 (1.3)	0
Sinusitis	5 (6.7)	1 (1.3)	4 (5.3)	0	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary tract infection	5 (6.7)	0	3 (4.0)	2 (2.7)	0
Influenza	4 (5.3)	1 (1.3)	3 (4.0)	0	0
Oral herpes	4 (5.3)	0	3 (4.0)	1 (1.3)	0
Otitis media	4 (5.3)	0	3 (4.0)	1 (1.3)	0
Parainfluenzae virus infection	4 (5.3)	2 (2.7)	1 (1.3)	1 (1.3)	0
Staphylococcal infection	4 (5.3)	1 (1.3)	0	2 (2.7)	1 (1.3)
Viral upper respiratory tract infection	4 (5.3)	2 (2.7)	1 (1.3)	1 (1.3)	0
Escherichia urinary tract infection	3 (4.0)	0	1 (1.3)	2 (2.7)	0
Viral infection	3 (4.0)	2 (2.7)	1 (1.3)	0	0
Bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Conjunctivitis	2 (2.7)	0	2 (2.7)	0	0
Cytomegalovirus infection	2 (2.7)	2 (2.7)	0	0	0
Ear infection	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Enterococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Fungal skin infection	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Otitis media acute	2 (2.7)	0	2 (2.7)	0	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Respiratory syncytial virus infection	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Sepsis	2 (2.7)	0	0	0	2 (2.7)
Skin infection	2 (2.7)	0	2 (2.7)	0	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Streptococcal infection	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Vulvovaginal candidiasis	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Abscess limb	1 (1.3)	0	0	1 (1.3)	0
Acute sinusitis	1 (1.3)	0	1 (1.3)	0	0
Alpha haemolytic streptococcal infection	1 (1.3)	0	0	1 (1.3)	0
Bacterial sepsis	1 (1.3)	0	0	0	1 (1.3)
Body tinea	1 (1.3)	1 (1.3)	0	0	0
Bronchitis	1 (1.3)	0	1 (1.3)	0	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Campylobacter infection	1 (1.3)	0	0	1 (1.3)	0
Candida sepsis	1 (1.3)	0	0	0	1 (1.3)
Catheter site cellulitis	1 (1.3)	1 (1.3)	0	0	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Catheter site infection	1 (1.3)	0	0	1 (1.3)	0
Cellulitis	1 (1.3)	0	0	1 (1.3)	0
Cellulitis of male external genital organ	1 (1.3)	0	0	1 (1.3)	0
Cholecystitis infective	1 (1.3)	0	0	1 (1.3)	0
Corona virus infection	1 (1.3)	0	0	1 (1.3)	0
Croup infectious	1 (1.3)	0	0	1 (1.3)	0
Cytomegalovirus viraemia	1 (1.3)	0	1 (1.3)	0	0
Enterococcal infection	1 (1.3)	1 (1.3)	0	0	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0
Escherichia infection	1 (1.3)	0	0	1 (1.3)	0
Escherichia sepsis	1 (1.3)	0	0	0	1 (1.3)
Folliculitis	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis norovirus	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis viral	1 (1.3)	1 (1.3)	0	0	0
Gingivitis	1 (1.3)	1 (1.3)	0	0	0
Haemophilus infection	1 (1.3)	0	1 (1.3)	0	0
Herpes simplex	1 (1.3)	1 (1.3)	0	0	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	1 (1.3)	0	0	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	0	1 (1.3)	0	0
Human polyomavirus infection	1 (1.3)	0	0	0	1 (1.3)
Hypopyon	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Meningitis aseptic	1 (1.3)	0	1 (1.3)	0	0
Metapneumovirus infection	1 (1.3)	0	1 (1.3)	0	0
Molluscum contagiosum	1 (1.3)	1 (1.3)	0	0	0
Necrotising fasciitis	1 (1.3)	0	0	1 (1.3)	0
Oral candidiasis	1 (1.3)	1 (1.3)	0	0	0
Orchitis	1 (1.3)	1 (1.3)	0	0	0
Otitis externa	1 (1.3)	0	1 (1.3)	0	0
Paronychia	1 (1.3)	1 (1.3)	0	0	0
Pharyngitis	1 (1.3)	0	1 (1.3)	0	0
Rash pustular	1 (1.3)	0	1 (1.3)	0	0
Respiratory syncytial virus bronchitis	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection	1 (1.3)	0	0	0	1 (1.3)
Respiratory tract infection viral	1 (1.3)	0	0	1 (1.3)	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinitis	1 (1.3)	1 (1.3)	0	0	0
Rotavirus infection	1 (1.3)	0	0	1 (1.3)	0
Septic embolus	1 (1.3)	0	0	0	1 (1.3)
Serratia infection	1 (1.3)	0	0	1 (1.3)	0
Skin papilloma	1 (1.3)	0	1 (1.3)	0	0
Staphylococcal scalded skin syndrome	1 (1.3)	0	1 (1.3)	0	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Streptococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Subcutaneous abscess	1 (1.3)	0	1 (1.3)	0	0
Tinea capitis	1 (1.3)	1 (1.3)	0	0	0
Urinary tract infection enterococcal	1 (1.3)	0	0	1 (1.3)	0
Vascular device infection	1 (1.3)	0	0	1 (1.3)	0
Vulvovaginal mycotic infection	1 (1.3)	0	1 (1.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	34 (45.3)	4 (5.3)	25 (33.3)	5 (6.7)	0
Hypogammaglobulinaemia	33 (44.0)	4 (5.3)	24 (32.0)	5 (6.7)	0
Blood immunoglobulin m decreased	5 (6.7)	5 (6.7)	0	0	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin a decreased	3 (4.0)	3 (4.0)	0	0	0
Blood immunoglobulin g decreased	1 (1.3)	0	1 (1.3)	0	0
Immunodeficiency	1 (1.3)	0	1 (1.3)	0	0
Serious neurological adverse reactions					
-Total	28 (37.3)	10 (13.3)	9 (12.0)	8 (10.7)	1 (1.3)
Confusional state	8 (10.7)	3 (4.0)	5 (6.7)	0	0
Delirium	5 (6.7)	2 (2.7)	2 (2.7)	1 (1.3)	0
Seizure	5 (6.7)	0	2 (2.7)	2 (2.7)	1 (1.3)
Encephalopathy	4 (5.3)	1 (1.3)	1 (1.3)	2 (2.7)	0
Mental status changes	4 (5.3)	3 (4.0)	0	1 (1.3)	0
Agitation	3 (4.0)	0	2 (2.7)	1 (1.3)	0
Irritability	3 (4.0)	3 (4.0)	0	0	0
Muscular weakness	3 (4.0)	2 (2.7)	1 (1.3)	0	0
Dysarthria	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Dysphagia	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Hallucination	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Somnolence	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Tremor	2 (2.7)	2 (2.7)	0	0	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Asterixis	1 (1.3)	1 (1.3)	0	0	0
Depressed level of consciousness	1 (1.3)	1 (1.3)	0	0	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Hyporesponsive to stimuli	1 (1.3)	0	0	1 (1.3)	0
Leukoencephalopathy	1 (1.3)	0	0	1 (1.3)	0
Listless	1 (1.3)	1 (1.3)	0	0	0
Tumour Lysis Syndrome					
-Total	5 (6.7)	0	0	5 (6.7)	0
Tumour lysis syndrome	5 (6.7)	0	0	5 (6.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202l
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (96.9)	0	3 (9.4)	15 (46.9)	13 (40.6)
Cytokine Release Syndrome					
-Total	20 (62.5)	3 (9.4)	11 (34.4)	4 (12.5)	2 (6.3)
Cytokine release syndrome	20 (62.5)	3 (9.4)	11 (34.4)	4 (12.5)	2 (6.3)
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	1 (3.1)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	13 (40.6)	1 (3.1)	1 (3.1)	6 (18.8)	5 (15.6)
White blood cell count decreased	8 (25.0)	0	1 (3.1)	5 (15.6)	2 (6.3)
Neutrophil count decreased	6 (18.8)	0	0	1 (3.1)	5 (15.6)
Platelet count decreased	4 (12.5)	0	0	1 (3.1)	3 (9.4)

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	3 (9.4)	0	0	3 (9.4)	0
Thrombocytopenia	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Febrile neutropenia	1 (3.1)	0	0	1 (3.1)	0
Lymphocyte count decreased	1 (3.1)	0	0	1 (3.1)	0
Infections					
-Total	25 (78.1)	2 (6.3)	4 (12.5)	12 (37.5)	7 (21.9)
Upper respiratory tract infection	6 (18.8)	4 (12.5)	1 (3.1)	1 (3.1)	0
Clostridium difficile infection	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Urinary tract infection	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Device related infection	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Otitis media	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Sinusitis	3 (9.4)	0	3 (9.4)	0	0
Bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Clostridium difficile colitis	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Cytomegalovirus infection	2 (6.3)	2 (6.3)	0	0	0
Enterococcal bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Escherichia urinary tract infection	2 (6.3)	0	0	2 (6.3)	0
Fungal skin infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Klebsiella sepsis	2 (6.3)	0	0	0	2 (6.3)
Oral herpes	2 (6.3)	0	2 (6.3)	0	0
Otitis media acute	2 (6.3)	0	2 (6.3)	0	0
Parainfluenzae virus infection	2 (6.3)	2 (6.3)	0	0	0
Pneumonia	2 (6.3)	0	2 (6.3)	0	0
Rhinovirus infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Sepsis	2 (6.3)	0	0	0	2 (6.3)
Staphylococcal bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Vulvovaginal candidiasis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Acute sinusitis	1 (3.1)	0	1 (3.1)	0	0
Body tinea	1 (3.1)	1 (3.1)	0	0	0
Bronchitis	1 (3.1)	0	1 (3.1)	0	0
Campylobacter infection	1 (3.1)	0	0	1 (3.1)	0
Catheter site cellulitis	1 (3.1)	1 (3.1)	0	0	0
Cellulitis of male external genital organ	1 (3.1)	0	0	1 (3.1)	0

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (3.1)	0	0	1 (3.1)	0
Conjunctivitis	1 (3.1)	0	1 (3.1)	0	0
Croup infectious	1 (3.1)	0	0	1 (3.1)	0
Cytomegalovirus viraemia	1 (3.1)	0	1 (3.1)	0	0
Ear infection	1 (3.1)	0	1 (3.1)	0	0
Enterococcal infection	1 (3.1)	1 (3.1)	0	0	0
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	0	0	1 (3.1)
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Haemophilus infection	1 (3.1)	0	1 (3.1)	0	0
Herpes simplex	1 (3.1)	1 (3.1)	0	0	0
Human herpesvirus 6 infection	1 (3.1)	0	1 (3.1)	0	0
Hypopyon	1 (3.1)	0	1 (3.1)	0	0
Klebsiella infection	1 (3.1)	0	0	1 (3.1)	0
Necrotising fasciitis	1 (3.1)	0	0	1 (3.1)	0
Oral candidiasis	1 (3.1)	1 (3.1)	0	0	0
Pneumonia fungal	1 (3.1)	0	1 (3.1)	0	0

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus bronchitis	1 (3.1)	0	0	1 (3.1)	0
Respiratory tract infection viral	1 (3.1)	0	0	1 (3.1)	0
Rhinitis	1 (3.1)	1 (3.1)	0	0	0
Rotavirus infection	1 (3.1)	0	0	1 (3.1)	0
Septic embolus	1 (3.1)	0	0	0	1 (3.1)
Skin infection	1 (3.1)	0	1 (3.1)	0	0
Skin papilloma	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal infection	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal scalded skin syndrome	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Vascular device infection	1 (3.1)	0	0	1 (3.1)	0
Viral upper respiratory tract infection	1 (3.1)	1 (3.1)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	14 (43.8)	3 (9.4)	10 (31.3)	1 (3.1)	0
Hypogammaglobulinaemia	14 (43.8)	3 (9.4)	10 (31.3)	1 (3.1)	0
Blood immunoglobulin m decreased	4 (12.5)	4 (12.5)	0	0	0

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	3 (9.4)	3 (9.4)	0	0	0
Serious neurological adverse reactions					
-Total	11 (34.4)	3 (9.4)	2 (6.3)	6 (18.8)	0
Confusional state	2 (6.3)	0	2 (6.3)	0	0
Encephalopathy	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Irritability	2 (6.3)	2 (6.3)	0	0	0
Mental status changes	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Seizure	2 (6.3)	0	0	2 (6.3)	0
Agitation	1 (3.1)	0	1 (3.1)	0	0
Delirium	1 (3.1)	0	0	1 (3.1)	0
Hallucination	1 (3.1)	0	1 (3.1)	0	0
Leukoencephalopathy	1 (3.1)	0	0	1 (3.1)	0
Listless	1 (3.1)	1 (3.1)	0	0	0
Muscular weakness	1 (3.1)	1 (3.1)	0	0	0
Somnolence	1 (3.1)	0	1 (3.1)	0	0
Tumour Lysis Syndrome					
-Total	2 (6.3)	0	0	2 (6.3)	0
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202l
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (93.0)	0	7 (16.3)	12 (27.9)	21 (48.8)
Cytokine Release Syndrome					
-Total	30 (69.8)	3 (7.0)	14 (32.6)	4 (9.3)	9 (20.9)
Cytokine release syndrome	30 (69.8)	3 (7.0)	14 (32.6)	4 (9.3)	9 (20.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	21 (48.8)	1 (2.3)	2 (4.7)	5 (11.6)	13 (30.2)
White blood cell count decreased	10 (23.3)	1 (2.3)	0	2 (4.7)	7 (16.3)
Neutrophil count decreased	7 (16.3)	0	0	2 (4.7)	5 (11.6)
Neutropenia	6 (14.0)	0	0	1 (2.3)	5 (11.6)
Anaemia	5 (11.6)	0	4 (9.3)	1 (2.3)	0
Platelet count decreased	4 (9.3)	1 (2.3)	1 (2.3)	0	2 (4.7)

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	2 (4.7)	0	0	2 (4.7)	0
Lymphocyte count decreased	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Pancytopenia	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Thrombocytopenia	2 (4.7)	0	0	0	2 (4.7)
Leukopenia	1 (2.3)	0	0	0	1 (2.3)
Lymphopenia	1 (2.3)	0	0	1 (2.3)	0
Infections					
-Total	30 (69.8)	2 (4.7)	11 (25.6)	12 (27.9)	5 (11.6)
Gastroenteritis	5 (11.6)	1 (2.3)	3 (7.0)	1 (2.3)	0
Pneumonia	5 (11.6)	0	3 (7.0)	1 (2.3)	1 (2.3)
Upper respiratory tract infection	5 (11.6)	1 (2.3)	4 (9.3)	0	0
Clostridium difficile colitis	4 (9.3)	1 (2.3)	1 (2.3)	2 (4.7)	0
Rhinovirus infection	4 (9.3)	4 (9.3)	0	0	0
Staphylococcal infection	3 (7.0)	1 (2.3)	0	2 (4.7)	0
Viral infection	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Viral upper respiratory tract infection	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Clostridium difficile infection	2 (4.7)	0	2 (4.7)	0	0
Device related infection	2 (4.7)	0	0	2 (4.7)	0

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	2 (4.7)	0	2 (4.7)	0	0
Oral herpes	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Parainfluenzae virus infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Respiratory syncytial virus infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Sinusitis	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Streptococcal infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Alpha haemolytic streptococcal infection	1 (2.3)	0	0	1 (2.3)	0
Bacterial sepsis	1 (2.3)	0	0	0	1 (2.3)
Bronchopulmonary aspergillosis	1 (2.3)	0	0	1 (2.3)	0
Candida sepsis	1 (2.3)	0	0	0	1 (2.3)
Catheter site infection	1 (2.3)	0	0	1 (2.3)	0
Cellulitis	1 (2.3)	0	0	1 (2.3)	0
Conjunctivitis	1 (2.3)	0	1 (2.3)	0	0
Corona virus infection	1 (2.3)	0	0	1 (2.3)	0
Ear infection	1 (2.3)	1 (2.3)	0	0	0
Escherichia bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Escherichia infection	1 (2.3)	0	0	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	1 (2.3)	0	1 (2.3)	0	0
Folliculitis	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis viral	1 (2.3)	1 (2.3)	0	0	0
Gingivitis	1 (2.3)	1 (2.3)	0	0	0
Herpes zoster	1 (2.3)	0	0	1 (2.3)	0
Human polyomavirus infection	1 (2.3)	0	0	0	1 (2.3)
Meningitis aseptic	1 (2.3)	0	1 (2.3)	0	0
Metapneumovirus infection	1 (2.3)	0	1 (2.3)	0	0
Molluscum contagiosum	1 (2.3)	1 (2.3)	0	0	0
Orchitis	1 (2.3)	1 (2.3)	0	0	0
Otitis externa	1 (2.3)	0	1 (2.3)	0	0
Otitis media	1 (2.3)	0	1 (2.3)	0	0
Paronychia	1 (2.3)	1 (2.3)	0	0	0
Pharyngitis	1 (2.3)	0	1 (2.3)	0	0
Pneumonia fungal	1 (2.3)	0	0	1 (2.3)	0
Rash pustular	1 (2.3)	0	1 (2.3)	0	0
Respiratory tract infection	1 (2.3)	0	0	0	1 (2.3)
Serratia infection	1 (2.3)	0	0	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	1 (2.3)	0	1 (2.3)	0	0
Subcutaneous abscess	1 (2.3)	0	1 (2.3)	0	0
Tinea capitis	1 (2.3)	1 (2.3)	0	0	0
Urinary tract infection	1 (2.3)	0	1 (2.3)	0	0
Urinary tract infection enterococcal	1 (2.3)	0	0	1 (2.3)	0
Vulvovaginal mycotic infection	1 (2.3)	0	1 (2.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	20 (46.5)	1 (2.3)	15 (34.9)	4 (9.3)	0
Hypogammaglobulinaemia	19 (44.2)	1 (2.3)	14 (32.6)	4 (9.3)	0
Blood immunoglobulin g decreased	1 (2.3)	0	1 (2.3)	0	0
Blood immunoglobulin m decreased	1 (2.3)	1 (2.3)	0	0	0
Immunodeficiency	1 (2.3)	0	1 (2.3)	0	0
Serious neurological adverse reactions					
-Total	17 (39.5)	7 (16.3)	7 (16.3)	2 (4.7)	1 (2.3)
Confusional state	6 (14.0)	3 (7.0)	3 (7.0)	0	0
Delirium	4 (9.3)	2 (4.7)	2 (4.7)	0	0
Seizure	3 (7.0)	0	2 (4.7)	0	1 (2.3)

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Dysarthria	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Dysphagia	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Encephalopathy	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Mental status changes	2 (4.7)	2 (4.7)	0	0	0
Muscular weakness	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Tremor	2 (4.7)	2 (4.7)	0	0	0
Asterixis	1 (2.3)	1 (2.3)	0	0	0
Depressed level of consciousness	1 (2.3)	1 (2.3)	0	0	0
Disturbance in attention	1 (2.3)	1 (2.3)	0	0	0
Hallucination	1 (2.3)	1 (2.3)	0	0	0
Hyporesponsive to stimuli	1 (2.3)	0	0	1 (2.3)	0
Irritability	1 (2.3)	1 (2.3)	0	0	0
Somnolence	1 (2.3)	1 (2.3)	0	0	0
Tumour Lysis Syndrome					
-Total	3 (7.0)	0	0	3 (7.0)	0
Tumour lysis syndrome	3 (7.0)	0	0	3 (7.0)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202m
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (88.9)	0	1 (5.6)	6 (33.3)	9 (50.0)
Cytokine Release Syndrome					
-Total	13 (72.2)	0	10 (55.6)	2 (11.1)	1 (5.6)
Cytokine release syndrome	13 (72.2)	0	10 (55.6)	2 (11.1)	1 (5.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	10 (55.6)	1 (5.6)	0	3 (16.7)	6 (33.3)
White blood cell count decreased	7 (38.9)	1 (5.6)	0	2 (11.1)	4 (22.2)
Neutrophil count decreased	4 (22.2)	0	0	1 (5.6)	3 (16.7)
Anaemia	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Febrile neutropenia	2 (11.1)	0	0	2 (11.1)	0
Neutropenia	2 (11.1)	0	0	0	2 (11.1)

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (11.1)	0	0	0	2 (11.1)
Lymphocyte count decreased	1 (5.6)	0	0	1 (5.6)	0
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
Infections					
-Total	13 (72.2)	0	3 (16.7)	7 (38.9)	3 (16.7)
Viral upper respiratory tract infection	3 (16.7)	2 (11.1)	0	1 (5.6)	0
Conjunctivitis	2 (11.1)	0	2 (11.1)	0	0
Device related infection	2 (11.1)	0	0	2 (11.1)	0
Escherichia urinary tract infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Influenza	2 (11.1)	0	2 (11.1)	0	0
Pneumonia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Urinary tract infection	2 (11.1)	0	2 (11.1)	0	0
Alpha haemolytic streptococcal infection	1 (5.6)	0	0	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Bronchopulmonary aspergillosis	1 (5.6)	0	0	1 (5.6)	0
Catheter site infection	1 (5.6)	0	0	1 (5.6)	0
Clostridium difficile colitis	1 (5.6)	0	0	1 (5.6)	0

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (5.6)	0	1 (5.6)	0	0
Corona virus infection	1 (5.6)	0	0	1 (5.6)	0
Cytomegalovirus infection	1 (5.6)	1 (5.6)	0	0	0
Escherichia infection	1 (5.6)	0	0	1 (5.6)	0
Folliculitis	1 (5.6)	0	1 (5.6)	0	0
Fungal skin infection	1 (5.6)	1 (5.6)	0	0	0
Gastroenteritis	1 (5.6)	0	1 (5.6)	0	0
Gastroenteritis viral	1 (5.6)	1 (5.6)	0	0	0
Molluscum contagiosum	1 (5.6)	1 (5.6)	0	0	0
Otitis externa	1 (5.6)	0	1 (5.6)	0	0
Parainfluenzae virus infection	1 (5.6)	0	0	1 (5.6)	0
Paronychia	1 (5.6)	1 (5.6)	0	0	0
Respiratory syncytial virus infection	1 (5.6)	0	0	1 (5.6)	0
Respiratory tract infection	1 (5.6)	0	0	0	1 (5.6)
Rhinovirus infection	1 (5.6)	1 (5.6)	0	0	0
Staphylococcal infection	1 (5.6)	1 (5.6)	0	0	0
Streptococcal infection	1 (5.6)	0	0	1 (5.6)	0
Subcutaneous abscess	1 (5.6)	0	1 (5.6)	0	0

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection enterococcal	1 (5.6)	0	0	1 (5.6)	0
Viral infection	1 (5.6)	0	1 (5.6)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	9 (50.0)	1 (5.6)	7 (38.9)	1 (5.6)	0
Hypogammaglobulinaemia	8 (44.4)	1 (5.6)	6 (33.3)	1 (5.6)	0
Blood immunoglobulin a decreased	1 (5.6)	1 (5.6)	0	0	0
Blood immunoglobulin g decreased	1 (5.6)	0	1 (5.6)	0	0
Blood immunoglobulin m decreased	1 (5.6)	1 (5.6)	0	0	0
Serious neurological adverse reactions					
-Total	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Muscular weakness	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Confusional state	1 (5.6)	0	1 (5.6)	0	0
Depressed level of consciousness	1 (5.6)	1 (5.6)	0	0	0
Dysarthria	1 (5.6)	0	1 (5.6)	0	0
Somnolence	1 (5.6)	1 (5.6)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (11.1)	0	0	2 (11.1)	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (11.1)	0	0	2 (11.1)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202m
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	55 (96.5)	0	9 (15.8)	21 (36.8)	25 (43.9)
Cytokine Release Syndrome					
-Total	37 (64.9)	6 (10.5)	15 (26.3)	6 (10.5)	10 (17.5)
Cytokine release syndrome	37 (64.9)	6 (10.5)	15 (26.3)	6 (10.5)	10 (17.5)
Haemophagocytic lymphohistiocytosis	1 (1.8)	0	1 (1.8)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	24 (42.1)	1 (1.8)	3 (5.3)	8 (14.0)	12 (21.1)
White blood cell count decreased	11 (19.3)	0	1 (1.8)	5 (8.8)	5 (8.8)
Neutrophil count decreased	9 (15.8)	0	0	2 (3.5)	7 (12.3)
Platelet count decreased	7 (12.3)	1 (1.8)	1 (1.8)	1 (1.8)	4 (7.0)

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	5 (8.8)	0	2 (3.5)	3 (5.3)	0
Neutropenia	4 (7.0)	0	0	1 (1.8)	3 (5.3)
Thrombocytopenia	3 (5.3)	1 (1.8)	0	2 (3.5)	0
Lymphocyte count decreased	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Pancytopenia	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Febrile neutropenia	1 (1.8)	0	0	1 (1.8)	0
Leukopenia	1 (1.8)	0	0	0	1 (1.8)
Lymphopenia	1 (1.8)	0	0	1 (1.8)	0
Infections					
-Total	42 (73.7)	4 (7.0)	12 (21.1)	17 (29.8)	9 (15.8)
Upper respiratory tract infection	11 (19.3)	5 (8.8)	5 (8.8)	1 (1.8)	0
Clostridium difficile colitis	5 (8.8)	1 (1.8)	2 (3.5)	2 (3.5)	0
Clostridium difficile infection	5 (8.8)	0	4 (7.0)	1 (1.8)	0
Pneumonia	5 (8.8)	0	5 (8.8)	0	0
Rhinovirus infection	5 (8.8)	4 (7.0)	1 (1.8)	0	0
Sinusitis	5 (8.8)	1 (1.8)	4 (7.0)	0	0
Gastroenteritis	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Oral herpes	4 (7.0)	0	3 (5.3)	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	4 (7.0)	0	3 (5.3)	1 (1.8)	0
Device related infection	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Parainfluenzae virus infection	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Staphylococcal infection	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Urinary tract infection	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Ear infection	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Enterococcal bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Escherichia bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Influenza	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Klebsiella sepsis	2 (3.5)	0	0	0	2 (3.5)
Otitis media acute	2 (3.5)	0	2 (3.5)	0	0
Pneumonia fungal	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Sepsis	2 (3.5)	0	0	0	2 (3.5)
Skin infection	2 (3.5)	0	2 (3.5)	0	0
Staphylococcal bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Viral infection	2 (3.5)	2 (3.5)	0	0	0
Vulvovaginal candidiasis	2 (3.5)	1 (1.8)	1 (1.8)	0	0

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (1.8)	0	0	1 (1.8)	0
Acute sinusitis	1 (1.8)	0	1 (1.8)	0	0
Body tinea	1 (1.8)	1 (1.8)	0	0	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Campylobacter infection	1 (1.8)	0	0	1 (1.8)	0
Candida sepsis	1 (1.8)	0	0	0	1 (1.8)
Catheter site cellulitis	1 (1.8)	1 (1.8)	0	0	0
Cellulitis	1 (1.8)	0	0	1 (1.8)	0
Cellulitis of male external genital organ	1 (1.8)	0	0	1 (1.8)	0
Cholecystitis infective	1 (1.8)	0	0	1 (1.8)	0
Croup infectious	1 (1.8)	0	0	1 (1.8)	0
Cytomegalovirus infection	1 (1.8)	1 (1.8)	0	0	0
Cytomegalovirus viraemia	1 (1.8)	0	1 (1.8)	0	0
Enterococcal infection	1 (1.8)	1 (1.8)	0	0	0
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Escherichia sepsis	1 (1.8)	0	0	0	1 (1.8)
Escherichia urinary tract infection	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Gingivitis	1 (1.8)	1 (1.8)	0	0	0
Haemophilus infection	1 (1.8)	0	1 (1.8)	0	0
Herpes simplex	1 (1.8)	1 (1.8)	0	0	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0
Human herpesvirus 6 infection	1 (1.8)	0	1 (1.8)	0	0
Human polyomavirus infection	1 (1.8)	0	0	0	1 (1.8)
Hypopyon	1 (1.8)	0	1 (1.8)	0	0
Klebsiella infection	1 (1.8)	0	0	1 (1.8)	0
Meningitis aseptic	1 (1.8)	0	1 (1.8)	0	0
Metapneumovirus infection	1 (1.8)	0	1 (1.8)	0	0
Necrotising fasciitis	1 (1.8)	0	0	1 (1.8)	0
Oral candidiasis	1 (1.8)	1 (1.8)	0	0	0
Orchitis	1 (1.8)	1 (1.8)	0	0	0
Pharyngitis	1 (1.8)	0	1 (1.8)	0	0
Rash pustular	1 (1.8)	0	1 (1.8)	0	0
Respiratory syncytial virus bronchitis	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (1.8)	0	1 (1.8)	0	0
Respiratory tract infection viral	1 (1.8)	0	0	1 (1.8)	0
Rhinitis	1 (1.8)	1 (1.8)	0	0	0
Rotavirus infection	1 (1.8)	0	0	1 (1.8)	0
Septic embolus	1 (1.8)	0	0	0	1 (1.8)
Serratia infection	1 (1.8)	0	0	1 (1.8)	0
Skin papilloma	1 (1.8)	0	1 (1.8)	0	0
Staphylococcal scalded skin syndrome	1 (1.8)	0	1 (1.8)	0	0
Staphylococcal sepsis	1 (1.8)	0	0	0	1 (1.8)
Streptococcal bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Streptococcal infection	1 (1.8)	0	1 (1.8)	0	0
Tinea capitis	1 (1.8)	1 (1.8)	0	0	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	0	1 (1.8)	0	0
Vulvovaginal mycotic infection	1 (1.8)	0	1 (1.8)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	25 (43.9)	3 (5.3)	18 (31.6)	4 (7.0)	0

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	25 (43.9)	3 (5.3)	18 (31.6)	4 (7.0)	0
Blood immunoglobulin m decreased	4 (7.0)	4 (7.0)	0	0	0
Blood immunoglobulin a decreased	2 (3.5)	2 (3.5)	0	0	0
Immunodeficiency	1 (1.8)	0	1 (1.8)	0	0
Serious neurological adverse reactions					
-Total	24 (42.1)	8 (14.0)	7 (12.3)	8 (14.0)	1 (1.8)
Confusional state	7 (12.3)	3 (5.3)	4 (7.0)	0	0
Delirium	5 (8.8)	2 (3.5)	2 (3.5)	1 (1.8)	0
Seizure	5 (8.8)	0	2 (3.5)	2 (3.5)	1 (1.8)
Encephalopathy	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Mental status changes	4 (7.0)	3 (5.3)	0	1 (1.8)	0
Agitation	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Irritability	3 (5.3)	3 (5.3)	0	0	0
Dysphagia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Hallucination	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Tremor	2 (3.5)	2 (3.5)	0	0	0
Asterixis	1 (1.8)	1 (1.8)	0	0	0
Disturbance in attention	1 (1.8)	1 (1.8)	0	0	0

Eligibility for SCT: No

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysarthria	1 (1.8)	1 (1.8)	0	0	0
Hyporesponsive to stimuli	1 (1.8)	0	0	1 (1.8)	0
Leukoencephalopathy	1 (1.8)	0	0	1 (1.8)	0
Listless	1 (1.8)	1 (1.8)	0	0	0
Muscular weakness	1 (1.8)	1 (1.8)	0	0	0
Somnolence	1 (1.8)	0	1 (1.8)	0	0
Tumour Lysis Syndrome					
-Total	3 (5.3)	0	0	3 (5.3)	0
Tumour lysis syndrome	3 (5.3)	0	0	3 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202n
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (95.5)	0	3 (13.6)	10 (45.5)	8 (36.4)
Cytokine Release Syndrome					
-Total	16 (72.7)	0	11 (50.0)	3 (13.6)	2 (9.1)
Cytokine release syndrome	16 (72.7)	0	11 (50.0)	3 (13.6)	2 (9.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	11 (50.0)	1 (4.5)	0	6 (27.3)	4 (18.2)
White blood cell count decreased	5 (22.7)	1 (4.5)	0	3 (13.6)	1 (4.5)
Neutrophil count decreased	4 (18.2)	0	0	2 (9.1)	2 (9.1)
Anaemia	3 (13.6)	0	1 (4.5)	2 (9.1)	0
Neutropenia	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Platelet count decreased	2 (9.1)	1 (4.5)	0	0	1 (4.5)

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	1 (4.5)	0	0	1 (4.5)	0
Lymphocyte count decreased	1 (4.5)	0	0	0	1 (4.5)
Lymphopenia	1 (4.5)	0	0	1 (4.5)	0
Pancytopenia	1 (4.5)	0	0	1 (4.5)	0
Thrombocytopenia	1 (4.5)	0	0	1 (4.5)	0
Infections					
-Total	16 (72.7)	1 (4.5)	7 (31.8)	6 (27.3)	2 (9.1)
Upper respiratory tract infection	5 (22.7)	1 (4.5)	4 (18.2)	0	0
Viral infection	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Gastroenteritis	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Influenza	2 (9.1)	0	2 (9.1)	0	0
Sinusitis	2 (9.1)	0	2 (9.1)	0	0
Acute sinusitis	1 (4.5)	0	1 (4.5)	0	0
Bacterial sepsis	1 (4.5)	0	0	0	1 (4.5)
Bronchitis	1 (4.5)	0	1 (4.5)	0	0
Cholecystitis infective	1 (4.5)	0	0	1 (4.5)	0
Clostridium difficile colitis	1 (4.5)	0	1 (4.5)	0	0
Conjunctivitis	1 (4.5)	0	1 (4.5)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (4.5)	0	0	1 (4.5)	0
Croup infectious	1 (4.5)	0	0	1 (4.5)	0
Device related infection	1 (4.5)	0	0	1 (4.5)	0
Ear infection	1 (4.5)	1 (4.5)	0	0	0
Escherichia urinary tract infection	1 (4.5)	0	1 (4.5)	0	0
Folliculitis	1 (4.5)	0	1 (4.5)	0	0
Fungal skin infection	1 (4.5)	1 (4.5)	0	0	0
Gingivitis	1 (4.5)	1 (4.5)	0	0	0
Haemophilus infection	1 (4.5)	0	1 (4.5)	0	0
Herpes simplex	1 (4.5)	1 (4.5)	0	0	0
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Oral candidiasis	1 (4.5)	1 (4.5)	0	0	0
Oral herpes	1 (4.5)	0	1 (4.5)	0	0
Orchitis	1 (4.5)	1 (4.5)	0	0	0
Otitis media	1 (4.5)	0	0	1 (4.5)	0
Otitis media acute	1 (4.5)	0	1 (4.5)	0	0
Pharyngitis	1 (4.5)	0	1 (4.5)	0	0
Pneumonia	1 (4.5)	0	1 (4.5)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (4.5)	0	0	1 (4.5)	0
Rhinovirus infection	1 (4.5)	1 (4.5)	0	0	0
Skin infection	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Staphylococcal infection	1 (4.5)	0	0	0	1 (4.5)
Streptococcal infection	1 (4.5)	0	1 (4.5)	0	0
Tinea capitis	1 (4.5)	1 (4.5)	0	0	0
Urinary tract infection enterococcal	1 (4.5)	0	0	1 (4.5)	0
Vascular device infection	1 (4.5)	0	0	1 (4.5)	0
Viral upper respiratory tract infection	1 (4.5)	1 (4.5)	0	0	0
Vulvovaginal candidiasis	1 (4.5)	1 (4.5)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	13 (59.1)	2 (9.1)	10 (45.5)	1 (4.5)	0
Hypogammaglobulinaemia	13 (59.1)	2 (9.1)	10 (45.5)	1 (4.5)	0
Blood immunoglobulin a decreased	1 (4.5)	1 (4.5)	0	0	0
Blood immunoglobulin m decreased	1 (4.5)	1 (4.5)	0	0	0
Serious neurological adverse reactions					

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (45.5)	4 (18.2)	2 (9.1)	3 (13.6)	1 (4.5)
Encephalopathy	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Seizure	3 (13.6)	0	1 (4.5)	1 (4.5)	1 (4.5)
Delirium	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Mental status changes	2 (9.1)	2 (9.1)	0	0	0
Agitation	1 (4.5)	0	0	1 (4.5)	0
Confusional state	1 (4.5)	1 (4.5)	0	0	0
Disturbance in attention	1 (4.5)	1 (4.5)	0	0	0
Hyporesponsive to stimuli	1 (4.5)	0	0	1 (4.5)	0
Muscular weakness	1 (4.5)	1 (4.5)	0	0	0
Somnolence	1 (4.5)	0	1 (4.5)	0	0
Tremor	1 (4.5)	1 (4.5)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (4.5)	0	0	1 (4.5)	0
Tumour lysis syndrome	1 (4.5)	0	0	1 (4.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202n
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (94.3)	0	7 (13.2)	17 (32.1)	26 (49.1)
Cytokine Release Syndrome					
-Total	34 (64.2)	6 (11.3)	14 (26.4)	5 (9.4)	9 (17.0)
Cytokine release syndrome	34 (64.2)	6 (11.3)	14 (26.4)	5 (9.4)	9 (17.0)
Haemophagocytic lymphohistiocytosis	1 (1.9)	0	1 (1.9)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	23 (43.4)	1 (1.9)	3 (5.7)	5 (9.4)	14 (26.4)
White blood cell count decreased	13 (24.5)	0	1 (1.9)	4 (7.5)	8 (15.1)
Neutrophil count decreased	9 (17.0)	0	0	1 (1.9)	8 (15.1)
Platelet count decreased	6 (11.3)	0	1 (1.9)	1 (1.9)	4 (7.5)

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	5 (9.4)	0	3 (5.7)	2 (3.8)	0
Thrombocytopenia	4 (7.5)	1 (1.9)	0	1 (1.9)	2 (3.8)
Neutropenia	3 (5.7)	0	0	0	3 (5.7)
Febrile neutropenia	2 (3.8)	0	0	2 (3.8)	0
Lymphocyte count decreased	2 (3.8)	0	0	2 (3.8)	0
Leukopenia	1 (1.9)	0	0	0	1 (1.9)
Pancytopenia	1 (1.9)	0	0	0	1 (1.9)
Infections					
-Total	39 (73.6)	3 (5.7)	8 (15.1)	18 (34.0)	10 (18.9)
Clostridium difficile infection	6 (11.3)	0	5 (9.4)	1 (1.9)	0
Pneumonia	6 (11.3)	0	4 (7.5)	1 (1.9)	1 (1.9)
Upper respiratory tract infection	6 (11.3)	4 (7.5)	1 (1.9)	1 (1.9)	0
Clostridium difficile colitis	5 (9.4)	1 (1.9)	1 (1.9)	3 (5.7)	0
Rhinovirus infection	5 (9.4)	4 (7.5)	1 (1.9)	0	0
Urinary tract infection	5 (9.4)	0	3 (5.7)	2 (3.8)	0
Device related infection	4 (7.5)	0	1 (1.9)	3 (5.7)	0
Parainfluenzae virus infection	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0
Gastroenteritis	3 (5.7)	1 (1.9)	2 (3.8)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Otitis media	3 (5.7)	0	3 (5.7)	0	0
Sinusitis	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Staphylococcal infection	3 (5.7)	1 (1.9)	0	2 (3.8)	0
Viral upper respiratory tract infection	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Cytomegalovirus infection	2 (3.8)	2 (3.8)	0	0	0
Enterococcal bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Escherichia bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Escherichia urinary tract infection	2 (3.8)	0	0	2 (3.8)	0
Influenza	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Klebsiella sepsis	2 (3.8)	0	0	0	2 (3.8)
Pneumonia fungal	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Sepsis	2 (3.8)	0	0	0	2 (3.8)
Abscess limb	1 (1.9)	0	0	1 (1.9)	0
Alpha haemolytic streptococcal infection	1 (1.9)	0	0	1 (1.9)	0
Body tinea	1 (1.9)	1 (1.9)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Campylobacter infection	1 (1.9)	0	0	1 (1.9)	0
Candida sepsis	1 (1.9)	0	0	0	1 (1.9)
Catheter site cellulitis	1 (1.9)	1 (1.9)	0	0	0
Catheter site infection	1 (1.9)	0	0	1 (1.9)	0
Cellulitis	1 (1.9)	0	0	1 (1.9)	0
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Conjunctivitis	1 (1.9)	0	1 (1.9)	0	0
Cytomegalovirus viraemia	1 (1.9)	0	1 (1.9)	0	0
Ear infection	1 (1.9)	0	1 (1.9)	0	0
Enterococcal infection	1 (1.9)	1 (1.9)	0	0	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	0	0	1 (1.9)
Fungal skin infection	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (1.9)	0	1 (1.9)	0	0
Human polyomavirus infection	1 (1.9)	0	0	0	1 (1.9)
Hypopyon	1 (1.9)	0	1 (1.9)	0	0
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Meningitis aseptic	1 (1.9)	0	1 (1.9)	0	0
Metapneumovirus infection	1 (1.9)	0	1 (1.9)	0	0
Molluscum contagiosum	1 (1.9)	1 (1.9)	0	0	0
Necrotising fasciitis	1 (1.9)	0	0	1 (1.9)	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Otitis media acute	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0
Rash pustular	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	0	0	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	0	1 (1.9)	0	0
Respiratory tract infection	1 (1.9)	0	0	0	1 (1.9)
Respiratory tract infection viral	1 (1.9)	0	0	1 (1.9)	0
Rhinitis	1 (1.9)	1 (1.9)	0	0	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	1 (1.9)	0	0	0	1 (1.9)
Serratia infection	1 (1.9)	0	0	1 (1.9)	0
Skin infection	1 (1.9)	0	1 (1.9)	0	0
Skin papilloma	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Streptococcal infection	1 (1.9)	0	0	1 (1.9)	0
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Vulvovaginal candidiasis	1 (1.9)	0	1 (1.9)	0	0
Vulvovaginal mycotic infection	1 (1.9)	0	1 (1.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	21 (39.6)	2 (3.8)	15 (28.3)	4 (7.5)	0
Hypogammaglobulinaemia	20 (37.7)	2 (3.8)	14 (26.4)	4 (7.5)	0
Blood immunoglobulin m decreased	4 (7.5)	4 (7.5)	0	0	0
Blood immunoglobulin a decreased	2 (3.8)	2 (3.8)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (1.9)	0	1 (1.9)	0	0
Immunodeficiency	1 (1.9)	0	1 (1.9)	0	0
Serious neurological adverse reactions					
-Total	18 (34.0)	6 (11.3)	7 (13.2)	5 (9.4)	0
Confusional state	7 (13.2)	2 (3.8)	5 (9.4)	0	0
Delirium	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Irritability	3 (5.7)	3 (5.7)	0	0	0
Agitation	2 (3.8)	0	2 (3.8)	0	0
Dysarthria	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Dysphagia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Hallucination	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Mental status changes	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Muscular weakness	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Seizure	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Asterixis	1 (1.9)	1 (1.9)	0	0	0
Depressed level of consciousness	1 (1.9)	1 (1.9)	0	0	0
Encephalopathy	1 (1.9)	0	0	1 (1.9)	0
Leukoencephalopathy	1 (1.9)	0	0	1 (1.9)	0

Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Listless	1 (1.9)	1 (1.9)	0	0	0
Somnolence	1 (1.9)	1 (1.9)	0	0	0
Tremor	1 (1.9)	1 (1.9)	0	0	0
Tumour Lysis Syndrome					
-Total	4 (7.5)	0	0	4 (7.5)	0
Tumour lysis syndrome	4 (7.5)	0	0	4 (7.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202o
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	1 (14.3)	3 (42.9)	2 (28.6)
Cytokine Release Syndrome					
-Total	4 (57.1)	2 (28.6)	1 (14.3)	0	1 (14.3)
Cytokine release syndrome	4 (57.1)	2 (28.6)	1 (14.3)	0	1 (14.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (57.1)	0	0	2 (28.6)	2 (28.6)
White blood cell count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Anaemia	1 (14.3)	0	0	1 (14.3)	0
Febrile neutropenia	1 (14.3)	0	0	1 (14.3)	0
Leukopenia	1 (14.3)	0	0	0	1 (14.3)
Neutropenia	1 (14.3)	0	0	0	1 (14.3)

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (14.3)	0	0	0	1 (14.3)
Infections					
-Total	4 (57.1)	0	0	4 (57.1)	0
Pneumonia	2 (28.6)	0	2 (28.6)	0	0
Sinusitis	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Device related infection	1 (14.3)	0	0	1 (14.3)	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Escherichia infection	1 (14.3)	0	0	1 (14.3)	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Haemophilus infection	1 (14.3)	0	1 (14.3)	0	0
Otitis media	1 (14.3)	0	0	1 (14.3)	0
Otitis media acute	1 (14.3)	0	1 (14.3)	0	0
Streptococcal infection	1 (14.3)	0	0	1 (14.3)	0
Subcutaneous abscess	1 (14.3)	0	1 (14.3)	0	0
Upper respiratory tract infection	1 (14.3)	1 (14.3)	0	0	0
Viral upper respiratory tract infection	1 (14.3)	0	0	1 (14.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Hypogammaglobulinaemia	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Immunodeficiency	1 (14.3)	0	1 (14.3)	0	0
Serious neurological adverse reactions					
-Total	4 (57.1)	0	1 (14.3)	3 (42.9)	0
Delirium	1 (14.3)	0	1 (14.3)	0	0
Dysarthria	1 (14.3)	0	1 (14.3)	0	0
Dysphagia	1 (14.3)	0	0	1 (14.3)	0
Irritability	1 (14.3)	1 (14.3)	0	0	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0
Muscular weakness	1 (14.3)	0	1 (14.3)	0	0
Seizure	1 (14.3)	0	0	1 (14.3)	0
Somnolence	1 (14.3)	1 (14.3)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (28.6)	0	0	2 (28.6)	0
Tumour lysis syndrome	2 (28.6)	0	0	2 (28.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose

apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202o
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	65 (95.6)	0	9 (13.2)	24 (35.3)	32 (47.1)
Cytokine Release Syndrome					
-Total	46 (67.6)	4 (5.9)	24 (35.3)	8 (11.8)	10 (14.7)
Cytokine release syndrome	46 (67.6)	4 (5.9)	24 (35.3)	8 (11.8)	10 (14.7)
Haemophagocytic lymphohistiocytosis	1 (1.5)	0	1 (1.5)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	30 (44.1)	2 (2.9)	3 (4.4)	9 (13.2)	16 (23.5)
White blood cell count decreased	16 (23.5)	1 (1.5)	1 (1.5)	6 (8.8)	8 (11.8)
Neutrophil count decreased	12 (17.6)	0	0	3 (4.4)	9 (13.2)
Platelet count decreased	8 (11.8)	1 (1.5)	1 (1.5)	1 (1.5)	5 (7.4)

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	7 (10.3)	0	4 (5.9)	3 (4.4)	0
Neutropenia	5 (7.4)	0	0	1 (1.5)	4 (5.9)
Thrombocytopenia	5 (7.4)	1 (1.5)	0	2 (2.9)	2 (2.9)
Lymphocyte count decreased	3 (4.4)	0	0	2 (2.9)	1 (1.5)
Febrile neutropenia	2 (2.9)	0	0	2 (2.9)	0
Pancytopenia	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Lymphopenia	1 (1.5)	0	0	1 (1.5)	0
Infections					
-Total	51 (75.0)	4 (5.9)	15 (22.1)	20 (29.4)	12 (17.6)
Upper respiratory tract infection	10 (14.7)	4 (5.9)	5 (7.4)	1 (1.5)	0
Clostridium difficile colitis	6 (8.8)	1 (1.5)	2 (2.9)	3 (4.4)	0
Clostridium difficile infection	6 (8.8)	0	5 (7.4)	1 (1.5)	0
Rhinovirus infection	6 (8.8)	5 (7.4)	1 (1.5)	0	0
Pneumonia	5 (7.4)	0	3 (4.4)	1 (1.5)	1 (1.5)
Urinary tract infection	5 (7.4)	0	3 (4.4)	2 (2.9)	0
Device related infection	4 (5.9)	0	1 (1.5)	3 (4.4)	0
Gastroenteritis	4 (5.9)	1 (1.5)	2 (2.9)	1 (1.5)	0
Influenza	4 (5.9)	1 (1.5)	3 (4.4)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	4 (5.9)	0	3 (4.4)	1 (1.5)	0
Parainfluenzae virus infection	4 (5.9)	2 (2.9)	1 (1.5)	1 (1.5)	0
Staphylococcal infection	4 (5.9)	1 (1.5)	0	2 (2.9)	1 (1.5)
Escherichia urinary tract infection	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Otitis media	3 (4.4)	0	3 (4.4)	0	0
Sinusitis	3 (4.4)	0	3 (4.4)	0	0
Viral infection	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Viral upper respiratory tract infection	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Conjunctivitis	2 (2.9)	0	2 (2.9)	0	0
Cytomegalovirus infection	2 (2.9)	2 (2.9)	0	0	0
Ear infection	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Enterococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Fungal skin infection	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Klebsiella sepsis	2 (2.9)	0	0	0	2 (2.9)
Pneumonia fungal	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Respiratory syncytial virus infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Sepsis	2 (2.9)	0	0	0	2 (2.9)

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	2 (2.9)	0	2 (2.9)	0	0
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Vulvovaginal candidiasis	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Acute sinusitis	1 (1.5)	0	1 (1.5)	0	0
Alpha haemolytic streptococcal infection	1 (1.5)	0	0	1 (1.5)	0
Bacterial sepsis	1 (1.5)	0	0	0	1 (1.5)
Body tinea	1 (1.5)	1 (1.5)	0	0	0
Bronchitis	1 (1.5)	0	1 (1.5)	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Campylobacter infection	1 (1.5)	0	0	1 (1.5)	0
Candida sepsis	1 (1.5)	0	0	0	1 (1.5)
Catheter site cellulitis	1 (1.5)	1 (1.5)	0	0	0
Catheter site infection	1 (1.5)	0	0	1 (1.5)	0
Cellulitis	1 (1.5)	0	0	1 (1.5)	0
Cellulitis of male external genital organ	1 (1.5)	0	0	1 (1.5)	0
Cholecystitis infective	1 (1.5)	0	0	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (1.5)	0	0	1 (1.5)	0
Croup infectious	1 (1.5)	0	0	1 (1.5)	0
Cytomegalovirus viraemia	1 (1.5)	0	1 (1.5)	0	0
Enterococcal infection	1 (1.5)	1 (1.5)	0	0	0
Enterovirus infection	1 (1.5)	0	0	1 (1.5)	0
Escherichia bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	0	0	1 (1.5)
Folliculitis	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis norovirus	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis viral	1 (1.5)	1 (1.5)	0	0	0
Gingivitis	1 (1.5)	1 (1.5)	0	0	0
Herpes simplex	1 (1.5)	1 (1.5)	0	0	0
Herpes zoster	1 (1.5)	0	0	1 (1.5)	0
Human herpesvirus 6 infection	1 (1.5)	0	1 (1.5)	0	0
Human polyomavirus infection	1 (1.5)	0	0	0	1 (1.5)
Hypopyon	1 (1.5)	0	1 (1.5)	0	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Meningitis aseptic	1 (1.5)	0	1 (1.5)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	1 (1.5)	0	1 (1.5)	0	0
Molluscum contagiosum	1 (1.5)	1 (1.5)	0	0	0
Necrotising fasciitis	1 (1.5)	0	0	1 (1.5)	0
Oral candidiasis	1 (1.5)	1 (1.5)	0	0	0
Orchitis	1 (1.5)	1 (1.5)	0	0	0
Otitis externa	1 (1.5)	0	1 (1.5)	0	0
Otitis media acute	1 (1.5)	0	1 (1.5)	0	0
Paronychia	1 (1.5)	1 (1.5)	0	0	0
Pharyngitis	1 (1.5)	0	1 (1.5)	0	0
Rash pustular	1 (1.5)	0	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	0	0	1 (1.5)	0
Respiratory tract infection	1 (1.5)	0	0	0	1 (1.5)
Respiratory tract infection viral	1 (1.5)	0	0	1 (1.5)	0
Rhinitis	1 (1.5)	1 (1.5)	0	0	0
Rotavirus infection	1 (1.5)	0	0	1 (1.5)	0
Septic embolus	1 (1.5)	0	0	0	1 (1.5)
Serratia infection	1 (1.5)	0	0	1 (1.5)	0
Skin papilloma	1 (1.5)	0	1 (1.5)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (1.5)	0	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Streptococcal infection	1 (1.5)	0	1 (1.5)	0	0
Tinea capitis	1 (1.5)	1 (1.5)	0	0	0
Urinary tract infection enterococcal	1 (1.5)	0	0	1 (1.5)	0
Vascular device infection	1 (1.5)	0	0	1 (1.5)	0
Vulvovaginal mycotic infection	1 (1.5)	0	1 (1.5)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	30 (44.1)	3 (4.4)	23 (33.8)	4 (5.9)	0
Hypogammaglobulinaemia	29 (42.6)	3 (4.4)	22 (32.4)	4 (5.9)	0
Blood immunoglobulin m decreased	5 (7.4)	5 (7.4)	0	0	0
Blood immunoglobulin a decreased	3 (4.4)	3 (4.4)	0	0	0
Blood immunoglobulin g decreased	1 (1.5)	0	1 (1.5)	0	0
Serious neurological adverse reactions					
-Total	24 (35.3)	10 (14.7)	8 (11.8)	5 (7.4)	1 (1.5)
Confusional state	8 (11.8)	3 (4.4)	5 (7.4)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	4 (5.9)	2 (2.9)	1 (1.5)	1 (1.5)	0
Encephalopathy	4 (5.9)	1 (1.5)	1 (1.5)	2 (2.9)	0
Seizure	4 (5.9)	0	2 (2.9)	1 (1.5)	1 (1.5)
Agitation	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Mental status changes	3 (4.4)	3 (4.4)	0	0	0
Hallucination	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Irritability	2 (2.9)	2 (2.9)	0	0	0
Muscular weakness	2 (2.9)	2 (2.9)	0	0	0
Tremor	2 (2.9)	2 (2.9)	0	0	0
Asterixis	1 (1.5)	1 (1.5)	0	0	0
Depressed level of consciousness	1 (1.5)	1 (1.5)	0	0	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Dysarthria	1 (1.5)	1 (1.5)	0	0	0
Dysphagia	1 (1.5)	0	1 (1.5)	0	0
Hyporesponsive to stimuli	1 (1.5)	0	0	1 (1.5)	0
Leukoencephalopathy	1 (1.5)	0	0	1 (1.5)	0
Listless	1 (1.5)	1 (1.5)	0	0	0
Somnolence	1 (1.5)	0	1 (1.5)	0	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	3 (4.4)	0	0	3 (4.4)	0
Tumour lysis syndrome	3 (4.4)	0	0	3 (4.4)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202p
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	2 (50.0)	1 (25.0)	1 (25.0)
Cytokine Release Syndrome					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Cytokine release syndrome	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (50.0)	1 (25.0)	0	0	1 (25.0)
Lymphocyte count decreased	1 (25.0)	0	0	0	1 (25.0)
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
White blood cell count decreased	1 (25.0)	1 (25.0)	0	0	0
Infections					
-Total	3 (75.0)	0	2 (50.0)	1 (25.0)	0

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	1 (25.0)	0	1 (25.0)	0	0
Corona virus infection	1 (25.0)	0	0	1 (25.0)	0
Fungal skin infection	1 (25.0)	1 (25.0)	0	0	0
Metapneumovirus infection	1 (25.0)	0	1 (25.0)	0	0
Rash pustular	1 (25.0)	0	1 (25.0)	0	0
Respiratory syncytial virus infection	1 (25.0)	0	0	1 (25.0)	0
Viral infection	1 (25.0)	0	1 (25.0)	0	0
Viral upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (25.0)	0	1 (25.0)	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)	0	0
Serious neurological adverse reactions					
-Total	1 (25.0)	1 (25.0)	0	0	0
Tremor	1 (25.0)	1 (25.0)	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202p
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	67 (94.4)	0	8 (11.3)	26 (36.6)	33 (46.5)
Cytokine Release Syndrome					
-Total	47 (66.2)	5 (7.0)	23 (32.4)	8 (11.3)	11 (15.5)
Cytokine release syndrome	47 (66.2)	5 (7.0)	23 (32.4)	8 (11.3)	11 (15.5)
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	32 (45.1)	1 (1.4)	3 (4.2)	11 (15.5)	17 (23.9)
White blood cell count decreased	17 (23.9)	0	1 (1.4)	7 (9.9)	9 (12.7)
Neutrophil count decreased	13 (18.3)	0	0	3 (4.2)	10 (14.1)
Anaemia	8 (11.3)	0	4 (5.6)	4 (5.6)	0

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (11.3)	1 (1.4)	1 (1.4)	1 (1.4)	5 (7.0)
Neutropenia	5 (7.0)	0	0	1 (1.4)	4 (5.6)
Thrombocytopenia	5 (7.0)	1 (1.4)	0	2 (2.8)	2 (2.8)
Febrile neutropenia	3 (4.2)	0	0	3 (4.2)	0
Lymphocyte count decreased	2 (2.8)	0	0	2 (2.8)	0
Pancytopenia	2 (2.8)	0	0	1 (1.4)	1 (1.4)
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	52 (73.2)	4 (5.6)	13 (18.3)	23 (32.4)	12 (16.9)
Upper respiratory tract infection	11 (15.5)	5 (7.0)	5 (7.0)	1 (1.4)	0
Pneumonia	7 (9.9)	0	5 (7.0)	1 (1.4)	1 (1.4)
Clostridium difficile colitis	6 (8.5)	1 (1.4)	2 (2.8)	3 (4.2)	0
Clostridium difficile infection	6 (8.5)	0	5 (7.0)	1 (1.4)	0
Rhinovirus infection	6 (8.5)	5 (7.0)	1 (1.4)	0	0
Device related infection	5 (7.0)	0	1 (1.4)	4 (5.6)	0
Gastroenteritis	5 (7.0)	1 (1.4)	3 (4.2)	1 (1.4)	0
Sinusitis	5 (7.0)	1 (1.4)	4 (5.6)	0	0

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	5 (7.0)	0	3 (4.2)	2 (2.8)	0
Influenza	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Oral herpes	4 (5.6)	0	3 (4.2)	1 (1.4)	0
Otitis media	4 (5.6)	0	3 (4.2)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Staphylococcal infection	4 (5.6)	1 (1.4)	0	2 (2.8)	1 (1.4)
Escherichia urinary tract infection	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Viral upper respiratory tract infection	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Cytomegalovirus infection	2 (2.8)	2 (2.8)	0	0	0
Ear infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Enterococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Escherichia bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Otitis media acute	2 (2.8)	0	2 (2.8)	0	0
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Sepsis	2 (2.8)	0	0	0	2 (2.8)
Skin infection	2 (2.8)	0	2 (2.8)	0	0

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Streptococcal infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Viral infection	2 (2.8)	2 (2.8)	0	0	0
Vulvovaginal candidiasis	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Body tinea	1 (1.4)	1 (1.4)	0	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site cellulitis	1 (1.4)	1 (1.4)	0	0	0
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus viraemia	1 (1.4)	0	1 (1.4)	0	0
Enterococcal infection	1 (1.4)	1 (1.4)	0	0	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Haemophilus infection	1 (1.4)	0	1 (1.4)	0	0
Herpes simplex	1 (1.4)	1 (1.4)	0	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	1 (1.4)	0	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypopyon	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Meningitis aseptic	1 (1.4)	0	1 (1.4)	0	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Oral candidiasis	1 (1.4)	1 (1.4)	0	0	0
Orchitis	1 (1.4)	1 (1.4)	0	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	1 (1.4)	0	0	0
Pharyngitis	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinitis	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin papilloma	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Subcutaneous abscess	1 (1.4)	0	1 (1.4)	0	0
Tinea capitis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection enterococcal	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal mycotic infection	1 (1.4)	0	1 (1.4)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	33 (46.5)	4 (5.6)	24 (33.8)	5 (7.0)	0
Hypogammaglobulinaemia	32 (45.1)	4 (5.6)	23 (32.4)	5 (7.0)	0
Blood immunoglobulin m decreased	4 (5.6)	4 (5.6)	0	0	0
Blood immunoglobulin a decreased	2 (2.8)	2 (2.8)	0	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Immunodeficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	27 (38.0)	9 (12.7)	9 (12.7)	8 (11.3)	1 (1.4)
Confusional state	8 (11.3)	3 (4.2)	5 (7.0)	0	0
Delirium	5 (7.0)	2 (2.8)	2 (2.8)	1 (1.4)	0
Seizure	5 (7.0)	0	2 (2.8)	2 (2.8)	1 (1.4)
Encephalopathy	4 (5.6)	1 (1.4)	1 (1.4)	2 (2.8)	0
Mental status changes	4 (5.6)	3 (4.2)	0	1 (1.4)	0
Agitation	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Irritability	3 (4.2)	3 (4.2)	0	0	0
Muscular weakness	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Dysarthria	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Dysphagia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hallucination	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Somnolence	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Asterixis	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	1 (1.4)	0	0	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Listless	1 (1.4)	1 (1.4)	0	0	0
Tremor	1 (1.4)	1 (1.4)	0	0	0
Tumour Lysis Syndrome					
-Total	5 (7.0)	0	0	5 (7.0)	0
Tumour lysis syndrome	5 (7.0)	0	0	5 (7.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202q
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	4 (12.5)	12 (37.5)	16 (50.0)
Cytokine Release Syndrome					
-Total	25 (78.1)	3 (9.4)	15 (46.9)	2 (6.3)	5 (15.6)
Cytokine release syndrome	25 (78.1)	3 (9.4)	15 (46.9)	2 (6.3)	5 (15.6)
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	1 (3.1)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	18 (56.3)	0	1 (3.1)	6 (18.8)	11 (34.4)
White blood cell count decreased	13 (40.6)	0	1 (3.1)	6 (18.8)	6 (18.8)
Neutrophil count decreased	9 (28.1)	0	0	3 (9.4)	6 (18.8)
Platelet count decreased	5 (15.6)	0	0	1 (3.1)	4 (12.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Neutropenia	3 (9.4)	0	0	0	3 (9.4)
Lymphocyte count decreased	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Thrombocytopenia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Febrile neutropenia	1 (3.1)	0	0	1 (3.1)	0
Pancytopenia	1 (3.1)	0	0	1 (3.1)	0
Infections					
-Total	24 (75.0)	1 (3.1)	9 (28.1)	10 (31.3)	4 (12.5)
Upper respiratory tract infection	6 (18.8)	2 (6.3)	4 (12.5)	0	0
Clostridium difficile infection	5 (15.6)	0	4 (12.5)	1 (3.1)	0
Rhinovirus infection	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Device related infection	4 (12.5)	0	0	4 (12.5)	0
Escherichia urinary tract infection	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Gastroenteritis	3 (9.4)	0	3 (9.4)	0	0
Influenza	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Urinary tract infection	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Viral upper respiratory tract infection	3 (9.4)	2 (6.3)	0	1 (3.1)	0
Conjunctivitis	2 (6.3)	0	2 (6.3)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection	2 (6.3)	2 (6.3)	0	0	0
Ear infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Parainfluenzae virus infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Pneumonia	2 (6.3)	0	2 (6.3)	0	0
Sinusitis	2 (6.3)	0	2 (6.3)	0	0
Skin infection	2 (6.3)	0	2 (6.3)	0	0
Vulvovaginal candidiasis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Alpha haemolytic streptococcal infection	1 (3.1)	0	0	1 (3.1)	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Bacterial sepsis	1 (3.1)	0	0	0	1 (3.1)
Campylobacter infection	1 (3.1)	0	0	1 (3.1)	0
Catheter site cellulitis	1 (3.1)	1 (3.1)	0	0	0
Catheter site infection	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Croup infectious	1 (3.1)	0	0	1 (3.1)	0
Cytomegalovirus viraemia	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Enterococcal infection	1 (3.1)	1 (3.1)	0	0	0
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Folliculitis	1 (3.1)	0	1 (3.1)	0	0
Fungal skin infection	1 (3.1)	1 (3.1)	0	0	0
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis viral	1 (3.1)	1 (3.1)	0	0	0
Molluscum contagiosum	1 (3.1)	1 (3.1)	0	0	0
Oral candidiasis	1 (3.1)	1 (3.1)	0	0	0
Oral herpes	1 (3.1)	0	1 (3.1)	0	0
Orchitis	1 (3.1)	1 (3.1)	0	0	0
Otitis media acute	1 (3.1)	0	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	0	0	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	0	1 (3.1)	0	0
Respiratory tract infection	1 (3.1)	0	0	0	1 (3.1)
Respiratory tract infection viral	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	1 (3.1)	1 (3.1)	0	0	0
Rotavirus infection	1 (3.1)	0	0	1 (3.1)	0
Sepsis	1 (3.1)	0	0	0	1 (3.1)
Septic embolus	1 (3.1)	0	0	0	1 (3.1)
Skin papilloma	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal scalded skin syndrome	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Subcutaneous abscess	1 (3.1)	0	1 (3.1)	0	0
Tinea capitis	1 (3.1)	1 (3.1)	0	0	0
Urinary tract infection enterococcal	1 (3.1)	0	0	1 (3.1)	0
Viral infection	1 (3.1)	1 (3.1)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	19 (59.4)	1 (3.1)	15 (46.9)	3 (9.4)	0
Hypogammaglobulinaemia	19 (59.4)	1 (3.1)	15 (46.9)	3 (9.4)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (6.3)	2 (6.3)	0	0	0
Blood immunoglobulin m decreased	2 (6.3)	2 (6.3)	0	0	0
Immunodeficiency	1 (3.1)	0	1 (3.1)	0	0
Serious neurological adverse reactions					
-Total	12 (37.5)	6 (18.8)	3 (9.4)	3 (9.4)	0
Confusional state	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Mental status changes	3 (9.4)	2 (6.3)	0	1 (3.1)	0
Muscular weakness	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Delirium	1 (3.1)	1 (3.1)	0	0	0
Disturbance in attention	1 (3.1)	1 (3.1)	0	0	0
Dysarthria	1 (3.1)	0	1 (3.1)	0	0
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Hallucination	1 (3.1)	1 (3.1)	0	0	0
Irritability	1 (3.1)	1 (3.1)	0	0	0
Seizure	1 (3.1)	0	0	1 (3.1)	0
Somnolence	1 (3.1)	1 (3.1)	0	0	0
Tremor	1 (3.1)	1 (3.1)	0	0	0
Tumour Lysis Syndrome					

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (6.3)	0	0	2 (6.3)	0
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0

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Table 202q
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (96.9)	0	6 (18.8)	14 (43.8)	11 (34.4)
Cytokine Release Syndrome					
-Total	25 (78.1)	3 (9.4)	10 (31.3)	6 (18.8)	6 (18.8)
Cytokine release syndrome	25 (78.1)	3 (9.4)	10 (31.3)	6 (18.8)	6 (18.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	16 (50.0)	2 (6.3)	2 (6.3)	5 (15.6)	7 (21.9)
White blood cell count decreased	5 (15.6)	1 (3.1)	0	1 (3.1)	3 (9.4)
Anaemia	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Neutrophil count decreased	4 (12.5)	0	0	0	4 (12.5)
Neutropenia	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Platelet count decreased	3 (9.4)	1 (3.1)	1 (3.1)	0	1 (3.1)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	3 (9.4)	1 (3.1)	0	1 (3.1)	1 (3.1)
Febrile neutropenia	2 (6.3)	0	0	2 (6.3)	0
Leukopenia	1 (3.1)	0	0	0	1 (3.1)
Lymphocyte count decreased	1 (3.1)	0	0	1 (3.1)	0
Lymphopenia	1 (3.1)	0	0	1 (3.1)	0
Pancytopenia	1 (3.1)	0	0	0	1 (3.1)
Infections					
-Total	24 (75.0)	3 (9.4)	6 (18.8)	13 (40.6)	2 (6.3)
Upper respiratory tract infection	5 (15.6)	3 (9.4)	1 (3.1)	1 (3.1)	0
Clostridium difficile colitis	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Otitis media	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Pneumonia	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Sinusitis	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Gastroenteritis	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Oral herpes	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Parainfluenzae virus infection	2 (6.3)	2 (6.3)	0	0	0
Staphylococcal infection	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Urinary tract infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Acute sinusitis	1 (3.1)	0	1 (3.1)	0	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Body tinea	1 (3.1)	1 (3.1)	0	0	0
Bronchopulmonary aspergillosis	1 (3.1)	0	0	1 (3.1)	0
Cellulitis	1 (3.1)	0	0	1 (3.1)	0
Cellulitis of male external genital organ	1 (3.1)	0	0	1 (3.1)	0
Cholecystitis infective	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile infection	1 (3.1)	0	1 (3.1)	0	0
Corona virus infection	1 (3.1)	0	0	1 (3.1)	0
Device related infection	1 (3.1)	0	1 (3.1)	0	0
Enterococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	0	0	1 (3.1)
Fungal skin infection	1 (3.1)	0	1 (3.1)	0	0
Gingivitis	1 (3.1)	1 (3.1)	0	0	0
Haemophilus infection	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes simplex	1 (3.1)	1 (3.1)	0	0	0
Herpes zoster	1 (3.1)	0	0	1 (3.1)	0
Human herpesvirus 6 infection	1 (3.1)	0	1 (3.1)	0	0
Human polyomavirus infection	1 (3.1)	0	0	0	1 (3.1)
Hypopyon	1 (3.1)	0	1 (3.1)	0	0
Influenza	1 (3.1)	0	1 (3.1)	0	0
Meningitis aseptic	1 (3.1)	0	1 (3.1)	0	0
Metapneumovirus infection	1 (3.1)	0	1 (3.1)	0	0
Necrotising fasciitis	1 (3.1)	0	0	1 (3.1)	0
Otitis externa	1 (3.1)	0	1 (3.1)	0	0
Otitis media acute	1 (3.1)	0	1 (3.1)	0	0
Paronychia	1 (3.1)	1 (3.1)	0	0	0
Pharyngitis	1 (3.1)	0	1 (3.1)	0	0
Rash pustular	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus infection	1 (3.1)	0	0	1 (3.1)	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Serratia infection	1 (3.1)	0	0	1 (3.1)	0
Streptococcal infection	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (3.1)	0	0	1 (3.1)	0
Viral upper respiratory tract infection	1 (3.1)	0	1 (3.1)	0	0
Vulvovaginal mycotic infection	1 (3.1)	0	1 (3.1)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	15 (46.9)	3 (9.4)	10 (31.3)	2 (6.3)	0
Hypogammaglobulinaemia	14 (43.8)	3 (9.4)	9 (28.1)	2 (6.3)	0
Blood immunoglobulin m decreased	3 (9.4)	3 (9.4)	0	0	0
Blood immunoglobulin a decreased	1 (3.1)	1 (3.1)	0	0	0
Blood immunoglobulin g decreased	1 (3.1)	0	1 (3.1)	0	0
Serious neurological adverse reactions					
-Total	12 (37.5)	4 (12.5)	5 (15.6)	3 (9.4)	0
Confusional state	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Delirium	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Encephalopathy	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Seizure	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Agitation	2 (6.3)	0	2 (6.3)	0	0
Dysphagia	2 (6.3)	0	1 (3.1)	1 (3.1)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	2 (6.3)	2 (6.3)	0	0	0
Asterixis	1 (3.1)	1 (3.1)	0	0	0
Depressed level of consciousness	1 (3.1)	1 (3.1)	0	0	0
Dysarthria	1 (3.1)	1 (3.1)	0	0	0
Hallucination	1 (3.1)	0	1 (3.1)	0	0
Listless	1 (3.1)	1 (3.1)	0	0	0
Mental status changes	1 (3.1)	1 (3.1)	0	0	0
Tremor	1 (3.1)	1 (3.1)	0	0	0
Tumour Lysis Syndrome					
-Total	3 (9.4)	0	0	3 (9.4)	0
Tumour lysis syndrome	3 (9.4)	0	0	3 (9.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202q
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	0	1 (9.1)	7 (63.6)
Infections					
-Total	7 (63.6)	0	0	1 (9.1)	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Bronchitis	1 (9.1)	0	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	0	0	1 (9.1)	0
Escherichia infection	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Oral herpes	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	0	0	1 (9.1)
Streptococcal infection	1 (9.1)	0	0	1 (9.1)	0
Serious neurological adverse reactions					
-Total	4 (36.4)	0	1 (9.1)	2 (18.2)	1 (9.1)
Agitation	1 (9.1)	0	0	1 (9.1)	0
Confusional state	1 (9.1)	0	1 (9.1)	0	0
Delirium	1 (9.1)	0	0	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	0	0	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	0	1 (9.1)
Somnolence	1 (9.1)	0	1 (9.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202r
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	2 (25.0)	2 (25.0)	4 (50.0)
Cytokine Release Syndrome					
-Total	5 (62.5)	0	2 (25.0)	0	3 (37.5)
Cytokine release syndrome	5 (62.5)	0	2 (25.0)	0	3 (37.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (37.5)	1 (12.5)	0	1 (12.5)	1 (12.5)
Anaemia	1 (12.5)	0	0	1 (12.5)	0
Neutropenia	1 (12.5)	0	0	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	0	1 (12.5)	0
White blood cell count decreased	1 (12.5)	1 (12.5)	0	0	0
Infections					

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (75.0)	1 (12.5)	2 (25.0)	1 (12.5)	2 (25.0)
Upper respiratory tract infection	2 (25.0)	0	2 (25.0)	0	0
Viral infection	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	1 (12.5)	0	0
Corona virus infection	1 (12.5)	0	0	1 (12.5)	0
Ear infection	1 (12.5)	1 (12.5)	0	0	0
Gastroenteritis	1 (12.5)	0	1 (12.5)	0	0
Human polyomavirus infection	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Respiratory syncytial virus infection	1 (12.5)	0	0	1 (12.5)	0
Rhinovirus infection	1 (12.5)	1 (12.5)	0	0	0
Skin infection	1 (12.5)	0	1 (12.5)	0	0
Tinea capitis	1 (12.5)	1 (12.5)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (50.0)	0	4 (50.0)	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypogammaglobulinaemia	4 (50.0)	0	4 (50.0)	0	0
Blood immunoglobulin m decreased	1 (12.5)	1 (12.5)	0	0	0
Serious neurological adverse reactions					
-Total	4 (50.0)	2 (25.0)	2 (25.0)	0	0
Confusional state	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Delirium	1 (12.5)	1 (12.5)	0	0	0
Muscular weakness	1 (12.5)	1 (12.5)	0	0	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202r
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (91.3)	0	3 (13.0)	9 (39.1)	9 (39.1)
Cytokine Release Syndrome					
-Total	16 (69.6)	2 (8.7)	7 (30.4)	2 (8.7)	5 (21.7)
Cytokine release syndrome	16 (69.6)	2 (8.7)	7 (30.4)	2 (8.7)	5 (21.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	11 (47.8)	0	1 (4.3)	4 (17.4)	6 (26.1)
White blood cell count decreased	5 (21.7)	0	0	2 (8.7)	3 (13.0)
Neutrophil count decreased	3 (13.0)	0	0	1 (4.3)	2 (8.7)
Anaemia	2 (8.7)	0	0	2 (8.7)	0
Febrile neutropenia	2 (8.7)	0	0	2 (8.7)	0
Neutropenia	2 (8.7)	0	0	0	2 (8.7)

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	2 (8.7)	0	1 (4.3)	0	1 (4.3)
Leukopenia	1 (4.3)	0	0	0	1 (4.3)
Lymphocyte count decreased	1 (4.3)	0	0	0	1 (4.3)
Pancytopenia	1 (4.3)	0	0	0	1 (4.3)
Infections					
-Total	18 (78.3)	1 (4.3)	5 (21.7)	11 (47.8)	1 (4.3)
Pneumonia	4 (17.4)	0	3 (13.0)	1 (4.3)	0
Gastroenteritis	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Influenza	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Clostridium difficile infection	2 (8.7)	0	2 (8.7)	0	0
Device related infection	2 (8.7)	0	0	2 (8.7)	0
Escherichia bacteraemia	2 (8.7)	0	0	2 (8.7)	0
Escherichia urinary tract infection	2 (8.7)	0	0	2 (8.7)	0
Otitis media	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Parainfluenzae virus infection	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Rhinovirus infection	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Sinusitis	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Staphylococcal infection	2 (8.7)	1 (4.3)	0	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Urinary tract infection	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Abscess limb	1 (4.3)	0	0	1 (4.3)	0
Bronchopulmonary aspergillosis	1 (4.3)	0	0	1 (4.3)	0
Catheter site cellulitis	1 (4.3)	1 (4.3)	0	0	0
Clostridium difficile colitis	1 (4.3)	0	0	1 (4.3)	0
Cytomegalovirus infection	1 (4.3)	1 (4.3)	0	0	0
Enterococcal infection	1 (4.3)	1 (4.3)	0	0	0
Gastroenteritis norovirus	1 (4.3)	0	1 (4.3)	0	0
Gingivitis	1 (4.3)	1 (4.3)	0	0	0
Haemophilus infection	1 (4.3)	0	1 (4.3)	0	0
Herpes zoster	1 (4.3)	0	0	1 (4.3)	0
Meningitis aseptic	1 (4.3)	0	1 (4.3)	0	0
Metapneumovirus infection	1 (4.3)	0	1 (4.3)	0	0
Oral herpes	1 (4.3)	0	1 (4.3)	0	0
Otitis media acute	1 (4.3)	0	1 (4.3)	0	0
Pharyngitis	1 (4.3)	0	1 (4.3)	0	0
Pneumonia fungal	1 (4.3)	0	1 (4.3)	0	0

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash pustular	1 (4.3)	0	1 (4.3)	0	0
Respiratory syncytial virus bronchitis	1 (4.3)	0	0	1 (4.3)	0
Respiratory syncytial virus infection	1 (4.3)	0	1 (4.3)	0	0
Rhinitis	1 (4.3)	1 (4.3)	0	0	0
Sepsis	1 (4.3)	0	0	0	1 (4.3)
Serratia infection	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal scalded skin syndrome	1 (4.3)	0	1 (4.3)	0	0
Staphylococcal sepsis	1 (4.3)	0	0	0	1 (4.3)
Streptococcal infection	1 (4.3)	0	1 (4.3)	0	0
Subcutaneous abscess	1 (4.3)	0	1 (4.3)	0	0
Viral infection	1 (4.3)	1 (4.3)	0	0	0
Viral upper respiratory tract infection	1 (4.3)	0	0	1 (4.3)	0
Vulvovaginal mycotic infection	1 (4.3)	0	1 (4.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (43.5)	1 (4.3)	7 (30.4)	2 (8.7)	0
Hypogammaglobulinaemia	10 (43.5)	1 (4.3)	7 (30.4)	2 (8.7)	0

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (4.3)	1 (4.3)	0	0	0
Blood immunoglobulin m decreased	1 (4.3)	1 (4.3)	0	0	0
Serious neurological adverse reactions					
-Total	12 (52.2)	5 (21.7)	3 (13.0)	3 (13.0)	1 (4.3)
Seizure	3 (13.0)	0	1 (4.3)	1 (4.3)	1 (4.3)
Agitation	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Delirium	2 (8.7)	0	2 (8.7)	0	0
Dysarthria	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Dysphagia	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Encephalopathy	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Mental status changes	2 (8.7)	2 (8.7)	0	0	0
Muscular weakness	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Tremor	2 (8.7)	2 (8.7)	0	0	0
Asterixis	1 (4.3)	1 (4.3)	0	0	0
Confusional state	1 (4.3)	1 (4.3)	0	0	0
Depressed level of consciousness	1 (4.3)	1 (4.3)	0	0	0
Hallucination	1 (4.3)	1 (4.3)	0	0	0
Hyporesponsive to stimuli	1 (4.3)	0	0	1 (4.3)	0

Number of previous relapses: 1

Group term Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Irritability	1 (4.3)	1 (4.3)	0	0	0
Somnolence	1 (4.3)	1 (4.3)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (8.7)	0	0	2 (8.7)	0
Tumour lysis syndrome	2 (8.7)	0	0	2 (8.7)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202r
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (95.8)	0	2 (8.3)	10 (41.7)	11 (45.8)
Cytokine Release Syndrome					
-Total	18 (75.0)	1 (4.2)	12 (50.0)	4 (16.7)	1 (4.2)
Cytokine release syndrome	18 (75.0)	1 (4.2)	12 (50.0)	4 (16.7)	1 (4.2)
Hematopoietic cytopenias not resolved by Day 28					
-Total	12 (50.0)	0	2 (8.3)	4 (16.7)	6 (25.0)
White blood cell count decreased	7 (29.2)	0	1 (4.2)	2 (8.3)	4 (16.7)
Anaemia	4 (16.7)	0	4 (16.7)	0	0
Neutrophil count decreased	4 (16.7)	0	0	1 (4.2)	3 (12.5)
Neutropenia	3 (12.5)	0	0	1 (4.2)	2 (8.3)

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	3 (12.5)	1 (4.2)	0	1 (4.2)	1 (4.2)
Thrombocytopenia	2 (8.3)	0	0	0	2 (8.3)
Febrile neutropenia	1 (4.2)	0	0	1 (4.2)	0
Lymphocyte count decreased	1 (4.2)	0	0	1 (4.2)	0
Lymphopenia	1 (4.2)	0	0	1 (4.2)	0
Pancytopenia	1 (4.2)	0	0	1 (4.2)	0
Infections					
-Total	16 (66.7)	1 (4.2)	5 (20.8)	5 (20.8)	5 (20.8)
Clostridium difficile colitis	3 (12.5)	1 (4.2)	1 (4.2)	1 (4.2)	0
Rhinovirus infection	3 (12.5)	3 (12.5)	0	0	0
Pneumonia	2 (8.3)	0	2 (8.3)	0	0
Sinusitis	2 (8.3)	0	2 (8.3)	0	0
Upper respiratory tract infection	2 (8.3)	0	2 (8.3)	0	0
Viral upper respiratory tract infection	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Acute sinusitis	1 (4.2)	0	1 (4.2)	0	0
Alpha haemolytic streptococcal infection	1 (4.2)	0	0	1 (4.2)	0
Bacterial sepsis	1 (4.2)	0	0	0	1 (4.2)

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida sepsis	1 (4.2)	0	0	0	1 (4.2)
Catheter site infection	1 (4.2)	0	0	1 (4.2)	0
Cholecystitis infective	1 (4.2)	0	0	1 (4.2)	0
Clostridium difficile infection	1 (4.2)	0	1 (4.2)	0	0
Conjunctivitis	1 (4.2)	0	1 (4.2)	0	0
Device related infection	1 (4.2)	0	0	1 (4.2)	0
Escherichia infection	1 (4.2)	0	0	1 (4.2)	0
Escherichia sepsis	1 (4.2)	0	0	0	1 (4.2)
Escherichia urinary tract infection	1 (4.2)	0	1 (4.2)	0	0
Folliculitis	1 (4.2)	0	1 (4.2)	0	0
Gastroenteritis	1 (4.2)	1 (4.2)	0	0	0
Gastroenteritis viral	1 (4.2)	1 (4.2)	0	0	0
Influenza	1 (4.2)	0	1 (4.2)	0	0
Molluscum contagiosum	1 (4.2)	1 (4.2)	0	0	0
Oral herpes	1 (4.2)	0	1 (4.2)	0	0
Orchitis	1 (4.2)	1 (4.2)	0	0	0
Otitis externa	1 (4.2)	0	1 (4.2)	0	0
Parainfluenzae virus infection	1 (4.2)	0	0	1 (4.2)	0

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (4.2)	1 (4.2)	0	0	0
Pneumonia fungal	1 (4.2)	0	0	1 (4.2)	0
Respiratory tract infection	1 (4.2)	0	0	0	1 (4.2)
Septic embolus	1 (4.2)	0	0	0	1 (4.2)
Staphylococcal infection	1 (4.2)	0	0	1 (4.2)	0
Streptococcal infection	1 (4.2)	0	0	1 (4.2)	0
Urinary tract infection	1 (4.2)	0	1 (4.2)	0	0
Urinary tract infection enterococcal	1 (4.2)	0	0	1 (4.2)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	13 (54.2)	1 (4.2)	9 (37.5)	3 (12.5)	0
Hypogammaglobulinaemia	12 (50.0)	1 (4.2)	8 (33.3)	3 (12.5)	0
Blood immunoglobulin g decreased	1 (4.2)	0	1 (4.2)	0	0
Blood immunoglobulin m decreased	1 (4.2)	1 (4.2)	0	0	0
Immunodeficiency	1 (4.2)	0	1 (4.2)	0	0
Serious neurological adverse reactions					
-Total	6 (25.0)	2 (8.3)	3 (12.5)	1 (4.2)	0
Confusional state	3 (12.5)	1 (4.2)	2 (8.3)	0	0

Number of previous relapses: 2

Group term Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Delirium	1 (4.2)	1 (4.2)	0	0	0
Disturbance in attention	1 (4.2)	1 (4.2)	0	0	0
Encephalopathy	1 (4.2)	0	0	1 (4.2)	0
Mental status changes	1 (4.2)	1 (4.2)	0	0	0
Seizure	1 (4.2)	0	1 (4.2)	0	0
Tumour Lysis Syndrome					
-Total	2 (8.3)	0	0	2 (8.3)	0
Tumour lysis syndrome	2 (8.3)	0	0	2 (8.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 202r
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (95.0)	0	3 (15.0)	6 (30.0)	10 (50.0)
Cytokine Release Syndrome					
-Total	11 (55.0)	3 (15.0)	4 (20.0)	2 (10.0)	2 (10.0)
Cytokine release syndrome	11 (55.0)	3 (15.0)	4 (20.0)	2 (10.0)	2 (10.0)
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	1 (5.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	8 (40.0)	1 (5.0)	0	2 (10.0)	5 (25.0)
Neutrophil count decreased	5 (25.0)	0	0	0	5 (25.0)
White blood cell count decreased	5 (25.0)	0	0	3 (15.0)	2 (10.0)
Platelet count decreased	3 (15.0)	0	0	0	3 (15.0)

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	3 (15.0)	1 (5.0)	0	2 (10.0)	0
Anaemia	1 (5.0)	0	0	1 (5.0)	0
Lymphocyte count decreased	1 (5.0)	0	0	1 (5.0)	0
Infections					
-Total	15 (75.0)	1 (5.0)	3 (15.0)	7 (35.0)	4 (20.0)
Upper respiratory tract infection	5 (25.0)	4 (20.0)	0	1 (5.0)	0
Bacteraemia	2 (10.0)	0	0	2 (10.0)	0
Clostridium difficile colitis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Clostridium difficile infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Device related infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Enterococcal bacteraemia	2 (10.0)	0	0	2 (10.0)	0
Fungal skin infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Klebsiella sepsis	2 (10.0)	0	0	0	2 (10.0)
Otitis media	2 (10.0)	0	2 (10.0)	0	0
Urinary tract infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Vulvovaginal candidiasis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Body tinea	1 (5.0)	1 (5.0)	0	0	0
Bronchitis	1 (5.0)	0	1 (5.0)	0	0

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (5.0)	0	0	1 (5.0)	0
Cellulitis of male external genital organ	1 (5.0)	0	0	1 (5.0)	0
Conjunctivitis	1 (5.0)	0	1 (5.0)	0	0
Croup infectious	1 (5.0)	0	0	1 (5.0)	0
Cytomegalovirus infection	1 (5.0)	1 (5.0)	0	0	0
Cytomegalovirus viraemia	1 (5.0)	0	1 (5.0)	0	0
Ear infection	1 (5.0)	0	1 (5.0)	0	0
Enterovirus infection	1 (5.0)	0	0	1 (5.0)	0
Herpes simplex	1 (5.0)	1 (5.0)	0	0	0
Human herpesvirus 6 infection	1 (5.0)	0	1 (5.0)	0	0
Hypopyon	1 (5.0)	0	1 (5.0)	0	0
Klebsiella infection	1 (5.0)	0	0	1 (5.0)	0
Necrotising fasciitis	1 (5.0)	0	0	1 (5.0)	0
Oral candidiasis	1 (5.0)	1 (5.0)	0	0	0
Oral herpes	1 (5.0)	0	1 (5.0)	0	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Parainfluenzae virus infection	1 (5.0)	1 (5.0)	0	0	0

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (5.0)	0	0	1 (5.0)	0
Rotavirus infection	1 (5.0)	0	0	1 (5.0)	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Sinusitis	1 (5.0)	0	1 (5.0)	0	0
Skin infection	1 (5.0)	0	1 (5.0)	0	0
Skin papilloma	1 (5.0)	0	1 (5.0)	0	0
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Staphylococcal infection	1 (5.0)	0	0	0	1 (5.0)
Streptococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Vascular device infection	1 (5.0)	0	0	1 (5.0)	0
Viral upper respiratory tract infection	1 (5.0)	1 (5.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	7 (35.0)	2 (10.0)	5 (25.0)	0	0
Hypogammaglobulinaemia	7 (35.0)	2 (10.0)	5 (25.0)	0	0
Blood immunoglobulin a decreased	2 (10.0)	2 (10.0)	0	0	0
Blood immunoglobulin m decreased	2 (10.0)	2 (10.0)	0	0	0
Serious neurological adverse reactions					

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (30.0)	1 (5.0)	1 (5.0)	4 (20.0)	0
Irritability	2 (10.0)	2 (10.0)	0	0	0
Agitation	1 (5.0)	0	1 (5.0)	0	0
Confusional state	1 (5.0)	0	1 (5.0)	0	0
Delirium	1 (5.0)	0	0	1 (5.0)	0
Encephalopathy	1 (5.0)	1 (5.0)	0	0	0
Hallucination	1 (5.0)	0	1 (5.0)	0	0
Leukoencephalopathy	1 (5.0)	0	0	1 (5.0)	0
Listless	1 (5.0)	1 (5.0)	0	0	0
Mental status changes	1 (5.0)	0	0	1 (5.0)	0
Seizure	1 (5.0)	0	0	1 (5.0)	0
Somnolence	1 (5.0)	0	1 (5.0)	0	0
Tumour Lysis Syndrome					
-Total	1 (5.0)	0	0	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 203a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Death within 30 days of CTL019 infusion, Age: <10 years

	All patients N=20
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	1 (5.0)
Nervous system disorders	
-Total	1 (5.0)
Embolic stroke	1 (5.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Death within 30 days of CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=34 All grades n (%)
Number of patients with at least one AE	1 (2.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (2.9)
Acute lymphocytic leukaemia	1 (2.9)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Death >30 days after CTL019 infusion, Age: <10 years

	All patients N=20
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	10 (50.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	10 (50.0)
Acute lymphocytic leukaemia	9 (45.0)
Glioblastoma multiforme	1 (5.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Death >30 days after CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	12 (35.3)
Injury, poisoning and procedural complications	
-Total	1 (2.9)
Complications of transplant surgery	1 (2.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	11 (32.4)
Acute lymphocytic leukaemia	11 (32.4)

- System organ classes are presented in alphabetical order; preferred terms are presented

in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Death >30 days after CTL019 infusion, Age: >=18

	All patients N=10
Primary system organ class **Preferred term**	**All grades** **n (%)**
Number of patients with at least one AE	6 (60.0)
Infections and infestations	
-Total	1 (10.0)
Sepsis	1 (10.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (40.0)
Acute lymphocytic leukaemia	4 (40.0)
Nervous system disorders	
-Total	1 (10.0)
Seizure	1 (10.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	11 (55.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	10 (50.0)
Acute lymphocytic leukaemia	9 (45.0)
Glioblastoma multiforme	1 (5.0)
Nervous system disorders	
-Total	1 (5.0)
Embolic stroke	1 (5.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	13 (38.2)
Injury, poisoning and procedural complications	
-Total	1 (2.9)
Complications of transplant surgery	1 (2.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	12 (35.3)
Acute lymphocytic leukaemia	12 (35.3)

- System organ classes are presented in alphabetical order; preferred terms are presented

in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	6 (60.0)
Infections and infestations	
-Total	1 (10.0)
Sepsis	1 (10.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (40.0)
Acute lymphocytic leukaemia	4 (40.0)
Nervous system disorders	
-Total	1 (10.0)
Seizure	1 (10.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203b
Deaths post CTL019 infusion by primary system organ class, preferred term and Gender
Safety Set

Timing: Death within 30 days of CTL019 infusion, Gender: Female

	All patients N=34
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	2 (5.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (2.9)
Acute lymphocytic leukaemia	1 (2.9)
Nervous system disorders	
-Total	1 (2.9)
Embolic stroke	1 (2.9)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203b
Deaths post CTL019 infusion by primary system organ class, preferred term and Gender
Safety Set

Timing: Death >30 days after CTL019 infusion, Gender: Male

	All patients N=30
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	11 (36.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	10 (33.3)
Acute lymphocytic leukaemia	9 (30.0)
Glioblastoma multiforme	1 (3.3)
Nervous system disorders	
-Total	1 (3.3)
Seizure	1 (3.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203b
Deaths post CTL019 infusion by primary system organ class, preferred term and Gender
Safety Set

Timing: Death >30 days after CTL019 infusion, Gender: Female

	All patients N=34
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	17 (50.0)
Infections and infestations	
-Total	1 (2.9)
Sepsis	1 (2.9)
Injury, poisoning and procedural complications	
-Total	1 (2.9)
Complications of transplant surgery	1 (2.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	15 (44.1)

Timing: Death >30 days after CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 All grades n (%)
Acute lymphocytic leukaemia	15 (44.1)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203b
Deaths post CTL019 infusion by primary system organ class, preferred term and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	11 (36.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	10 (33.3)
Acute lymphocytic leukaemia	9 (30.0)
Glioblastoma multiforme	1 (3.3)
Nervous system disorders	
-Total	1 (3.3)
Seizure	1 (3.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203b
Deaths post CTL019 infusion by primary system organ class, preferred term and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	19 (55.9)
Infections and infestations	
-Total	1 (2.9)
Sepsis	1 (2.9)
Injury, poisoning and procedural complications	
-Total	1 (2.9)
Complications of transplant surgery	1 (2.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	16 (47.1)
Acute lymphocytic leukaemia	16 (47.1)

Timing: Any time post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 All grades n (%)
Nervous system disorders	
-Total	1 (2.9)
Embolic stroke	1 (2.9)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Death within 30 days of CTL019 infusion, Race: White

	All patients N=52
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	2 (3.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.9)
Acute lymphocytic leukaemia	1 (1.9)
Nervous system disorders	
-Total	1 (1.9)
Embolic stroke	1 (1.9)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Death >30 days after CTL019 infusion, Race: White

Primary system organ class **Preferred term**	**All patients** **N=52** **All grades** **n (%)**
Number of patients with at least one AE	23 (44.2)
Injury, poisoning and procedural complications	
-Total	1 (1.9)
Complications of transplant surgery	1 (1.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	21 (40.4)
Acute lymphocytic leukaemia	20 (38.5)
Glioblastoma multiforme	1 (1.9)
Nervous system disorders	
-Total	1 (1.9)

Timing: Death >30 days after CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=52 All grades n (%)
Seizure	1 (1.9)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Death >30 days after CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All patients N=5 All grades n (%)
Number of patients with at least one AE	3 (60.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	3 (60.0)
Acute lymphocytic leukaemia	3 (60.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Death >30 days after CTL019 infusion, Race: Other

Primary system organ class **Preferred term**	**All patients** **N=7** **All grades** **n (%)**
Number of patients with at least one AE	2 (28.6)
Infections and infestations	
-Total	1 (14.3)
Sepsis	1 (14.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (14.3)
Acute lymphocytic leukaemia	1 (14.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class **Preferred term**	**All patients** **N=52** **All grades** **n (%)**
Number of patients with at least one AE	25 (48.1)
Injury, poisoning and procedural complications	
-Total	1 (1.9)
Complications of transplant surgery	1 (1.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	22 (42.3)
Acute lymphocytic leukaemia	21 (40.4)
Glioblastoma multiforme	1 (1.9)
Nervous system disorders	
-Total	2 (3.8)

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=52 All grades n (%)
Embolic stroke	1 (1.9)
Seizure	1 (1.9)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All patients N=5 All grades n (%)
Number of patients with at least one AE	3 (60.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	3 (60.0)
Acute lymphocytic leukaemia	3 (60.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=7 All grades n (%)
Number of patients with at least one AE	2 (28.6)
Infections and infestations	
-Total	1 (14.3)
Sepsis	1 (14.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (14.3)
Acute lymphocytic leukaemia	1 (14.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203d
Deaths post CTL019 infusion by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: Death within 30 days of CTL019 infusion, Ethnicity: Other

	All patients N=39
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	2 (5.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (2.6)
Acute lymphocytic leukaemia	1 (2.6)
Nervous system disorders	
-Total	1 (2.6)
Embolic stroke	1 (2.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203d
Deaths post CTL019 infusion by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: Death >30 days after CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25
Primary system organ class **Preferred term**	**All grades** **n (%)**
Number of patients with at least one AE	6 (24.0)
Injury, poisoning and procedural complications	
-Total	1 (4.0)
Complications of transplant surgery	1 (4.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (16.0)
Acute lymphocytic leukaemia	4 (16.0)
Nervous system disorders	
-Total	1 (4.0)
Seizure	1 (4.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203d
Deaths post CTL019 infusion by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: Death >30 days after CTL019 infusion, Ethnicity: Other

	All patients N=39
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	22 (56.4)
Infections and infestations	
-Total	1 (2.6)
Sepsis	1 (2.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	21 (53.8)
Acute lymphocytic leukaemia	20 (51.3)
Glioblastoma multiforme	1 (2.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.

- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203d
Deaths post CTL019 infusion by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	6 (24.0)
Injury, poisoning and procedural complications	
-Total	1 (4.0)
Complications of transplant surgery	1 (4.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (16.0)
Acute lymphocytic leukaemia	4 (16.0)
Nervous system disorders	
-Total	1 (4.0)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=25 All grades n (%)
Seizure	1 (4.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203d
Deaths post CTL019 infusion by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	24 (61.5)
Infections and infestations	
-Total	1 (2.6)
Sepsis	1 (2.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	22 (56.4)
Acute lymphocytic leukaemia	21 (53.8)
Glioblastoma multiforme	1 (2.6)
Nervous system disorders	
-Total	1 (2.6)
Embolic stroke	1 (2.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203e
Deaths post CTL019 infusion by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: Death within 30 days of CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	1 (14.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (14.3)
Acute lymphocytic leukaemia	1 (14.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203e
Deaths post CTL019 infusion by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: Death within 30 days of CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	1 (1.8)
Nervous system disorders	
-Total	1 (1.8)
Embolic stroke	1 (1.8)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203e
Deaths post CTL019 infusion by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: Death >30 days after CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class **Preferred term**	**All patients** **N=7** **All grades** **n (%)**
Number of patients with at least one AE	1 (14.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (14.3)
Acute lymphocytic leukaemia	1 (14.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203e
Deaths post CTL019 infusion by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: Death >30 days after CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class **Preferred term**	**All patients** **N=57** **All grades** **n (%)**
Number of patients with at least one AE	27 (47.4)
Infections and infestations	
-Total	1 (1.8)
Sepsis	1 (1.8)
Injury, poisoning and procedural complications	
-Total	1 (1.8)
Complications of transplant surgery	1 (1.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	24 (42.1)

Timing: Death >30 days after CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All patients N=57 All grades n (%)
Acute lymphocytic leukaemia	23 (40.4)
Glioblastoma multiforme	1 (1.8)
Nervous system disorders	
-Total	1 (1.8)
Seizure	1 (1.8)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203e
Deaths post CTL019 infusion by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class **Preferred term**	**All patients** **N=7** **All grades** **n (%)**
Number of patients with at least one AE	2 (28.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	2 (28.6)
Acute lymphocytic leukaemia	2 (28.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203e
Deaths post CTL019 infusion by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class **Preferred term**	**All patients** **N=57** **All grades** **n (%)**
Number of patients with at least one AE	28 (49.1)
Infections and infestations	
-Total	1 (1.8)
Sepsis	1 (1.8)
Injury, poisoning and procedural complications	
-Total	1 (1.8)
Complications of transplant surgery	1 (1.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	24 (42.1)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All patients N=57 All grades n (%)
Acute lymphocytic leukaemia	23 (40.4)
Glioblastoma multiforme	1 (1.8)
Nervous system disorders	
-Total	2 (3.5)
Embolic stroke	1 (1.8)
Seizure	1 (1.8)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203f
Deaths post CTL019 infusion by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Death within 30 days of CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	2 (3.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.6)
Acute lymphocytic leukaemia	1 (1.6)
Nervous system disorders	
-Total	1 (1.6)
Embolic stroke	1 (1.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203f
Deaths post CTL019 infusion by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Death >30 days after CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	28 (45.2)
Infections and infestations	
-Total	1 (1.6)
Sepsis	1 (1.6)
Injury, poisoning and procedural complications	
-Total	1 (1.6)
Complications of transplant surgery	1 (1.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	25 (40.3)
Acute lymphocytic leukaemia	24 (38.7)

Timing: Death >30 days after CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All patients N=62 All grades n (%)
Glioblastoma multiforme	1 (1.6)
Nervous system disorders	
-Total	1 (1.6)
Seizure	1 (1.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203f
Deaths post CTL019 infusion by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	30 (48.4)
Infections and infestations	
-Total	1 (1.6)
Sepsis	1 (1.6)
Injury, poisoning and procedural complications	
-Total	1 (1.6)
Complications of transplant surgery	1 (1.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	26 (41.9)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All patients N=62 All grades n (%)
Acute lymphocytic leukaemia	25 (40.3)
Glioblastoma multiforme	1 (1.6)
Nervous system disorders	
-Total	2 (3.2)
Embolic stroke	1 (1.6)
Seizure	1 (1.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203g
Deaths post CTL019 infusion by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: Death within 30 days of CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	2 (3.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.6)
Acute lymphocytic leukaemia	1 (1.6)
Nervous system disorders	
-Total	1 (1.6)
Embolic stroke	1 (1.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203g
Deaths post CTL019 infusion by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: Death >30 days after CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	2 (66.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	2 (66.7)
Acute lymphocytic leukaemia	2 (66.7)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203g
Deaths post CTL019 infusion by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: Death >30 days after CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	26 (42.6)
Infections and infestations	
-Total	1 (1.6)
Sepsis	1 (1.6)
Injury, poisoning and procedural complications	
-Total	1 (1.6)
Complications of transplant surgery	1 (1.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	23 (37.7)

Timing: Death >30 days after CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=61 All grades n (%)
Acute lymphocytic leukaemia	22 (36.1)
Glioblastoma multiforme	1 (1.6)
Nervous system disorders	
-Total	1 (1.6)
Seizure	1 (1.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203g
Deaths post CTL019 infusion by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class **Preferred term**	**All patients** **N=3** **All grades** **n (%)**
Number of patients with at least one AE	2 (66.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	2 (66.7)
Acute lymphocytic leukaemia	2 (66.7)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203g
Deaths post CTL019 infusion by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class **Preferred term**	**All patients** **N=61** **All grades** **n (%)**
Number of patients with at least one AE	28 (45.9)
Infections and infestations	
-Total	1 (1.6)
Sepsis	1 (1.6)
Injury, poisoning and procedural complications	
-Total	1 (1.6)
Complications of transplant surgery	1 (1.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	24 (39.3)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=61 All grades n (%)
Acute lymphocytic leukaemia	23 (37.7)
Glioblastoma multiforme	1 (1.6)
Nervous system disorders	
-Total	2 (3.3)
Embolic stroke	1 (1.6)
Seizure	1 (1.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203h
Deaths post CTL019 infusion by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: Death within 30 days of CTL019 infusion, Hypodiploidy: No

	All patients N=63
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	2 (3.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.6)
Acute lymphocytic leukaemia	1 (1.6)
Nervous system disorders	
-Total	1 (1.6)
Embolic stroke	1 (1.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203h
Deaths post CTL019 infusion by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: Death >30 days after CTL019 infusion, Hypodiploidy: Yes

	All patients N=1
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	1 (100)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (100)
Acute lymphocytic leukaemia	1 (100)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203h
Deaths post CTL019 infusion by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: Death >30 days after CTL019 infusion, Hypodiploidy: No

	All patients N=63
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	27 (42.9)
Infections and infestations	
-Total	1 (1.6)
Sepsis	1 (1.6)
Injury, poisoning and procedural complications	
-Total	1 (1.6)
Complications of transplant surgery	1 (1.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	24 (38.1)

Timing: Death >30 days after CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=63 All grades n (%)
Acute lymphocytic leukaemia	23 (36.5)
Glioblastoma multiforme	1 (1.6)
Nervous system disorders	
-Total	1 (1.6)
Seizure	1 (1.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203h
Deaths post CTL019 infusion by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

Primary system organ class Preferred term	All patients N=1 All grades n (%)
Number of patients with at least one AE	1 (100)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (100)
Acute lymphocytic leukaemia	1 (100)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203h
Deaths post CTL019 infusion by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	29 (46.0)
Infections and infestations	
-Total	1 (1.6)
Sepsis	1 (1.6)
Injury, poisoning and procedural complications	
-Total	1 (1.6)
Complications of transplant surgery	1 (1.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	25 (39.7)
Acute lymphocytic leukaemia	24 (38.1)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=63 All grades n (%)
Glioblastoma multiforme	1 (1.6)
Nervous system disorders	
-Total	2 (3.2)
Embolic stroke	1 (1.6)
Seizure	1 (1.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203i
Deaths post CTL019 infusion by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: Death within 30 days of CTL019 infusion, BCR-ABL1-like: No

	All patients N=60
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	2 (3.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.7)
Acute lymphocytic leukaemia	1 (1.7)
Nervous system disorders	
-Total	1 (1.7)
Embolic stroke	1 (1.7)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203i
Deaths post CTL019 infusion by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: Death >30 days after CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	1 (25.0)
Injury, poisoning and procedural complications	
-Total	1 (25.0)
Complications of transplant surgery	1 (25.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203i
Deaths post CTL019 infusion by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: Death >30 days after CTL019 infusion, BCR-ABL1-like: No

	All patients N=60
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	27 (45.0)
Infections and infestations	
-Total	1 (1.7)
Sepsis	1 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	25 (41.7)
Acute lymphocytic leukaemia	24 (40.0)
Glioblastoma multiforme	1 (1.7)
Nervous system disorders	
-Total	1 (1.7)

Timing: Death >30 days after CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)
Seizure	1 (1.7)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203i
Deaths post CTL019 infusion by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4
Primary system organ class **Preferred term**	**All grades** **n (%)**
Number of patients with at least one AE	1 (25.0)
Injury, poisoning and procedural complications	
-Total	1 (25.0)
Complications of transplant surgery	1 (25.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203i
Deaths post CTL019 infusion by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	29 (48.3)
Infections and infestations	
-Total	1 (1.7)
Sepsis	1 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	26 (43.3)
Acute lymphocytic leukaemia	25 (41.7)
Glioblastoma multiforme	1 (1.7)
Nervous system disorders	
-Total	2 (3.3)
Embolic stroke	1 (1.7)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)
Seizure	1 (1.7)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203j
Deaths post CTL019 infusion by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: Death within 30 days of CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All patients N=19 All grades n (%)
Number of patients with at least one AE	1 (5.3)
Nervous system disorders	
-Total	1 (5.3)
Embolic stroke	1 (5.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203j
Deaths post CTL019 infusion by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: Death within 30 days of CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	1 (2.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (2.2)
Acute lymphocytic leukaemia	1 (2.2)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203j
Deaths post CTL019 infusion by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: Death >30 days after CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	8 (42.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	8 (42.1)
Acute lymphocytic leukaemia	8 (42.1)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203j
Deaths post CTL019 infusion by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: Death >30 days after CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	20 (44.4)
Infections and infestations	
-Total	1 (2.2)
Sepsis	1 (2.2)
Injury, poisoning and procedural complications	
-Total	1 (2.2)
Complications of transplant surgery	1 (2.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	17 (37.8)

Timing: Death >30 days after CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=45 All grades n (%)
Acute lymphocytic leukaemia	16 (35.6)
Glioblastoma multiforme	1 (2.2)
Nervous system disorders	
-Total	1 (2.2)
Seizure	1 (2.2)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203j
Deaths post CTL019 infusion by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All patients N=19 All grades n (%)
Number of patients with at least one AE	9 (47.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	8 (42.1)
Acute lymphocytic leukaemia	8 (42.1)
Nervous system disorders	
-Total	1 (5.3)
Embolic stroke	1 (5.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203j
Deaths post CTL019 infusion by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	21 (46.7)
Infections and infestations	
-Total	1 (2.2)
Sepsis	1 (2.2)
Injury, poisoning and procedural complications	
-Total	1 (2.2)
Complications of transplant surgery	1 (2.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	18 (40.0)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=45 All grades n (%)
Acute lymphocytic leukaemia	17 (37.8)
Glioblastoma multiforme	1 (2.2)
Nervous system disorders	
-Total	1 (2.2)
Seizure	1 (2.2)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203k
Deaths post CTL019 infusion by primary system organ class, preferred term and Region
Safety Set

Timing: Death within 30 days of CTL019 infusion, Region: US

	All patients N=64
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	2 (3.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.6)
Acute lymphocytic leukaemia	1 (1.6)
Nervous system disorders	
-Total	1 (1.6)
Embolic stroke	1 (1.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203k
Deaths post CTL019 infusion by primary system organ class, preferred term and Region
Safety Set

Timing: Death >30 days after CTL019 infusion, Region: US

Primary system organ class **Preferred term**	**All patients** **N=64** **All grades** **n (%)**
Number of patients with at least one AE	28 (43.8)
Infections and infestations	
-Total	1 (1.6)
Sepsis	1 (1.6)
Injury, poisoning and procedural complications	
-Total	1 (1.6)
Complications of transplant surgery	1 (1.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	25 (39.1)
Acute lymphocytic leukaemia	24 (37.5)
Glioblastoma multiforme	1 (1.6)

Timing: Death >30 days after CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=64 All grades n (%)
Nervous system disorders	
-Total	1 (1.6)
Seizure	1 (1.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203k
Deaths post CTL019 infusion by primary system organ class, preferred term and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	30 (46.9)
Infections and infestations	
-Total	1 (1.6)
Sepsis	1 (1.6)
Injury, poisoning and procedural complications	
-Total	1 (1.6)
Complications of transplant surgery	1 (1.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	26 (40.6)
Acute lymphocytic leukaemia	25 (39.1)

Timing: Any time post CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=64 All grades n (%)
Glioblastoma multiforme	1 (1.6)
Nervous system disorders	
-Total	2 (3.1)
Embolic stroke	1 (1.6)
Seizure	1 (1.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203l
Deaths post CTL019 infusion by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: Death within 30 days of CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	1 (3.6)
Nervous system disorders	
-Total	1 (3.6)
Embolic stroke	1 (3.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203l
Deaths post CTL019 infusion by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: Death within 30 days of CTL019 infusion, Prior SCT therapy: No

	All patients N=36
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	1 (2.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (2.8)
Acute lymphocytic leukaemia	1 (2.8)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203l
Deaths post CTL019 infusion by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: Death >30 days after CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	13 (46.4)
Infections and infestations	
-Total	1 (3.6)
Sepsis	1 (3.6)
Injury, poisoning and procedural complications	
-Total	1 (3.6)
Complications of transplant surgery	1 (3.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	11 (39.3)

Timing: Death >30 days after CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=28 All grades n (%)
Acute lymphocytic leukaemia	10 (35.7)
Glioblastoma multiforme	1 (3.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203l
Deaths post CTL019 infusion by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: Death >30 days after CTL019 infusion, Prior SCT therapy: No

	All patients N=36
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	15 (41.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	14 (38.9)
Acute lymphocytic leukaemia	14 (38.9)
Nervous system disorders	
-Total	1 (2.8)
Seizure	1 (2.8)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203l
Deaths post CTL019 infusion by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	14 (50.0)
Infections and infestations	
-Total	1 (3.6)
Sepsis	1 (3.6)
Injury, poisoning and procedural complications	
-Total	1 (3.6)
Complications of transplant surgery	1 (3.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	11 (39.3)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=28 All grades n (%)
Acute lymphocytic leukaemia	10 (35.7)
Glioblastoma multiforme	1 (3.6)
Nervous system disorders	
-Total	1 (3.6)
Embolic stroke	1 (3.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203l
Deaths post CTL019 infusion by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	16 (44.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	15 (41.7)
Acute lymphocytic leukaemia	15 (41.7)
Nervous system disorders	
-Total	1 (2.8)
Seizure	1 (2.8)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203m
Deaths post CTL019 infusion by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: Death within 30 days of CTL019 infusion, Eligibility for SCT: No

	All patients N=50
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	2 (4.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (2.0)
Acute lymphocytic leukaemia	1 (2.0)
Nervous system disorders	
-Total	1 (2.0)
Embolic stroke	1 (2.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203m
Deaths post CTL019 infusion by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: Death >30 days after CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	4 (28.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (28.6)
Acute lymphocytic leukaemia	4 (28.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203m
Deaths post CTL019 infusion by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: Death >30 days after CTL019 infusion, Eligibility for SCT: No

	All patients N=50
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	24 (48.0)
Infections and infestations	
-Total	1 (2.0)
Sepsis	1 (2.0)
Injury, poisoning and procedural complications	
-Total	1 (2.0)
Complications of transplant surgery	1 (2.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	21 (42.0)

Timing: Death >30 days after CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=50 All grades n (%)
Acute lymphocytic leukaemia	20 (40.0)
Glioblastoma multiforme	1 (2.0)
Nervous system disorders	
-Total	1 (2.0)
Seizure	1 (2.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203m
Deaths post CTL019 infusion by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	4 (28.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (28.6)
Acute lymphocytic leukaemia	4 (28.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203m
Deaths post CTL019 infusion by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	26 (52.0)
Infections and infestations	
-Total	1 (2.0)
Sepsis	1 (2.0)
Injury, poisoning and procedural complications	
-Total	1 (2.0)
Complications of transplant surgery	1 (2.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	22 (44.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=50 All grades n (%)
Acute lymphocytic leukaemia	21 (42.0)
Glioblastoma multiforme	1 (2.0)
Nervous system disorders	
-Total	2 (4.0)
Embolic stroke	1 (2.0)
Seizure	1 (2.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203n
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: Death within 30 days of CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	2 (4.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (2.3)
Acute lymphocytic leukaemia	1 (2.3)
Nervous system disorders	
-Total	1 (2.3)
Embolic stroke	1 (2.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203n
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: Death >30 days after CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	6 (30.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	6 (30.0)
Acute lymphocytic leukaemia	5 (25.0)
Glioblastoma multiforme	1 (5.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203n
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: Death >30 days after CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	22 (50.0)
Infections and infestations	
-Total	1 (2.3)
Sepsis	1 (2.3)
Injury, poisoning and procedural complications	
-Total	1 (2.3)
Complications of transplant surgery	1 (2.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	19 (43.2)

Timing: Death >30 days after CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=44 All grades n (%)
Acute lymphocytic leukaemia	19 (43.2)
Nervous system disorders	
-Total	1 (2.3)
Seizure	1 (2.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203n
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	6 (30.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	6 (30.0)
Acute lymphocytic leukaemia	5 (25.0)
Glioblastoma multiforme	1 (5.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203n
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	24 (54.5)
Infections and infestations	
-Total	1 (2.3)
Sepsis	1 (2.3)
Injury, poisoning and procedural complications	
-Total	1 (2.3)
Complications of transplant surgery	1 (2.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	20 (45.5)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=44 All grades n (%)
Acute lymphocytic leukaemia	20 (45.5)
Nervous system disorders	
-Total	2 (4.5)
Embolic stroke	1 (2.3)
Seizure	1 (2.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203o
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: Death within 30 days of CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	2 (3.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.7)
Acute lymphocytic leukaemia	1 (1.7)
Nervous system disorders	
-Total	1 (1.7)
Embolic stroke	1 (1.7)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203o
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: Death >30 days after CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	2 (40.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	2 (40.0)
Acute lymphocytic leukaemia	1 (20.0)
Glioblastoma multiforme	1 (20.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203o
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: Death >30 days after CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	26 (44.1)
Infections and infestations	
-Total	1 (1.7)
Sepsis	1 (1.7)
Injury, poisoning and procedural complications	
-Total	1 (1.7)
Complications of transplant surgery	1 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	23 (39.0)

Timing: Death >30 days after CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=59 All grades n (%)
Acute lymphocytic leukaemia	23 (39.0)
Nervous system disorders	
-Total	1 (1.7)
Seizure	1 (1.7)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203o
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	2 (40.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	2 (40.0)
Acute lymphocytic leukaemia	1 (20.0)
Glioblastoma multiforme	1 (20.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203o
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59
Primary system organ class **Preferred term**	**All grades** **n (%)**
Number of patients with at least one AE	28 (47.5)
Infections and infestations	
-Total	1 (1.7)
Sepsis	1 (1.7)
Injury, poisoning and procedural complications	
-Total	1 (1.7)
Complications of transplant surgery	1 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	24 (40.7)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=59 All grades n (%)
Acute lymphocytic leukaemia	24 (40.7)
Nervous system disorders	
-Total	2 (3.4)
Embolic stroke	1 (1.7)
Seizure	1 (1.7)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203p
Deaths post CTL019 infusion by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: Death within 30 days of CTL019 infusion, Down syndrome: No

	All patients N=60
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	2 (3.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.7)
Acute lymphocytic leukaemia	1 (1.7)
Nervous system disorders	
-Total	1 (1.7)
Embolic stroke	1 (1.7)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203p
Deaths post CTL019 infusion by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: Death >30 days after CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)
Number of patients with at least one AE	1 (25.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (25.0)
Acute lymphocytic leukaemia	1 (25.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203p
Deaths post CTL019 infusion by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: Death >30 days after CTL019 infusion, Down syndrome: No

	All patients N=60
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	27 (45.0)
Infections and infestations	
-Total	1 (1.7)
Sepsis	1 (1.7)
Injury, poisoning and procedural complications	
-Total	1 (1.7)
Complications of transplant surgery	1 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	24 (40.0)

Timing: Death >30 days after CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)
Acute lymphocytic leukaemia	23 (38.3)
Glioblastoma multiforme	1 (1.7)
Nervous system disorders	
-Total	1 (1.7)
Seizure	1 (1.7)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203p
Deaths post CTL019 infusion by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)
Number of patients with at least one AE	1 (25.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (25.0)
Acute lymphocytic leukaemia	1 (25.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203p
Deaths post CTL019 infusion by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	29 (48.3)
Infections and infestations	
-Total	1 (1.7)
Sepsis	1 (1.7)
Injury, poisoning and procedural complications	
-Total	1 (1.7)
Complications of transplant surgery	1 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	25 (41.7)
Acute lymphocytic leukaemia	24 (40.0)

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)
Glioblastoma multiforme	1 (1.7)
Nervous system disorders	
-Total	2 (3.3)
Embolic stroke	1 (1.7)
Seizure	1 (1.7)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203q
Deaths post CTL019 infusion by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: Death within 30 days of CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	1 (3.1)
Nervous system disorders	
-Total	1 (3.1)
Embolic stroke	1 (3.1)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203q
Deaths post CTL019 infusion by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: Death within 30 days of CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	1 (3.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (3.1)
Acute lymphocytic leukaemia	1 (3.1)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203q
Deaths post CTL019 infusion by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: Death >30 days after CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	11 (34.4)
Infections and infestations	
-Total	1 (3.1)
Sepsis	1 (3.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	10 (31.3)
Acute lymphocytic leukaemia	10 (31.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203q
Deaths post CTL019 infusion by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: Death >30 days after CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)
Number of patients with at least one AE	17 (53.1)
Injury, poisoning and procedural complications	
-Total	1 (3.1)
Complications of transplant surgery	1 (3.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	15 (46.9)
Acute lymphocytic leukaemia	14 (43.8)
Glioblastoma multiforme	1 (3.1)
Nervous system disorders	

Timing: Death >30 days after CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)
-Total	1 (3.1)
Seizure	1 (3.1)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203q
Deaths post CTL019 infusion by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)
Number of patients with at least one AE	12 (37.5)
Infections and infestations	
-Total	1 (3.1)
Sepsis	1 (3.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	10 (31.3)
Acute lymphocytic leukaemia	10 (31.3)
Nervous system disorders	
-Total	1 (3.1)
Embolic stroke	1 (3.1)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203q
Deaths post CTL019 infusion by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	18 (56.3)
Injury, poisoning and procedural complications	
-Total	1 (3.1)
Complications of transplant surgery	1 (3.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	16 (50.0)
Acute lymphocytic leukaemia	15 (46.9)
Glioblastoma multiforme	1 (3.1)
Nervous system disorders	

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)
-Total	1 (3.1)
Seizure	1 (3.1)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Death within 30 days of CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=7 All grades n (%)
Number of patients with at least one AE	1 (14.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (14.3)
Acute lymphocytic leukaemia	1 (14.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Death within 30 days of CTL019 infusion, Number of previous relapses: 2

	All patients N=21
Primary system organ class Preferred term	**All grades n (%)**
Number of patients with at least one AE	1 (4.8)
Nervous system disorders	
-Total	1 (4.8)
Embolic stroke	1 (4.8)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Death >30 days after CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=7 All grades n (%)
Number of patients with at least one AE	1 (14.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (14.3)
Acute lymphocytic leukaemia	1 (14.3)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Death >30 days after CTL019 infusion, Number of previous relapses: 1

	All patients N=20
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	11 (55.0)
Infections and infestations	
-Total	1 (5.0)
Sepsis	1 (5.0)
Injury, poisoning and procedural complications	
-Total	1 (5.0)
Complications of transplant surgery	1 (5.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	8 (40.0)

Timing: Death >30 days after CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=20 All grades n (%)
Acute lymphocytic leukaemia	7 (35.0)
Glioblastoma multiforme	1 (5.0)
Nervous system disorders	
-Total	1 (5.0)
Seizure	1 (5.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Death >30 days after CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=21 All grades n (%)
Number of patients with at least one AE	9 (42.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	9 (42.9)
Acute lymphocytic leukaemia	9 (42.9)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Death >30 days after CTL019 infusion, Number of previous relapses: >=3

	All patients N=16
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	7 (43.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	7 (43.8)
Acute lymphocytic leukaemia	7 (43.8)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=7 All grades n (%)
Number of patients with at least one AE	2 (28.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	2 (28.6)
Acute lymphocytic leukaemia	2 (28.6)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20
Primary system organ class **Preferred term**	**All grades n (%)**
Number of patients with at least one AE	11 (55.0)
Infections and infestations	
-Total	1 (5.0)
Sepsis	1 (5.0)
Injury, poisoning and procedural complications	
-Total	1 (5.0)
Complications of transplant surgery	1 (5.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	8 (40.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=20 All grades n (%)
Acute lymphocytic leukaemia	7 (35.0)
Glioblastoma multiforme	1 (5.0)
Nervous system disorders	
-Total	1 (5.0)
Seizure	1 (5.0)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

Primary system organ class **Preferred term**	**All patients** **N=21** **All grades** **n (%)**
Number of patients with at least one AE	10 (47.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	9 (42.9)
Acute lymphocytic leukaemia	9 (42.9)
Nervous system disorders	
-Total	1 (4.8)
Embolic stroke	1 (4.8)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 203r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=16 All grades n (%)
Number of patients with at least one AE	7 (43.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	7 (43.8)
Acute lymphocytic leukaemia	7 (43.8)

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
- MedDRA version 22.0 has been used for the reporting of adverse events.

Table 215a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (65.0)	1 (5.0)	5 (25.0)	4 (20.0)	3 (15.0)
Cytokine Release Syndrome					
-Total	12 (60.0)	2 (10.0)	5 (25.0)	3 (15.0)	2 (10.0)
Cytokine release syndrome	12 (60.0)	2 (10.0)	5 (25.0)	3 (15.0)	2 (10.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (5.0)	0	0	1 (5.0)	0
Febrile neutropenia	1 (5.0)	0	0	1 (5.0)	0
Infections					
-Total	4 (20.0)	0	1 (5.0)	2 (10.0)	1 (5.0)
Clostridium difficile infection	2 (10.0)	0	2 (10.0)	0	0
Catheter site infection	1 (5.0)	0	0	1 (5.0)	0

Timing: Within 8 weeks post CTL019 infusion, Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Rhinovirus infection	1 (5.0)	1 (5.0)	0	0	0
Septic embolus	1 (5.0)	0	0	0	1 (5.0)
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (5.0)	0	0	1 (5.0)	0
Seizure	1 (5.0)	0	0	1 (5.0)	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (67.6)	2 (5.9)	9 (26.5)	7 (20.6)	5 (14.7)
Cytokine Release Syndrome					
-Total	23 (67.6)	2 (5.9)	11 (32.4)	5 (14.7)	5 (14.7)
Cytokine release syndrome	23 (67.6)	2 (5.9)	11 (32.4)	5 (14.7)	5 (14.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (5.9)	0	0	2 (5.9)	0
Febrile neutropenia	2 (5.9)	0	0	2 (5.9)	0
Infections					
-Total	5 (14.7)	0	3 (8.8)	2 (5.9)	0
Clostridium difficile infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Pneumonia	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Clostridium difficile colitis	2 (5.9)	0	2 (5.9)	0	0
Gastroenteritis	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal infection	1 (2.9)	0	0	1 (2.9)	0
Serious neurological adverse reactions					
-Total	6 (17.6)	1 (2.9)	3 (8.8)	2 (5.9)	0
Seizure	2 (5.9)	0	2 (5.9)	0	0
Delirium	1 (2.9)	0	1 (2.9)	0	0
Encephalopathy	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (60.0)	0	3 (30.0)	0	3 (30.0)
Cytokine Release Syndrome					
-Total	6 (60.0)	0	3 (30.0)	0	3 (30.0)
Cytokine release syndrome	6 (60.0)	0	3 (30.0)	0	3 (30.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (20.0)	0	0	4 (20.0)	0
Infections					
-Total	3 (15.0)	0	0	3 (15.0)	0
Corona virus infection	1 (5.0)	0	0	1 (5.0)	0
Enterovirus infection	1 (5.0)	0	0	1 (5.0)	0
Parainfluenzae virus infection	1 (5.0)	0	0	1 (5.0)	0
Respiratory syncytial virus infection	1 (5.0)	0	0	1 (5.0)	0
Rotavirus infection	1 (5.0)	0	0	1 (5.0)	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (5.0)	0	0	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (17.6)	0	1 (2.9)	5 (14.7)	0
Infections					
-Total	6 (17.6)	0	1 (2.9)	5 (14.7)	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	1 (2.9)	0	0	1 (2.9)	0
Cholecystitis infective	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Herpes zoster	1 (2.9)	0	0	1 (2.9)	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Vascular device infection	1 (2.9)	0	0	1 (2.9)	0
Viral upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (30.0)	0	0	1 (10.0)	2 (20.0)
Infections					
-Total	3 (30.0)	0	0	1 (10.0)	2 (20.0)
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Bacterial sepsis	1 (10.0)	0	0	0	1 (10.0)
Cellulitis of male external genital organ	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cholecystitis infective	1 (10.0)	0	0	1 (10.0)	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Sepsis	1 (10.0)	0	0	0	1 (10.0)
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (15.0)	0	0	2 (10.0)	1 (5.0)
Infections					
-Total	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Campylobacter infection	1 (5.0)	0	0	1 (5.0)	0
Clostridium difficile infection	1 (5.0)	0	0	1 (5.0)	0
Respiratory tract infection	1 (5.0)	0	0	0	1 (5.0)
Respiratory tract infection viral	1 (5.0)	0	0	1 (5.0)	0
Urinary tract infection	1 (5.0)	0	1 (5.0)	0	0
Vulvovaginal candidiasis	1 (5.0)	0	1 (5.0)	0	0
Cellulitis of male external genital organ	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (5.0)	0	0	1 (5.0)	0
Seizure	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Infections					
-Total	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Campylobacter infection	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Vulvovaginal candidiasis	0	0	0	0	0
Cellulitis of male external genital organ	1 (2.9)	0	0	1 (2.9)	0
Pneumonia	1 (2.9)	0	1 (2.9)	0	0

Timing: >1 year post CTL019 infusion, Age: >=10 years to <18 years

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Age: >=18

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (75.0)	1 (5.0)	4 (20.0)	6 (30.0)	4 (20.0)
Cytokine Release Syndrome					
-Total	12 (60.0)	2 (10.0)	5 (25.0)	3 (15.0)	2 (10.0)
Cytokine release syndrome	12 (60.0)	2 (10.0)	5 (25.0)	3 (15.0)	2 (10.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (5.0)	0	0	1 (5.0)	0
Febrile neutropenia	1 (5.0)	0	0	1 (5.0)	0
Infections					
-Total	7 (35.0)	0	1 (5.0)	4 (20.0)	2 (10.0)
Clostridium difficile infection	3 (15.0)	0	2 (10.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (5.0)	0	0	1 (5.0)	0
Catheter site infection	1 (5.0)	0	0	1 (5.0)	0
Corona virus infection	1 (5.0)	0	0	1 (5.0)	0
Enterovirus infection	1 (5.0)	0	0	1 (5.0)	0
Parainfluenzae virus infection	1 (5.0)	0	0	1 (5.0)	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Respiratory syncytial virus infection	1 (5.0)	0	0	1 (5.0)	0
Respiratory tract infection	1 (5.0)	0	0	0	1 (5.0)
Respiratory tract infection viral	1 (5.0)	0	0	1 (5.0)	0
Rhinovirus infection	1 (5.0)	1 (5.0)	0	0	0
Rotavirus infection	1 (5.0)	0	0	1 (5.0)	0
Septic embolus	1 (5.0)	0	0	0	1 (5.0)
Urinary tract infection	1 (5.0)	0	1 (5.0)	0	0
Vulvovaginal candidiasis	1 (5.0)	0	1 (5.0)	0	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Sepsis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (10.0)	0	0	2 (10.0)	0
Seizure	2 (10.0)	0	0	2 (10.0)	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (5.0)	0	0	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	25 (73.5)	1 (2.9)	10 (29.4)	9 (26.5)	5 (14.7)
Cytokine Release Syndrome					
-Total	23 (67.6)	2 (5.9)	11 (32.4)	5 (14.7)	5 (14.7)
Cytokine release syndrome	23 (67.6)	2 (5.9)	11 (32.4)	5 (14.7)	5 (14.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (5.9)	0	0	2 (5.9)	0
Febrile neutropenia	2 (5.9)	0	0	2 (5.9)	0
Infections					
-Total	9 (26.5)	0	3 (8.8)	6 (17.6)	0
Clostridium difficile infection	0	0	0	0	0
Campylobacter infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	1 (2.9)	0	1 (2.9)	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Vulvovaginal candidiasis	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	1 (2.9)	0	0	1 (2.9)	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	2 (5.9)	0	2 (5.9)	0	0
Gastroenteritis	1 (2.9)	0	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Herpes zoster	1 (2.9)	0	0	1 (2.9)	0
Sepsis	0	0	0	0	0
Staphylococcal infection	1 (2.9)	0	0	1 (2.9)	0
Upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Vascular device infection	1 (2.9)	0	0	1 (2.9)	0
Viral upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Serious neurological adverse reactions					
-Total	6 (17.6)	1 (2.9)	3 (8.8)	2 (5.9)	0
Seizure	2 (5.9)	0	2 (5.9)	0	0
Delirium	1 (2.9)	0	1 (2.9)	0	0
Encephalopathy	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (70.0)	0	1 (10.0)	1 (10.0)	5 (50.0)
Cytokine Release Syndrome					
-Total	6 (60.0)	0	3 (30.0)	0	3 (30.0)
Cytokine release syndrome	6 (60.0)	0	3 (30.0)	0	3 (30.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	3 (30.0)	0	0	1 (10.0)	2 (20.0)
Clostridium difficile infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Bacterial sepsis	1 (10.0)	0	0	0	1 (10.0)
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	1 (10.0)	0	0	1 (10.0)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Sepsis	1 (10.0)	0	0	0	1 (10.0)
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (63.3)	2 (6.7)	7 (23.3)	5 (16.7)	5 (16.7)
Cytokine Release Syndrome					
-Total	19 (63.3)	3 (10.0)	8 (26.7)	3 (10.0)	5 (16.7)
Cytokine release syndrome	19 (63.3)	3 (10.0)	8 (26.7)	3 (10.0)	5 (16.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (6.7)	0	0	2 (6.7)	0
Febrile neutropenia	2 (6.7)	0	0	2 (6.7)	0
Infections					
-Total	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Clostridium difficile infection	1 (3.3)	0	1 (3.3)	0	0
Gastroenteritis	1 (3.3)	0	0	1 (3.3)	0

Timing: Within 8 weeks post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Encephalopathy	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Seizure	1 (3.3)	0	1 (3.3)	0	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (67.6)	1 (2.9)	10 (29.4)	6 (17.6)	6 (17.6)
Cytokine Release Syndrome					
-Total	22 (64.7)	1 (2.9)	11 (32.4)	5 (14.7)	5 (14.7)
Cytokine release syndrome	22 (64.7)	1 (2.9)	11 (32.4)	5 (14.7)	5 (14.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (2.9)	0	0	1 (2.9)	0
Febrile neutropenia	1 (2.9)	0	0	1 (2.9)	0
Infections					
-Total	7 (20.6)	0	3 (8.8)	3 (8.8)	1 (2.9)
Clostridium difficile infection	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (2.9)	0	0	1 (2.9)	0
Clostridium difficile colitis	2 (5.9)	0	2 (5.9)	0	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Pneumonia	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	1 (2.9)	1 (2.9)	0	0	0
Septic embolus	1 (2.9)	0	0	0	1 (2.9)
Staphylococcal infection	1 (2.9)	0	0	1 (2.9)	0
Serious neurological adverse reactions					
-Total	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Encephalopathy	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Seizure	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Delirium	1 (2.9)	0	1 (2.9)	0	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (16.7)	0	0	5 (16.7)	0
Infections					
-Total	5 (16.7)	0	0	5 (16.7)	0
Cellulitis of male external genital organ	1 (3.3)	0	0	1 (3.3)	0
Cholecystitis infective	1 (3.3)	0	0	1 (3.3)	0
Corona virus infection	1 (3.3)	0	0	1 (3.3)	0
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Respiratory syncytial virus infection	1 (3.3)	0	0	1 (3.3)	0
Viral upper respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Bacterial sepsis	0	0	0	0	0
Enterovirus infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (23.5)	0	1 (2.9)	5 (14.7)	2 (5.9)
Infections					
-Total	7 (20.6)	0	1 (2.9)	4 (11.8)	2 (5.9)
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Bacterial sepsis	1 (2.9)	0	0	0	1 (2.9)
Enterovirus infection	1 (2.9)	0	0	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Parainfluenzae virus infection	1 (2.9)	0	0	1 (2.9)	0
Rotavirus infection	1 (2.9)	0	0	1 (2.9)	0
Sepsis	1 (2.9)	0	0	0	1 (2.9)
Upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Vascular device infection	1 (2.9)	0	0	1 (2.9)	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post CTL019 infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (6.7)	0	0	2 (6.7)	0
Infections					
-Total	1 (3.3)	0	0	1 (3.3)	0
Cellulitis of male external genital organ	1 (3.3)	0	0	1 (3.3)	0
Urinary tract infection	1 (3.3)	0	0	1 (3.3)	0
Campylobacter infection	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.3)	0	0	1 (3.3)	0
Seizure	1 (3.3)	0	0	1 (3.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (8.8)	0	1 (2.9)	1 (2.9)	1 (2.9)
Infections					
-Total	3 (8.8)	0	1 (2.9)	1 (2.9)	1 (2.9)
Cellulitis of male external genital organ	0	0	0	0	0
Urinary tract infection	1 (2.9)	0	1 (2.9)	0	0
Campylobacter infection	1 (2.9)	0	0	1 (2.9)	0
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0
Pneumonia	1 (2.9)	0	1 (2.9)	0	0
Respiratory tract infection	1 (2.9)	0	0	0	1 (2.9)
Respiratory tract infection viral	1 (2.9)	0	0	1 (2.9)	0

Timing: >1 year post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	21 (70.0)	2 (6.7)	5 (16.7)	9 (30.0)	5 (16.7)
Cytokine Release Syndrome					
-Total	19 (63.3)	3 (10.0)	8 (26.7)	3 (10.0)	5 (16.7)
Cytokine release syndrome	19 (63.3)	3 (10.0)	8 (26.7)	3 (10.0)	5 (16.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (6.7)	0	0	2 (6.7)	0
Febrile neutropenia	2 (6.7)	0	0	2 (6.7)	0
Infections					
-Total	6 (20.0)	0	1 (3.3)	5 (16.7)	0
Cellulitis of male external genital organ	1 (3.3)	0	0	1 (3.3)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (3.3)	0	0	1 (3.3)	0
Clostridium difficile infection	1 (3.3)	0	1 (3.3)	0	0
Corona virus infection	1 (3.3)	0	0	1 (3.3)	0
Gastroenteritis	1 (3.3)	0	0	1 (3.3)	0
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Respiratory syncytial virus infection	1 (3.3)	0	0	1 (3.3)	0
Urinary tract infection	1 (3.3)	0	0	1 (3.3)	0
Viral upper respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (13.3)	0	2 (6.7)	2 (6.7)	0
Encephalopathy	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Seizure	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	26 (76.5)	0	10 (29.4)	7 (20.6)	9 (26.5)
Cytokine Release Syndrome					
-Total	22 (64.7)	1 (2.9)	11 (32.4)	5 (14.7)	5 (14.7)
Cytokine release syndrome	22 (64.7)	1 (2.9)	11 (32.4)	5 (14.7)	5 (14.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (2.9)	0	0	1 (2.9)	0
Febrile neutropenia	1 (2.9)	0	0	1 (2.9)	0
Infections					
-Total	13 (38.2)	0	3 (8.8)	6 (17.6)	4 (11.8)
Cellulitis of male external genital organ	0	0	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	0	0	0	0	0
Clostridium difficile infection	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Corona virus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Urinary tract infection	1 (2.9)	0	1 (2.9)	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Bacterial sepsis	1 (2.9)	0	0	0	1 (2.9)
Campylobacter infection	1 (2.9)	0	0	1 (2.9)	0
Catheter site infection	1 (2.9)	0	0	1 (2.9)	0
Clostridium difficile colitis	2 (5.9)	0	2 (5.9)	0	0
Enterovirus infection	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Parainfluenzae virus infection	1 (2.9)	0	0	1 (2.9)	0
Pneumonia	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	0	0	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	1 (2.9)	1 (2.9)	0	0	0
Rotavirus infection	1 (2.9)	0	0	1 (2.9)	0
Sepsis	1 (2.9)	0	0	0	1 (2.9)
Septic embolus	1 (2.9)	0	0	0	1 (2.9)
Staphylococcal infection	1 (2.9)	0	0	1 (2.9)	0
Upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Vascular device infection	1 (2.9)	0	0	1 (2.9)	0
Vulvovaginal candidiasis	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					
-Total	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Encephalopathy	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Seizure	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Delirium	1 (2.9)	0	1 (2.9)	0	0
Tumour Lysis Syndrome					
-Total	2 (5.9)	0	0	2 (5.9)	0
Tumour lysis syndrome	2 (5.9)	0	0	2 (5.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	34 (65.4)	2 (3.8)	13 (25.0)	9 (17.3)	10 (19.2)
Cytokine Release Syndrome					
-Total	33 (63.5)	3 (5.8)	14 (26.9)	7 (13.5)	9 (17.3)
Cytokine release syndrome	33 (63.5)	3 (5.8)	14 (26.9)	7 (13.5)	9 (17.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (5.8)	0	0	3 (5.8)	0
Febrile neutropenia	3 (5.8)	0	0	3 (5.8)	0
Infections					
-Total	7 (13.5)	0	3 (5.8)	3 (5.8)	1 (1.9)
Clostridium difficile infection	2 (3.8)	0	2 (3.8)	0	0
Catheter site infection	1 (1.9)	0	0	1 (1.9)	0

Timing: Within 8 weeks post CTL019 infusion, Race: White

Group term Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Pneumonia	1 (1.9)	0	0	1 (1.9)	0
Rhinovirus infection	1 (1.9)	1 (1.9)	0	0	0
Septic embolus	1 (1.9)	0	0	0	1 (1.9)
Staphylococcal infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	5 (9.6)	0	2 (3.8)	3 (5.8)	0
Encephalopathy	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Seizure	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (60.0)	0	2 (40.0)	1 (20.0)	0
Cytokine Release Syndrome					
-Total	3 (60.0)	0	3 (60.0)	0	0
Cytokine release syndrome	3 (60.0)	0	3 (60.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	1 (20.0)	0	0	1 (20.0)	0
Clostridium difficile infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Gastroenteritis	1 (20.0)	0	0	1 (20.0)	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	1 (14.3)	2 (28.6)	1 (14.3)	1 (14.3)
Cytokine Release Syndrome					
-Total	5 (71.4)	1 (14.3)	2 (28.6)	1 (14.3)	1 (14.3)
Cytokine release syndrome	5 (71.4)	1 (14.3)	2 (28.6)	1 (14.3)	1 (14.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	1 (14.3)	0	1 (14.3)	0	0
Clostridium difficile infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Encephalopathy	1 (14.3)	1 (14.3)	0	0	0
Seizure	1 (14.3)	0	1 (14.3)	0	0
Delirium	1 (14.3)	0	1 (14.3)	0	0
Tumour Lysis Syndrome					
-Total	1 (14.3)	0	0	1 (14.3)	0
Tumour lysis syndrome	1 (14.3)	0	0	1 (14.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (19.2)	0	1 (1.9)	8 (15.4)	1 (1.9)
Infections					
-Total	9 (17.3)	0	1 (1.9)	7 (13.5)	1 (1.9)
Bacterial sepsis	1 (1.9)	0	0	0	1 (1.9)
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Parainfluenzae virus infection	1 (1.9)	0	0	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Group term Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	1 (1.9)	0	0	1 (1.9)	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Herpes zoster	0	0	0	0	0
Sepsis	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (20.0)	0	0	1 (20.0)	0
Infections					
-Total	1 (20.0)	0	0	1 (20.0)	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Herpes zoster	1 (20.0)	0	0	1 (20.0)	0
Sepsis	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Infections					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Vascular device infection	1 (14.3)	0	0	1 (14.3)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (7.7)	0	1 (1.9)	3 (5.8)	0
Infections					
-Total	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Urinary tract infection	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Campylobacter infection	1 (1.9)	0	0	1 (1.9)	0
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Clostridium difficile infection	1 (1.9)	0	0	1 (1.9)	0
Pneumonia	1 (1.9)	0	1 (1.9)	0	0
Respiratory tract infection viral	1 (1.9)	0	0	1 (1.9)	0
Vulvovaginal candidiasis	1 (1.9)	0	1 (1.9)	0	0

Timing: >1 year post CTL019 infusion, Race: White

Group term Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (1.9)	0	0	1 (1.9)	0
Seizure	1 (1.9)	0	0	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post CTL019 infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (20.0)	0	0	0	1 (20.0)
Infections					
-Total	1 (20.0)	0	0	0	1 (20.0)
Urinary tract infection	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	1 (20.0)	0	0	0	1 (20.0)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	37 (71.2)	1 (1.9)	11 (21.2)	14 (26.9)	11 (21.2)
Cytokine Release Syndrome					
-Total	33 (63.5)	3 (5.8)	14 (26.9)	7 (13.5)	9 (17.3)
Cytokine release syndrome	33 (63.5)	3 (5.8)	14 (26.9)	7 (13.5)	9 (17.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (5.8)	0	0	3 (5.8)	0
Febrile neutropenia	3 (5.8)	0	0	3 (5.8)	0
Infections					
-Total	15 (28.8)	0	4 (7.7)	9 (17.3)	2 (3.8)
Clostridium difficile infection	3 (5.8)	0	2 (3.8)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Urinary tract infection	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Bacterial sepsis	1 (1.9)	0	0	0	1 (1.9)
Campylobacter infection	1 (1.9)	0	0	1 (1.9)	0
Catheter site infection	1 (1.9)	0	0	1 (1.9)	0
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Clostridium difficile colitis	1 (1.9)	0	1 (1.9)	0	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Parainfluenzae virus infection	1 (1.9)	0	0	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	0	0	1 (1.9)	0
Respiratory tract infection viral	1 (1.9)	0	0	1 (1.9)	0
Rhinovirus infection	1 (1.9)	1 (1.9)	0	0	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Septic embolus	1 (1.9)	0	0	0	1 (1.9)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (1.9)	0	0	1 (1.9)	0
Upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Vulvovaginal candidiasis	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	6 (11.5)	0	2 (3.8)	4 (7.7)	0
Encephalopathy	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Seizure	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (80.0)	0	2 (40.0)	1 (20.0)	1 (20.0)
Cytokine Release Syndrome					
-Total	3 (60.0)	0	3 (60.0)	0	0
Cytokine release syndrome	3 (60.0)	0	3 (60.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Clostridium difficile infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Gastroenteritis	1 (20.0)	0	0	1 (20.0)	0
Herpes zoster	1 (20.0)	0	0	1 (20.0)	0
Respiratory tract infection	1 (20.0)	0	0	0	1 (20.0)
Sepsis	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (85.7)	1 (14.3)	2 (28.6)	1 (14.3)	2 (28.6)
Cytokine Release Syndrome					
-Total	5 (71.4)	1 (14.3)	2 (28.6)	1 (14.3)	1 (14.3)
Cytokine release syndrome	5 (71.4)	1 (14.3)	2 (28.6)	1 (14.3)	1 (14.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Clostridium difficile infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Vascular device infection	1 (14.3)	0	0	1 (14.3)	0
Serious neurological adverse reactions					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Encephalopathy	1 (14.3)	1 (14.3)	0	0	0
Seizure	1 (14.3)	0	1 (14.3)	0	0
Delirium	1 (14.3)	0	1 (14.3)	0	0
Tumour Lysis Syndrome					
-Total	1 (14.3)	0	0	1 (14.3)	0
Tumour lysis syndrome	1 (14.3)	0	0	1 (14.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (64.0)	1 (4.0)	8 (32.0)	4 (16.0)	3 (12.0)
Cytokine Release Syndrome					
-Total	16 (64.0)	1 (4.0)	9 (36.0)	3 (12.0)	3 (12.0)
Cytokine release syndrome	16 (64.0)	1 (4.0)	9 (36.0)	3 (12.0)	3 (12.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (4.0)	0	0	1 (4.0)	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Infections					
-Total	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Gastroenteritis norovirus	1 (4.0)	0	1 (4.0)	0	0
Staphylococcal infection	1 (4.0)	0	0	1 (4.0)	0
Catheter site infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (12.0)	0	2 (8.0)	1 (4.0)	0
Seizure	2 (8.0)	0	2 (8.0)	0	0
Delirium	1 (4.0)	0	1 (4.0)	0	0
Encephalopathy	1 (4.0)	0	0	1 (4.0)	0
Tumour Lysis Syndrome					
-Total	1 (4.0)	0	0	1 (4.0)	0
Tumour lysis syndrome	1 (4.0)	0	0	1 (4.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	26 (66.7)	2 (5.1)	9 (23.1)	7 (17.9)	8 (20.5)
Cytokine Release Syndrome					
-Total	25 (64.1)	3 (7.7)	10 (25.6)	5 (12.8)	7 (17.9)
Cytokine release syndrome	25 (64.1)	3 (7.7)	10 (25.6)	5 (12.8)	7 (17.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (5.1)	0	0	2 (5.1)	0
Febrile neutropenia	2 (5.1)	0	0	2 (5.1)	0
Infections					
-Total	7 (17.9)	0	3 (7.7)	3 (7.7)	1 (2.6)
Gastroenteritis norovirus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (2.6)	0	0	1 (2.6)	0
Clostridium difficile colitis	2 (5.1)	0	2 (5.1)	0	0
Clostridium difficile infection	2 (5.1)	0	2 (5.1)	0	0
Gastroenteritis	1 (2.6)	0	0	1 (2.6)	0
Pneumonia	1 (2.6)	0	0	1 (2.6)	0
Rhinovirus infection	1 (2.6)	1 (2.6)	0	0	0
Septic embolus	1 (2.6)	0	0	0	1 (2.6)
Serious neurological adverse reactions					
-Total	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Seizure	1 (2.6)	0	0	1 (2.6)	0
Delirium	0	0	0	0	0
Encephalopathy	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (20.0)	0	1 (4.0)	4 (16.0)	0
Infections					
-Total	4 (16.0)	0	1 (4.0)	3 (12.0)	0
Cellulitis of male external genital organ	1 (4.0)	0	0	1 (4.0)	0
Corona virus infection	1 (4.0)	0	0	1 (4.0)	0
Gastroenteritis norovirus	1 (4.0)	0	1 (4.0)	0	0
Respiratory syncytial virus infection	1 (4.0)	0	0	1 (4.0)	0
Viral upper respiratory tract infection	1 (4.0)	0	0	1 (4.0)	0
Bacterial sepsis	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Enterovirus infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=25 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (4.0)	0	0	1 (4.0)	0
Tumour lysis syndrome	1 (4.0)	0	0	1 (4.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (20.5)	0	0	6 (15.4)	2 (5.1)
Infections					
-Total	8 (20.5)	0	0	6 (15.4)	2 (5.1)
Cellulitis of male external genital organ	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Bacterial sepsis	1 (2.6)	0	0	0	1 (2.6)
Cholecystitis infective	1 (2.6)	0	0	1 (2.6)	0
Enterovirus infection	1 (2.6)	0	0	1 (2.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Group term Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	1 (2.6)	0	0	1 (2.6)	0
Parainfluenzae virus infection	1 (2.6)	0	0	1 (2.6)	0
Rotavirus infection	1 (2.6)	0	0	1 (2.6)	0
Sepsis	1 (2.6)	0	0	0	1 (2.6)
Upper respiratory tract infection	1 (2.6)	0	0	1 (2.6)	0
Vascular device infection	1 (2.6)	0	0	1 (2.6)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (4.0)	0	0	1 (4.0)	0
Infections					
-Total	1 (4.0)	0	0	1 (4.0)	0
Cellulitis of male external genital organ	1 (4.0)	0	0	1 (4.0)	0
Urinary tract infection	1 (4.0)	0	0	1 (4.0)	0
Campylobacter infection	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=25 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (10.3)	0	1 (2.6)	2 (5.1)	1 (2.6)
Infections					
-Total	3 (7.7)	0	1 (2.6)	1 (2.6)	1 (2.6)
Cellulitis of male external genital organ	0	0	0	0	0
Urinary tract infection	1 (2.6)	0	1 (2.6)	0	0
Campylobacter infection	1 (2.6)	0	0	1 (2.6)	0
Clostridium difficile infection	1 (2.6)	0	0	1 (2.6)	0
Pneumonia	1 (2.6)	0	1 (2.6)	0	0
Respiratory tract infection	1 (2.6)	0	0	0	1 (2.6)
Respiratory tract infection viral	1 (2.6)	0	0	1 (2.6)	0

Timing: >1 year post CTL019 infusion, Ethnicity: Other

Group term Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	1 (2.6)	0	1 (2.6)	0	0
Serious neurological adverse reactions					
-Total	1 (2.6)	0	0	1 (2.6)	0
Seizure	1 (2.6)	0	0	1 (2.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	17 (68.0)	1 (4.0)	7 (28.0)	6 (24.0)	3 (12.0)
Cytokine Release Syndrome					
-Total	16 (64.0)	1 (4.0)	9 (36.0)	3 (12.0)	3 (12.0)
Cytokine release syndrome	16 (64.0)	1 (4.0)	9 (36.0)	3 (12.0)	3 (12.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (4.0)	0	0	1 (4.0)	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Infections					
-Total	5 (20.0)	0	1 (4.0)	4 (16.0)	0
Cellulitis of male external genital organ	1 (4.0)	0	0	1 (4.0)	0
Corona virus infection	1 (4.0)	0	0	1 (4.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (4.0)	0	1 (4.0)	0	0
Respiratory syncytial virus infection	1 (4.0)	0	0	1 (4.0)	0
Staphylococcal infection	1 (4.0)	0	0	1 (4.0)	0
Urinary tract infection	1 (4.0)	0	0	1 (4.0)	0
Viral upper respiratory tract infection	1 (4.0)	0	0	1 (4.0)	0
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=25 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (12.0)	0	2 (8.0)	1 (4.0)	0
Seizure	2 (8.0)	0	2 (8.0)	0	0
Delirium	1 (4.0)	0	1 (4.0)	0	0
Encephalopathy	1 (4.0)	0	0	1 (4.0)	0
Tumour Lysis Syndrome					
-Total	2 (8.0)	0	0	2 (8.0)	0
Tumour lysis syndrome	2 (8.0)	0	0	2 (8.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	30 (76.9)	1 (2.6)	8 (20.5)	10 (25.6)	11 (28.2)
Cytokine Release Syndrome					
-Total	25 (64.1)	3 (7.7)	10 (25.6)	5 (12.8)	7 (17.9)
Cytokine release syndrome	25 (64.1)	3 (7.7)	10 (25.6)	5 (12.8)	7 (17.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (5.1)	0	0	2 (5.1)	0
Febrile neutropenia	2 (5.1)	0	0	2 (5.1)	0
Infections					
-Total	14 (35.9)	0	3 (7.7)	7 (17.9)	4 (10.3)
Cellulitis of male external genital organ	0	0	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Urinary tract infection	1 (2.6)	0	1 (2.6)	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Bacterial sepsis	1 (2.6)	0	0	0	1 (2.6)
Campylobacter infection	1 (2.6)	0	0	1 (2.6)	0
Catheter site infection	1 (2.6)	0	0	1 (2.6)	0
Cholecystitis infective	1 (2.6)	0	0	1 (2.6)	0
Clostridium difficile colitis	2 (5.1)	0	2 (5.1)	0	0
Clostridium difficile infection	3 (7.7)	0	2 (5.1)	1 (2.6)	0
Enterovirus infection	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis	1 (2.6)	0	0	1 (2.6)	0
Herpes zoster	1 (2.6)	0	0	1 (2.6)	0
Parainfluenzae virus infection	1 (2.6)	0	0	1 (2.6)	0
Pneumonia	2 (5.1)	0	1 (2.6)	1 (2.6)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	1 (2.6)	0	0	0	1 (2.6)
Respiratory tract infection viral	1 (2.6)	0	0	1 (2.6)	0
Rhinovirus infection	1 (2.6)	1 (2.6)	0	0	0
Rotavirus infection	1 (2.6)	0	0	1 (2.6)	0
Sepsis	1 (2.6)	0	0	0	1 (2.6)
Septic embolus	1 (2.6)	0	0	0	1 (2.6)
Upper respiratory tract infection	1 (2.6)	0	0	1 (2.6)	0
Vascular device infection	1 (2.6)	0	0	1 (2.6)	0
Vulvovaginal candidiasis	1 (2.6)	0	1 (2.6)	0	0
Serious neurological adverse reactions					
-Total	5 (12.8)	1 (2.6)	1 (2.6)	3 (7.7)	0
Seizure	2 (5.1)	0	0	2 (5.1)	0
Delirium	0	0	0	0	0
Encephalopathy	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Cytokine Release Syndrome					
-Total	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=57			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	37 (64.9)	3 (5.3)	15 (26.3)	11 (19.3)	8 (14.0)
Cytokine Release Syndrome					
-Total	36 (63.2)	4 (7.0)	17 (29.8)	8 (14.0)	7 (12.3)
Cytokine release syndrome	36 (63.2)	4 (7.0)	17 (29.8)	8 (14.0)	7 (12.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (5.3)	0	0	3 (5.3)	0
Febrile neutropenia	3 (5.3)	0	0	3 (5.3)	0
Infections					
-Total	9 (15.8)	0	4 (7.0)	4 (7.0)	1 (1.8)
Catheter site infection	1 (1.8)	0	0	1 (1.8)	0
Clostridium difficile colitis	2 (3.5)	0	2 (3.5)	0	0
Clostridium difficile infection	2 (3.5)	0	2 (3.5)	0	0

Timing: Within 8 weeks post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Pneumonia	1 (1.8)	0	0	1 (1.8)	0
Rhinovirus infection	1 (1.8)	1 (1.8)	0	0	0
Septic embolus	1 (1.8)	0	0	0	1 (1.8)
Staphylococcal infection	1 (1.8)	0	0	1 (1.8)	0
Serious neurological adverse reactions					
-Total	7 (12.3)	1 (1.8)	3 (5.3)	3 (5.3)	0
Delirium	1 (1.8)	0	1 (1.8)	0	0
Encephalopathy	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Seizure	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Tumour Lysis Syndrome					
-Total	1 (1.8)	0	0	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (14.3)	0	0	1 (14.3)	0
Infections					
-Total	1 (14.3)	0	0	1 (14.3)	0
Corona virus infection	1 (14.3)	0	0	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=57			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (21.1)	0	1 (1.8)	9 (15.8)	2 (3.5)
Infections					
-Total	11 (19.3)	0	1 (1.8)	8 (14.0)	2 (3.5)
Corona virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Cellulitis of male external genital organ	1 (1.8)	0	0	1 (1.8)	0
Cholecystitis infective	1 (1.8)	0	0	1 (1.8)	0
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	1 (1.8)	0	0	1 (1.8)	0
Rotavirus infection	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Upper respiratory tract infection	1 (1.8)	0	0	1 (1.8)	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	0	0	1 (1.8)	0
Tumour Lysis Syndrome					
-Total	1 (1.8)	0	0	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Response status at study entry: Primary refractory

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (8.8)	0	1 (1.8)	3 (5.3)	1 (1.8)
Infections					
-Total	4 (7.0)	0	1 (1.8)	2 (3.5)	1 (1.8)
Campylobacter infection	1 (1.8)	0	0	1 (1.8)	0
Cellulitis of male external genital organ	1 (1.8)	0	0	1 (1.8)	0
Clostridium difficile infection	1 (1.8)	0	0	1 (1.8)	0
Pneumonia	1 (1.8)	0	1 (1.8)	0	0
Respiratory tract infection	1 (1.8)	0	0	0	1 (1.8)
Respiratory tract infection viral	1 (1.8)	0	0	1 (1.8)	0
Urinary tract infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Vulvovaginal candidiasis	1 (1.8)	0	1 (1.8)	0	0

Timing: >1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (1.8)	0	0	1 (1.8)	0
Seizure	1 (1.8)	0	0	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	0	1 (14.3)	1 (14.3)	3 (42.9)
Cytokine Release Syndrome					
-Total	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	1 (14.3)	0	0	1 (14.3)	0
Corona virus infection	1 (14.3)	0	0	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	42 (73.7)	2 (3.5)	14 (24.6)	15 (26.3)	11 (19.3)
Cytokine Release Syndrome					
-Total	36 (63.2)	4 (7.0)	17 (29.8)	8 (14.0)	7 (12.3)
Cytokine release syndrome	36 (63.2)	4 (7.0)	17 (29.8)	8 (14.0)	7 (12.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (5.3)	0	0	3 (5.3)	0
Febrile neutropenia	3 (5.3)	0	0	3 (5.3)	0
Infections					
-Total	18 (31.6)	0	4 (7.0)	10 (17.5)	4 (7.0)
Corona virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Campylobacter infection	1 (1.8)	0	0	1 (1.8)	0
Catheter site infection	1 (1.8)	0	0	1 (1.8)	0
Cellulitis of male external genital organ	1 (1.8)	0	0	1 (1.8)	0
Cholecystitis infective	1 (1.8)	0	0	1 (1.8)	0
Clostridium difficile colitis	2 (3.5)	0	2 (3.5)	0	0
Clostridium difficile infection	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0
Parainfluenzae virus infection	1 (1.8)	0	0	1 (1.8)	0
Pneumonia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Respiratory tract infection	1 (1.8)	0	0	0	1 (1.8)
Respiratory tract infection viral	1 (1.8)	0	0	1 (1.8)	0
Rhinovirus infection	1 (1.8)	1 (1.8)	0	0	0
Rotavirus infection	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	1 (1.8)	0	0	0	1 (1.8)
Staphylococcal infection	1 (1.8)	0	0	1 (1.8)	0
Upper respiratory tract infection	1 (1.8)	0	0	1 (1.8)	0
Urinary tract infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	0	0	1 (1.8)	0
Vulvovaginal candidiasis	1 (1.8)	0	1 (1.8)	0	0
Serious neurological adverse reactions					
-Total	8 (14.0)	1 (1.8)	3 (5.3)	4 (7.0)	0
Delirium	1 (1.8)	0	1 (1.8)	0	0
Encephalopathy	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Seizure	4 (7.0)	0	2 (3.5)	2 (3.5)	0
Tumour Lysis Syndrome					
-Total	2 (3.5)	0	0	2 (3.5)	0
Tumour lysis syndrome	2 (3.5)	0	0	2 (3.5)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Cytokine release syndrome	0	0	0	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	42 (67.7)	3 (4.8)	17 (27.4)	11 (17.7)	11 (17.7)
Cytokine Release Syndrome					
-Total	41 (66.1)	4 (6.5)	19 (30.6)	8 (12.9)	10 (16.1)
Cytokine release syndrome	41 (66.1)	4 (6.5)	19 (30.6)	8 (12.9)	10 (16.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (4.8)	0	0	3 (4.8)	0
Febrile neutropenia	3 (4.8)	0	0	3 (4.8)	0
Infections					
-Total	9 (14.5)	0	4 (6.5)	4 (6.5)	1 (1.6)
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Clostridium difficile colitis	2 (3.2)	0	2 (3.2)	0	0
Clostridium difficile infection	2 (3.2)	0	2 (3.2)	0	0

Timing: Within 8 weeks post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Pneumonia	1 (1.6)	0	0	1 (1.6)	0
Rhinovirus infection	1 (1.6)	1 (1.6)	0	0	0
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal infection	1 (1.6)	0	0	1 (1.6)	0
Serious neurological adverse reactions					
-Total	7 (11.3)	1 (1.6)	3 (4.8)	3 (4.8)	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Encephalopathy	4 (6.5)	1 (1.6)	1 (1.6)	2 (3.2)	0
Seizure	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	0	0	1 (50.0)	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0
Bacterial sepsis	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (19.4)	0	1 (1.6)	9 (14.5)	2 (3.2)
Infections					
-Total	11 (17.7)	0	1 (1.6)	8 (12.9)	2 (3.2)
Cellulitis of male external genital organ	0	0	0	0	0
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	0	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Group term Preferred term	All patients N=62 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	0	0	1 (50.0)	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0
Urinary tract infection	1 (50.0)	0	0	1 (50.0)	0
Campylobacter infection	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 215f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (6.5)	0	1 (1.6)	2 (3.2)	1 (1.6)
Infections					
-Total	3 (4.8)	0	1 (1.6)	1 (1.6)	1 (1.6)
Cellulitis of male external genital organ	0	0	0	0	0
Urinary tract infection	1 (1.6)	0	1 (1.6)	0	0
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Clostridium difficile infection	1 (1.6)	0	0	1 (1.6)	0
Pneumonia	1 (1.6)	0	1 (1.6)	0	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Vulvovaginal candidiasis	1 (1.6)	0	1 (1.6)	0	0

Timing: >1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Group term Preferred term	All patients N=62 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (1.6)	0	0	1 (1.6)	0
Seizure	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	0	0	1 (50.0)	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Cytokine release syndrome	0	0	0	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0
Urinary tract infection	1 (50.0)	0	0	1 (50.0)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	46 (74.2)	2 (3.2)	15 (24.2)	15 (24.2)	14 (22.6)
Cytokine Release Syndrome					
-Total	41 (66.1)	4 (6.5)	19 (30.6)	8 (12.9)	10 (16.1)
Cytokine release syndrome	41 (66.1)	4 (6.5)	19 (30.6)	8 (12.9)	10 (16.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (4.8)	0	0	3 (4.8)	0
Febrile neutropenia	3 (4.8)	0	0	3 (4.8)	0
Infections					
-Total	18 (29.0)	0	4 (6.5)	10 (16.1)	4 (6.5)
Cellulitis of male external genital organ	0	0	0	0	0
Urinary tract infection	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Clostridium difficile colitis	2 (3.2)	0	2 (3.2)	0	0
Clostridium difficile infection	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	0	0	1 (1.6)	0
Pneumonia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Rhinovirus infection	1 (1.6)	1 (1.6)	0	0	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal infection	1 (1.6)	0	0	1 (1.6)	0
Upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Vulvovaginal candidiasis	1 (1.6)	0	1 (1.6)	0	0
Serious neurological adverse reactions					
-Total	8 (12.9)	1 (1.6)	3 (4.8)	4 (6.5)	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Encephalopathy	4 (6.5)	1 (1.6)	1 (1.6)	2 (3.2)	0
Seizure	4 (6.5)	0	2 (3.2)	2 (3.2)	0
Tumour Lysis Syndrome					
-Total	2 (3.2)	0	0	2 (3.2)	0
Tumour lysis syndrome	2 (3.2)	0	0	2 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (66.7)	0	0	0	2 (66.7)
Cytokine Release Syndrome					
-Total	2 (66.7)	0	0	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	0	0	2 (66.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	40 (65.6)	3 (4.9)	17 (27.9)	11 (18.0)	9 (14.8)
Cytokine Release Syndrome					
-Total	39 (63.9)	4 (6.6)	19 (31.1)	8 (13.1)	8 (13.1)
Cytokine release syndrome	39 (63.9)	4 (6.6)	19 (31.1)	8 (13.1)	8 (13.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (4.9)	0	0	3 (4.9)	0
Febrile neutropenia	3 (4.9)	0	0	3 (4.9)	0
Infections					
-Total	9 (14.8)	0	4 (6.6)	4 (6.6)	1 (1.6)
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Clostridium difficile colitis	2 (3.3)	0	2 (3.3)	0	0
Clostridium difficile infection	2 (3.3)	0	2 (3.3)	0	0

Timing: Within 8 weeks post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Pneumonia	1 (1.6)	0	0	1 (1.6)	0
Rhinovirus infection	1 (1.6)	1 (1.6)	0	0	0
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal infection	1 (1.6)	0	0	1 (1.6)	0
Serious neurological adverse reactions					
-Total	7 (11.5)	1 (1.6)	3 (4.9)	3 (4.9)	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Encephalopathy	4 (6.6)	1 (1.6)	1 (1.6)	2 (3.3)	0
Seizure	3 (4.9)	0	2 (3.3)	1 (1.6)	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (21.3)	0	1 (1.6)	10 (16.4)	2 (3.3)
Infections					
-Total	12 (19.7)	0	1 (1.6)	9 (14.8)	2 (3.3)
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	0	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=61 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (8.2)	0	1 (1.6)	3 (4.9)	1 (1.6)
Infections					
-Total	4 (6.6)	0	1 (1.6)	2 (3.3)	1 (1.6)
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Clostridium difficile infection	1 (1.6)	0	0	1 (1.6)	0
Pneumonia	1 (1.6)	0	1 (1.6)	0	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Urinary tract infection	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Vulvovaginal candidiasis	1 (1.6)	0	1 (1.6)	0	0

Timing: >1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Group term Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (1.6)	0	0	1 (1.6)	0
Seizure	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (66.7)	0	0	0	2 (66.7)
Cytokine Release Syndrome					
-Total	2 (66.7)	0	0	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	0	0	2 (66.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	45 (73.8)	2 (3.3)	15 (24.6)	16 (26.2)	12 (19.7)
Cytokine Release Syndrome					
-Total	39 (63.9)	4 (6.6)	19 (31.1)	8 (13.1)	8 (13.1)
Cytokine release syndrome	39 (63.9)	4 (6.6)	19 (31.1)	8 (13.1)	8 (13.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (4.9)	0	0	3 (4.9)	0
Febrile neutropenia	3 (4.9)	0	0	3 (4.9)	0
Infections					
-Total	19 (31.1)	0	4 (6.6)	11 (18.0)	4 (6.6)
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Clostridium difficile colitis	2 (3.3)	0	2 (3.3)	0	0
Clostridium difficile infection	3 (4.9)	0	2 (3.3)	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	0	0	1 (1.6)	0
Pneumonia	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Rhinovirus infection	1 (1.6)	1 (1.6)	0	0	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Group term Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal infection	1 (1.6)	0	0	1 (1.6)	0
Upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Urinary tract infection	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Vulvovaginal candidiasis	1 (1.6)	0	1 (1.6)	0	0
Serious neurological adverse reactions					
-Total	8 (13.1)	1 (1.6)	3 (4.9)	4 (6.6)	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Encephalopathy	4 (6.6)	1 (1.6)	1 (1.6)	2 (3.3)	0
Seizure	4 (6.6)	0	2 (3.3)	2 (3.3)	0
Tumour Lysis Syndrome					
-Total	2 (3.3)	0	0	2 (3.3)	0
Tumour lysis syndrome	2 (3.3)	0	0	2 (3.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (100)	0	1 (100)	0	0
Cytokine Release Syndrome					
-Total	1 (100)	0	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	1 (100)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (100)	0	1 (100)	0	0
Encephalopathy	1 (100)	0	1 (100)	0	0
Delirium	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	41 (65.1)	3 (4.8)	16 (25.4)	11 (17.5)	11 (17.5)
Cytokine Release Syndrome					
-Total	40 (63.5)	4 (6.3)	18 (28.6)	8 (12.7)	10 (15.9)
Cytokine release syndrome	40 (63.5)	4 (6.3)	18 (28.6)	8 (12.7)	10 (15.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (4.8)	0	0	3 (4.8)	0
Febrile neutropenia	3 (4.8)	0	0	3 (4.8)	0
Infections					
-Total	9 (14.3)	0	4 (6.3)	4 (6.3)	1 (1.6)
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Clostridium difficile colitis	2 (3.2)	0	2 (3.2)	0	0
Clostridium difficile infection	2 (3.2)	0	2 (3.2)	0	0

Timing: Within 8 weeks post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Pneumonia	1 (1.6)	0	0	1 (1.6)	0
Rhinovirus infection	1 (1.6)	1 (1.6)	0	0	0
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal infection	1 (1.6)	0	0	1 (1.6)	0
Serious neurological adverse reactions					
-Total	6 (9.5)	1 (1.6)	2 (3.2)	3 (4.8)	0
Encephalopathy	3 (4.8)	1 (1.6)	0	2 (3.2)	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Seizure	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

Group term Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (20.6)	0	1 (1.6)	10 (15.9)	2 (3.2)
Infections					
-Total	12 (19.0)	0	1 (1.6)	9 (14.3)	2 (3.2)
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	0	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Group term Preferred term	All patients N=63 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Hypodiploidy: Yes

Group term Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (7.9)	0	1 (1.6)	3 (4.8)	1 (1.6)
Infections					
-Total	4 (6.3)	0	1 (1.6)	2 (3.2)	1 (1.6)
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Clostridium difficile infection	1 (1.6)	0	0	1 (1.6)	0
Pneumonia	1 (1.6)	0	1 (1.6)	0	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Urinary tract infection	2 (3.2)	0	1 (1.6)	1 (1.6)	0

Timing: >1 year post CTL019 infusion, Hypodiploidy: No

Group term Preferred term	All patients N=63 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	1 (1.6)	0	1 (1.6)	0	0
Serious neurological adverse reactions					
-Total	1 (1.6)	0	0	1 (1.6)	0
Seizure	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (100)	0	1 (100)	0	0
Cytokine Release Syndrome					
-Total	1 (100)	0	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	1 (100)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (100)	0	1 (100)	0	0
Encephalopathy	1 (100)	0	1 (100)	0	0
Delirium	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	46 (73.0)	2 (3.2)	14 (22.2)	16 (25.4)	14 (22.2)
Cytokine Release Syndrome					
-Total	40 (63.5)	4 (6.3)	18 (28.6)	8 (12.7)	10 (15.9)
Cytokine release syndrome	40 (63.5)	4 (6.3)	18 (28.6)	8 (12.7)	10 (15.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (4.8)	0	0	3 (4.8)	0
Febrile neutropenia	3 (4.8)	0	0	3 (4.8)	0
Infections					
-Total	19 (30.2)	0	4 (6.3)	11 (17.5)	4 (6.3)
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Clostridium difficile colitis	2 (3.2)	0	2 (3.2)	0	0
Clostridium difficile infection	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	0	0	1 (1.6)	0
Pneumonia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Rhinovirus infection	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal infection	1 (1.6)	0	0	1 (1.6)	0
Upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Urinary tract infection	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Vulvovaginal candidiasis	1 (1.6)	0	1 (1.6)	0	0
Serious neurological adverse reactions					
-Total	7 (11.1)	1 (1.6)	2 (3.2)	4 (6.3)	0
Encephalopathy	3 (4.8)	1 (1.6)	0	2 (3.2)	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Seizure	4 (6.3)	0	2 (3.2)	2 (3.2)	0
Tumour Lysis Syndrome					
-Total	2 (3.2)	0	0	2 (3.2)	0
Tumour lysis syndrome	2 (3.2)	0	0	2 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Within 8 weeks post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (50.0)	0	0	2 (50.0)	0
Cytokine Release Syndrome					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Cytokine release syndrome	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	1 (25.0)	0	0	1 (25.0)	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Within 8 weeks post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	40 (66.7)	3 (5.0)	17 (28.3)	9 (15.0)	11 (18.3)
Cytokine Release Syndrome					
-Total	39 (65.0)	4 (6.7)	18 (30.0)	7 (11.7)	10 (16.7)
Cytokine release syndrome	39 (65.0)	4 (6.7)	18 (30.0)	7 (11.7)	10 (16.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (5.0)	0	0	3 (5.0)	0
Febrile neutropenia	3 (5.0)	0	0	3 (5.0)	0
Infections					
-Total	8 (13.3)	0	4 (6.7)	3 (5.0)	1 (1.7)
Gastroenteritis	0	0	0	0	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Clostridium difficile colitis	2 (3.3)	0	2 (3.3)	0	0

Timing: Within 8 weeks post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	2 (3.3)	0	2 (3.3)	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Pneumonia	1 (1.7)	0	0	1 (1.7)	0
Rhinovirus infection	1 (1.7)	1 (1.7)	0	0	0
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Staphylococcal infection	1 (1.7)	0	0	1 (1.7)	0
Serious neurological adverse reactions					
-Total	7 (11.7)	1 (1.7)	3 (5.0)	3 (5.0)	0
Delirium	1 (1.7)	0	1 (1.7)	0	0
Encephalopathy	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Seizure	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (25.0)	0	0	1 (25.0)	0
Infections					
-Total	1 (25.0)	0	0	1 (25.0)	0
Herpes zoster	1 (25.0)	0	0	1 (25.0)	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

		All patients N=60			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (20.0)	0	1 (1.7)	9 (15.0)	2 (3.3)
Infections					
-Total	11 (18.3)	0	1 (1.7)	8 (13.3)	2 (3.3)
Herpes zoster	0	0	0	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Corona virus infection	1 (1.7)	0	0	1 (1.7)	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	0	0	1 (1.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	1 (1.7)	0	0	1 (1.7)	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Viral upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	0	0	0	0	0

Timing: >1 year post CTL019 infusion, BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (8.3)	0	1 (1.7)	3 (5.0)	1 (1.7)
Infections					
-Total	4 (6.7)	0	1 (1.7)	2 (3.3)	1 (1.7)
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Clostridium difficile infection	1 (1.7)	0	0	1 (1.7)	0
Pneumonia	1 (1.7)	0	1 (1.7)	0	0
Respiratory tract infection	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Urinary tract infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0

Timing: >1 year post CTL019 infusion, BCR-ABL1-like: No

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	1 (1.7)	0	0	1 (1.7)	0
Seizure	1 (1.7)	0	0	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (50.0)	0	0	2 (50.0)	0
Cytokine Release Syndrome					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Cytokine release syndrome	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	1 (25.0)	0	0	1 (25.0)	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	1 (25.0)	0	0	1 (25.0)	0
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	45 (75.0)	2 (3.3)	15 (25.0)	14 (23.3)	14 (23.3)
Cytokine Release Syndrome					
-Total	39 (65.0)	4 (6.7)	18 (30.0)	7 (11.7)	10 (16.7)
Cytokine release syndrome	39 (65.0)	4 (6.7)	18 (30.0)	7 (11.7)	10 (16.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (5.0)	0	0	3 (5.0)	0
Febrile neutropenia	3 (5.0)	0	0	3 (5.0)	0
Infections					
-Total	18 (30.0)	0	4 (6.7)	10 (16.7)	4 (6.7)
Gastroenteritis	0	0	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	0	0	0	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Clostridium difficile colitis	2 (3.3)	0	2 (3.3)	0	0
Clostridium difficile infection	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Corona virus infection	1 (1.7)	0	0	1 (1.7)	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	0	0	1 (1.7)	0
Pneumonia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Respiratory syncytial virus infection	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Rhinovirus infection	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Staphylococcal infection	1 (1.7)	0	0	1 (1.7)	0
Upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Urinary tract infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Viral upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Vulvovaginal candidiasis	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	8 (13.3)	1 (1.7)	3 (5.0)	4 (6.7)	0
Delirium	1 (1.7)	0	1 (1.7)	0	0
Encephalopathy	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Seizure	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Tumour Lysis Syndrome					
-Total	2 (3.3)	0	0	2 (3.3)	0
Tumour lysis syndrome	2 (3.3)	0	0	2 (3.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (84.2)	1 (5.3)	5 (26.3)	4 (21.1)	6 (31.6)
Cytokine Release Syndrome					
-Total	16 (84.2)	1 (5.3)	7 (36.8)	3 (15.8)	5 (26.3)
Cytokine release syndrome	16 (84.2)	1 (5.3)	7 (36.8)	3 (15.8)	5 (26.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	4 (21.1)	0	1 (5.3)	2 (10.5)	1 (5.3)
Clostridium difficile colitis	1 (5.3)	0	1 (5.3)	0	0
Clostridium difficile infection	1 (5.3)	0	1 (5.3)	0	0

Timing: Within 8 weeks post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (5.3)	0	0	1 (5.3)	0
Rhinovirus infection	1 (5.3)	1 (5.3)	0	0	0
Septic embolus	1 (5.3)	0	0	0	1 (5.3)
Staphylococcal infection	1 (5.3)	0	0	1 (5.3)	0
Catheter site infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (15.8)	1 (5.3)	0	2 (10.5)	0
Encephalopathy	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Seizure	1 (5.3)	0	0	1 (5.3)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	26 (57.8)	2 (4.4)	12 (26.7)	7 (15.6)	5 (11.1)
Cytokine Release Syndrome					
-Total	25 (55.6)	3 (6.7)	12 (26.7)	5 (11.1)	5 (11.1)
Cytokine release syndrome	25 (55.6)	3 (6.7)	12 (26.7)	5 (11.1)	5 (11.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (6.7)	0	0	3 (6.7)	0
Febrile neutropenia	3 (6.7)	0	0	3 (6.7)	0
Infections					
-Total	5 (11.1)	0	3 (6.7)	2 (4.4)	0
Clostridium difficile colitis	1 (2.2)	0	1 (2.2)	0	0
Clostridium difficile infection	1 (2.2)	0	1 (2.2)	0	0

Timing: Within 8 weeks post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Catheter site infection	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis norovirus	1 (2.2)	0	1 (2.2)	0	0
Pneumonia	1 (2.2)	0	0	1 (2.2)	0
Serious neurological adverse reactions					
-Total	4 (8.9)	0	3 (6.7)	1 (2.2)	0
Encephalopathy	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Seizure	2 (4.4)	0	2 (4.4)	0	0
Delirium	1 (2.2)	0	1 (2.2)	0	0
Tumour Lysis Syndrome					
-Total	1 (2.2)	0	0	1 (2.2)	0
Tumour lysis syndrome	1 (2.2)	0	0	1 (2.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (26.3)	0	0	4 (21.1)	1 (5.3)
Infections					
-Total	5 (26.3)	0	0	4 (21.1)	1 (5.3)
Bacterial sepsis	1 (5.3)	0	0	0	1 (5.3)
Cellulitis of male external genital organ	1 (5.3)	0	0	1 (5.3)	0
Enterovirus infection	1 (5.3)	0	0	1 (5.3)	0
Herpes zoster	1 (5.3)	0	0	1 (5.3)	0
Rotavirus infection	1 (5.3)	0	0	1 (5.3)	0
Vascular device infection	1 (5.3)	0	0	1 (5.3)	0
Cholecystitis infective	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (17.8)	0	1 (2.2)	6 (13.3)	1 (2.2)
Infections					
-Total	7 (15.6)	0	1 (2.2)	5 (11.1)	1 (2.2)
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Cholecystitis infective	1 (2.2)	0	0	1 (2.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis norovirus	1 (2.2)	0	1 (2.2)	0	0
Parainfluenzae virus infection	1 (2.2)	0	0	1 (2.2)	0
Respiratory syncytial virus infection	1 (2.2)	0	0	1 (2.2)	0
Sepsis	1 (2.2)	0	0	0	1 (2.2)
Upper respiratory tract infection	1 (2.2)	0	0	1 (2.2)	0
Viral upper respiratory tract infection	1 (2.2)	0	0	1 (2.2)	0
Tumour Lysis Syndrome					
-Total	1 (2.2)	0	0	1 (2.2)	0
Tumour lysis syndrome	1 (2.2)	0	0	1 (2.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (15.8)	0	0	2 (10.5)	1 (5.3)
Infections					
-Total	3 (15.8)	0	0	2 (10.5)	1 (5.3)
Urinary tract infection	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Campylobacter infection	1 (5.3)	0	0	1 (5.3)	0
Cellulitis of male external genital organ	1 (5.3)	0	0	1 (5.3)	0
Clostridium difficile infection	1 (5.3)	0	0	1 (5.3)	0
Respiratory tract infection	1 (5.3)	0	0	0	1 (5.3)
Respiratory tract infection viral	1 (5.3)	0	0	1 (5.3)	0
Vulvovaginal candidiasis	1 (5.3)	0	1 (5.3)	0	0
Pneumonia	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Group term Preferred term	All patients N=19 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Infections					
-Total	1 (2.2)	0	1 (2.2)	0	0
Urinary tract infection	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Pneumonia	1 (2.2)	0	1 (2.2)	0	0

Timing: >1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (2.2)	0	0	1 (2.2)	0
Seizure	1 (2.2)	0	0	1 (2.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (94.7)	1 (5.3)	4 (21.1)	5 (26.3)	8 (42.1)
Cytokine Release Syndrome					
-Total	16 (84.2)	1 (5.3)	7 (36.8)	3 (15.8)	5 (26.3)
Cytokine release syndrome	16 (84.2)	1 (5.3)	7 (36.8)	3 (15.8)	5 (26.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	8 (42.1)	0	0	5 (26.3)	3 (15.8)
Clostridium difficile infection	2 (10.5)	0	1 (5.3)	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Bacterial sepsis	1 (5.3)	0	0	0	1 (5.3)
Campylobacter infection	1 (5.3)	0	0	1 (5.3)	0
Cellulitis of male external genital organ	1 (5.3)	0	0	1 (5.3)	0
Clostridium difficile colitis	1 (5.3)	0	1 (5.3)	0	0
Enterovirus infection	1 (5.3)	0	0	1 (5.3)	0
Gastroenteritis	1 (5.3)	0	0	1 (5.3)	0
Herpes zoster	1 (5.3)	0	0	1 (5.3)	0
Respiratory tract infection	1 (5.3)	0	0	0	1 (5.3)
Respiratory tract infection viral	1 (5.3)	0	0	1 (5.3)	0
Rhinovirus infection	1 (5.3)	1 (5.3)	0	0	0
Rotavirus infection	1 (5.3)	0	0	1 (5.3)	0
Septic embolus	1 (5.3)	0	0	0	1 (5.3)
Staphylococcal infection	1 (5.3)	0	0	1 (5.3)	0
Vascular device infection	1 (5.3)	0	0	1 (5.3)	0
Vulvovaginal candidiasis	1 (5.3)	0	1 (5.3)	0	0
Catheter site infection	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (15.8)	1 (5.3)	0	2 (10.5)	0
Encephalopathy	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Seizure	1 (5.3)	0	0	1 (5.3)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (64.4)	1 (2.2)	11 (24.4)	11 (24.4)	6 (13.3)
Cytokine Release Syndrome					
-Total	25 (55.6)	3 (6.7)	12 (26.7)	5 (11.1)	5 (11.1)
Cytokine release syndrome	25 (55.6)	3 (6.7)	12 (26.7)	5 (11.1)	5 (11.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (6.7)	0	0	3 (6.7)	0
Febrile neutropenia	3 (6.7)	0	0	3 (6.7)	0
Infections					
-Total	11 (24.4)	0	4 (8.9)	6 (13.3)	1 (2.2)
Clostridium difficile infection	1 (2.2)	0	1 (2.2)	0	0
Urinary tract infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile colitis	1 (2.2)	0	1 (2.2)	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Catheter site infection	1 (2.2)	0	0	1 (2.2)	0
Cholecystitis infective	1 (2.2)	0	0	1 (2.2)	0
Corona virus infection	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (2.2)	0	1 (2.2)	0	0
Parainfluenzae virus infection	1 (2.2)	0	0	1 (2.2)	0
Pneumonia	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Respiratory syncytial virus infection	1 (2.2)	0	0	1 (2.2)	0
Sepsis	1 (2.2)	0	0	0	1 (2.2)
Upper respiratory tract infection	1 (2.2)	0	0	1 (2.2)	0
Viral upper respiratory tract infection	1 (2.2)	0	0	1 (2.2)	0
Serious neurological adverse reactions					
-Total	5 (11.1)	0	3 (6.7)	2 (4.4)	0
Encephalopathy	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Seizure	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Delirium	1 (2.2)	0	1 (2.2)	0	0
Tumour Lysis Syndrome					
-Total	2 (4.4)	0	0	2 (4.4)	0
Tumour lysis syndrome	2 (4.4)	0	0	2 (4.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	42 (65.6)	3 (4.7)	17 (26.6)	11 (17.2)	11 (17.2)
Cytokine release syndrome	41 (64.1)	4 (6.3)	19 (29.7)	8 (12.5)	10 (15.6)
Cytokine Release Syndrome					
-Total	41 (64.1)	4 (6.3)	19 (29.7)	8 (12.5)	10 (15.6)
Febrile neutropenia	3 (4.7)	0	0	3 (4.7)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (4.7)	0	0	3 (4.7)	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Clostridium difficile colitis	2 (3.1)	0	2 (3.1)	0	0
Clostridium difficile infection	2 (3.1)	0	2 (3.1)	0	0
Gastroenteritis	1 (1.6)	0	0	1 (1.6)	0

Timing: Within 8 weeks post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Pneumonia	1 (1.6)	0	0	1 (1.6)	0
Rhinovirus infection	1 (1.6)	1 (1.6)	0	0	0
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal infection	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	9 (14.1)	0	4 (6.3)	4 (6.3)	1 (1.6)
Delirium	1 (1.6)	0	1 (1.6)	0	0
Encephalopathy	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.1)	0
Seizure	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Serious neurological adverse reactions					
-Total	7 (10.9)	1 (1.6)	3 (4.7)	3 (4.7)	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (20.3)	0	1 (1.6)	10 (15.6)	2 (3.1)
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Group term Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	12 (18.8)	0	1 (1.6)	9 (14.1)	2 (3.1)
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (7.8)	0	1 (1.6)	3 (4.7)	1 (1.6)
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Clostridium difficile infection	1 (1.6)	0	0	1 (1.6)	0
Pneumonia	1 (1.6)	0	1 (1.6)	0	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Urinary tract infection	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Vulvovaginal candidiasis	1 (1.6)	0	1 (1.6)	0	0
Infections					

Timing: >1 year post CTL019 infusion, Region: US

Group term Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	4 (6.3)	0	1 (1.6)	2 (3.1)	1 (1.6)
Seizure	1 (1.6)	0	0	1 (1.6)	0
Serious neurological adverse reactions					
-Total	1 (1.6)	0	0	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	47 (73.4)	2 (3.1)	15 (23.4)	16 (25.0)	14 (21.9)
Cytokine release syndrome	41 (64.1)	4 (6.3)	19 (29.7)	8 (12.5)	10 (15.6)
Cytokine Release Syndrome					
-Total	41 (64.1)	4 (6.3)	19 (29.7)	8 (12.5)	10 (15.6)
Febrile neutropenia	3 (4.7)	0	0	3 (4.7)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (4.7)	0	0	3 (4.7)	0
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Clostridium difficile colitis	2 (3.1)	0	2 (3.1)	0	0
Clostridium difficile infection	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	0	0	1 (1.6)	0
Pneumonia	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Rhinovirus infection	1 (1.6)	1 (1.6)	0	0	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal infection	1 (1.6)	0	0	1 (1.6)	0
Upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Urinary tract infection	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Vulvovaginal candidiasis	1 (1.6)	0	1 (1.6)	0	0
Infections					
-Total	19 (29.7)	0	4 (6.3)	11 (17.2)	4 (6.3)
Delirium	1 (1.6)	0	1 (1.6)	0	0
Encephalopathy	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.1)	0
Seizure	4 (6.3)	0	2 (3.1)	2 (3.1)	0
Serious neurological adverse reactions					
-Total	8 (12.5)	1 (1.6)	3 (4.7)	4 (6.3)	0
Tumour lysis syndrome	2 (3.1)	0	0	2 (3.1)	0
Tumour Lysis Syndrome					
-Total	2 (3.1)	0	0	2 (3.1)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	17 (60.7)	2 (7.1)	8 (28.6)	4 (14.3)	3 (10.7)
Cytokine Release Syndrome					
-Total	17 (60.7)	2 (7.1)	9 (32.1)	4 (14.3)	2 (7.1)
Cytokine release syndrome	17 (60.7)	2 (7.1)	9 (32.1)	4 (14.3)	2 (7.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (3.6)	0	0	1 (3.6)	0
Febrile neutropenia	1 (3.6)	0	0	1 (3.6)	0
Infections					
-Total	3 (10.7)	0	2 (7.1)	0	1 (3.6)
Clostridium difficile colitis	1 (3.6)	0	1 (3.6)	0	0
Clostridium difficile infection	1 (3.6)	0	1 (3.6)	0	0
Gastroenteritis norovirus	1 (3.6)	0	1 (3.6)	0	0

Timing: Within 8 weeks post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (3.6)	1 (3.6)	0	0	0
Septic embolus	1 (3.6)	0	0	0	1 (3.6)
Catheter site infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Encephalopathy	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Seizure	1 (3.6)	0	0	1 (3.6)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	25 (69.4)	1 (2.8)	9 (25.0)	7 (19.4)	8 (22.2)
Cytokine Release Syndrome					
-Total	24 (66.7)	2 (5.6)	10 (27.8)	4 (11.1)	8 (22.2)
Cytokine release syndrome	24 (66.7)	2 (5.6)	10 (27.8)	4 (11.1)	8 (22.2)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (5.6)	0	0	2 (5.6)	0
Febrile neutropenia	2 (5.6)	0	0	2 (5.6)	0
Infections					
-Total	6 (16.7)	0	2 (5.6)	4 (11.1)	0
Clostridium difficile colitis	1 (2.8)	0	1 (2.8)	0	0
Clostridium difficile infection	1 (2.8)	0	1 (2.8)	0	0
Gastroenteritis norovirus	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Catheter site infection	1 (2.8)	0	0	1 (2.8)	0
Gastroenteritis	1 (2.8)	0	0	1 (2.8)	0
Pneumonia	1 (2.8)	0	0	1 (2.8)	0
Staphylococcal infection	1 (2.8)	0	0	1 (2.8)	0
Serious neurological adverse reactions					
-Total	4 (11.1)	0	3 (8.3)	1 (2.8)	0
Encephalopathy	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Seizure	2 (5.6)	0	2 (5.6)	0	0
Delirium	1 (2.8)	0	1 (2.8)	0	0
Tumour Lysis Syndrome					
-Total	1 (2.8)	0	0	1 (2.8)	0
Tumour lysis syndrome	1 (2.8)	0	0	1 (2.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (25.0)	0	1 (3.6)	5 (17.9)	1 (3.6)
Infections					
-Total	7 (25.0)	0	1 (3.6)	5 (17.9)	1 (3.6)
Cellulitis of male external genital organ	1 (3.6)	0	0	1 (3.6)	0
Cholecystitis infective	1 (3.6)	0	0	1 (3.6)	0
Enterovirus infection	1 (3.6)	0	0	1 (3.6)	0
Gastroenteritis norovirus	1 (3.6)	0	1 (3.6)	0	0
Rotavirus infection	1 (3.6)	0	0	1 (3.6)	0
Sepsis	1 (3.6)	0	0	0	1 (3.6)
Upper respiratory tract infection	1 (3.6)	0	0	1 (3.6)	0
Vascular device infection	1 (3.6)	0	0	1 (3.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacterial sepsis	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (16.7)	0	0	5 (13.9)	1 (2.8)
Infections					
-Total	5 (13.9)	0	0	4 (11.1)	1 (2.8)
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Group term Preferred term	All patients N=36 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacterial sepsis	1 (2.8)	0	0	0	1 (2.8)
Corona virus infection	1 (2.8)	0	0	1 (2.8)	0
Herpes zoster	1 (2.8)	0	0	1 (2.8)	0
Parainfluenzae virus infection	1 (2.8)	0	0	1 (2.8)	0
Respiratory syncytial virus infection	1 (2.8)	0	0	1 (2.8)	0
Viral upper respiratory tract infection	1 (2.8)	0	0	1 (2.8)	0
Tumour Lysis Syndrome					
-Total	1 (2.8)	0	0	1 (2.8)	0
Tumour lysis syndrome	1 (2.8)	0	0	1 (2.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 215l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (10.7)	0	0	3 (10.7)	0
Infections					
-Total	2 (7.1)	0	0	2 (7.1)	0
Urinary tract infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Campylobacter infection	1 (3.6)	0	0	1 (3.6)	0
Cellulitis of male external genital organ	1 (3.6)	0	0	1 (3.6)	0
Clostridium difficile infection	1 (3.6)	0	0	1 (3.6)	0
Respiratory tract infection viral	1 (3.6)	0	0	1 (3.6)	0
Vulvovaginal candidiasis	1 (3.6)	0	1 (3.6)	0	0
Pneumonia	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Prior SCT therapy: Yes

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.6)	0	0	1 (3.6)	0
Seizure	1 (3.6)	0	0	1 (3.6)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 215l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (5.6)	0	1 (2.8)	0	1 (2.8)
Infections					
-Total	2 (5.6)	0	1 (2.8)	0	1 (2.8)
Urinary tract infection	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Pneumonia	1 (2.8)	0	1 (2.8)	0	0

Timing: >1 year post CTL019 infusion, Prior SCT therapy: No

Group term Preferred term	All patients N=36 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	1 (2.8)	0	0	0	1 (2.8)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (71.4)	1 (3.6)	7 (25.0)	8 (28.6)	4 (14.3)
Cytokine Release Syndrome					
-Total	17 (60.7)	2 (7.1)	9 (32.1)	4 (14.3)	2 (7.1)
Cytokine release syndrome	17 (60.7)	2 (7.1)	9 (32.1)	4 (14.3)	2 (7.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (3.6)	0	0	1 (3.6)	0
Febrile neutropenia	1 (3.6)	0	0	1 (3.6)	0
Infections					
-Total	8 (28.6)	0	1 (3.6)	5 (17.9)	2 (7.1)
Clostridium difficile infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Campylobacter infection	1 (3.6)	0	0	1 (3.6)	0
Cellulitis of male external genital organ	1 (3.6)	0	0	1 (3.6)	0
Cholecystitis infective	1 (3.6)	0	0	1 (3.6)	0
Clostridium difficile colitis	1 (3.6)	0	1 (3.6)	0	0
Enterovirus infection	1 (3.6)	0	0	1 (3.6)	0
Gastroenteritis norovirus	1 (3.6)	0	1 (3.6)	0	0
Respiratory tract infection viral	1 (3.6)	0	0	1 (3.6)	0
Rhinovirus infection	1 (3.6)	1 (3.6)	0	0	0
Rotavirus infection	1 (3.6)	0	0	1 (3.6)	0
Sepsis	1 (3.6)	0	0	0	1 (3.6)
Septic embolus	1 (3.6)	0	0	0	1 (3.6)
Upper respiratory tract infection	1 (3.6)	0	0	1 (3.6)	0
Vascular device infection	1 (3.6)	0	0	1 (3.6)	0
Vulvovaginal candidiasis	1 (3.6)	0	1 (3.6)	0	0
Bacterial sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (14.3)	1 (3.6)	0	3 (10.7)	0
Encephalopathy	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Seizure	2 (7.1)	0	0	2 (7.1)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	27 (75.0)	1 (2.8)	8 (22.2)	8 (22.2)	10 (27.8)
Cytokine Release Syndrome					
-Total	24 (66.7)	2 (5.6)	10 (27.8)	4 (11.1)	8 (22.2)
Cytokine release syndrome	24 (66.7)	2 (5.6)	10 (27.8)	4 (11.1)	8 (22.2)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (5.6)	0	0	2 (5.6)	0
Febrile neutropenia	2 (5.6)	0	0	2 (5.6)	0
Infections					
-Total	11 (30.6)	0	3 (8.3)	6 (16.7)	2 (5.6)
Clostridium difficile infection	1 (2.8)	0	1 (2.8)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	1 (2.8)	0	1 (2.8)	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Bacterial sepsis	1 (2.8)	0	0	0	1 (2.8)
Catheter site infection	1 (2.8)	0	0	1 (2.8)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (2.8)	0	0	1 (2.8)	0
Gastroenteritis	1 (2.8)	0	0	1 (2.8)	0
Herpes zoster	1 (2.8)	0	0	1 (2.8)	0
Parainfluenzae virus infection	1 (2.8)	0	0	1 (2.8)	0
Pneumonia	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Respiratory syncytial virus infection	1 (2.8)	0	0	1 (2.8)	0
Respiratory tract infection	1 (2.8)	0	0	0	1 (2.8)
Staphylococcal infection	1 (2.8)	0	0	1 (2.8)	0
Viral upper respiratory tract infection	1 (2.8)	0	0	1 (2.8)	0
Serious neurological adverse reactions					
-Total	4 (11.1)	0	3 (8.3)	1 (2.8)	0
Encephalopathy	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Seizure	2 (5.6)	0	2 (5.6)	0	0
Delirium	1 (2.8)	0	1 (2.8)	0	0
Tumour Lysis Syndrome					
-Total	2 (5.6)	0	0	2 (5.6)	0
Tumour lysis syndrome	2 (5.6)	0	0	2 (5.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (71.4)	0	5 (35.7)	4 (28.6)	1 (7.1)
Cytokine Release Syndrome					
-Total	9 (64.3)	0	6 (42.9)	2 (14.3)	1 (7.1)
Cytokine release syndrome	9 (64.3)	0	6 (42.9)	2 (14.3)	1 (7.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (14.3)	0	0	2 (14.3)	0
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0
Infections					
-Total	2 (14.3)	0	0	2 (14.3)	0
Catheter site infection	1 (7.1)	0	0	1 (7.1)	0
Pneumonia	1 (7.1)	0	0	1 (7.1)	0
Clostridium difficile colitis	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	32 (64.0)	3 (6.0)	12 (24.0)	7 (14.0)	10 (20.0)
Cytokine Release Syndrome					
-Total	32 (64.0)	4 (8.0)	13 (26.0)	6 (12.0)	9 (18.0)
Cytokine release syndrome	32 (64.0)	4 (8.0)	13 (26.0)	6 (12.0)	9 (18.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (2.0)	0	0	1 (2.0)	0
Febrile neutropenia	1 (2.0)	0	0	1 (2.0)	0
Infections					
-Total	7 (14.0)	0	4 (8.0)	2 (4.0)	1 (2.0)
Catheter site infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Clostridium difficile colitis	2 (4.0)	0	2 (4.0)	0	0

Timing: Within 8 weeks post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	2 (4.0)	0	2 (4.0)	0	0
Gastroenteritis	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis norovirus	1 (2.0)	0	1 (2.0)	0	0
Rhinovirus infection	1 (2.0)	1 (2.0)	0	0	0
Septic embolus	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal infection	1 (2.0)	0	0	1 (2.0)	0
Serious neurological adverse reactions					
-Total	7 (14.0)	1 (2.0)	3 (6.0)	3 (6.0)	0
Delirium	1 (2.0)	0	1 (2.0)	0	0
Encephalopathy	4 (8.0)	1 (2.0)	1 (2.0)	2 (4.0)	0
Seizure	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Tumour Lysis Syndrome					
-Total	1 (2.0)	0	0	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	0	0	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (35.7)	0	0	4 (28.6)	1 (7.1)
Infections					
-Total	4 (28.6)	0	0	3 (21.4)	1 (7.1)
Bacterial sepsis	1 (7.1)	0	0	0	1 (7.1)
Corona virus infection	1 (7.1)	0	0	1 (7.1)	0
Parainfluenzae virus infection	1 (7.1)	0	0	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	0	0	1 (7.1)	0
Viral upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Enterovirus infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (7.1)	0	0	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (16.0)	0	1 (2.0)	6 (12.0)	1 (2.0)
Infections					
-Total	8 (16.0)	0	1 (2.0)	6 (12.0)	1 (2.0)
Bacterial sepsis	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Cellulitis of male external genital organ	1 (2.0)	0	0	1 (2.0)	0
Cholecystitis infective	1 (2.0)	0	0	1 (2.0)	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Group term Preferred term	All patients N=50 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis norovirus	1 (2.0)	0	1 (2.0)	0	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Rotavirus infection	1 (2.0)	0	0	1 (2.0)	0
Sepsis	1 (2.0)	0	0	0	1 (2.0)
Upper respiratory tract infection	1 (2.0)	0	0	1 (2.0)	0
Vascular device infection	1 (2.0)	0	0	1 (2.0)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (7.1)	0	0	0	1 (7.1)
Infections					
-Total	1 (7.1)	0	0	0	1 (7.1)
Respiratory tract infection	1 (7.1)	0	0	0	1 (7.1)
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Eligibility for SCT: Yes

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (8.0)	0	1 (2.0)	3 (6.0)	0
Infections					
-Total	3 (6.0)	0	1 (2.0)	2 (4.0)	0
Respiratory tract infection	0	0	0	0	0
Campylobacter infection	1 (2.0)	0	0	1 (2.0)	0
Cellulitis of male external genital organ	1 (2.0)	0	0	1 (2.0)	0
Clostridium difficile infection	1 (2.0)	0	0	1 (2.0)	0
Pneumonia	1 (2.0)	0	1 (2.0)	0	0
Respiratory tract infection viral	1 (2.0)	0	0	1 (2.0)	0
Urinary tract infection	2 (4.0)	0	1 (2.0)	1 (2.0)	0

Timing: >1 year post CTL019 infusion, Eligibility for SCT: No

Group term Preferred term	All patients N=50 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	1 (2.0)	0	1 (2.0)	0	0
Serious neurological adverse reactions					
-Total	1 (2.0)	0	0	1 (2.0)	0
Seizure	1 (2.0)	0	0	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (78.6)	0	3 (21.4)	5 (35.7)	3 (21.4)
Cytokine Release Syndrome					
-Total	9 (64.3)	0	6 (42.9)	2 (14.3)	1 (7.1)
Cytokine release syndrome	9 (64.3)	0	6 (42.9)	2 (14.3)	1 (7.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (14.3)	0	0	2 (14.3)	0
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0
Infections					
-Total	6 (42.9)	0	0	4 (28.6)	2 (14.3)
Bacterial sepsis	1 (7.1)	0	0	0	1 (7.1)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (7.1)	0	0	1 (7.1)	0
Corona virus infection	1 (7.1)	0	0	1 (7.1)	0
Parainfluenzae virus infection	1 (7.1)	0	0	1 (7.1)	0
Pneumonia	1 (7.1)	0	0	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	0	0	1 (7.1)	0
Respiratory tract infection	1 (7.1)	0	0	0	1 (7.1)
Viral upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (7.1)	0	0	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	36 (72.0)	2 (4.0)	12 (24.0)	11 (22.0)	11 (22.0)
Cytokine Release Syndrome					
-Total	32 (64.0)	4 (8.0)	13 (26.0)	6 (12.0)	9 (18.0)
Cytokine release syndrome	32 (64.0)	4 (8.0)	13 (26.0)	6 (12.0)	9 (18.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (2.0)	0	0	1 (2.0)	0
Febrile neutropenia	1 (2.0)	0	0	1 (2.0)	0
Infections					
-Total	13 (26.0)	0	4 (8.0)	7 (14.0)	2 (4.0)
Bacterial sepsis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	1 (2.0)	0	1 (2.0)	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Campylobacter infection	1 (2.0)	0	0	1 (2.0)	0
Cellulitis of male external genital organ	1 (2.0)	0	0	1 (2.0)	0
Cholecystitis infective	1 (2.0)	0	0	1 (2.0)	0
Clostridium difficile colitis	2 (4.0)	0	2 (4.0)	0	0
Clostridium difficile infection	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis norovirus	1 (2.0)	0	1 (2.0)	0	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Respiratory tract infection viral	1 (2.0)	0	0	1 (2.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (2.0)	1 (2.0)	0	0	0
Rotavirus infection	1 (2.0)	0	0	1 (2.0)	0
Sepsis	1 (2.0)	0	0	0	1 (2.0)
Septic embolus	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal infection	1 (2.0)	0	0	1 (2.0)	0
Upper respiratory tract infection	1 (2.0)	0	0	1 (2.0)	0
Urinary tract infection	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Vascular device infection	1 (2.0)	0	0	1 (2.0)	0
Vulvovaginal candidiasis	1 (2.0)	0	1 (2.0)	0	0
Serious neurological adverse reactions					
-Total	8 (16.0)	1 (2.0)	3 (6.0)	4 (8.0)	0
Delirium	1 (2.0)	0	1 (2.0)	0	0
Encephalopathy	4 (8.0)	1 (2.0)	1 (2.0)	2 (4.0)	0
Seizure	4 (8.0)	0	2 (4.0)	2 (4.0)	0
Tumour Lysis Syndrome					
-Total	1 (2.0)	0	0	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	0	0	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (70.0)	0	8 (40.0)	4 (20.0)	2 (10.0)
Cytokine Release Syndrome					
-Total	14 (70.0)	0	9 (45.0)	3 (15.0)	2 (10.0)
Cytokine release syndrome	14 (70.0)	0	9 (45.0)	3 (15.0)	2 (10.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (5.0)	0	0	1 (5.0)	0
Febrile neutropenia	1 (5.0)	0	0	1 (5.0)	0
Infections					
-Total	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Clostridium difficile colitis	1 (5.0)	0	1 (5.0)	0	0
Gastroenteritis	1 (5.0)	0	0	1 (5.0)	0
Catheter site infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (20.0)	1 (5.0)	2 (10.0)	1 (5.0)	0
Encephalopathy	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Seizure	1 (5.0)	0	1 (5.0)	0	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	28 (63.6)	3 (6.8)	9 (20.5)	7 (15.9)	9 (20.5)
Cytokine Release Syndrome					
-Total	27 (61.4)	4 (9.1)	10 (22.7)	5 (11.4)	8 (18.2)
Cytokine release syndrome	27 (61.4)	4 (9.1)	10 (22.7)	5 (11.4)	8 (18.2)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (4.5)	0	0	2 (4.5)	0
Febrile neutropenia	2 (4.5)	0	0	2 (4.5)	0
Infections					
-Total	7 (15.9)	0	3 (6.8)	3 (6.8)	1 (2.3)
Clostridium difficile colitis	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis	0	0	0	0	0
Catheter site infection	1 (2.3)	0	0	1 (2.3)	0

Timing: Within 8 weeks post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	2 (4.5)	0	2 (4.5)	0	0
Gastroenteritis norovirus	1 (2.3)	0	1 (2.3)	0	0
Pneumonia	1 (2.3)	0	0	1 (2.3)	0
Rhinovirus infection	1 (2.3)	1 (2.3)	0	0	0
Septic embolus	1 (2.3)	0	0	0	1 (2.3)
Staphylococcal infection	1 (2.3)	0	0	1 (2.3)	0
Serious neurological adverse reactions					
-Total	3 (6.8)	0	1 (2.3)	2 (4.5)	0
Encephalopathy	1 (2.3)	0	0	1 (2.3)	0
Seizure	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Delirium	1 (2.3)	0	1 (2.3)	0	0
Tumour Lysis Syndrome					
-Total	1 (2.3)	0	0	1 (2.3)	0
Tumour lysis syndrome	1 (2.3)	0	0	1 (2.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (25.0)	0	0	4 (20.0)	1 (5.0)
Infections					
-Total	5 (25.0)	0	0	4 (20.0)	1 (5.0)
Bacterial sepsis	1 (5.0)	0	0	0	1 (5.0)
Cholecystitis infective	1 (5.0)	0	0	1 (5.0)	0
Corona virus infection	1 (5.0)	0	0	1 (5.0)	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0
Respiratory syncytial virus infection	1 (5.0)	0	0	1 (5.0)	0
Vascular device infection	1 (5.0)	0	0	1 (5.0)	0
Cellulitis of male external genital organ	0	0	0	0	0
Enterovirus infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (18.2)	0	1 (2.3)	6 (13.6)	1 (2.3)
Infections					
-Total	7 (15.9)	0	1 (2.3)	5 (11.4)	1 (2.3)
Bacterial sepsis	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Cellulitis of male external genital organ	1 (2.3)	0	0	1 (2.3)	0
Enterovirus infection	1 (2.3)	0	0	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=44 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis norovirus	1 (2.3)	0	1 (2.3)	0	0
Parainfluenzae virus infection	1 (2.3)	0	0	1 (2.3)	0
Rotavirus infection	1 (2.3)	0	0	1 (2.3)	0
Sepsis	1 (2.3)	0	0	0	1 (2.3)
Upper respiratory tract infection	1 (2.3)	0	0	1 (2.3)	0
Viral upper respiratory tract infection	1 (2.3)	0	0	1 (2.3)	0
Tumour Lysis Syndrome					
-Total	1 (2.3)	0	0	1 (2.3)	0
Tumour lysis syndrome	1 (2.3)	0	0	1 (2.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (5.0)	0	0	1 (5.0)	0
Infections					
-Total	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (5.0)	0	0	1 (5.0)	0
Seizure	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (9.1)	0	1 (2.3)	2 (4.5)	1 (2.3)
Infections					
-Total	4 (9.1)	0	1 (2.3)	2 (4.5)	1 (2.3)
Campylobacter infection	1 (2.3)	0	0	1 (2.3)	0
Cellulitis of male external genital organ	1 (2.3)	0	0	1 (2.3)	0
Clostridium difficile infection	1 (2.3)	0	0	1 (2.3)	0
Pneumonia	1 (2.3)	0	1 (2.3)	0	0
Respiratory tract infection	1 (2.3)	0	0	0	1 (2.3)
Respiratory tract infection viral	1 (2.3)	0	0	1 (2.3)	0
Urinary tract infection	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Vulvovaginal candidiasis	1 (2.3)	0	1 (2.3)	0	0

Timing: >1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (75.0)	0	5 (25.0)	7 (35.0)	3 (15.0)
Cytokine Release Syndrome					
-Total	14 (70.0)	0	9 (45.0)	3 (15.0)	2 (10.0)
Cytokine release syndrome	14 (70.0)	0	9 (45.0)	3 (15.0)	2 (10.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (5.0)	0	0	1 (5.0)	0
Febrile neutropenia	1 (5.0)	0	0	1 (5.0)	0
Infections					
-Total	5 (25.0)	0	0	4 (20.0)	1 (5.0)
Bacterial sepsis	1 (5.0)	0	0	0	1 (5.0)
Cholecystitis infective	1 (5.0)	0	0	1 (5.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (5.0)	0	1 (5.0)	0	0
Corona virus infection	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis	1 (5.0)	0	0	1 (5.0)	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0
Respiratory syncytial virus infection	1 (5.0)	0	0	1 (5.0)	0
Vascular device infection	1 (5.0)	0	0	1 (5.0)	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	5 (25.0)	1 (5.0)	2 (10.0)	2 (10.0)	0
Encephalopathy	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Seizure	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	32 (72.7)	2 (4.5)	10 (22.7)	9 (20.5)	11 (25.0)
Cytokine Release Syndrome					
-Total	27 (61.4)	4 (9.1)	10 (22.7)	5 (11.4)	8 (18.2)
Cytokine release syndrome	27 (61.4)	4 (9.1)	10 (22.7)	5 (11.4)	8 (18.2)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (4.5)	0	0	2 (4.5)	0
Febrile neutropenia	2 (4.5)	0	0	2 (4.5)	0
Infections					
-Total	14 (31.8)	0	4 (9.1)	7 (15.9)	3 (6.8)
Bacterial sepsis	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (2.3)	0	1 (2.3)	0	0
Corona virus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Campylobacter infection	1 (2.3)	0	0	1 (2.3)	0
Catheter site infection	1 (2.3)	0	0	1 (2.3)	0
Cellulitis of male external genital organ	1 (2.3)	0	0	1 (2.3)	0
Clostridium difficile infection	3 (6.8)	0	2 (4.5)	1 (2.3)	0
Enterovirus infection	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis norovirus	1 (2.3)	0	1 (2.3)	0	0
Parainfluenzae virus infection	1 (2.3)	0	0	1 (2.3)	0
Pneumonia	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Respiratory tract infection	1 (2.3)	0	0	0	1 (2.3)
Respiratory tract infection viral	1 (2.3)	0	0	1 (2.3)	0
Rhinovirus infection	1 (2.3)	1 (2.3)	0	0	0
Rotavirus infection	1 (2.3)	0	0	1 (2.3)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (2.3)	0	0	0	1 (2.3)
Septic embolus	1 (2.3)	0	0	0	1 (2.3)
Staphylococcal infection	1 (2.3)	0	0	1 (2.3)	0
Upper respiratory tract infection	1 (2.3)	0	0	1 (2.3)	0
Urinary tract infection	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Viral upper respiratory tract infection	1 (2.3)	0	0	1 (2.3)	0
Vulvovaginal candidiasis	1 (2.3)	0	1 (2.3)	0	0
Serious neurological adverse reactions					
-Total	3 (6.8)	0	1 (2.3)	2 (4.5)	0
Encephalopathy	1 (2.3)	0	0	1 (2.3)	0
Seizure	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Delirium	1 (2.3)	0	1 (2.3)	0	0
Tumour Lysis Syndrome					
-Total	2 (4.5)	0	0	2 (4.5)	0
Tumour lysis syndrome	2 (4.5)	0	0	2 (4.5)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (60.0)	1 (20.0)	0	1 (20.0)	1 (20.0)
Cytokine Release Syndrome					
-Total	3 (60.0)	1 (20.0)	1 (20.0)	0	1 (20.0)
Cytokine release syndrome	3 (60.0)	1 (20.0)	1 (20.0)	0	1 (20.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (20.0)	0	0	1 (20.0)	0
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Infections					
-Total	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	39 (66.1)	2 (3.4)	17 (28.8)	10 (16.9)	10 (16.9)
Cytokine Release Syndrome					
-Total	38 (64.4)	3 (5.1)	18 (30.5)	8 (13.6)	9 (15.3)
Cytokine release syndrome	38 (64.4)	3 (5.1)	18 (30.5)	8 (13.6)	9 (15.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (3.4)	0	0	2 (3.4)	0
Febrile neutropenia	2 (3.4)	0	0	2 (3.4)	0
Infections					
-Total	9 (15.3)	0	4 (6.8)	4 (6.8)	1 (1.7)
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Clostridium difficile colitis	2 (3.4)	0	2 (3.4)	0	0
Clostridium difficile infection	2 (3.4)	0	2 (3.4)	0	0

Timing: Within 8 weeks post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Pneumonia	1 (1.7)	0	0	1 (1.7)	0
Rhinovirus infection	1 (1.7)	1 (1.7)	0	0	0
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Staphylococcal infection	1 (1.7)	0	0	1 (1.7)	0
Serious neurological adverse reactions					
-Total	7 (11.9)	1 (1.7)	3 (5.1)	3 (5.1)	0
Delirium	1 (1.7)	0	1 (1.7)	0	0
Encephalopathy	4 (6.8)	1 (1.7)	1 (1.7)	2 (3.4)	0
Seizure	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (20.0)	0	0	1 (20.0)	0
Infections					
-Total	1 (20.0)	0	0	1 (20.0)	0
Viral upper respiratory tract infection	1 (20.0)	0	0	1 (20.0)	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=59			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (20.3)	0	1 (1.7)	9 (15.3)	2 (3.4)
Infections					
-Total	11 (18.6)	0	1 (1.7)	8 (13.6)	2 (3.4)
Viral upper respiratory tract infection	0	0	0	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Corona virus infection	1 (1.7)	0	0	1 (1.7)	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Herpes zoster	1 (1.7)	0	0	1 (1.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=59 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	1 (1.7)	0	0	1 (1.7)	0
Respiratory syncytial virus infection	1 (1.7)	0	0	1 (1.7)	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (20.0)	0	0	1 (20.0)	0
Infections					
-Total	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (20.0)	0	0	1 (20.0)	0
Seizure	1 (20.0)	0	0	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (6.8)	0	1 (1.7)	2 (3.4)	1 (1.7)
Infections					
-Total	4 (6.8)	0	1 (1.7)	2 (3.4)	1 (1.7)
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Clostridium difficile infection	1 (1.7)	0	0	1 (1.7)	0
Pneumonia	1 (1.7)	0	1 (1.7)	0	0
Respiratory tract infection	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Urinary tract infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Vulvovaginal candidiasis	1 (1.7)	0	1 (1.7)	0	0

Timing: >1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=59 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (80.0)	1 (20.0)	0	2 (40.0)	1 (20.0)
Cytokine Release Syndrome					
-Total	3 (60.0)	1 (20.0)	1 (20.0)	0	1 (20.0)
Cytokine release syndrome	3 (60.0)	1 (20.0)	1 (20.0)	0	1 (20.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (20.0)	0	0	1 (20.0)	0
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Infections					
-Total	1 (20.0)	0	0	1 (20.0)	0
Viral upper respiratory tract infection	1 (20.0)	0	0	1 (20.0)	0
Bacterial sepsis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (20.0)	0	0	1 (20.0)	0
Seizure	1 (20.0)	0	0	1 (20.0)	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	43 (72.9)	1 (1.7)	15 (25.4)	14 (23.7)	13 (22.0)
Cytokine Release Syndrome					
-Total	38 (64.4)	3 (5.1)	18 (30.5)	8 (13.6)	9 (15.3)
Cytokine release syndrome	38 (64.4)	3 (5.1)	18 (30.5)	8 (13.6)	9 (15.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (3.4)	0	0	2 (3.4)	0
Febrile neutropenia	2 (3.4)	0	0	2 (3.4)	0
Infections					
-Total	18 (30.5)	0	4 (6.8)	10 (16.9)	4 (6.8)
Viral upper respiratory tract infection	0	0	0	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Clostridium difficile colitis	2 (3.4)	0	2 (3.4)	0	0
Clostridium difficile infection	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Corona virus infection	1 (1.7)	0	0	1 (1.7)	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Herpes zoster	1 (1.7)	0	0	1 (1.7)	0
Parainfluenzae virus infection	1 (1.7)	0	0	1 (1.7)	0
Pneumonia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Respiratory syncytial virus infection	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Rhinovirus infection	1 (1.7)	1 (1.7)	0	0	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Staphylococcal infection	1 (1.7)	0	0	1 (1.7)	0
Upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Urinary tract infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Vulvovaginal candidiasis	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	7 (11.9)	1 (1.7)	3 (5.1)	3 (5.1)	0
Seizure	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Delirium	1 (1.7)	0	1 (1.7)	0	0
Encephalopathy	4 (6.8)	1 (1.7)	1 (1.7)	2 (3.4)	0
Tumour Lysis Syndrome					
-Total	2 (3.4)	0	0	2 (3.4)	0
Tumour lysis syndrome	2 (3.4)	0	0	2 (3.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (50.0)	0	2 (50.0)	0	0
Cytokine Release Syndrome					
-Total	2 (50.0)	0	2 (50.0)	0	0
Cytokine release syndrome	2 (50.0)	0	2 (50.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	40 (66.7)	3 (5.0)	15 (25.0)	11 (18.3)	11 (18.3)
Cytokine Release Syndrome					
-Total	39 (65.0)	4 (6.7)	17 (28.3)	8 (13.3)	10 (16.7)
Cytokine release syndrome	39 (65.0)	4 (6.7)	17 (28.3)	8 (13.3)	10 (16.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (5.0)	0	0	3 (5.0)	0
Febrile neutropenia	3 (5.0)	0	0	3 (5.0)	0
Infections					
-Total	9 (15.0)	0	4 (6.7)	4 (6.7)	1 (1.7)
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Clostridium difficile colitis	2 (3.3)	0	2 (3.3)	0	0
Clostridium difficile infection	2 (3.3)	0	2 (3.3)	0	0

Timing: Within 8 weeks post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Pneumonia	1 (1.7)	0	0	1 (1.7)	0
Rhinovirus infection	1 (1.7)	1 (1.7)	0	0	0
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Staphylococcal infection	1 (1.7)	0	0	1 (1.7)	0
Serious neurological adverse reactions					
-Total	7 (11.7)	1 (1.7)	3 (5.0)	3 (5.0)	0
Delirium	1 (1.7)	0	1 (1.7)	0	0
Encephalopathy	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Seizure	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (25.0)	0	0	1 (25.0)	0
Infections					
-Total	1 (25.0)	0	0	1 (25.0)	0
Corona virus infection	1 (25.0)	0	0	1 (25.0)	0
Respiratory syncytial virus infection	1 (25.0)	0	0	1 (25.0)	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (20.0)	0	1 (1.7)	9 (15.0)	2 (3.3)
Infections					
-Total	11 (18.3)	0	1 (1.7)	8 (13.3)	2 (3.3)
Corona virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Herpes zoster	1 (1.7)	0	0	1 (1.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	1 (1.7)	0	0	1 (1.7)	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Viral upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (8.3)	0	1 (1.7)	3 (5.0)	1 (1.7)
Infections					
-Total	4 (6.7)	0	1 (1.7)	2 (3.3)	1 (1.7)
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Clostridium difficile infection	1 (1.7)	0	0	1 (1.7)	0
Pneumonia	1 (1.7)	0	1 (1.7)	0	0
Respiratory tract infection	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Urinary tract infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0

Timing: >1 year post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	1 (1.7)	0	0	1 (1.7)	0
Seizure	1 (1.7)	0	0	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Cytokine Release Syndrome					
-Total	2 (50.0)	0	2 (50.0)	0	0
Cytokine release syndrome	2 (50.0)	0	2 (50.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	1 (25.0)	0	0	1 (25.0)	0
Corona virus infection	1 (25.0)	0	0	1 (25.0)	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	1 (25.0)	0	0	1 (25.0)	0
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	45 (75.0)	2 (3.3)	14 (23.3)	15 (25.0)	14 (23.3)
Cytokine Release Syndrome					
-Total	39 (65.0)	4 (6.7)	17 (28.3)	8 (13.3)	10 (16.7)
Cytokine release syndrome	39 (65.0)	4 (6.7)	17 (28.3)	8 (13.3)	10 (16.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (5.0)	0	0	3 (5.0)	0
Febrile neutropenia	3 (5.0)	0	0	3 (5.0)	0
Infections					
-Total	18 (30.0)	0	4 (6.7)	10 (16.7)	4 (6.7)
Corona virus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	0	0	0	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Clostridium difficile colitis	2 (3.3)	0	2 (3.3)	0	0
Clostridium difficile infection	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Herpes zoster	1 (1.7)	0	0	1 (1.7)	0
Parainfluenzae virus infection	1 (1.7)	0	0	1 (1.7)	0
Pneumonia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Rhinovirus infection	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Staphylococcal infection	1 (1.7)	0	0	1 (1.7)	0
Upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Urinary tract infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Viral upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Vulvovaginal candidiasis	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	8 (13.3)	1 (1.7)	3 (5.0)	4 (6.7)	0
Delirium	1 (1.7)	0	1 (1.7)	0	0
Encephalopathy	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Seizure	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Tumour Lysis Syndrome					
-Total	2 (3.3)	0	0	2 (3.3)	0
Tumour lysis syndrome	2 (3.3)	0	0	2 (3.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (62.5)	2 (6.3)	9 (28.1)	4 (12.5)	5 (15.6)
Cytokine Release Syndrome					
-Total	19 (59.4)	3 (9.4)	10 (31.3)	2 (6.3)	4 (12.5)
Cytokine release syndrome	19 (59.4)	3 (9.4)	10 (31.3)	2 (6.3)	4 (12.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (3.1)	0	0	1 (3.1)	0
Febrile neutropenia	1 (3.1)	0	0	1 (3.1)	0
Infections					
-Total	5 (15.6)	0	2 (6.3)	2 (6.3)	1 (3.1)
Clostridium difficile infection	2 (6.3)	0	2 (6.3)	0	0
Catheter site infection	1 (3.1)	0	0	1 (3.1)	0

Timing: Within 8 weeks post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Septic embolus	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (6.3)	0	0	2 (6.3)	0
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Seizure	1 (3.1)	0	0	1 (3.1)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	22 (68.8)	1 (3.1)	8 (25.0)	7 (21.9)	6 (18.8)
Cytokine Release Syndrome					
-Total	22 (68.8)	1 (3.1)	9 (28.1)	6 (18.8)	6 (18.8)
Cytokine release syndrome	22 (68.8)	1 (3.1)	9 (28.1)	6 (18.8)	6 (18.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (6.3)	0	0	2 (6.3)	0
Febrile neutropenia	2 (6.3)	0	0	2 (6.3)	0
Infections					
-Total	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Clostridium difficile infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Clostridium difficile colitis	2 (6.3)	0	2 (6.3)	0	0
Gastroenteritis	1 (3.1)	0	0	1 (3.1)	0
Pneumonia	1 (3.1)	0	0	1 (3.1)	0
Serious neurological adverse reactions					
-Total	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Encephalopathy	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Seizure	2 (6.3)	0	2 (6.3)	0	0
Delirium	1 (3.1)	0	1 (3.1)	0	0
Tumour Lysis Syndrome					
-Total	1 (3.1)	0	0	1 (3.1)	0
Tumour lysis syndrome	1 (3.1)	0	0	1 (3.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (18.8)	0	1 (3.1)	3 (9.4)	2 (6.3)
Infections					
-Total	6 (18.8)	0	1 (3.1)	3 (9.4)	2 (6.3)
Bacterial sepsis	1 (3.1)	0	0	0	1 (3.1)
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Parainfluenzae virus infection	1 (3.1)	0	0	1 (3.1)	0
Rotavirus infection	1 (3.1)	0	0	1 (3.1)	0
Sepsis	1 (3.1)	0	0	0	1 (3.1)
Viral upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Cellulitis of male external genital organ	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cholecystitis infective	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (21.9)	0	0	7 (21.9)	0
Infections					
-Total	6 (18.8)	0	0	6 (18.8)	0
Bacterial sepsis	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Cellulitis of male external genital organ	1 (3.1)	0	0	1 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cholecystitis infective	1 (3.1)	0	0	1 (3.1)	0
Corona virus infection	1 (3.1)	0	0	1 (3.1)	0
Herpes zoster	1 (3.1)	0	0	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	0	0	1 (3.1)	0
Upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Vascular device infection	1 (3.1)	0	0	1 (3.1)	0
Tumour Lysis Syndrome					
-Total	1 (3.1)	0	0	1 (3.1)	0
Tumour lysis syndrome	1 (3.1)	0	0	1 (3.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (9.4)	0	1 (3.1)	1 (3.1)	1 (3.1)
Infections					
-Total	3 (9.4)	0	1 (3.1)	1 (3.1)	1 (3.1)
Campylobacter infection	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile infection	1 (3.1)	0	0	1 (3.1)	0
Pneumonia	1 (3.1)	0	1 (3.1)	0	0
Respiratory tract infection	1 (3.1)	0	0	0	1 (3.1)
Respiratory tract infection viral	1 (3.1)	0	0	1 (3.1)	0
Urinary tract infection	1 (3.1)	0	1 (3.1)	0	0
Vulvovaginal candidiasis	1 (3.1)	0	1 (3.1)	0	0
Cellulitis of male external genital organ	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (6.3)	0	0	2 (6.3)	0
Infections					
-Total	1 (3.1)	0	0	1 (3.1)	0
Campylobacter infection	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Vulvovaginal candidiasis	0	0	0	0	0
Cellulitis of male external genital organ	1 (3.1)	0	0	1 (3.1)	0

Timing: >1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (3.1)	0	0	1 (3.1)	0
Seizure	1 (3.1)	0	0	1 (3.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (71.9)	2 (6.3)	9 (28.1)	4 (12.5)	8 (25.0)
Cytokine Release Syndrome					
-Total	19 (59.4)	3 (9.4)	10 (31.3)	2 (6.3)	4 (12.5)
Cytokine release syndrome	19 (59.4)	3 (9.4)	10 (31.3)	2 (6.3)	4 (12.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (3.1)	0	0	1 (3.1)	0
Febrile neutropenia	1 (3.1)	0	0	1 (3.1)	0
Infections					
-Total	11 (34.4)	0	3 (9.4)	4 (12.5)	4 (12.5)
Clostridium difficile infection	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Bacterial sepsis	1 (3.1)	0	0	0	1 (3.1)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (3.1)	0	0	1 (3.1)	0
Catheter site infection	1 (3.1)	0	0	1 (3.1)	0
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Parainfluenzae virus infection	1 (3.1)	0	0	1 (3.1)	0
Pneumonia	1 (3.1)	0	1 (3.1)	0	0
Respiratory tract infection	1 (3.1)	0	0	0	1 (3.1)
Respiratory tract infection viral	1 (3.1)	0	0	1 (3.1)	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Rotavirus infection	1 (3.1)	0	0	1 (3.1)	0
Sepsis	1 (3.1)	0	0	0	1 (3.1)
Septic embolus	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Urinary tract infection	1 (3.1)	0	1 (3.1)	0	0
Viral upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Vulvovaginal candidiasis	1 (3.1)	0	1 (3.1)	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (6.3)	0	0	2 (6.3)	0
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Seizure	1 (3.1)	0	0	1 (3.1)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	24 (75.0)	0	6 (18.8)	12 (37.5)	6 (18.8)
Cytokine Release Syndrome					
-Total	22 (68.8)	1 (3.1)	9 (28.1)	6 (18.8)	6 (18.8)
Cytokine release syndrome	22 (68.8)	1 (3.1)	9 (28.1)	6 (18.8)	6 (18.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (6.3)	0	0	2 (6.3)	0
Febrile neutropenia	2 (6.3)	0	0	2 (6.3)	0
Infections					
-Total	8 (25.0)	0	1 (3.1)	7 (21.9)	0
Clostridium difficile infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	1 (3.1)	0	0	1 (3.1)	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Cellulitis of male external genital organ	1 (3.1)	0	0	1 (3.1)	0
Cholecystitis infective	1 (3.1)	0	0	1 (3.1)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	2 (6.3)	0	2 (6.3)	0	0
Corona virus infection	1 (3.1)	0	0	1 (3.1)	0
Gastroenteritis	1 (3.1)	0	0	1 (3.1)	0
Herpes zoster	1 (3.1)	0	0	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	0	0	1 (3.1)	0
Upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Vascular device infection	1 (3.1)	0	0	1 (3.1)	0
Serious neurological adverse reactions					
-Total	6 (18.8)	1 (3.1)	3 (9.4)	2 (6.3)	0
Encephalopathy	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Seizure	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Delirium	1 (3.1)	0	1 (3.1)	0	0
Tumour Lysis Syndrome					
-Total	2 (6.3)	0	0	2 (6.3)	0
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Cytokine Release Syndrome					
-Total	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (70.0)	1 (5.0)	5 (25.0)	4 (20.0)	4 (20.0)
Cytokine Release Syndrome					
-Total	14 (70.0)	2 (10.0)	6 (30.0)	2 (10.0)	4 (20.0)
Cytokine release syndrome	14 (70.0)	2 (10.0)	6 (30.0)	2 (10.0)	4 (20.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (10.0)	0	0	2 (10.0)	0
Febrile neutropenia	2 (10.0)	0	0	2 (10.0)	0
Infections					
-Total	5 (25.0)	0	2 (10.0)	3 (15.0)	0
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	1 (5.0)	0	1 (5.0)	0	0

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 1

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis norovirus	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	1 (5.0)	0	0	1 (5.0)	0
Serious neurological adverse reactions					
-Total	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Delirium	1 (5.0)	0	1 (5.0)	0	0
Encephalopathy	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Seizure	1 (5.0)	0	1 (5.0)	0	0
Tumour Lysis Syndrome					
-Total	1 (5.0)	0	0	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (71.4)	0	8 (38.1)	5 (23.8)	2 (9.5)
Cytokine Release Syndrome					
-Total	14 (66.7)	0	9 (42.9)	4 (19.0)	1 (4.8)
Cytokine release syndrome	14 (66.7)	0	9 (42.9)	4 (19.0)	1 (4.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (4.8)	0	0	1 (4.8)	0
Febrile neutropenia	1 (4.8)	0	0	1 (4.8)	0
Infections					
-Total	3 (14.3)	0	1 (4.8)	1 (4.8)	1 (4.8)
Catheter site infection	1 (4.8)	0	0	1 (4.8)	0
Clostridium difficile colitis	1 (4.8)	0	1 (4.8)	0	0

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (4.8)	0	1 (4.8)	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	1 (4.8)	1 (4.8)	0	0	0
Septic embolus	1 (4.8)	0	0	0	1 (4.8)
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Delirium	0	0	0	0	0
Encephalopathy	1 (4.8)	0	0	1 (4.8)	0
Seizure	1 (4.8)	0	1 (4.8)	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (50.0)	2 (12.5)	2 (12.5)	2 (12.5)	2 (12.5)
Cytokine Release Syndrome					
-Total	8 (50.0)	2 (12.5)	2 (12.5)	2 (12.5)	2 (12.5)
Cytokine release syndrome	8 (50.0)	2 (12.5)	2 (12.5)	2 (12.5)	2 (12.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	1 (6.3)	0	1 (6.3)	0	0
Catheter site infection	0	0	0	0	0
Clostridium difficile colitis	1 (6.3)	0	1 (6.3)	0	0

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: >=3

Group term Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Delirium	0	0	0	0	0
Encephalopathy	1 (6.3)	1 (6.3)	0	0	0
Seizure	1 (6.3)	0	0	1 (6.3)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (14.3)	0	0	1 (14.3)	0
Infections					
-Total	1 (14.3)	0	0	1 (14.3)	0
Corona virus infection	1 (14.3)	0	0	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (20.0)	0	1 (5.0)	2 (10.0)	1 (5.0)
Infections					
-Total	4 (20.0)	0	1 (5.0)	2 (10.0)	1 (5.0)
Corona virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	1 (5.0)	0	1 (5.0)	0	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	1 (5.0)	0	0	1 (5.0)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (19.0)	0	0	3 (14.3)	1 (4.8)
Infections					
-Total	3 (14.3)	0	0	2 (9.5)	1 (4.8)
Corona virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Bacterial sepsis	1 (4.8)	0	0	0	1 (4.8)
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	1 (4.8)	0	0	1 (4.8)	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Group term Preferred term	All patients N=21 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	1 (4.8)	0	0	1 (4.8)	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (4.8)	0	0	1 (4.8)	0
Tumour lysis syndrome	1 (4.8)	0	0	1 (4.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (25.0)	0	0	4 (25.0)	0
Infections					
-Total	4 (25.0)	0	0	4 (25.0)	0
Corona virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Cellulitis of male external genital organ	1 (6.3)	0	0	1 (6.3)	0
Cholecystitis infective	0	0	0	0	0
Enterovirus infection	1 (6.3)	0	0	1 (6.3)	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Group term Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	0	0	0	0	0
Rotavirus infection	1 (6.3)	0	0	1 (6.3)	0
Sepsis	0	0	0	0	0
Upper respiratory tract infection	1 (6.3)	0	0	1 (6.3)	0
Vascular device infection	1 (6.3)	0	0	1 (6.3)	0
Viral upper respiratory tract infection	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (5.0)	0	0	1 (5.0)	0
Infections					
-Total	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Number of previous relapses: 1

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (5.0)	0	0	1 (5.0)	0
Seizure	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (9.5)	0	1 (4.8)	0	1 (4.8)
Infections					
-Total	2 (9.5)	0	1 (4.8)	0	1 (4.8)
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Pneumonia	1 (4.8)	0	1 (4.8)	0	0
Respiratory tract infection	1 (4.8)	0	0	0	1 (4.8)
Respiratory tract infection viral	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Number of previous relapses: 2

Group term Preferred term	All patients N=21 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (12.5)	0	0	2 (12.5)	0
Infections					
-Total	2 (12.5)	0	0	2 (12.5)	0
Campylobacter infection	1 (6.3)	0	0	1 (6.3)	0
Cellulitis of male external genital organ	1 (6.3)	0	0	1 (6.3)	0
Clostridium difficile infection	1 (6.3)	0	0	1 (6.3)	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	1 (6.3)	0	0	1 (6.3)	0
Urinary tract infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Vulvovaginal candidiasis	1 (6.3)	0	1 (6.3)	0	0

Timing: >1 year post CTL019 infusion, Number of previous relapses: >=3

Group term Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	0	1 (14.3)	1 (14.3)	3 (42.9)
Cytokine Release Syndrome					
-Total	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	1 (14.3)	0	0	1 (14.3)	0
Corona virus infection	1 (14.3)	0	0	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (80.0)	1 (5.0)	5 (25.0)	5 (25.0)	5 (25.0)
Cytokine Release Syndrome					
-Total	14 (70.0)	2 (10.0)	6 (30.0)	2 (10.0)	4 (20.0)
Cytokine release syndrome	14 (70.0)	2 (10.0)	6 (30.0)	2 (10.0)	4 (20.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (10.0)	0	0	2 (10.0)	0
Febrile neutropenia	2 (10.0)	0	0	2 (10.0)	0
Infections					
-Total	7 (35.0)	0	2 (10.0)	4 (20.0)	1 (5.0)
Corona virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	1 (5.0)	0	1 (5.0)	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis norovirus	1 (5.0)	0	1 (5.0)	0	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic embolus	0	0	0	0	0
Staphylococcal infection	1 (5.0)	0	0	1 (5.0)	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	1 (5.0)	0	0	1 (5.0)	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (20.0)	0	2 (10.0)	2 (10.0)	0
Delirium	1 (5.0)	0	1 (5.0)	0	0
Encephalopathy	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Seizure	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Tumour Lysis Syndrome					
-Total	1 (5.0)	0	0	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	17 (81.0)	0	7 (33.3)	6 (28.6)	4 (19.0)
Cytokine Release Syndrome					
-Total	14 (66.7)	0	9 (42.9)	4 (19.0)	1 (4.8)
Cytokine release syndrome	14 (66.7)	0	9 (42.9)	4 (19.0)	1 (4.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (4.8)	0	0	1 (4.8)	0
Febrile neutropenia	1 (4.8)	0	0	1 (4.8)	0
Infections					
-Total	7 (33.3)	0	2 (9.5)	2 (9.5)	3 (14.3)
Corona virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (4.8)	0	0	0	1 (4.8)
Campylobacter infection	0	0	0	0	0
Catheter site infection	1 (4.8)	0	0	1 (4.8)	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	1 (4.8)	0	0	1 (4.8)	0
Clostridium difficile colitis	1 (4.8)	0	1 (4.8)	0	0
Clostridium difficile infection	1 (4.8)	0	1 (4.8)	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	1 (4.8)	0	0	1 (4.8)	0
Pneumonia	1 (4.8)	0	1 (4.8)	0	0
Respiratory tract infection	1 (4.8)	0	0	0	1 (4.8)
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	1 (4.8)	1 (4.8)	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

Group term Preferred term	All patients N=21 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic embolus	1 (4.8)	0	0	0	1 (4.8)
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Delirium	0	0	0	0	0
Encephalopathy	1 (4.8)	0	0	1 (4.8)	0
Seizure	1 (4.8)	0	1 (4.8)	0	0
Tumour Lysis Syndrome					
-Total	1 (4.8)	0	0	1 (4.8)	0
Tumour lysis syndrome	1 (4.8)	0	0	1 (4.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (56.3)	1 (6.3)	2 (12.5)	4 (25.0)	2 (12.5)
Cytokine Release Syndrome					
-Total	8 (50.0)	2 (12.5)	2 (12.5)	2 (12.5)	2 (12.5)
Cytokine release syndrome	8 (50.0)	2 (12.5)	2 (12.5)	2 (12.5)	2 (12.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	4 (25.0)	0	0	4 (25.0)	0
Corona virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	1 (6.3)	0	0	1 (6.3)	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	1 (6.3)	0	0	1 (6.3)	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	1 (6.3)	0	1 (6.3)	0	0
Clostridium difficile infection	1 (6.3)	0	0	1 (6.3)	0
Enterovirus infection	1 (6.3)	0	0	1 (6.3)	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	1 (6.3)	0	0	1 (6.3)	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	1 (6.3)	0	0	1 (6.3)	0
Sepsis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Upper respiratory tract infection	1 (6.3)	0	0	1 (6.3)	0
Urinary tract infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Vascular device infection	1 (6.3)	0	0	1 (6.3)	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	1 (6.3)	0	1 (6.3)	0	0
Serious neurological adverse reactions					
-Total	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Delirium	0	0	0	0	0
Encephalopathy	1 (6.3)	1 (6.3)	0	0	0
Seizure	1 (6.3)	0	0	1 (6.3)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217a
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (10.0)	0	0	2 (10.0)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	2 (10.0)	0	0	2 (10.0)	0
Bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Device related infection	1 (5.0)	0	0	1 (5.0)	0
Bronchitis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217a
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (3.0)	0	0	1 (3.0)	0
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Infections					
-Total	1 (3.0)	0	0	0	1 (3.0)
Bacteraemia	0	0	0	0	0
Device related infection	0	0	0	0	0
Bronchitis	1 (3.0)	0	1 (3.0)	0	0
Necrotising fasciitis	0	0	0	0	0
Staphylococcal infection	1 (3.0)	0	0	0	1 (3.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217a
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (12.5)	0	0	1 (12.5)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	1 (12.5)	0	0	1 (12.5)	0
Bacteraemia	0	0	0	0	0
Device related infection	0	0	0	0	0
Bronchitis	0	0	0	0	0
Necrotising fasciitis	1 (12.5)	0	0	1 (12.5)	0

Age: >=18

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217b
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (6.9)	0	0	1 (3.4)	1 (3.4)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (3.4)	0	0	1 (3.4)	0
Pancytopenia	1 (3.4)	0	0	1 (3.4)	0
Infections					
-Total	1 (3.4)	0	0	0	1 (3.4)
Bronchitis	1 (3.4)	0	1 (3.4)	0	0
Staphylococcal infection	1 (3.4)	0	0	0	1 (3.4)
Bacteraemia	0	0	0	0	0
Device related infection	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217b
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (9.4)	0	0	3 (9.4)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	3 (9.4)	0	0	3 (9.4)	0
Bronchitis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Device related infection	1 (3.1)	0	0	1 (3.1)	0
Necrotising fasciitis	1 (3.1)	0	0	1 (3.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217c
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (10.0)	0	0	4 (8.0)	1 (2.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (2.0)	0	0	1 (2.0)	0
Pancytopenia	1 (2.0)	0	0	1 (2.0)	0
Infections					
-Total	4 (8.0)	0	0	3 (6.0)	1 (2.0)
Bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Bronchitis	1 (2.0)	0	1 (2.0)	0	0
Device related infection	1 (2.0)	0	0	1 (2.0)	0
Necrotising fasciitis	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal infection	1 (2.0)	0	0	0	1 (2.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217c
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217c
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one AE	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 217d
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (4.3)	0	0	1 (4.3)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	1 (4.3)	0	0	1 (4.3)	0
Bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Bronchitis	0	0	0	0	0
Device related infection	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217d
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=38				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (10.5)	0	0	3 (7.9)	1 (2.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (2.6)	0	0	1 (2.6)	0
Pancytopenia	1 (2.6)	0	0	1 (2.6)	0
Infections					
-Total	3 (7.9)	0	0	2 (5.3)	1 (2.6)
Bacteraemia	0	0	0	0	0
Bronchitis	1 (2.6)	0	1 (2.6)	0	0
Device related infection	1 (2.6)	0	0	1 (2.6)	0
Necrotising fasciitis	1 (2.6)	0	0	1 (2.6)	0
Staphylococcal infection	1 (2.6)	0	0	0	1 (2.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217e
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217e
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (9.3)	0	0	4 (7.4)	1 (1.9)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.9)	0	0	1 (1.9)	0
Pancytopenia	1 (1.9)	0	0	1 (1.9)	0
Infections					
-Total	4 (7.4)	0	0	3 (5.6)	1 (1.9)
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Bronchitis	1 (1.9)	0	1 (1.9)	0	0
Device related infection	1 (1.9)	0	0	1 (1.9)	0
Necrotising fasciitis	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal infection	1 (1.9)	0	0	0	1 (1.9)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217f
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217f
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (8.5)	0	0	4 (6.8)	1 (1.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.7)	0	0	1 (1.7)	0
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	4 (6.8)	0	0	3 (5.1)	1 (1.7)
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Device related infection	1 (1.7)	0	0	1 (1.7)	0
Necrotising fasciitis	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal infection	1 (1.7)	0	0	0	1 (1.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217g
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217g
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (8.6)	0	0	4 (6.9)	1 (1.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.7)	0	0	1 (1.7)	0
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	4 (6.9)	0	0	3 (5.2)	1 (1.7)
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Device related infection	1 (1.7)	0	0	1 (1.7)	0
Necrotising fasciitis	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal infection	1 (1.7)	0	0	0	1 (1.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217h
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217h
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (8.3)	0	0	4 (6.7)	1 (1.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.7)	0	0	1 (1.7)	0
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	4 (6.7)	0	0	3 (5.0)	1 (1.7)
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Device related infection	1 (1.7)	0	0	1 (1.7)	0
Necrotising fasciitis	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal infection	1 (1.7)	0	0	0	1 (1.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217i
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (25.0)	0	0	1 (25.0)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	1 (25.0)	0	0	1 (25.0)	0
Bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Bronchitis	0	0	0	0	0
Device related infection	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217i
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (7.0)	0	0	3 (5.3)	1 (1.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.8)	0	0	1 (1.8)	0
Pancytopenia	1 (1.8)	0	0	1 (1.8)	0
Infections					
-Total	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Bacteraemia	0	0	0	0	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Necrotising fasciitis	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217j
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (5.6)	0	0	1 (5.6)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (5.6)	0	0	1 (5.6)	0
Pancytopenia	1 (5.6)	0	0	1 (5.6)	0
Infections					
-Total	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchitis	0	0	0	0	0
Device related infection	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217j
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (9.3)	0	0	3 (7.0)	1 (2.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	4 (9.3)	0	0	3 (7.0)	1 (2.3)
Bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Bronchitis	1 (2.3)	0	1 (2.3)	0	0
Device related infection	1 (2.3)	0	0	1 (2.3)	0
Necrotising fasciitis	1 (2.3)	0	0	1 (2.3)	0
Staphylococcal infection	1 (2.3)	0	0	0	1 (2.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217k
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (8.2)	0	0	4 (6.6)	1 (1.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.6)	0	0	1 (1.6)	0
Pancytopenia	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	4 (6.6)	0	0	3 (4.9)	1 (1.6)
Bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Bronchitis	1 (1.6)	0	1 (1.6)	0	0
Device related infection	1 (1.6)	0	0	1 (1.6)	0
Necrotising fasciitis	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal infection	1 (1.6)	0	0	0	1 (1.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217l
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (14.3)	0	0	3 (10.7)	1 (3.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	4 (14.3)	0	0	3 (10.7)	1 (3.6)
Bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Bronchitis	1 (3.6)	0	1 (3.6)	0	0
Device related infection	1 (3.6)	0	0	1 (3.6)	0
Necrotising fasciitis	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal infection	1 (3.6)	0	0	0	1 (3.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217l
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (3.0)	0	0	1 (3.0)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (3.0)	0	0	1 (3.0)	0
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Infections					
-Total	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchitis	0	0	0	0	0
Device related infection	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217m
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 217m
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=47				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (10.6)	0	0	4 (8.5)	1 (2.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (2.1)	0	0	1 (2.1)	0
Pancytopenia	1 (2.1)	0	0	1 (2.1)	0
Infections					
-Total	4 (8.5)	0	0	3 (6.4)	1 (2.1)
Bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Bronchitis	1 (2.1)	0	1 (2.1)	0	0
Device related infection	1 (2.1)	0	0	1 (2.1)	0
Necrotising fasciitis	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal infection	1 (2.1)	0	0	0	1 (2.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217n
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (14.3)	0	0	2 (9.5)	1 (4.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (4.8)	0	0	1 (4.8)	0
Pancytopenia	1 (4.8)	0	0	1 (4.8)	0
Infections					
-Total	2 (9.5)	0	0	1 (4.8)	1 (4.8)
Bronchitis	1 (4.8)	0	1 (4.8)	0	0
Device related infection	1 (4.8)	0	0	1 (4.8)	0
Staphylococcal infection	1 (4.8)	0	0	0	1 (4.8)
Bacteraemia	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217n
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (5.0)	0	0	2 (5.0)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	2 (5.0)	0	0	2 (5.0)	0
Bronchitis	0	0	0	0	0
Device related infection	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Necrotising fasciitis	1 (2.5)	0	0	1 (2.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217o
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 217o
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (8.8)	0	0	4 (7.0)	1 (1.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.8)	0	0	1 (1.8)	0
Pancytopenia	1 (1.8)	0	0	1 (1.8)	0
Infections					
-Total	4 (7.0)	0	0	3 (5.3)	1 (1.8)
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Necrotising fasciitis	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217p
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217p
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (8.8)	0	0	4 (7.0)	1 (1.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.8)	0	0	1 (1.8)	0
Pancytopenia	1 (1.8)	0	0	1 (1.8)	0
Infections					
-Total	4 (7.0)	0	0	3 (5.3)	1 (1.8)
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Necrotising fasciitis	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217q
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (9.7)	0	0	3 (9.7)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (3.2)	0	0	1 (3.2)	0
Pancytopenia	1 (3.2)	0	0	1 (3.2)	0
Infections					
-Total	2 (6.5)	0	0	2 (6.5)	0
Bacteraemia	1 (3.2)	0	0	1 (3.2)	0
Device related infection	1 (3.2)	0	0	1 (3.2)	0
Bronchitis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217q
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (3.4)	0	0	1 (3.4)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	1 (3.4)	0	0	1 (3.4)	0
Bacteraemia	0	0	0	0	0
Device related infection	0	0	0	0	0
Bronchitis	0	0	0	0	0
Necrotising fasciitis	1 (3.4)	0	0	1 (3.4)	0
Staphylococcal infection	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217q
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	1 (100)	0	0	0	1 (100)
Bacteraemia	0	0	0	0	0
Device related infection	0	0	0	0	0
Bronchitis	1 (100)	0	1 (100)	0	0
Necrotising fasciitis	0	0	0	0	0

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	1 (100)	0	0	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217r
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217r
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217r
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (5.3)	0	0	1 (5.3)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (5.3)	0	0	1 (5.3)	0
Pancytopenia	1 (5.3)	0	0	1 (5.3)	0
Infections					
-Total	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchitis	0	0	0	0	0
Device related infection	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0

Number of previous relapses: 2

Group term Preferred term	All patients N=19 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217r
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (25.0)	0	0	3 (18.8)	1 (6.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	4 (25.0)	0	0	3 (18.8)	1 (6.3)
Bacteraemia	1 (6.3)	0	0	1 (6.3)	0
Bronchitis	1 (6.3)	0	1 (6.3)	0	0
Device related infection	1 (6.3)	0	0	1 (6.3)	0
Necrotising fasciitis	1 (6.3)	0	0	1 (6.3)	0

Number of previous relapses: >=3

Group term Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	1 (6.3)	0	0	0	1 (6.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219a
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (77.3)	1 (4.5)	3 (13.6)	9 (40.9)	4 (18.2)
Cytokine Release Syndrome					
-Total	12 (54.5)	2 (9.1)	5 (22.7)	3 (13.6)	2 (9.1)
Cytokine release syndrome	12 (54.5)	2 (9.1)	5 (22.7)	3 (13.6)	2 (9.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (4.5)	0	0	1 (4.5)	0
Febrile neutropenia	1 (4.5)	0	0	1 (4.5)	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	10 (45.5)	0	1 (4.5)	7 (31.8)	2 (9.1)
Clostridium difficile infection	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Device related infection	2 (9.1)	0	0	2 (9.1)	0

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Alpha haemolytic streptococcal infection	1 (4.5)	0	0	1 (4.5)	0
Bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Bronchopulmonary aspergillosis	1 (4.5)	0	0	1 (4.5)	0
Campylobacter infection	1 (4.5)	0	0	1 (4.5)	0
Catheter site infection	1 (4.5)	0	0	1 (4.5)	0
Corona virus infection	1 (4.5)	0	0	1 (4.5)	0
Enterococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Enterovirus infection	1 (4.5)	0	0	1 (4.5)	0
Parainfluenzae virus infection	1 (4.5)	0	0	1 (4.5)	0
Pneumonia	1 (4.5)	0	0	1 (4.5)	0
Respiratory tract infection	1 (4.5)	0	0	0	1 (4.5)
Respiratory tract infection viral	1 (4.5)	0	0	1 (4.5)	0
Rhinovirus infection	1 (4.5)	1 (4.5)	0	0	0
Rotavirus infection	1 (4.5)	0	0	1 (4.5)	0
Septic embolus	1 (4.5)	0	0	0	1 (4.5)
Staphylococcal infection	1 (4.5)	0	0	1 (4.5)	0
Streptococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary tract infection	1 (4.5)	0	1 (4.5)	0	0
Vulvovaginal candidiasis	1 (4.5)	0	1 (4.5)	0	0
Abscess limb	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (9.1)	0	0	2 (9.1)	0
Seizure	2 (9.1)	0	0	2 (9.1)	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (4.5)	0	0	1 (4.5)	0

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	1 (4.5)	0	0	1 (4.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219a
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (74.4)	0	7 (17.9)	13 (33.3)	9 (23.1)
Cytokine Release Syndrome					
-Total	23 (59.0)	2 (5.1)	11 (28.2)	5 (12.8)	5 (12.8)
Cytokine release syndrome	23 (59.0)	2 (5.1)	11 (28.2)	5 (12.8)	5 (12.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (10.3)	0	0	3 (7.7)	1 (2.6)
Febrile neutropenia	2 (5.1)	0	0	2 (5.1)	0
Pancytopenia	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Infections					
-Total	16 (41.0)	0	2 (5.1)	10 (25.6)	4 (10.3)
Clostridium difficile infection	0	0	0	0	0
Device related infection	2 (5.1)	0	0	2 (5.1)	0

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Parainfluenzae virus infection	1 (2.6)	0	1 (2.6)	0	0
Pneumonia	2 (5.1)	0	2 (5.1)	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Streptococcal bacteraemia	0	0	0	0	0

Age: >=10 years to <18 years

Group term Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary tract infection	1 (2.6)	0	0	1 (2.6)	0
Vulvovaginal candidiasis	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	1 (2.6)	0	1 (2.6)	0	0
Candida sepsis	1 (2.6)	0	0	0	1 (2.6)
Cellulitis	1 (2.6)	0	0	1 (2.6)	0
Cellulitis of male external genital organ	1 (2.6)	0	0	1 (2.6)	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	2 (5.1)	0	2 (5.1)	0	0
Escherichia bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis norovirus	1 (2.6)	0	1 (2.6)	0	0
Herpes zoster	1 (2.6)	0	0	1 (2.6)	0
Klebsiella sepsis	1 (2.6)	0	0	0	1 (2.6)
Necrotising fasciitis	0	0	0	0	0

Age: >=10 years to <18 years

Group term Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	1 (2.6)	0	0	1 (2.6)	0
Respiratory syncytial virus bronchitis	1 (2.6)	0	0	1 (2.6)	0
Sepsis	1 (2.6)	0	0	0	1 (2.6)
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	2 (5.1)	0	0	2 (5.1)	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	1 (2.6)	0	0	1 (2.6)	0
Vascular device infection	1 (2.6)	0	0	1 (2.6)	0
Viral upper respiratory tract infection	1 (2.6)	0	0	1 (2.6)	0
Serious neurological adverse reactions					
-Total	7 (17.9)	1 (2.6)	3 (7.7)	3 (7.7)	0
Seizure	2 (5.1)	0	2 (5.1)	0	0
Delirium	1 (2.6)	0	1 (2.6)	0	0
Encephalopathy	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Mental status changes	1 (2.6)	0	0	1 (2.6)	0
Tumour Lysis Syndrome					
-Total	1 (2.6)	0	0	1 (2.6)	0

Age: >=10 years to <18 years

Group term Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	1 (2.6)	0	0	1 (2.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219a
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (78.6)	0	0	3 (21.4)	8 (57.1)
Cytokine Release Syndrome					
-Total	6 (42.9)	0	3 (21.4)	0	3 (21.4)
Cytokine release syndrome	6 (42.9)	0	3 (21.4)	0	3 (21.4)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	8 (57.1)	0	0	3 (21.4)	5 (35.7)
Clostridium difficile infection	0	0	0	0	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	1 (7.1)	0	0	0	1 (7.1)
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Streptococcal bacteraemia	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Abscess limb	1 (7.1)	0	0	1 (7.1)	0
Bacterial sepsis	1 (7.1)	0	0	0	1 (7.1)
Bronchitis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	1 (7.1)	0	0	1 (7.1)	0
Clostridium difficile colitis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	1 (7.1)	0	0	0	1 (7.1)
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	1 (7.1)	0	0	0	1 (7.1)

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Necrotising fasciitis	1 (7.1)	0	0	1 (7.1)	0
Pneumonia fungal	1 (7.1)	0	1 (7.1)	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Sepsis	1 (7.1)	0	0	0	1 (7.1)
Serratia infection	1 (7.1)	0	0	1 (7.1)	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal scalded skin syndrome	1 (7.1)	0	1 (7.1)	0	0
Staphylococcal sepsis	1 (7.1)	0	0	0	1 (7.1)
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219b
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (70.0)	1 (2.5)	5 (12.5)	11 (27.5)	11 (27.5)
Cytokine Release Syndrome					
-Total	19 (47.5)	3 (7.5)	8 (20.0)	3 (7.5)	5 (12.5)
Cytokine release syndrome	19 (47.5)	3 (7.5)	8 (20.0)	3 (7.5)	5 (12.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (7.5)	0	0	3 (7.5)	0
Febrile neutropenia	2 (5.0)	0	0	2 (5.0)	0
Pancytopenia	1 (2.5)	0	0	1 (2.5)	0
Infections					
-Total	13 (32.5)	0	1 (2.5)	6 (15.0)	6 (15.0)
Klebsiella sepsis	2 (5.0)	0	0	0	2 (5.0)
Respiratory syncytial virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Candida sepsis	1 (2.5)	0	0	0	1 (2.5)
Cellulitis of male external genital organ	1 (2.5)	0	0	1 (2.5)	0
Cholecystitis infective	1 (2.5)	0	0	1 (2.5)	0
Clostridium difficile infection	1 (2.5)	0	1 (2.5)	0	0
Corona virus infection	1 (2.5)	0	0	1 (2.5)	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis	1 (2.5)	0	0	1 (2.5)	0
Herpes zoster	1 (2.5)	0	0	1 (2.5)	0
Pneumonia	1 (2.5)	0	0	0	1 (2.5)
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Serratia infection	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal infection	1 (2.5)	0	0	0	1 (2.5)
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	5 (12.5)	0	2 (5.0)	3 (7.5)	0
Encephalopathy	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Seizure	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219b
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (82.9)	0	5 (14.3)	14 (40.0)	10 (28.6)
Cytokine Release Syndrome					
-Total	22 (62.9)	1 (2.9)	11 (31.4)	5 (14.3)	5 (14.3)
Cytokine release syndrome	22 (62.9)	1 (2.9)	11 (31.4)	5 (14.3)	5 (14.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Febrile neutropenia	1 (2.9)	0	0	1 (2.9)	0
Pancytopenia	1 (2.9)	0	0	0	1 (2.9)
Infections					
-Total	21 (60.0)	0	2 (5.7)	14 (40.0)	5 (14.3)
Klebsiella sepsis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Bronchitis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile infection	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Corona virus infection	0	0	0	0	0
Device related infection	3 (8.6)	0	0	3 (8.6)	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Pneumonia	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Pneumonia fungal	1 (2.9)	0	1 (2.9)	0	0
Sepsis	1 (2.9)	0	0	0	1 (2.9)
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal infection	2 (5.7)	0	0	2 (5.7)	0
Urinary tract infection	1 (2.9)	0	1 (2.9)	0	0
Viral upper respiratory tract infection	0	0	0	0	0

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (2.9)	0	0	1 (2.9)	0
Alpha haemolytic streptococcal infection	1 (2.9)	0	0	1 (2.9)	0
Bacterial sepsis	1 (2.9)	0	0	0	1 (2.9)
Bronchopulmonary aspergillosis	1 (2.9)	0	0	1 (2.9)	0
Campylobacter infection	1 (2.9)	0	0	1 (2.9)	0
Catheter site infection	1 (2.9)	0	0	1 (2.9)	0
Cellulitis	1 (2.9)	0	0	1 (2.9)	0
Clostridium difficile colitis	2 (5.7)	0	2 (5.7)	0	0
Enterococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Enterovirus infection	1 (2.9)	0	0	1 (2.9)	0
Escherichia bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Escherichia sepsis	1 (2.9)	0	0	0	1 (2.9)
Escherichia urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Necrotising fasciitis	1 (2.9)	0	0	1 (2.9)	0
Parainfluenzae virus infection	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Respiratory syncytial virus bronchitis	1 (2.9)	0	0	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	0	0	1 (2.9)

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection viral	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	1 (2.9)	1 (2.9)	0	0	0
Rotavirus infection	1 (2.9)	0	0	1 (2.9)	0
Septic embolus	1 (2.9)	0	0	0	1 (2.9)
Staphylococcal scalded skin syndrome	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Streptococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Vascular device infection	1 (2.9)	0	0	1 (2.9)	0
Vulvovaginal candidiasis	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					
-Total	4 (11.4)	1 (2.9)	1 (2.9)	2 (5.7)	0
Encephalopathy	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Seizure	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Mental status changes	0	0	0	0	0
Delirium	1 (2.9)	0	1 (2.9)	0	0
Tumour Lysis Syndrome					
-Total	2 (5.7)	0	0	2 (5.7)	0

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (5.7)	0	0	2 (5.7)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (76.7)	1 (1.7)	9 (15.0)	19 (31.7)	17 (28.3)
Cytokine Release Syndrome					
-Total	33 (55.0)	3 (5.0)	14 (23.3)	7 (11.7)	9 (15.0)
Cytokine release syndrome	33 (55.0)	3 (5.0)	14 (23.3)	7 (11.7)	9 (15.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (6.7)	0	0	4 (6.7)	0
Febrile neutropenia	3 (5.0)	0	0	3 (5.0)	0
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	26 (43.3)	0	3 (5.0)	15 (25.0)	8 (13.3)
Pneumonia	4 (6.7)	0	2 (3.3)	1 (1.7)	1 (1.7)
Clostridium difficile infection	3 (5.0)	0	2 (3.3)	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Device related infection	2 (3.3)	0	0	2 (3.3)	0
Parainfluenzae virus infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Respiratory syncytial virus infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Staphylococcal bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Staphylococcal infection	2 (3.3)	0	0	1 (1.7)	1 (1.7)
Urinary tract infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Bronchopulmonary aspergillosis	1 (1.7)	0	0	1 (1.7)	0
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Candida sepsis	1 (1.7)	0	0	0	1 (1.7)
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Clostridium difficile colitis	1 (1.7)	0	1 (1.7)	0	0
Corona virus infection	1 (1.7)	0	0	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Escherichia bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Escherichia sepsis	1 (1.7)	0	0	0	1 (1.7)
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Klebsiella sepsis	1 (1.7)	0	0	0	1 (1.7)
Necrotising fasciitis	1 (1.7)	0	0	1 (1.7)	0
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Respiratory syncytial virus bronchitis	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Rhinovirus infection	1 (1.7)	1 (1.7)	0	0	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Serratia infection	1 (1.7)	0	0	1 (1.7)	0
Streptococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Viral upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	1 (1.7)	0	1 (1.7)	0	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	6 (10.0)	0	2 (3.3)	4 (6.7)	0
Encephalopathy	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Seizure	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Delirium	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (66.7)	0	1 (16.7)	2 (33.3)	1 (16.7)
Cytokine Release Syndrome					
-Total	3 (50.0)	0	3 (50.0)	0	0
Cytokine release syndrome	3 (50.0)	0	3 (50.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Pneumonia	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	0	0	0	0	0
Device related infection	1 (16.7)	0	0	1 (16.7)	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	1 (16.7)	0	0	1 (16.7)	0
Urinary tract infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Corona virus infection	0	0	0	0	0

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Serratia infection	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	0	0	0	0	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	1 (16.7)	0	0	1 (16.7)	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	1 (16.7)	0	0	1 (16.7)	0
Herpes zoster	1 (16.7)	0	0	1 (16.7)	0
Respiratory tract infection	1 (16.7)	0	0	0	1 (16.7)
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Delirium	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (77.8)	0	0	4 (44.4)	3 (33.3)
Cytokine Release Syndrome					
-Total	5 (55.6)	1 (11.1)	2 (22.2)	1 (11.1)	1 (11.1)
Cytokine release syndrome	5 (55.6)	1 (11.1)	2 (22.2)	1 (11.1)	1 (11.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (11.1)	0	0	0	1 (11.1)
Febrile neutropenia	0	0	0	0	0
Pancytopenia	1 (11.1)	0	0	0	1 (11.1)
Infections					
-Total	5 (55.6)	0	0	3 (33.3)	2 (22.2)
Pneumonia	0	0	0	0	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Device related infection	1 (11.1)	0	0	1 (11.1)	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	1 (11.1)	0	1 (11.1)	0	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Corona virus infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Klebsiella sepsis	1 (11.1)	0	0	0	1 (11.1)
Necrotising fasciitis	0	0	0	0	0
Pneumonia fungal	1 (11.1)	0	1 (11.1)	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	1 (11.1)	0	0	0	1 (11.1)
Septic embolus	0	0	0	0	0
Serratia infection	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Abscess limb	1 (11.1)	0	0	1 (11.1)	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Escherichia urinary tract infection	1 (11.1)	0	0	1 (11.1)	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal sepsis	1 (11.1)	0	0	0	1 (11.1)
Vascular device infection	1 (11.1)	0	0	1 (11.1)	0
Serious neurological adverse reactions					
-Total	3 (33.3)	1 (11.1)	1 (11.1)	1 (11.1)	0
Encephalopathy	1 (11.1)	1 (11.1)	0	0	0
Seizure	1 (11.1)	0	1 (11.1)	0	0
Delirium	1 (11.1)	0	1 (11.1)	0	0
Mental status changes	1 (11.1)	0	0	1 (11.1)	0
Tumour Lysis Syndrome					

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (11.1)	0	0	1 (11.1)	0
Tumour lysis syndrome	1 (11.1)	0	0	1 (11.1)	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219d
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (73.3)	0	4 (13.3)	11 (36.7)	7 (23.3)
Cytokine Release Syndrome					
-Total	16 (53.3)	1 (3.3)	9 (30.0)	3 (10.0)	3 (10.0)
Cytokine release syndrome	16 (53.3)	1 (3.3)	9 (30.0)	3 (10.0)	3 (10.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Febrile neutropenia	1 (3.3)	0	0	1 (3.3)	0
Pancytopenia	1 (3.3)	0	0	0	1 (3.3)
Infections					
-Total	12 (40.0)	0	0	8 (26.7)	4 (13.3)
Bacteraemia	2 (6.7)	0	0	2 (6.7)	0
Candida sepsis	1 (3.3)	0	0	0	1 (3.3)

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (3.3)	0	0	1 (3.3)	0
Corona virus infection	1 (3.3)	0	0	1 (3.3)	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Enterococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Escherichia sepsis	1 (3.3)	0	0	0	1 (3.3)
Escherichia urinary tract infection	1 (3.3)	0	0	1 (3.3)	0
Gastroenteritis norovirus	1 (3.3)	0	1 (3.3)	0	0
Klebsiella sepsis	1 (3.3)	0	0	0	1 (3.3)
Parainfluenzae virus infection	1 (3.3)	0	1 (3.3)	0	0
Pneumonia	1 (3.3)	0	1 (3.3)	0	0
Pneumonia fungal	1 (3.3)	0	0	1 (3.3)	0
Respiratory syncytial virus bronchitis	1 (3.3)	0	0	1 (3.3)	0
Respiratory syncytial virus infection	1 (3.3)	0	0	1 (3.3)	0
Sepsis	1 (3.3)	0	0	0	1 (3.3)
Serratia infection	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal infection	1 (3.3)	0	0	1 (3.3)	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Urinary tract infection	1 (3.3)	0	0	1 (3.3)	0
Viral upper respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (13.3)	0	2 (6.7)	2 (6.7)	0
Seizure	2 (6.7)	0	2 (6.7)	0	0
Delirium	1 (3.3)	0	1 (3.3)	0	0
Encephalopathy	1 (3.3)	0	0	1 (3.3)	0
Mental status changes	1 (3.3)	0	0	1 (3.3)	0
Tumour Lysis Syndrome					
-Total	2 (6.7)	0	0	2 (6.7)	0

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (6.7)	0	0	2 (6.7)	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219d
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (77.8)	1 (2.2)	6 (13.3)	14 (31.1)	14 (31.1)
Cytokine Release Syndrome					
-Total	25 (55.6)	3 (6.7)	10 (22.2)	5 (11.1)	7 (15.6)
Cytokine release syndrome	25 (55.6)	3 (6.7)	10 (22.2)	5 (11.1)	7 (15.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (6.7)	0	0	3 (6.7)	0
Febrile neutropenia	2 (4.4)	0	0	2 (4.4)	0
Pancytopenia	1 (2.2)	0	0	1 (2.2)	0
Infections					
-Total	22 (48.9)	0	3 (6.7)	12 (26.7)	7 (15.6)
Bacteraemia	0	0	0	0	0
Candida sepsis	0	0	0	0	0

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cellulitis of male external genital organ	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Device related infection	3 (6.7)	0	0	3 (6.7)	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Klebsiella sepsis	1 (2.2)	0	0	0	1 (2.2)
Parainfluenzae virus infection	1 (2.2)	0	0	1 (2.2)	0
Pneumonia	3 (6.7)	0	1 (2.2)	1 (2.2)	1 (2.2)
Pneumonia fungal	1 (2.2)	0	1 (2.2)	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	1 (2.2)	0	1 (2.2)	0	0
Sepsis	1 (2.2)	0	0	0	1 (2.2)
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal infection	2 (4.4)	0	0	1 (2.2)	1 (2.2)

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Streptococcal bacteraemia	0	0	0	0	0
Urinary tract infection	1 (2.2)	0	1 (2.2)	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Abscess limb	1 (2.2)	0	0	1 (2.2)	0
Alpha haemolytic streptococcal infection	1 (2.2)	0	0	1 (2.2)	0
Bacterial sepsis	1 (2.2)	0	0	0	1 (2.2)
Bronchitis	1 (2.2)	0	1 (2.2)	0	0
Bronchopulmonary aspergillosis	1 (2.2)	0	0	1 (2.2)	0
Campylobacter infection	1 (2.2)	0	0	1 (2.2)	0
Catheter site infection	1 (2.2)	0	0	1 (2.2)	0
Cellulitis	1 (2.2)	0	0	1 (2.2)	0
Cholecystitis infective	1 (2.2)	0	0	1 (2.2)	0
Clostridium difficile colitis	2 (4.4)	0	2 (4.4)	0	0
Clostridium difficile infection	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Enterovirus infection	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis	1 (2.2)	0	0	1 (2.2)	0
Herpes zoster	1 (2.2)	0	0	1 (2.2)	0
Necrotising fasciitis	1 (2.2)	0	0	1 (2.2)	0

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	1 (2.2)	0	0	0	1 (2.2)
Respiratory tract infection viral	1 (2.2)	0	0	1 (2.2)	0
Rhinovirus infection	1 (2.2)	1 (2.2)	0	0	0
Rotavirus infection	1 (2.2)	0	0	1 (2.2)	0
Septic embolus	1 (2.2)	0	0	0	1 (2.2)
Staphylococcal scalded skin syndrome	1 (2.2)	0	1 (2.2)	0	0
Staphylococcal sepsis	1 (2.2)	0	0	0	1 (2.2)
Upper respiratory tract infection	1 (2.2)	0	0	1 (2.2)	0
Vascular device infection	1 (2.2)	0	0	1 (2.2)	0
Vulvovaginal candidiasis	1 (2.2)	0	1 (2.2)	0	0
Serious neurological adverse reactions					
-Total	5 (11.1)	1 (2.2)	1 (2.2)	3 (6.7)	0
Seizure	2 (4.4)	0	0	2 (4.4)	0
Delirium	0	0	0	0	0
Encephalopathy	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219e
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (75.0)	0	1 (12.5)	1 (12.5)	4 (50.0)
Cytokine Release Syndrome					
-Total	5 (62.5)	0	2 (25.0)	0	3 (37.5)
Cytokine release syndrome	5 (62.5)	0	2 (25.0)	0	3 (37.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Corona virus infection	1 (12.5)	0	0	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Respiratory syncytial virus infection	1 (12.5)	0	0	1 (12.5)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Serratia infection	0	0	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219e
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (76.1)	1 (1.5)	9 (13.4)	24 (35.8)	17 (25.4)
Cytokine Release Syndrome					
-Total	36 (53.7)	4 (6.0)	17 (25.4)	8 (11.9)	7 (10.4)
Cytokine release syndrome	36 (53.7)	4 (6.0)	17 (25.4)	8 (11.9)	7 (10.4)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (7.5)	0	0	4 (6.0)	1 (1.5)
Febrile neutropenia	3 (4.5)	0	0	3 (4.5)	0
Pancytopenia	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Infections					
-Total	31 (46.3)	0	3 (4.5)	18 (26.9)	10 (14.9)
Cellulitis	0	0	0	0	0
Corona virus infection	0	0	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	1 (1.5)	0	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Alpha haemolytic streptococcal infection	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Bacterial sepsis	1 (1.5)	0	0	0	1 (1.5)
Bronchitis	1 (1.5)	0	1 (1.5)	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Campylobacter infection	1 (1.5)	0	0	1 (1.5)	0
Candida sepsis	1 (1.5)	0	0	0	1 (1.5)
Catheter site infection	1 (1.5)	0	0	1 (1.5)	0
Cellulitis of male external genital organ	1 (1.5)	0	0	1 (1.5)	0
Cholecystitis infective	1 (1.5)	0	0	1 (1.5)	0
Clostridium difficile colitis	2 (3.0)	0	2 (3.0)	0	0
Clostridium difficile infection	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Device related infection	4 (6.0)	0	0	4 (6.0)	0
Enterococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Enterovirus infection	1 (1.5)	0	0	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	0	0	1 (1.5)
Escherichia urinary tract infection	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis norovirus	1 (1.5)	0	1 (1.5)	0	0
Herpes zoster	1 (1.5)	0	0	1 (1.5)	0
Klebsiella sepsis	2 (3.0)	0	0	0	2 (3.0)
Necrotising fasciitis	1 (1.5)	0	0	1 (1.5)	0
Parainfluenzae virus infection	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Pneumonia fungal	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Respiratory syncytial virus bronchitis	1 (1.5)	0	0	1 (1.5)	0
Respiratory tract infection	1 (1.5)	0	0	0	1 (1.5)
Respiratory tract infection viral	1 (1.5)	0	0	1 (1.5)	0
Rhinovirus infection	1 (1.5)	1 (1.5)	0	0	0
Rotavirus infection	1 (1.5)	0	0	1 (1.5)	0
Sepsis	2 (3.0)	0	0	0	2 (3.0)
Septic embolus	1 (1.5)	0	0	0	1 (1.5)
Serratia infection	1 (1.5)	0	0	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Staphylococcal infection	3 (4.5)	0	0	2 (3.0)	1 (1.5)
Staphylococcal scalded skin syndrome	1 (1.5)	0	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Upper respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Urinary tract infection	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Vascular device infection	1 (1.5)	0	0	1 (1.5)	0
Viral upper respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Vulvovaginal candidiasis	1 (1.5)	0	1 (1.5)	0	0
Serious neurological adverse reactions					
-Total	9 (13.4)	1 (1.5)	3 (4.5)	5 (7.5)	0
Delirium	1 (1.5)	0	1 (1.5)	0	0
Encephalopathy	4 (6.0)	1 (1.5)	1 (1.5)	2 (3.0)	0
Mental status changes	1 (1.5)	0	0	1 (1.5)	0
Seizure	4 (6.0)	0	2 (3.0)	2 (3.0)	0
Tumour Lysis Syndrome					
-Total	2 (3.0)	0	0	2 (3.0)	0

Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (3.0)	0	0	2 (3.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219f
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	1 (50.0)	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Cytokine release syndrome	0	0	0	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Bacteraemia	1 (50.0)	0	0	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (50.0)	0	0	1 (50.0)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219f
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (76.7)	1 (1.4)	10 (13.7)	24 (32.9)	21 (28.8)
Cytokine Release Syndrome					
-Total	41 (56.2)	4 (5.5)	19 (26.0)	8 (11.0)	10 (13.7)
Cytokine release syndrome	41 (56.2)	4 (5.5)	19 (26.0)	8 (11.0)	10 (13.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (6.8)	0	0	4 (5.5)	1 (1.4)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Pancytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Infections					
-Total	33 (45.2)	0	3 (4.1)	19 (26.0)	11 (15.1)
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Cellulitis of male external genital organ	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (1.4)	0	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile colitis	2 (2.7)	0	2 (2.7)	0	0
Clostridium difficile infection	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Corona virus infection	1 (1.4)	0	0	1 (1.4)	0
Device related infection	4 (5.5)	0	0	4 (5.5)	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Pneumonia	4 (5.5)	0	2 (2.7)	1 (1.4)	1 (1.4)
Pneumonia fungal	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinovirus infection	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Sepsis	2 (2.7)	0	0	0	2 (2.7)
Septic embolus	1 (1.4)	0	0	0	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Staphylococcal infection	3 (4.1)	0	0	2 (2.7)	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal candidiasis	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	9 (12.3)	1 (1.4)	3 (4.1)	5 (6.8)	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Encephalopathy	4 (5.5)	1 (1.4)	1 (1.4)	2 (2.7)	0
Mental status changes	1 (1.4)	0	0	1 (1.4)	0
Seizure	4 (5.5)	0	2 (2.7)	2 (2.7)	0
Tumour Lysis Syndrome					
-Total	2 (2.7)	0	0	2 (2.7)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (2.7)	0	0	2 (2.7)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219g
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	0	0	2 (66.7)
Cytokine Release Syndrome					
-Total	2 (66.7)	0	0	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	0	0	2 (66.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Serratia infection	0	0	0	0	0

Mixed-lineage leukemia rearrangement: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Mixed-lineage leukemia rearrangement: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219g
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	55 (76.4)	1 (1.4)	10 (13.9)	25 (34.7)	19 (26.4)
Cytokine Release Syndrome					
-Total	39 (54.2)	4 (5.6)	19 (26.4)	8 (11.1)	8 (11.1)
Cytokine release syndrome	39 (54.2)	4 (5.6)	19 (26.4)	8 (11.1)	8 (11.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (6.9)	0	0	4 (5.6)	1 (1.4)
Febrile neutropenia	3 (4.2)	0	0	3 (4.2)	0
Pancytopenia	2 (2.8)	0	0	1 (1.4)	1 (1.4)
Infections					
-Total	34 (47.2)	0	3 (4.2)	20 (27.8)	11 (15.3)
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile colitis	2 (2.8)	0	2 (2.8)	0	0
Clostridium difficile infection	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Corona virus infection	1 (1.4)	0	0	1 (1.4)	0
Device related infection	4 (5.6)	0	0	4 (5.6)	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Pneumonia	4 (5.6)	0	2 (2.8)	1 (1.4)	1 (1.4)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinovirus infection	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Sepsis	2 (2.8)	0	0	0	2 (2.8)
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Staphylococcal infection	3 (4.2)	0	0	2 (2.8)	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal candidiasis	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	9 (12.5)	1 (1.4)	3 (4.2)	5 (6.9)	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Encephalopathy	4 (5.6)	1 (1.4)	1 (1.4)	2 (2.8)	0
Mental status changes	1 (1.4)	0	0	1 (1.4)	0
Seizure	4 (5.6)	0	2 (2.8)	2 (2.8)	0
Tumour Lysis Syndrome					
-Total	2 (2.8)	0	0	2 (2.8)	0

Mixed-lineage leukemia rearrangement: No

Group term Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (2.8)	0	0	2 (2.8)	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219h
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Cytokine Release Syndrome					
-Total	1 (100)	0	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	1 (100)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Serratia infection	0	0	0	0	0

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (100)	0	1 (100)	0	0
Encephalopathy	1 (100)	0	1 (100)	0	0
Delirium	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219h
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (75.7)	1 (1.4)	9 (12.2)	25 (33.8)	21 (28.4)
Cytokine Release Syndrome					
-Total	40 (54.1)	4 (5.4)	18 (24.3)	8 (10.8)	10 (13.5)
Cytokine release syndrome	40 (54.1)	4 (5.4)	18 (24.3)	8 (10.8)	10 (13.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (6.8)	0	0	4 (5.4)	1 (1.4)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Pancytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Infections					
-Total	34 (45.9)	0	3 (4.1)	20 (27.0)	11 (14.9)
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile colitis	2 (2.7)	0	2 (2.7)	0	0
Clostridium difficile infection	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Corona virus infection	1 (1.4)	0	0	1 (1.4)	0
Device related infection	4 (5.4)	0	0	4 (5.4)	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Pneumonia	4 (5.4)	0	2 (2.7)	1 (1.4)	1 (1.4)
Pneumonia fungal	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinovirus infection	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Sepsis	2 (2.7)	0	0	0	2 (2.7)
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Staphylococcal infection	3 (4.1)	0	0	2 (2.7)	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal candidiasis	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	8 (10.8)	1 (1.4)	2 (2.7)	5 (6.8)	0
Encephalopathy	3 (4.1)	1 (1.4)	0	2 (2.7)	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Mental status changes	1 (1.4)	0	0	1 (1.4)	0
Seizure	4 (5.4)	0	2 (2.7)	2 (2.7)	0
Tumour Lysis Syndrome					
-Total	2 (2.7)	0	0	2 (2.7)	0

Hypodiploidy: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (2.7)	0	0	2 (2.7)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219i
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	0	0	3 (75.0)	0
Cytokine Release Syndrome					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Cytokine release syndrome	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	2 (50.0)	0	0	2 (50.0)	0
Bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Enterococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Herpes zoster	1 (25.0)	0	0	1 (25.0)	0
Streptococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Device related infection	0	0	0	0	0

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219i
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (76.1)	1 (1.4)	10 (14.1)	22 (31.0)	21 (29.6)
Cytokine Release Syndrome					
-Total	39 (54.9)	4 (5.6)	18 (25.4)	7 (9.9)	10 (14.1)
Cytokine release syndrome	39 (54.9)	4 (5.6)	18 (25.4)	7 (9.9)	10 (14.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (7.0)	0	0	4 (5.6)	1 (1.4)
Febrile neutropenia	3 (4.2)	0	0	3 (4.2)	0
Pancytopenia	2 (2.8)	0	0	1 (1.4)	1 (1.4)
Infections					
-Total	32 (45.1)	0	3 (4.2)	18 (25.4)	11 (15.5)
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Enterococcal bacteraemia	0	0	0	0	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile colitis	2 (2.8)	0	2 (2.8)	0	0
Clostridium difficile infection	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Corona virus infection	1 (1.4)	0	0	1 (1.4)	0
Device related infection	4 (5.6)	0	0	4 (5.6)	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Pneumonia	4 (5.6)	0	2 (2.8)	1 (1.4)	1 (1.4)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinovirus infection	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Sepsis	2 (2.8)	0	0	0	2 (2.8)
Septic embolus	1 (1.4)	0	0	0	1 (1.4)

BCR-ABL1-like: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Staphylococcal infection	3 (4.2)	0	0	2 (2.8)	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal candidiasis	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	9 (12.7)	1 (1.4)	3 (4.2)	5 (7.0)	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Encephalopathy	4 (5.6)	1 (1.4)	1 (1.4)	2 (2.8)	0
Mental status changes	1 (1.4)	0	0	1 (1.4)	0
Seizure	4 (5.6)	0	2 (2.8)	2 (2.8)	0
Tumour Lysis Syndrome					
-Total	2 (2.8)	0	0	2 (2.8)	0

BCR-ABL1-like: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (2.8)	0	0	2 (2.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219j
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (90.9)	1 (4.5)	3 (13.6)	6 (27.3)	10 (45.5)
Cytokine Release Syndrome					
-Total	16 (72.7)	1 (4.5)	7 (31.8)	3 (13.6)	5 (22.7)
Cytokine release syndrome	16 (72.7)	1 (4.5)	7 (31.8)	3 (13.6)	5 (22.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (4.5)	0	0	1 (4.5)	0
Pancytopenia	1 (4.5)	0	0	1 (4.5)	0
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	11 (50.0)	0	0	6 (27.3)	5 (22.7)
Clostridium difficile infection	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Device related infection	2 (9.1)	0	0	2 (9.1)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Alpha haemolytic streptococcal infection	1 (4.5)	0	0	1 (4.5)	0
Bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Bacterial sepsis	1 (4.5)	0	0	0	1 (4.5)
Campylobacter infection	1 (4.5)	0	0	1 (4.5)	0
Candida sepsis	1 (4.5)	0	0	0	1 (4.5)
Cellulitis of male external genital organ	1 (4.5)	0	0	1 (4.5)	0
Clostridium difficile colitis	1 (4.5)	0	1 (4.5)	0	0
Enterovirus infection	1 (4.5)	0	0	1 (4.5)	0
Gastroenteritis	1 (4.5)	0	0	1 (4.5)	0
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Parainfluenzae virus infection	1 (4.5)	0	1 (4.5)	0	0
Pneumonia fungal	1 (4.5)	0	0	1 (4.5)	0
Respiratory tract infection	1 (4.5)	0	0	0	1 (4.5)
Respiratory tract infection viral	1 (4.5)	0	0	1 (4.5)	0
Rhinovirus infection	1 (4.5)	1 (4.5)	0	0	0
Rotavirus infection	1 (4.5)	0	0	1 (4.5)	0
Sepsis	1 (4.5)	0	0	0	1 (4.5)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	1 (4.5)	0	0	0	1 (4.5)
Staphylococcal infection	1 (4.5)	0	0	1 (4.5)	0
Vascular device infection	1 (4.5)	0	0	1 (4.5)	0
Vulvovaginal candidiasis	1 (4.5)	0	1 (4.5)	0	0
Abscess limb	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Encephalopathy	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Seizure	1 (4.5)	0	0	1 (4.5)	0
Delirium	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219j
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (69.8)	0	7 (13.2)	19 (35.8)	11 (20.8)
Cytokine Release Syndrome					
-Total	25 (47.2)	3 (5.7)	12 (22.6)	5 (9.4)	5 (9.4)
Cytokine release syndrome	25 (47.2)	3 (5.7)	12 (22.6)	5 (9.4)	5 (9.4)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (7.5)	0	0	3 (5.7)	1 (1.9)
Pancytopenia	1 (1.9)	0	0	0	1 (1.9)
Febrile neutropenia	3 (5.7)	0	0	3 (5.7)	0
Infections					
-Total	23 (43.4)	0	3 (5.7)	14 (26.4)	6 (11.3)
Clostridium difficile infection	1 (1.9)	0	1 (1.9)	0	0
Device related infection	2 (3.8)	0	0	2 (3.8)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile colitis	1 (1.9)	0	1 (1.9)	0	0
Enterovirus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	1 (1.9)	0	0	1 (1.9)	0
Pneumonia fungal	1 (1.9)	0	1 (1.9)	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	0	0	0	0	0
Staphylococcal infection	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Vascular device infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Abscess limb	1 (1.9)	0	0	1 (1.9)	0
Bronchitis	1 (1.9)	0	1 (1.9)	0	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Catheter site infection	1 (1.9)	0	0	1 (1.9)	0
Cellulitis	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0
Enterococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	0	0	1 (1.9)
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Klebsiella sepsis	2 (3.8)	0	0	0	2 (3.8)
Necrotising fasciitis	1 (1.9)	0	0	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	4 (7.5)	0	2 (3.8)	1 (1.9)	1 (1.9)
Respiratory syncytial virus bronchitis	1 (1.9)	0	0	1 (1.9)	0
Respiratory syncytial virus infection	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Serratia infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Serious neurological adverse reactions					
-Total	6 (11.3)	0	3 (5.7)	3 (5.7)	0
Encephalopathy	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Seizure	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Delirium	1 (1.9)	0	1 (1.9)	0	0
Mental status changes	1 (1.9)	0	0	1 (1.9)	0
Tumour Lysis Syndrome					
-Total	2 (3.8)	0	0	2 (3.8)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (3.8)	0	0	2 (3.8)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219k
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	57 (76.0)	1 (1.3)	10 (13.3)	25 (33.3)	21 (28.0)
Cytokine Release Syndrome					
-Total	41 (54.7)	4 (5.3)	19 (25.3)	8 (10.7)	10 (13.3)
Cytokine release syndrome	41 (54.7)	4 (5.3)	19 (25.3)	8 (10.7)	10 (13.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (6.7)	0	0	4 (5.3)	1 (1.3)
Febrile neutropenia	3 (4.0)	0	0	3 (4.0)	0
Pancytopenia	2 (2.7)	0	0	1 (1.3)	1 (1.3)
Infections					
-Total	34 (45.3)	0	3 (4.0)	20 (26.7)	11 (14.7)
Device related infection	4 (5.3)	0	0	4 (5.3)	0
Pneumonia	4 (5.3)	0	2 (2.7)	1 (1.3)	1 (1.3)

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile infection	3 (4.0)	0	2 (2.7)	1 (1.3)	0
Staphylococcal infection	3 (4.0)	0	0	2 (2.7)	1 (1.3)
Bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Clostridium difficile colitis	2 (2.7)	0	2 (2.7)	0	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Parainfluenzae virus infection	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Pneumonia fungal	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Respiratory syncytial virus infection	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Sepsis	2 (2.7)	0	0	0	2 (2.7)
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Urinary tract infection	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Abscess limb	1 (1.3)	0	0	1 (1.3)	0
Alpha haemolytic streptococcal infection	1 (1.3)	0	0	1 (1.3)	0
Bacterial sepsis	1 (1.3)	0	0	0	1 (1.3)
Bronchitis	1 (1.3)	0	1 (1.3)	0	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Campylobacter infection	1 (1.3)	0	0	1 (1.3)	0
Candida sepsis	1 (1.3)	0	0	0	1 (1.3)

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Catheter site infection	1 (1.3)	0	0	1 (1.3)	0
Cellulitis	1 (1.3)	0	0	1 (1.3)	0
Cellulitis of male external genital organ	1 (1.3)	0	0	1 (1.3)	0
Cholecystitis infective	1 (1.3)	0	0	1 (1.3)	0
Corona virus infection	1 (1.3)	0	0	1 (1.3)	0
Enterococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0
Escherichia bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Escherichia sepsis	1 (1.3)	0	0	0	1 (1.3)
Escherichia urinary tract infection	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis norovirus	1 (1.3)	0	1 (1.3)	0	0
Herpes zoster	1 (1.3)	0	0	1 (1.3)	0
Necrotising fasciitis	1 (1.3)	0	0	1 (1.3)	0
Respiratory syncytial virus bronchitis	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection	1 (1.3)	0	0	0	1 (1.3)
Respiratory tract infection viral	1 (1.3)	0	0	1 (1.3)	0
Rhinovirus infection	1 (1.3)	1 (1.3)	0	0	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rotavirus infection	1 (1.3)	0	0	1 (1.3)	0
Septic embolus	1 (1.3)	0	0	0	1 (1.3)
Serratia infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal scalded skin syndrome	1 (1.3)	0	1 (1.3)	0	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Streptococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Vascular device infection	1 (1.3)	0	0	1 (1.3)	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Vulvovaginal candidiasis	1 (1.3)	0	1 (1.3)	0	0
Serious neurological adverse reactions					
-Total	9 (12.0)	1 (1.3)	3 (4.0)	5 (6.7)	0
Encephalopathy	4 (5.3)	1 (1.3)	1 (1.3)	2 (2.7)	0
Seizure	4 (5.3)	0	2 (2.7)	2 (2.7)	0
Delirium	1 (1.3)	0	1 (1.3)	0	0
Mental status changes	1 (1.3)	0	0	1 (1.3)	0
Tumour Lysis Syndrome					
-Total	2 (2.7)	0	0	2 (2.7)	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (2.7)	0	0	2 (2.7)	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219l
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (84.4)	0	3 (9.4)	15 (46.9)	9 (28.1)
Cytokine Release Syndrome					
-Total	17 (53.1)	2 (6.3)	9 (28.1)	4 (12.5)	2 (6.3)
Cytokine release syndrome	17 (53.1)	2 (6.3)	9 (28.1)	4 (12.5)	2 (6.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (3.1)	0	0	1 (3.1)	0
Febrile neutropenia	1 (3.1)	0	0	1 (3.1)	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	18 (56.3)	0	0	11 (34.4)	7 (21.9)
Bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Clostridium difficile infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (6.3)	0	0	2 (6.3)	0
Klebsiella sepsis	2 (6.3)	0	0	0	2 (6.3)
Sepsis	2 (6.3)	0	0	0	2 (6.3)
Staphylococcal bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Urinary tract infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Bronchitis	1 (3.1)	0	1 (3.1)	0	0
Campylobacter infection	1 (3.1)	0	0	1 (3.1)	0
Cellulitis of male external genital organ	1 (3.1)	0	0	1 (3.1)	0
Cholecystitis infective	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	1 (3.1)	0	0
Enterococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	0	0	1 (3.1)
Escherichia urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Necrotising fasciitis	1 (3.1)	0	0	1 (3.1)	0

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (3.1)	0	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	0	0	1 (3.1)	0
Respiratory tract infection viral	1 (3.1)	0	0	1 (3.1)	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Rotavirus infection	1 (3.1)	0	0	1 (3.1)	0
Septic embolus	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal infection	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal scalded skin syndrome	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Vascular device infection	1 (3.1)	0	0	1 (3.1)	0
Vulvovaginal candidiasis	1 (3.1)	0	1 (3.1)	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	0	0	0	0	0

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Serratia infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	5 (15.6)	1 (3.1)	0	4 (12.5)	0
Encephalopathy	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Seizure	2 (6.3)	0	0	2 (6.3)	0
Mental status changes	1 (3.1)	0	0	1 (3.1)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Prior SCT therapy: Yes

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219l
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (69.8)	1 (2.3)	7 (16.3)	10 (23.3)	12 (27.9)
Cytokine Release Syndrome					
-Total	24 (55.8)	2 (4.7)	10 (23.3)	4 (9.3)	8 (18.6)
Cytokine release syndrome	24 (55.8)	2 (4.7)	10 (23.3)	4 (9.3)	8 (18.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (9.3)	0	0	3 (7.0)	1 (2.3)
Febrile neutropenia	2 (4.7)	0	0	2 (4.7)	0
Pancytopenia	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Infections					
-Total	16 (37.2)	0	3 (7.0)	9 (20.9)	4 (9.3)
Bacteraemia	0	0	0	0	0
Clostridium difficile infection	1 (2.3)	0	1 (2.3)	0	0

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (4.7)	0	0	2 (4.7)	0
Klebsiella sepsis	0	0	0	0	0
Sepsis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bronchitis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	1 (2.3)	0	1 (2.3)	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	3 (7.0)	0	1 (2.3)	1 (2.3)	1 (2.3)
Pneumonia fungal	1 (2.3)	0	0	1 (2.3)	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal infection	2 (4.7)	0	0	2 (4.7)	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Alpha haemolytic streptococcal infection	1 (2.3)	0	0	1 (2.3)	0
Bacterial sepsis	1 (2.3)	0	0	0	1 (2.3)
Bronchopulmonary aspergillosis	1 (2.3)	0	0	1 (2.3)	0
Candida sepsis	1 (2.3)	0	0	0	1 (2.3)

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (2.3)	0	0	1 (2.3)	0
Cellulitis	1 (2.3)	0	0	1 (2.3)	0
Corona virus infection	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis	1 (2.3)	0	0	1 (2.3)	0
Herpes zoster	1 (2.3)	0	0	1 (2.3)	0
Parainfluenzae virus infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Respiratory syncytial virus infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Respiratory tract infection	1 (2.3)	0	0	0	1 (2.3)
Serratia infection	1 (2.3)	0	0	1 (2.3)	0
Viral upper respiratory tract infection	1 (2.3)	0	0	1 (2.3)	0
Serious neurological adverse reactions					
-Total	4 (9.3)	0	3 (7.0)	1 (2.3)	0
Encephalopathy	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Seizure	2 (4.7)	0	2 (4.7)	0	0
Mental status changes	0	0	0	0	0
Delirium	1 (2.3)	0	1 (2.3)	0	0
Tumour Lysis Syndrome					
-Total	2 (4.7)	0	0	2 (4.7)	0

Prior SCT therapy: No

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (4.7)	0	0	2 (4.7)	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219m
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (66.7)	0	2 (11.1)	6 (33.3)	4 (22.2)
Cytokine Release Syndrome					
-Total	9 (50.0)	0	6 (33.3)	2 (11.1)	1 (5.6)
Cytokine release syndrome	9 (50.0)	0	6 (33.3)	2 (11.1)	1 (5.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (11.1)	0	0	2 (11.1)	0
Febrile neutropenia	2 (11.1)	0	0	2 (11.1)	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	8 (44.4)	0	0	5 (27.8)	3 (16.7)
Device related infection	2 (11.1)	0	0	2 (11.1)	0
Pneumonia	2 (11.1)	0	0	1 (5.6)	1 (5.6)

Eligibility for SCT: Yes

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alpha haemolytic streptococcal infection	1 (5.6)	0	0	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Bronchopulmonary aspergillosis	1 (5.6)	0	0	1 (5.6)	0
Catheter site infection	1 (5.6)	0	0	1 (5.6)	0
Corona virus infection	1 (5.6)	0	0	1 (5.6)	0
Escherichia urinary tract infection	1 (5.6)	0	0	1 (5.6)	0
Parainfluenzae virus infection	1 (5.6)	0	0	1 (5.6)	0
Respiratory syncytial virus infection	1 (5.6)	0	0	1 (5.6)	0
Respiratory tract infection	1 (5.6)	0	0	0	1 (5.6)
Viral upper respiratory tract infection	1 (5.6)	0	0	1 (5.6)	0
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchitis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (5.6)	0	0	1 (5.6)	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	1 (5.6)	0	0	1 (5.6)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219m
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (78.9)	1 (1.8)	8 (14.0)	19 (33.3)	17 (29.8)
Cytokine Release Syndrome					
-Total	32 (56.1)	4 (7.0)	13 (22.8)	6 (10.5)	9 (15.8)
Cytokine release syndrome	32 (56.1)	4 (7.0)	13 (22.8)	6 (10.5)	9 (15.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Febrile neutropenia	1 (1.8)	0	0	1 (1.8)	0
Pancytopenia	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Infections					
-Total	26 (45.6)	0	3 (5.3)	15 (26.3)	8 (14.0)
Device related infection	2 (3.5)	0	0	2 (3.5)	0
Pneumonia	2 (3.5)	0	2 (3.5)	0	0

Eligibility for SCT: No

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Parainfluenzae virus infection	1 (1.8)	0	1 (1.8)	0	0
Respiratory syncytial virus infection	1 (1.8)	0	1 (1.8)	0	0
Respiratory tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Abscess limb	1 (1.8)	0	0	1 (1.8)	0
Bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Campylobacter infection	1 (1.8)	0	0	1 (1.8)	0
Candida sepsis	1 (1.8)	0	0	0	1 (1.8)
Cellulitis	1 (1.8)	0	0	1 (1.8)	0
Cellulitis of male external genital organ	1 (1.8)	0	0	1 (1.8)	0
Cholecystitis infective	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	2 (3.5)	0	2 (3.5)	0	0
Clostridium difficile infection	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Enterococcal bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Escherichia bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Escherichia sepsis	1 (1.8)	0	0	0	1 (1.8)
Gastroenteritis	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0
Klebsiella sepsis	2 (3.5)	0	0	0	2 (3.5)
Necrotising fasciitis	1 (1.8)	0	0	1 (1.8)	0
Pneumonia fungal	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Respiratory syncytial virus bronchitis	1 (1.8)	0	0	1 (1.8)	0
Respiratory tract infection viral	1 (1.8)	0	0	1 (1.8)	0
Rhinovirus infection	1 (1.8)	1 (1.8)	0	0	0
Rotavirus infection	1 (1.8)	0	0	1 (1.8)	0
Sepsis	2 (3.5)	0	0	0	2 (3.5)
Septic embolus	1 (1.8)	0	0	0	1 (1.8)

Eligibility for SCT: No

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Staphylococcal infection	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Staphylococcal scalded skin syndrome	1 (1.8)	0	1 (1.8)	0	0
Staphylococcal sepsis	1 (1.8)	0	0	0	1 (1.8)
Streptococcal bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Upper respiratory tract infection	1 (1.8)	0	0	1 (1.8)	0
Urinary tract infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Vulvovaginal candidiasis	1 (1.8)	0	1 (1.8)	0	0
Serious neurological adverse reactions					
-Total	9 (15.8)	1 (1.8)	3 (5.3)	5 (8.8)	0
Delirium	1 (1.8)	0	1 (1.8)	0	0
Encephalopathy	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Mental status changes	1 (1.8)	0	0	1 (1.8)	0
Seizure	4 (7.0)	0	2 (3.5)	2 (3.5)	0
Tumour Lysis Syndrome					
-Total	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219n
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (77.3)	0	5 (22.7)	8 (36.4)	4 (18.2)
Cytokine Release Syndrome					
-Total	14 (63.6)	0	9 (40.9)	3 (13.6)	2 (9.1)
Cytokine release syndrome	14 (63.6)	0	9 (40.9)	3 (13.6)	2 (9.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (9.1)	0	0	2 (9.1)	0
Febrile neutropenia	1 (4.5)	0	0	1 (4.5)	0
Pancytopenia	1 (4.5)	0	0	1 (4.5)	0
Infections					
-Total	7 (31.8)	0	0	5 (22.7)	2 (9.1)
Bacterial sepsis	1 (4.5)	0	0	0	1 (4.5)
Bronchitis	1 (4.5)	0	1 (4.5)	0	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cholecystitis infective	1 (4.5)	0	0	1 (4.5)	0
Clostridium difficile colitis	1 (4.5)	0	1 (4.5)	0	0
Corona virus infection	1 (4.5)	0	0	1 (4.5)	0
Device related infection	1 (4.5)	0	0	1 (4.5)	0
Gastroenteritis	1 (4.5)	0	0	1 (4.5)	0
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Respiratory syncytial virus infection	1 (4.5)	0	0	1 (4.5)	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Staphylococcal infection	1 (4.5)	0	0	0	1 (4.5)
Vascular device infection	1 (4.5)	0	0	1 (4.5)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cellulitis of male external genital organ	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	5 (22.7)	1 (4.5)	2 (9.1)	2 (9.1)	0
Encephalopathy	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Seizure	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Delirium	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219n
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (75.5)	1 (1.9)	5 (9.4)	17 (32.1)	17 (32.1)
Cytokine Release Syndrome					
-Total	27 (50.9)	4 (7.5)	10 (18.9)	5 (9.4)	8 (15.1)
Cytokine release syndrome	27 (50.9)	4 (7.5)	10 (18.9)	5 (9.4)	8 (15.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (5.7)	0	0	2 (3.8)	1 (1.9)
Febrile neutropenia	2 (3.8)	0	0	2 (3.8)	0
Pancytopenia	1 (1.9)	0	0	0	1 (1.9)
Infections					
-Total	27 (50.9)	0	3 (5.7)	15 (28.3)	9 (17.0)
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	1 (1.9)	0	1 (1.9)	0	0
Corona virus infection	0	0	0	0	0
Device related infection	3 (5.7)	0	0	3 (5.7)	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Respiratory syncytial virus infection	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal infection	2 (3.8)	0	0	2 (3.8)	0
Vascular device infection	0	0	0	0	0
Abscess limb	1 (1.9)	0	0	1 (1.9)	0
Alpha haemolytic streptococcal infection	1 (1.9)	0	0	1 (1.9)	0
Bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Campylobacter infection	1 (1.9)	0	0	1 (1.9)	0
Candida sepsis	1 (1.9)	0	0	0	1 (1.9)
Catheter site infection	1 (1.9)	0	0	1 (1.9)	0
Cellulitis	1 (1.9)	0	0	1 (1.9)	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Clostridium difficile infection	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Enterococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	0	0	1 (1.9)
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Klebsiella sepsis	2 (3.8)	0	0	0	2 (3.8)
Necrotising fasciitis	1 (1.9)	0	0	1 (1.9)	0
Parainfluenzae virus infection	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Pneumonia	4 (7.5)	0	2 (3.8)	1 (1.9)	1 (1.9)
Pneumonia fungal	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Respiratory syncytial virus bronchitis	1 (1.9)	0	0	1 (1.9)	0
Respiratory tract infection	1 (1.9)	0	0	0	1 (1.9)
Respiratory tract infection viral	1 (1.9)	0	0	1 (1.9)	0
Rhinovirus infection	1 (1.9)	1 (1.9)	0	0	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	2 (3.8)	0	0	0	2 (3.8)
Septic embolus	1 (1.9)	0	0	0	1 (1.9)
Serratia infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Urinary tract infection	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Vulvovaginal candidiasis	1 (1.9)	0	1 (1.9)	0	0
Serious neurological adverse reactions					
-Total	4 (7.5)	0	1 (1.9)	3 (5.7)	0
Encephalopathy	1 (1.9)	0	0	1 (1.9)	0
Seizure	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Delirium	1 (1.9)	0	1 (1.9)	0	0
Mental status changes	1 (1.9)	0	0	1 (1.9)	0
Tumour Lysis Syndrome					
-Total	2 (3.8)	0	0	2 (3.8)	0

Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (3.8)	0	0	2 (3.8)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219o
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (57.1)	0	0	3 (42.9)	1 (14.3)
Cytokine Release Syndrome					
-Total	3 (42.9)	1 (14.3)	1 (14.3)	0	1 (14.3)
Cytokine release syndrome	3 (42.9)	1 (14.3)	1 (14.3)	0	1 (14.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (14.3)	0	0	1 (14.3)	0
Febrile neutropenia	1 (14.3)	0	0	1 (14.3)	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	1 (14.3)	0	0	1 (14.3)	0
Device related infection	1 (14.3)	0	0	1 (14.3)	0
Viral upper respiratory tract infection	1 (14.3)	0	0	1 (14.3)	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (28.6)	0	0	2 (28.6)	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0
Seizure	1 (14.3)	0	0	1 (14.3)	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219o
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (77.9)	1 (1.5)	10 (14.7)	22 (32.4)	20 (29.4)
Cytokine Release Syndrome					
-Total	38 (55.9)	3 (4.4)	18 (26.5)	8 (11.8)	9 (13.2)
Cytokine release syndrome	38 (55.9)	3 (4.4)	18 (26.5)	8 (11.8)	9 (13.2)
Hematopoietic cytopenias not resolved by Day 28					
-Total	4 (5.9)	0	0	3 (4.4)	1 (1.5)
Febrile neutropenia	2 (2.9)	0	0	2 (2.9)	0
Pancytopenia	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Infections					
-Total	33 (48.5)	0	3 (4.4)	19 (27.9)	11 (16.2)
Device related infection	3 (4.4)	0	0	3 (4.4)	0
Viral upper respiratory tract infection	0	0	0	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Alpha haemolytic streptococcal infection	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Bacterial sepsis	1 (1.5)	0	0	0	1 (1.5)
Bronchitis	1 (1.5)	0	1 (1.5)	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Campylobacter infection	1 (1.5)	0	0	1 (1.5)	0
Candida sepsis	1 (1.5)	0	0	0	1 (1.5)
Catheter site infection	1 (1.5)	0	0	1 (1.5)	0
Cellulitis	1 (1.5)	0	0	1 (1.5)	0
Cellulitis of male external genital organ	1 (1.5)	0	0	1 (1.5)	0
Cholecystitis infective	1 (1.5)	0	0	1 (1.5)	0
Clostridium difficile colitis	2 (2.9)	0	2 (2.9)	0	0
Clostridium difficile infection	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Corona virus infection	1 (1.5)	0	0	1 (1.5)	0
Enterococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Enterovirus infection	1 (1.5)	0	0	1 (1.5)	0
Escherichia bacteraemia	1 (1.5)	0	0	1 (1.5)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia sepsis	1 (1.5)	0	0	0	1 (1.5)
Escherichia urinary tract infection	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis norovirus	1 (1.5)	0	1 (1.5)	0	0
Herpes zoster	1 (1.5)	0	0	1 (1.5)	0
Klebsiella sepsis	2 (2.9)	0	0	0	2 (2.9)
Necrotising fasciitis	1 (1.5)	0	0	1 (1.5)	0
Parainfluenzae virus infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Pneumonia	4 (5.9)	0	2 (2.9)	1 (1.5)	1 (1.5)
Pneumonia fungal	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Respiratory syncytial virus bronchitis	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Respiratory tract infection	1 (1.5)	0	0	0	1 (1.5)
Respiratory tract infection viral	1 (1.5)	0	0	1 (1.5)	0
Rhinovirus infection	1 (1.5)	1 (1.5)	0	0	0
Rotavirus infection	1 (1.5)	0	0	1 (1.5)	0
Sepsis	2 (2.9)	0	0	0	2 (2.9)
Septic embolus	1 (1.5)	0	0	0	1 (1.5)

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Staphylococcal infection	3 (4.4)	0	0	2 (2.9)	1 (1.5)
Staphylococcal scalded skin syndrome	1 (1.5)	0	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Upper respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Urinary tract infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Vascular device infection	1 (1.5)	0	0	1 (1.5)	0
Vulvovaginal candidiasis	1 (1.5)	0	1 (1.5)	0	0
Serious neurological adverse reactions					
-Total	7 (10.3)	1 (1.5)	3 (4.4)	3 (4.4)	0
Mental status changes	0	0	0	0	0
Seizure	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Delirium	1 (1.5)	0	1 (1.5)	0	0
Encephalopathy	4 (5.9)	1 (1.5)	1 (1.5)	2 (2.9)	0
Tumour Lysis Syndrome					
-Total	2 (2.9)	0	0	2 (2.9)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (2.9)	0	0	2 (2.9)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219p
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Cytokine Release Syndrome					
-Total	2 (50.0)	0	2 (50.0)	0	0
Cytokine release syndrome	2 (50.0)	0	2 (50.0)	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	1 (25.0)	0	0	1 (25.0)	0
Corona virus infection	1 (25.0)	0	0	1 (25.0)	0
Respiratory syncytial virus infection	1 (25.0)	0	0	1 (25.0)	0

Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0

Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Serratia infection	0	0	0	0	0

Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219p
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	55 (77.5)	1 (1.4)	9 (12.7)	24 (33.8)	21 (29.6)
Cytokine Release Syndrome					
-Total	39 (54.9)	4 (5.6)	17 (23.9)	8 (11.3)	10 (14.1)
Cytokine release syndrome	39 (54.9)	4 (5.6)	17 (23.9)	8 (11.3)	10 (14.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	5 (7.0)	0	0	4 (5.6)	1 (1.4)
Febrile neutropenia	3 (4.2)	0	0	3 (4.2)	0
Pancytopenia	2 (2.8)	0	0	1 (1.4)	1 (1.4)
Infections					
-Total	33 (46.5)	0	3 (4.2)	19 (26.8)	11 (15.5)
Corona virus infection	0	0	0	0	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile colitis	2 (2.8)	0	2 (2.8)	0	0
Clostridium difficile infection	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Device related infection	4 (5.6)	0	0	4 (5.6)	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Pneumonia	4 (5.6)	0	2 (2.8)	1 (1.4)	1 (1.4)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinovirus infection	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Sepsis	2 (2.8)	0	0	0	2 (2.8)
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Staphylococcal infection	3 (4.2)	0	0	2 (2.8)	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal candidiasis	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	9 (12.7)	1 (1.4)	3 (4.2)	5 (7.0)	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Encephalopathy	4 (5.6)	1 (1.4)	1 (1.4)	2 (2.8)	0
Mental status changes	1 (1.4)	0	0	1 (1.4)	0
Seizure	4 (5.6)	0	2 (2.8)	2 (2.8)	0
Tumour Lysis Syndrome					
-Total	2 (2.8)	0	0	2 (2.8)	0

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (2.8)	0	0	2 (2.8)	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219q
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (78.1)	1 (3.1)	6 (18.8)	10 (31.3)	8 (25.0)
Cytokine Release Syndrome					
-Total	19 (59.4)	3 (9.4)	10 (31.3)	2 (6.3)	4 (12.5)
Cytokine release syndrome	19 (59.4)	3 (9.4)	10 (31.3)	2 (6.3)	4 (12.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (6.3)	0	0	2 (6.3)	0
Febrile neutropenia	1 (3.1)	0	0	1 (3.1)	0
Pancytopenia	1 (3.1)	0	0	1 (3.1)	0
Infections					
-Total	15 (46.9)	0	2 (6.3)	9 (28.1)	4 (12.5)
Device related infection	4 (12.5)	0	0	4 (12.5)	0
Clostridium difficile infection	3 (9.4)	0	2 (6.3)	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Pneumonia	2 (6.3)	0	2 (6.3)	0	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Alpha haemolytic streptococcal infection	1 (3.1)	0	0	1 (3.1)	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Bacterial sepsis	1 (3.1)	0	0	0	1 (3.1)
Campylobacter infection	1 (3.1)	0	0	1 (3.1)	0
Catheter site infection	1 (3.1)	0	0	1 (3.1)	0
Enterococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	0	0	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	0	1 (3.1)	0	0
Respiratory tract infection	1 (3.1)	0	0	0	1 (3.1)
Respiratory tract infection viral	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Rotavirus infection	1 (3.1)	0	0	1 (3.1)	0
Sepsis	1 (3.1)	0	0	0	1 (3.1)
Septic embolus	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal scalded skin syndrome	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Urinary tract infection	1 (3.1)	0	1 (3.1)	0	0
Viral upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Vulvovaginal candidiasis	1 (3.1)	0	1 (3.1)	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (9.4)	0	0	3 (9.4)	0
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Mental status changes	1 (3.1)	0	0	1 (3.1)	0
Seizure	1 (3.1)	0	0	1 (3.1)	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219q
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (81.3)	0	4 (12.5)	15 (46.9)	7 (21.9)
Cytokine Release Syndrome					
-Total	22 (68.8)	1 (3.1)	9 (28.1)	6 (18.8)	6 (18.8)
Cytokine release syndrome	22 (68.8)	1 (3.1)	9 (28.1)	6 (18.8)	6 (18.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (9.4)	0	0	2 (6.3)	1 (3.1)
Febrile neutropenia	2 (6.3)	0	0	2 (6.3)	0
Pancytopenia	1 (3.1)	0	0	0	1 (3.1)
Infections					
-Total	13 (40.6)	0	1 (3.1)	11 (34.4)	1 (3.1)
Device related infection	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	1 (3.1)	0	0	1 (3.1)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	1 (3.1)	0	0	1 (3.1)	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	1 (3.1)	0	0	1 (3.1)	0
Candida sepsis	0	0	0	0	0
Cellulitis	1 (3.1)	0	0	1 (3.1)	0
Cellulitis of male external genital organ	1 (3.1)	0	0	1 (3.1)	0
Cholecystitis infective	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	2 (6.3)	0	2 (6.3)	0	0
Corona virus infection	1 (3.1)	0	0	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	0	0	1 (3.1)
Gastroenteritis	1 (3.1)	0	0	1 (3.1)	0
Herpes zoster	1 (3.1)	0	0	1 (3.1)	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	1 (3.1)	0	0	1 (3.1)	0
Serratia infection	1 (3.1)	0	0	1 (3.1)	0
Upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Vascular device infection	1 (3.1)	0	0	1 (3.1)	0
Serious neurological adverse reactions					
-Total	6 (18.8)	1 (3.1)	3 (9.4)	2 (6.3)	0
Encephalopathy	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Mental status changes	0	0	0	0	0
Seizure	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Delirium	1 (3.1)	0	1 (3.1)	0	0
Tumour Lysis Syndrome					
-Total	2 (6.3)	0	0	2 (6.3)	0

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219q
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (54.5)	0	0	0	6 (54.5)
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Cytokine release syndrome	0	0	0	0	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	6 (54.5)	0	0	0	6 (54.5)
Device related infection	0	0	0	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Pneumonia fungal	1 (9.1)	0	0	1 (9.1)	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Septic embolus	0	0	0	0	0
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Bronchitis	1 (9.1)	0	1 (9.1)	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Cellulitis	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Corona virus infection	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Necrotising fasciitis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Delirium	0	0	0	0	0
Tumour Lysis Syndrome					

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (75.0)	0	1 (12.5)	1 (12.5)	4 (50.0)
Cytokine Release Syndrome					
-Total	5 (62.5)	0	2 (25.0)	0	3 (37.5)
Cytokine release syndrome	5 (62.5)	0	2 (25.0)	0	3 (37.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Corona virus infection	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Respiratory syncytial virus infection	1 (12.5)	0	0	1 (12.5)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	0	0	0	0	0
Serratia infection	0	0	0	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (73.9)	1 (4.3)	2 (8.7)	9 (39.1)	5 (21.7)
Cytokine Release Syndrome					
-Total	14 (60.9)	2 (8.7)	6 (26.1)	2 (8.7)	4 (17.4)
Cytokine release syndrome	14 (60.9)	2 (8.7)	6 (26.1)	2 (8.7)	4 (17.4)
Hematopoietic cytopenias not resolved by Day 28					
-Total	3 (13.0)	0	0	2 (8.7)	1 (4.3)
Febrile neutropenia	2 (8.7)	0	0	2 (8.7)	0
Pancytopenia	1 (4.3)	0	0	0	1 (4.3)
Infections					
-Total	10 (43.5)	0	1 (4.3)	8 (34.8)	1 (4.3)
Cellulitis	0	0	0	0	0
Corona virus infection	0	0	0	0	0

Number of previous relapses: 1

Group term Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Respiratory syncytial virus infection	1 (4.3)	0	1 (4.3)	0	0
Abscess limb	1 (4.3)	0	0	1 (4.3)	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	1 (4.3)	0	0	1 (4.3)	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Clostridium difficile infection	1 (4.3)	0	1 (4.3)	0	0
Device related infection	2 (8.7)	0	0	2 (8.7)	0
Enterococcal bacteraemia	0	0	0	0	0
Enterovirus infection	0	0	0	0	0

Number of previous relapses: 1

Group term Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	1 (4.3)	0	0	1 (4.3)	0
Gastroenteritis	1 (4.3)	0	0	1 (4.3)	0
Gastroenteritis norovirus	1 (4.3)	0	1 (4.3)	0	0
Herpes zoster	1 (4.3)	0	0	1 (4.3)	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Parainfluenzae virus infection	1 (4.3)	0	1 (4.3)	0	0
Pneumonia fungal	1 (4.3)	0	1 (4.3)	0	0
Respiratory syncytial virus bronchitis	1 (4.3)	0	0	1 (4.3)	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	1 (4.3)	0	0	0	1 (4.3)
Septic embolus	0	0	0	0	0
Serratia infection	1 (4.3)	0	0	1 (4.3)	0

Number of previous relapses: 1

Group term Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal infection	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal scalded skin syndrome	1 (4.3)	0	1 (4.3)	0	0
Staphylococcal sepsis	1 (4.3)	0	0	0	1 (4.3)
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	1 (4.3)	0	0	1 (4.3)	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (17.4)	0	2 (8.7)	2 (8.7)	0
Delirium	1 (4.3)	0	1 (4.3)	0	0
Encephalopathy	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Mental status changes	0	0	0	0	0
Seizure	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Tumour Lysis Syndrome					
-Total	1 (4.3)	0	0	1 (4.3)	0

Number of previous relapses: 1

Group term Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	1 (4.3)	0	0	1 (4.3)	0

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- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (75.0)	0	5 (20.8)	7 (29.2)	6 (25.0)
Cytokine Release Syndrome					
-Total	14 (58.3)	0	9 (37.5)	4 (16.7)	1 (4.2)
Cytokine release syndrome	14 (58.3)	0	9 (37.5)	4 (16.7)	1 (4.2)
Hematopoietic cytopenias not resolved by Day 28					
-Total	2 (8.3)	0	0	2 (8.3)	0
Febrile neutropenia	1 (4.2)	0	0	1 (4.2)	0
Pancytopenia	1 (4.2)	0	0	1 (4.2)	0
Infections					
-Total	10 (41.7)	0	2 (8.3)	3 (12.5)	5 (20.8)
Cellulitis	0	0	0	0	0

Number of previous relapses: 2

Group term Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Corona virus infection	0	0	0	0	0
Pneumonia	1 (4.2)	0	1 (4.2)	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	1 (4.2)	0	0	1 (4.2)	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	1 (4.2)	0	0	0	1 (4.2)
Bronchitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	0	0	0	0	0
Candida sepsis	1 (4.2)	0	0	0	1 (4.2)
Catheter site infection	1 (4.2)	0	0	1 (4.2)	0
Cellulitis of male external genital organ	0	0	0	0	0
Cholecystitis infective	1 (4.2)	0	0	1 (4.2)	0
Clostridium difficile colitis	1 (4.2)	0	1 (4.2)	0	0
Clostridium difficile infection	1 (4.2)	0	1 (4.2)	0	0
Device related infection	1 (4.2)	0	0	1 (4.2)	0
Enterococcal bacteraemia	0	0	0	0	0

Number of previous relapses: 2

Group term Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterovirus infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	1 (4.2)	0	0	0	1 (4.2)
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Necrotising fasciitis	0	0	0	0	0
Parainfluenzae virus infection	1 (4.2)	0	0	1 (4.2)	0
Pneumonia fungal	1 (4.2)	0	0	1 (4.2)	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory tract infection	1 (4.2)	0	0	0	1 (4.2)
Respiratory tract infection viral	0	0	0	0	0
Rhinovirus infection	1 (4.2)	1 (4.2)	0	0	0
Rotavirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic embolus	1 (4.2)	0	0	0	1 (4.2)

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	1 (4.2)	0	0	1 (4.2)	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (8.3)	0	1 (4.2)	1 (4.2)	0
Delirium	0	0	0	0	0
Encephalopathy	1 (4.2)	0	0	1 (4.2)	0
Mental status changes	0	0	0	0	0
Seizure	1 (4.2)	0	1 (4.2)	0	0
Tumour Lysis Syndrome					

Number of previous relapses: 2

Group term Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (4.2)	0	0	1 (4.2)	0
Tumour lysis syndrome	1 (4.2)	0	0	1 (4.2)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (80.0)	0	2 (10.0)	8 (40.0)	6 (30.0)
Cytokine Release Syndrome					
-Total	8 (40.0)	2 (10.0)	2 (10.0)	2 (10.0)	2 (10.0)
Cytokine release syndrome	8 (40.0)	2 (10.0)	2 (10.0)	2 (10.0)	2 (10.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	11 (55.0)	0	0	7 (35.0)	4 (20.0)
Cellulitis	0	0	0	0	0

Number of previous relapses: >=3

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Corona virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	2 (10.0)	0	0	2 (10.0)	0
Bacterial sepsis	0	0	0	0	0
Bronchitis	1 (5.0)	0	1 (5.0)	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Campylobacter infection	1 (5.0)	0	0	1 (5.0)	0
Candida sepsis	0	0	0	0	0
Catheter site infection	0	0	0	0	0
Cellulitis of male external genital organ	1 (5.0)	0	0	1 (5.0)	0
Cholecystitis infective	0	0	0	0	0
Clostridium difficile colitis	1 (5.0)	0	1 (5.0)	0	0
Clostridium difficile infection	1 (5.0)	0	0	1 (5.0)	0
Device related infection	1 (5.0)	0	0	1 (5.0)	0
Enterococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus infection	1 (5.0)	0	0	1 (5.0)	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis norovirus	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella sepsis	2 (10.0)	0	0	0	2 (10.0)
Necrotising fasciitis	1 (5.0)	0	0	1 (5.0)	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Respiratory tract infection viral	1 (5.0)	0	0	1 (5.0)	0
Rhinovirus infection	0	0	0	0	0
Rotavirus infection	1 (5.0)	0	0	1 (5.0)	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Septic embolus	0	0	0	0	0

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Staphylococcal infection	1 (5.0)	0	0	0	1 (5.0)
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Upper respiratory tract infection	1 (5.0)	0	0	1 (5.0)	0
Urinary tract infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Vascular device infection	1 (5.0)	0	0	1 (5.0)	0
Viral upper respiratory tract infection	0	0	0	0	0
Vulvovaginal candidiasis	1 (5.0)	0	1 (5.0)	0	0
Serious neurological adverse reactions					
-Total	3 (15.0)	1 (5.0)	0	2 (10.0)	0
Delirium	0	0	0	0	0
Encephalopathy	1 (5.0)	1 (5.0)	0	0	0
Mental status changes	1 (5.0)	0	0	1 (5.0)	0
Seizure	1 (5.0)	0	0	1 (5.0)	0
Tumour Lysis Syndrome					

Number of previous relapses: >=3

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	421	19 (95.00)	155	14 (70.00)
Blood and lymphatic system disorders				
- Total	28	11 (55.00)	23	9 (45.00)
Thrombocytopenia	9	1 (5.00)	8	1 (5.00)
Anaemia	8	6 (30.00)	6	4 (20.00)
Febrile neutropenia	8	6 (30.00)	8	6 (30.00)
Disseminated intravascular coagulation	2	1 (5.00)	1	1 (5.00)
Coagulopathy	1	1 (5.00)	0	0 (0.00)
Cardiac disorders				
- Total	11	8 (40.00)	0	0 (0.00)
Sinus tachycardia	3	3 (15.00)	0	0 (0.00)
Tachycardia	3	2 (10.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Atrioventricular block second degree	1	1 (5.00)	0	0 (0.00)
Bradycardia	1	1 (5.00)	0	0 (0.00)
Cardiac dysfunction	1	1 (5.00)	0	0 (0.00)
Palpitations	1	1 (5.00)	0	0 (0.00)
Pericardial effusion	1	1 (5.00)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Ear pain	1	1 (5.00)	0	0 (0.00)
Eye disorders				
- Total	7	4 (20.00)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (10.00)	0	0 (0.00)
Periorbital oedema	2	2 (10.00)	0	0 (0.00)
Photophobia	2	1 (5.00)	0	0 (0.00)
Retinal haemorrhage	1	1 (5.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	44	12 (60.00)	6	5 (25.00)
Vomiting	12	7 (35.00)	0	0 (0.00)
Nausea	10	8 (40.00)	2	2 (10.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Diarrhoea	6	6 (30.00)	0	0 (0.00)
Abdominal pain	5	4 (20.00)	0	0 (0.00)
Constipation	3	3 (15.00)	0	0 (0.00)
Pancreatitis	2	2 (10.00)	1	1 (5.00)
Abdominal distension	1	1 (5.00)	0	0 (0.00)
Abdominal tenderness	1	1 (5.00)	0	0 (0.00)
Ascites	1	1 (5.00)	1	1 (5.00)
Dysphagia	1	1 (5.00)	1	1 (5.00)
Ileus	1	1 (5.00)	1	1 (5.00)
Tooth socket haemorrhage	1	1 (5.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	20	8 (40.00)	6	3 (15.00)
Pyrexia	7	4 (20.00)	2	2 (10.00)
Fatigue	3	3 (15.00)	0	0 (0.00)
Catheter site pain	2	2 (10.00)	0	0 (0.00)
Oedema peripheral	2	2 (10.00)	1	1 (5.00)
Chills	1	1 (5.00)	0	0 (0.00)
Face oedema	1	1 (5.00)	1	1 (5.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Generalised oedema	1	1 (5.00)	0	0 (0.00)
Localised oedema	1	1 (5.00)	1	1 (5.00)
Mucosal haemorrhage	1	1 (5.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (5.00)	1	1 (5.00)
Hepatobiliary disorders				
- Total	2	2 (10.00)	1	1 (5.00)
Hepatosplenomegaly	1	1 (5.00)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (5.00)	1	1 (5.00)
Immune system disorders				
- Total	38	19 (95.00)	11	6 (30.00)
Cytokine release syndrome	28	16 (80.00)	10	6 (30.00)
Hypogammaglobulinaemia	9	9 (45.00)	1	1 (5.00)
Haemophagocytic lymphohistiocytosis	1	1 (5.00)	0	0 (0.00)
Infections and infestations				
- Total	17	10 (50.00)	4	4 (20.00)
Clostridium difficile infection	3	3 (15.00)	0	0 (0.00)
Rhinovirus infection	3	3 (15.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Clostridium difficile colitis	2	2 (10.00)	1	1 (5.00)
Catheter site infection	1	1 (5.00)	1	1 (5.00)
Gastroenteritis	1	1 (5.00)	0	0 (0.00)
Oral candidiasis	1	1 (5.00)	0	0 (0.00)
Pneumonia	1	1 (5.00)	1	1 (5.00)
Septic embolus	1	1 (5.00)	1	1 (5.00)
Staphylococcal infection	1	1 (5.00)	0	0 (0.00)
Viral infection	1	1 (5.00)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (5.00)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (5.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	9	5 (25.00)	0	0 (0.00)
Procedural pain	2	2 (10.00)	0	0 (0.00)
Transfusion reaction	2	1 (5.00)	0	0 (0.00)
Infusion related reaction	1	1 (5.00)	0	0 (0.00)
Procedural complication	1	1 (5.00)	0	0 (0.00)
Procedural site reaction	1	1 (5.00)	0	0 (0.00)
Stoma site irritation	1	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Tibia fracture	1	1 (5.00)	0	0 (0.00)
Investigations				
- Total	111	15 (75.00)	63	13 (65.00)
White blood cell count decreased	20	9 (45.00)	14	7 (35.00)
Neutrophil count decreased	18	8 (40.00)	16	7 (35.00)
Aspartate aminotransferase increased	13	7 (35.00)	8	5 (25.00)
Platelet count decreased	10	3 (15.00)	9	3 (15.00)
Alanine aminotransferase increased	7	6 (30.00)	4	4 (20.00)
Blood bilirubin increased	7	3 (15.00)	1	1 (5.00)
Blood fibrinogen decreased	6	2 (10.00)	2	2 (10.00)
Lymphocyte count decreased	4	4 (20.00)	2	2 (10.00)
Prothrombin time prolonged	4	2 (10.00)	0	0 (0.00)
Blood sodium increased	2	1 (5.00)	0	0 (0.00)
Blood urea increased	2	2 (10.00)	1	1 (5.00)
Blood uric acid increased	2	1 (5.00)	0	0 (0.00)
International normalised ratio increased	2	2 (10.00)	1	1 (5.00)
Lipase increased	2	2 (10.00)	2	2 (10.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Activated partial thromboplastin time prolonged	1	1 (5.00)	0	0 (0.00)
Blood creatinine increased	1	1 (5.00)	1	1 (5.00)
Blood immunoglobulin G decreased	1	1 (5.00)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (5.00)	0	0 (0.00)
Blood lactic acid increased	1	1 (5.00)	1	1 (5.00)
Blood phosphorus decreased	1	1 (5.00)	0	0 (0.00)
Blood phosphorus increased	1	1 (5.00)	0	0 (0.00)
Fibrin D dimer increased	1	1 (5.00)	0	0 (0.00)
Protein total decreased	1	1 (5.00)	1	1 (5.00)
Pulmonary function test decreased	1	1 (5.00)	0	0 (0.00)
Serum ferritin increased	1	1 (5.00)	0	0 (0.00)
Transaminases increased	1	1 (5.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	50	13 (65.00)	20	7 (35.00)
Decreased appetite	8	6 (30.00)	4	3 (15.00)
Hypokalaemia	8	7 (35.00)	5	5 (25.00)
Hypophosphataemia	8	5 (25.00)	5	3 (15.00)
Hypertriglyceridaemia	3	2 (10.00)	1	1 (5.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Hypoalbuminaemia	3	2 (10.00)	1	1 (5.00)
Hypocalcaemia	3	2 (10.00)	0	0 (0.00)
Hypercalcaemia	2	1 (5.00)	0	0 (0.00)
Hyperglycaemia	2	1 (5.00)	0	0 (0.00)
Hypernatraemia	2	1 (5.00)	0	0 (0.00)
Hyponatraemia	2	1 (5.00)	2	1 (5.00)
Acidosis	1	1 (5.00)	1	1 (5.00)
Fluid overload	1	1 (5.00)	0	0 (0.00)
Hyperalbuminaemia	1	1 (5.00)	0	0 (0.00)
Hyperchloraemia	1	1 (5.00)	0	0 (0.00)
Hypermagnesaemia	1	1 (5.00)	0	0 (0.00)
Hyperphosphataemia	1	1 (5.00)	0	0 (0.00)
Hypomagnesaemia	1	1 (5.00)	0	0 (0.00)
Malnutrition	1	1 (5.00)	1	1 (5.00)
Metabolic alkalosis	1	1 (5.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	3	3 (15.00)	0	0 (0.00)
Pain in extremity	2	2 (10.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Osteopenia	1	1 (5.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (5.00)	0	0 (0.00)
Skin papilloma	1	1 (5.00)	0	0 (0.00)
Nervous system disorders				
- Total	12	9 (45.00)	2	2 (10.00)
Headache	7	7 (35.00)	0	0 (0.00)
Depressed level of consciousness	1	1 (5.00)	0	0 (0.00)
Dizziness	1	1 (5.00)	0	0 (0.00)
Embolic stroke	1	1 (5.00)	1	1 (5.00)
Migraine	1	1 (5.00)	0	0 (0.00)
Seizure	1	1 (5.00)	1	1 (5.00)
Psychiatric disorders				
- Total	6	4 (20.00)	0	0 (0.00)
Confusional state	2	2 (10.00)	0	0 (0.00)
Anxiety	1	1 (5.00)	0	0 (0.00)
Delirium	1	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Insomnia	1	1 (5.00)	0	0 (0.00)
Irritability	1	1 (5.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	4 (20.00)	2	2 (10.00)
Acute kidney injury	2	2 (10.00)	1	1 (5.00)
Dysuria	1	1 (5.00)	0	0 (0.00)
Pollakiuria	1	1 (5.00)	0	0 (0.00)
Renal impairment	1	1 (5.00)	1	1 (5.00)
Reproductive system and breast disorders				
- Total	2	2 (10.00)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (10.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	22	9 (45.00)	10	5 (25.00)
Hypoxia	5	4 (20.00)	3	3 (15.00)
Cough	4	4 (20.00)	0	0 (0.00)
Pleural effusion	4	4 (20.00)	2	2 (10.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Epistaxis	2	2 (10.00)	1	1 (5.00)
Pulmonary oedema	2	2 (10.00)	2	2 (10.00)
Tachypnoea	2	1 (5.00)	0	0 (0.00)
Respiratory distress	1	1 (5.00)	1	1 (5.00)
Respiratory failure	1	1 (5.00)	1	1 (5.00)
Wheezing	1	1 (5.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	16	8 (40.00)	0	0 (0.00)
Hyperhidrosis	3	2 (10.00)	0	0 (0.00)
Rash	2	2 (10.00)	0	0 (0.00)
Rash maculo-papular	2	2 (10.00)	0	0 (0.00)
Rash papular	2	2 (10.00)	0	0 (0.00)
Dermatitis diaper	1	1 (5.00)	0	0 (0.00)
Erythema	1	1 (5.00)	0	0 (0.00)
Macule	1	1 (5.00)	0	0 (0.00)
Petechiae	1	1 (5.00)	0	0 (0.00)
Rash erythematous	1	1 (5.00)	0	0 (0.00)
Rash follicular	1	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Rash macular	1	1 (5.00)	0	0 (0.00)
Vascular disorders				
- Total	16	8 (40.00)	7	5 (25.00)
Hypotension	6	5 (25.00)	5	4 (20.00)
Hypertension	5	5 (25.00)	0	0 (0.00)
Flushing	3	2 (10.00)	0	0 (0.00)
Capillary leak syndrome	1	1 (5.00)	1	1 (5.00)
Embolism	1	1 (5.00)	1	1 (5.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Total number of AE per patient	701	34 (100.00)	236	30 (88.24)
Blood and lymphatic system disorders				
- Total	67	25 (73.53)	51	22 (64.71)
Anaemia	29	18 (52.94)	19	12 (35.29)
Febrile neutropenia	16	14 (41.18)	16	14 (41.18)
Thrombocytopenia	12	4 (11.76)	8	4 (11.76)
Neutropenia	5	5 (14.71)	5	5 (14.71)
Disseminated intravascular coagulation	3	3 (8.82)	1	1 (2.94)
Lymphopenia	2	2 (5.88)	2	2 (5.88)
Cardiac disorders				
- Total	16	10 (29.41)	1	1 (2.94)
Tachycardia	10	9 (26.47)	1	1 (2.94)
Sinus bradycardia	2	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Sinus tachycardia	2	2 (5.88)	0	0 (0.00)
Pericardial effusion	1	1 (2.94)	0	0 (0.00)
Ventricular tachycardia	1	1 (2.94)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (2.94)	0	0 (0.00)
Ear pain	1	1 (2.94)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.94)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.94)	0	0 (0.00)
Eye disorders				
- Total	15	7 (20.59)	0	0 (0.00)
Eye pain	4	3 (8.82)	0	0 (0.00)
Vision blurred	4	3 (8.82)	0	0 (0.00)
Periorbital oedema	2	2 (5.88)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (2.94)	0	0 (0.00)
Ocular hypertension	1	1 (2.94)	0	0 (0.00)
Photophobia	1	1 (2.94)	0	0 (0.00)
Retinal haemorrhage	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Uveitis	1	1 (2.94)	0	0 (0.00)
Gastrointestinal disorders				
- Total	63	19 (55.88)	5	4 (11.76)
Vomiting	20	12 (35.29)	2	2 (5.88)
Nausea	10	9 (26.47)	0	0 (0.00)
Diarrhoea	8	8 (23.53)	1	1 (2.94)
Abdominal pain	4	4 (11.76)	0	0 (0.00)
Constipation	4	3 (8.82)	0	0 (0.00)
Anal incontinence	2	1 (2.94)	0	0 (0.00)
Haematemesis	2	2 (5.88)	0	0 (0.00)
Mouth haemorrhage	2	1 (2.94)	2	1 (2.94)
Stomatitis	2	2 (5.88)	0	0 (0.00)
Abdominal distension	1	1 (2.94)	0	0 (0.00)
Abdominal pain lower	1	1 (2.94)	0	0 (0.00)
Abdominal pain upper	1	1 (2.94)	0	0 (0.00)
Dysphagia	1	1 (2.94)	0	0 (0.00)
Flatulence	1	1 (2.94)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (2.94)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Glossodynia	1	1 (2.94)	0	0 (0.00)
Lip pain	1	1 (2.94)	0	0 (0.00)
General disorders and administration site conditions				
- Total	41	19 (55.88)	6	5 (14.71)
Pyrexia	13	8 (23.53)	2	2 (5.88)
Fatigue	9	8 (23.53)	1	1 (2.94)
Chills	4	4 (11.76)	0	0 (0.00)
Pain	3	3 (8.82)	2	2 (5.88)
Generalised oedema	2	1 (2.94)	0	0 (0.00)
Malaise	2	2 (5.88)	0	0 (0.00)
Catheter site extravasation	1	1 (2.94)	0	0 (0.00)
Catheter site haemorrhage	1	1 (2.94)	0	0 (0.00)
Catheter site pain	1	1 (2.94)	0	0 (0.00)
Face oedema	1	1 (2.94)	0	0 (0.00)
Injection site haematoma	1	1 (2.94)	0	0 (0.00)
Non-cardiac chest pain	1	1 (2.94)	0	0 (0.00)
Peripheral swelling	1	1 (2.94)	0	0 (0.00)
Physical deconditioning	1	1 (2.94)	1	1 (2.94)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Hepatobiliary disorders				
- Total	6	4 (11.76)	1	1 (2.94)
Hyperbilirubinaemia	3	2 (5.88)	1	1 (2.94)
Hepatomegaly	2	2 (5.88)	0	0 (0.00)
Gallbladder enlargement	1	1 (2.94)	0	0 (0.00)
Immune system disorders				
- Total	62	30 (88.24)	19	13 (38.24)
Cytokine release syndrome	46	26 (76.47)	16	10 (29.41)
Hypogammaglobulinaemia	14	14 (41.18)	3	3 (8.82)
Drug hypersensitivity	1	1 (2.94)	0	0 (0.00)
Graft versus host disease in skin	1	1 (2.94)	0	0 (0.00)
Infections and infestations				
- Total	20	13 (38.24)	2	2 (5.88)
Clostridium difficile colitis	2	2 (5.88)	0	0 (0.00)
Acute sinusitis	1	1 (2.94)	0	0 (0.00)
Body tinea	1	1 (2.94)	0	0 (0.00)
Catheter site cellulitis	1	1 (2.94)	0	0 (0.00)
Clostridium difficile infection	1	1 (2.94)	0	0 (0.00)
Cytomegalovirus infection	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Enterococcal infection	1	1 (2.94)	0	0 (0.00)
Fungal skin infection	1	1 (2.94)	0	0 (0.00)
Gastroenteritis	1	1 (2.94)	1	1 (2.94)
Gastroenteritis norovirus	1	1 (2.94)	0	0 (0.00)
Herpes simplex	1	1 (2.94)	0	0 (0.00)
Hypopyon	1	1 (2.94)	0	0 (0.00)
Influenza	1	1 (2.94)	0	0 (0.00)
Orchitis	1	1 (2.94)	0	0 (0.00)
Pharyngitis	1	1 (2.94)	0	0 (0.00)
Skin infection	1	1 (2.94)	0	0 (0.00)
Staphylococcal infection	1	1 (2.94)	1	1 (2.94)
Streptococcal infection	1	1 (2.94)	0	0 (0.00)
Upper respiratory tract infection	1	1 (2.94)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	11	7 (20.59)	1	1 (2.94)
Contusion	1	1 (2.94)	0	0 (0.00)
Infusion related reaction	1	1 (2.94)	0	0 (0.00)
Mouth injury	1	1 (2.94)	0	0 (0.00)
Post procedural haemorrhage	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Procedural headache	1	1 (2.94)	0	0 (0.00)
Procedural pain	1	1 (2.94)	0	0 (0.00)
Skin abrasion	1	1 (2.94)	0	0 (0.00)
Subdural haemorrhage	1	1 (2.94)	0	0 (0.00)
Tongue injury	1	1 (2.94)	0	0 (0.00)
Transfusion reaction	1	1 (2.94)	0	0 (0.00)
Transfusion related complication	1	1 (2.94)	1	1 (2.94)
Investigations				
- Total	184	29 (85.29)	100	23 (67.65)
Neutrophil count decreased	28	16 (47.06)	27	15 (44.12)
Platelet count decreased	28	13 (38.24)	25	10 (29.41)
White blood cell count decreased	28	17 (50.00)	18	15 (44.12)
Alanine aminotransferase increased	20	12 (35.29)	10	7 (20.59)
Aspartate aminotransferase increased	17	9 (26.47)	7	5 (14.71)
Lymphocyte count decreased	11	9 (26.47)	9	8 (23.53)
Blood creatinine increased	10	8 (23.53)	1	1 (2.94)
Activated partial thromboplastin time prolonged	7	4 (11.76)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
International normalised ratio increased	7	6 (17.65)	0	0 (0.00)
Prothrombin time prolonged	7	4 (11.76)	0	0 (0.00)
Blood bilirubin increased	6	4 (11.76)	1	1 (2.94)
Blood immunoglobulin A decreased	3	3 (8.82)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (5.88)	0	0 (0.00)
Blood phosphorus increased	2	1 (2.94)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (2.94)	0	0 (0.00)
Blood magnesium decreased	1	1 (2.94)	1	1 (2.94)
Blood urea increased	1	1 (2.94)	0	0 (0.00)
Cardiac murmur	1	1 (2.94)	0	0 (0.00)
Culture stool positive	1	1 (2.94)	0	0 (0.00)
Haemoglobin decreased	1	1 (2.94)	1	1 (2.94)
Norovirus test positive	1	1 (2.94)	0	0 (0.00)
Transaminases increased	1	1 (2.94)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	50	19 (55.88)	16	12 (35.29)
Decreased appetite	12	10 (29.41)	6	6 (17.65)
Hypokalaemia	8	6 (17.65)	2	2 (5.88)
Hyperphosphataemia	7	6 (17.65)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Hypernatraemia	5	3 (8.82)	1	1 (2.94)
Hypophosphataemia	4	3 (8.82)	3	3 (8.82)
Hyperuricaemia	3	2 (5.88)	0	0 (0.00)
Hypoalbuminaemia	3	3 (8.82)	0	0 (0.00)
Dehydration	2	2 (5.88)	1	1 (2.94)
Acidosis	1	1 (2.94)	0	0 (0.00)
Fluid overload	1	1 (2.94)	0	0 (0.00)
Hyperglycaemia	1	1 (2.94)	0	0 (0.00)
Hypocalcaemia	1	1 (2.94)	1	1 (2.94)
Hyponatraemia	1	1 (2.94)	1	1 (2.94)
Tumour lysis syndrome	1	1 (2.94)	1	1 (2.94)
Musculoskeletal and connective tissue disorders				
- Total	16	10 (29.41)	1	1 (2.94)
Myalgia	5	5 (14.71)	0	0 (0.00)
Arthralgia	4	4 (11.76)	1	1 (2.94)
Musculoskeletal pain	2	2 (5.88)	0	0 (0.00)
Coccydynia	1	1 (2.94)	0	0 (0.00)
Muscle spasms	1	1 (2.94)	0	0 (0.00)
Muscular weakness	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Musculoskeletal chest pain	1	1 (2.94)	0	0 (0.00)
Pain in extremity	1	1 (2.94)	0	0 (0.00)
Nervous system disorders				
- Total	41	20 (58.82)	4	3 (8.82)
Headache	22	15 (44.12)	2	2 (5.88)
Encephalopathy	6	4 (11.76)	2	2 (5.88)
Dysarthria	2	2 (5.88)	0	0 (0.00)
Seizure	2	2 (5.88)	0	0 (0.00)
Tremor	2	2 (5.88)	0	0 (0.00)
Asterixis	1	1 (2.94)	0	0 (0.00)
Ataxia	1	1 (2.94)	0	0 (0.00)
Dizziness	1	1 (2.94)	0	0 (0.00)
Myoclonus	1	1 (2.94)	0	0 (0.00)
Neuropathy peripheral	1	1 (2.94)	0	0 (0.00)
Pleocytosis	1	1 (2.94)	0	0 (0.00)
Somnolence	1	1 (2.94)	0	0 (0.00)
Product issues				
- Total	1	1 (2.94)	0	0 (0.00)
Device occlusion	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Psychiatric disorders				
- Total	20	8 (23.53)	0	0 (0.00)
Anxiety	4	4 (11.76)	0	0 (0.00)
Agitation	3	2 (5.88)	0	0 (0.00)
Confusional state	3	3 (8.82)	0	0 (0.00)
Hallucination	3	2 (5.88)	0	0 (0.00)
Delirium	2	2 (5.88)	0	0 (0.00)
Adjustment disorder	1	1 (2.94)	0	0 (0.00)
Irritability	1	1 (2.94)	0	0 (0.00)
Listless	1	1 (2.94)	0	0 (0.00)
Mental status changes	1	1 (2.94)	0	0 (0.00)
Suicidal ideation	1	1 (2.94)	0	0 (0.00)
Renal and urinary disorders				
- Total	9	5 (14.71)	6	3 (8.82)
Acute kidney injury	3	3 (8.82)	2	2 (5.88)
Haematuria	2	2 (5.88)	1	1 (2.94)
Oliguria	2	2 (5.88)	2	2 (5.88)
Dysuria	1	1 (2.94)	0	0 (0.00)
Renal failure	1	1 (2.94)	1	1 (2.94)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	41	16 (47.06)	12	5 (14.71)
Epistaxis	8	4 (11.76)	3	3 (8.82)
Hypoxia	5	4 (11.76)	2	2 (5.88)
Tachypnoea	4	4 (11.76)	1	1 (2.94)
Cough	3	3 (8.82)	0	0 (0.00)
Haemoptysis	3	2 (5.88)	1	1 (2.94)
Pulmonary oedema	3	3 (8.82)	2	2 (5.88)
Dyspnoea	2	1 (2.94)	1	1 (2.94)
Oropharyngeal pain	2	2 (5.88)	0	0 (0.00)
Pleural effusion	2	2 (5.88)	0	0 (0.00)
Respiratory failure	2	2 (5.88)	2	2 (5.88)
Atelectasis	1	1 (2.94)	0	0 (0.00)
Nasal congestion	1	1 (2.94)	0	0 (0.00)
Oropharyngeal plaque	1	1 (2.94)	0	0 (0.00)
Pharyngeal ulceration	1	1 (2.94)	0	0 (0.00)
Respiratory depression	1	1 (2.94)	0	0 (0.00)
Rhinitis allergic	1	1 (2.94)	0	0 (0.00)
Rhinorrhoea	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	19	10 (29.41)	1	1 (2.94)
Dry skin	4	4 (11.76)	0	0 (0.00)
Erythema	3	2 (5.88)	0	0 (0.00)
Ecchymosis	1	1 (2.94)	1	1 (2.94)
Hyperhidrosis	1	1 (2.94)	0	0 (0.00)
Ingrowing nail	1	1 (2.94)	0	0 (0.00)
Livedo reticularis	1	1 (2.94)	0	0 (0.00)
Night sweats	1	1 (2.94)	0	0 (0.00)
Petechiae	1	1 (2.94)	0	0 (0.00)
Pruritus	1	1 (2.94)	0	0 (0.00)
Rash	1	1 (2.94)	0	0 (0.00)
Rash vesicular	1	1 (2.94)	0	0 (0.00)
Skin exfoliation	1	1 (2.94)	0	0 (0.00)
Skin fissures	1	1 (2.94)	0	0 (0.00)
Skin irritation	1	1 (2.94)	0	0 (0.00)
Vascular disorders				
- Total	17	11 (32.35)	10	9 (26.47)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Hypotension	11	9 (26.47)	9	9 (26.47)
Hypertension	3	2 (5.88)	1	1 (2.94)
Haematoma	1	1 (2.94)	0	0 (0.00)
Orthostatic hypotension	1	1 (2.94)	0	0 (0.00)
Secondary hypertension	1	1 (2.94)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Total number of AE per patient	192	10 (100.00)	67	10 (100.00)
Blood and lymphatic system disorders				
- Total	27	7 (70.00)	19	7 (70.00)
Anaemia	10	3 (30.00)	6	3 (30.00)
Thrombocytopenia	9	3 (30.00)	7	3 (30.00)
Neutropenia	4	3 (30.00)	3	3 (30.00)
Febrile neutropenia	2	2 (20.00)	2	2 (20.00)
Lymphopenia	1	1 (10.00)	0	0 (0.00)
Pancytopenia	1	1 (10.00)	1	1 (10.00)
Cardiac disorders				
- Total	5	4 (40.00)	2	1 (10.00)
Tachycardia	4	4 (40.00)	1	1 (10.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Left ventricular dysfunction	1	1 (10.00)	1	1 (10.00)
Ear and labyrinth disorders				
- Total	1	1 (10.00)	0	0 (0.00)
Hypoacusis	1	1 (10.00)	0	0 (0.00)
Eye disorders				
- Total	3	2 (20.00)	0	0 (0.00)
Papilloedema	1	1 (10.00)	0	0 (0.00)
Uveitis	1	1 (10.00)	0	0 (0.00)
Visual impairment	1	1 (10.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	19	5 (50.00)	4	2 (20.00)
Nausea	6	4 (40.00)	1	1 (10.00)
Diarrhoea	4	4 (40.00)	0	0 (0.00)
Vomiting	3	3 (30.00)	1	1 (10.00)
Abdominal discomfort	1	1 (10.00)	0	0 (0.00)
Abdominal pain	1	1 (10.00)	1	1 (10.00)
Abdominal pain upper	1	1 (10.00)	0	0 (0.00)
Constipation	1	1 (10.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Dyspepsia	1	1 (10.00)	0	0 (0.00)
Intestinal obstruction	1	1 (10.00)	1	1 (10.00)
General disorders and administration site conditions				
- Total	16	5 (50.00)	2	2 (20.00)
Pyrexia	7	4 (40.00)	2	2 (20.00)
Chills	4	3 (30.00)	0	0 (0.00)
Fatigue	2	2 (20.00)	0	0 (0.00)
Asthenia	1	1 (10.00)	0	0 (0.00)
Facial pain	1	1 (10.00)	0	0 (0.00)
Malaise	1	1 (10.00)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (10.00)	0	0 (0.00)
Hepatomegaly	1	1 (10.00)	0	0 (0.00)
Immune system disorders				
- Total	16	8 (80.00)	3	3 (30.00)
Cytokine release syndrome	12	8 (80.00)	3	3 (30.00)
Hypogammaglobulinaemia	4	3 (30.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Infections and infestations				
- Total	4	3 (30.00)	1	1 (10.00)
Folliculitis	1	1 (10.00)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (10.00)	0	0 (0.00)
Pneumonia	1	1 (10.00)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (10.00)	1	1 (10.00)
Injury, poisoning and procedural complications				
- Total	5	3 (30.00)	1	1 (10.00)
Tracheal haemorrhage	2	1 (10.00)	1	1 (10.00)
Incision site pain	1	1 (10.00)	0	0 (0.00)
Limb injury	1	1 (10.00)	0	0 (0.00)
Transfusion reaction	1	1 (10.00)	0	0 (0.00)
Investigations				
- Total	37	8 (80.00)	15	8 (80.00)
Blood fibrinogen decreased	9	2 (20.00)	2	1 (10.00)
White blood cell count decreased	7	4 (40.00)	5	4 (40.00)
Prothrombin time prolonged	6	3 (30.00)	1	1 (10.00)
Platelet count decreased	5	3 (30.00)	3	1 (10.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Aspartate aminotransferase increased	2	2 (20.00)	1	1 (10.00)
International normalised ratio increased	2	1 (10.00)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (10.00)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (10.00)	0	0 (0.00)
C-reactive protein increased	1	1 (10.00)	1	1 (10.00)
Hepatic enzyme increased	1	1 (10.00)	0	0 (0.00)
Lymphocyte count decreased	1	1 (10.00)	1	1 (10.00)
Neutrophil count decreased	1	1 (10.00)	1	1 (10.00)
Metabolism and nutrition disorders				
- Total	16	7 (70.00)	7	5 (50.00)
Decreased appetite	4	4 (40.00)	3	3 (30.00)
Hypokalaemia	4	3 (30.00)	0	0 (0.00)
Hyperphosphataemia	2	1 (10.00)	0	0 (0.00)
Dehydration	1	1 (10.00)	1	1 (10.00)
Fluid overload	1	1 (10.00)	0	0 (0.00)
Hyperglycaemia	1	1 (10.00)	1	1 (10.00)
Hyperuricaemia	1	1 (10.00)	1	1 (10.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Hypophosphataemia	1	1 (10.00)	1	1 (10.00)
Metabolic acidosis	1	1 (10.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	4	2 (20.00)	0	0 (0.00)
Musculoskeletal pain	2	1 (10.00)	0	0 (0.00)
Limb discomfort	1	1 (10.00)	0	0 (0.00)
Pain in extremity	1	1 (10.00)	0	0 (0.00)
Nervous system disorders				
- Total	5	4 (40.00)	0	0 (0.00)
Dizziness	2	2 (20.00)	0	0 (0.00)
Headache	2	2 (20.00)	0	0 (0.00)
Idiopathic intracranial hypertension	1	1 (10.00)	0	0 (0.00)
Psychiatric disorders				
- Total	4	4 (40.00)	1	1 (10.00)
Anxiety	1	1 (10.00)	1	1 (10.00)
Confusional state	1	1 (10.00)	0	0 (0.00)
Delirium	1	1 (10.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Panic attack	1	1 (10.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	4	2 (20.00)	3	2 (20.00)
Acute kidney injury	2	2 (20.00)	2	2 (20.00)
Haematuria	2	2 (20.00)	1	1 (10.00)
Reproductive system and breast disorders				
- Total	2	1 (10.00)	0	0 (0.00)
Oedema genital	2	1 (10.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	10	3 (30.00)	6	2 (20.00)
Hypoxia	3	2 (20.00)	3	2 (20.00)
Pleural effusion	2	2 (20.00)	0	0 (0.00)
Cough	1	1 (10.00)	0	0 (0.00)
Dyspnoea	1	1 (10.00)	1	1 (10.00)
Epistaxis	1	1 (10.00)	0	0 (0.00)
Interstitial lung disease	1	1 (10.00)	1	1 (10.00)

Timing: within 8 weeks post infusion, Age: >=18				
Primary system organ class Preferred term	**All grades Total events**	**All patients N=10 n (%)[1]**	**Grade >= 3 Total events**	**All patients N=10 n (%)[2]**
Pulmonary oedema	1	1 (10.00)	1	1 (10.00)
Skin and subcutaneous tissue disorders				
- Total	6	3 (30.00)	1	1 (10.00)
Ingrowing nail	2	1 (10.00)	0	0 (0.00)
Petechiae	1	1 (10.00)	0	0 (0.00)
Pruritus	1	1 (10.00)	0	0 (0.00)
Rash	1	1 (10.00)	0	0 (0.00)
Rash maculo-papular	1	1 (10.00)	1	1 (10.00)
Vascular disorders				
- Total	7	5 (50.00)	2	2 (20.00)
Hypertension	4	3 (30.00)	0	0 (0.00)
Hypotension	2	2 (20.00)	2	2 (20.00)
Orthostatic hypotension	1	1 (10.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Total number of AE per patient	93	15 (83.33)	12	6 (33.33)
Blood and lymphatic system disorders				
- Total	2	2 (11.11)	1	1 (5.56)
Leukopenia	1	1 (5.56)	1	1 (5.56)
Thrombocytopenia	1	1 (5.56)	0	0 (0.00)
Eye disorders				
- Total	3	3 (16.67)	0	0 (0.00)
Conjunctivitis allergic	1	1 (5.56)	0	0 (0.00)
Dry eye	1	1 (5.56)	0	0 (0.00)
Vision blurred	1	1 (5.56)	0	0 (0.00)
Gastrointestinal disorders				
- Total	13	5 (27.78)	1	1 (5.56)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Vomiting	6	4 (22.22)	0	0 (0.00)
Diarrhoea	3	3 (16.67)	0	0 (0.00)
Nausea	2	2 (11.11)	0	0 (0.00)
Abdominal pain	1	1 (5.56)	0	0 (0.00)
Enterocolitis	1	1 (5.56)	1	1 (5.56)
General disorders and administration site conditions				
- Total	9	7 (38.89)	0	0 (0.00)
Pyrexia	5	5 (27.78)	0	0 (0.00)
Acquired gene mutation	1	1 (5.56)	0	0 (0.00)
Crying	1	1 (5.56)	0	0 (0.00)
Fatigue	1	1 (5.56)	0	0 (0.00)
Malaise	1	1 (5.56)	0	0 (0.00)
Immune system disorders				
- Total	3	3 (16.67)	1	1 (5.56)
Hypogammaglobulinaemia	2	2 (11.11)	1	1 (5.56)
Seasonal allergy	1	1 (5.56)	0	0 (0.00)
Infections and infestations				
- Total	23	11 (61.11)	5	3 (16.67)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Upper respiratory tract infection	3	3 (16.67)	0	0 (0.00)
Ear infection	2	2 (11.11)	0	0 (0.00)
Gastroenteritis	2	2 (11.11)	0	0 (0.00)
Corona virus infection	1	1 (5.56)	1	1 (5.56)
Cytomegalovirus infection	1	1 (5.56)	0	0 (0.00)
Enterovirus infection	1	1 (5.56)	1	1 (5.56)
Gastroenteritis viral	1	1 (5.56)	0	0 (0.00)
Molluscum contagiosum	1	1 (5.56)	0	0 (0.00)
Otitis externa	1	1 (5.56)	0	0 (0.00)
Otitis media acute	1	1 (5.56)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (5.56)	1	1 (5.56)
Paronychia	1	1 (5.56)	0	0 (0.00)
Rash pustular	1	1 (5.56)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (5.56)	1	1 (5.56)
Rotavirus infection	1	1 (5.56)	1	1 (5.56)
Sinusitis	1	1 (5.56)	0	0 (0.00)
Tinea capitis	1	1 (5.56)	0	0 (0.00)
Urinary tract infection	1	1 (5.56)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (5.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Injury, poisoning and procedural complications				
- Total	5	4 (22.22)	0	0 (0.00)
Contusion	1	1 (5.56)	0	0 (0.00)
Infusion related reaction	1	1 (5.56)	0	0 (0.00)
Procedural pain	1	1 (5.56)	0	0 (0.00)
Radius fracture	1	1 (5.56)	0	0 (0.00)
Skin abrasion	1	1 (5.56)	0	0 (0.00)
Investigations				
- Total	7	5 (27.78)	2	2 (11.11)
Blood urea increased	2	1 (5.56)	0	0 (0.00)
Neutrophil count decreased	1	1 (5.56)	1	1 (5.56)
Oxygen saturation decreased	1	1 (5.56)	0	0 (0.00)
Weight decreased	1	1 (5.56)	0	0 (0.00)
Weight increased	1	1 (5.56)	0	0 (0.00)
White blood cell count decreased	1	1 (5.56)	1	1 (5.56)
Metabolism and nutrition disorders				
- Total	6	4 (22.22)	2	2 (11.11)
Hyperalbuminaemia	2	1 (5.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Decreased appetite	1	1 (5.56)	0	0 (0.00)
Dehydration	1	1 (5.56)	1	1 (5.56)
Hypercalcaemia	1	1 (5.56)	0	0 (0.00)
Tumour lysis syndrome	1	1 (5.56)	1	1 (5.56)
Musculoskeletal and connective tissue disorders				
- Total	7	7 (38.89)	0	0 (0.00)
Pain in extremity	6	6 (33.33)	0	0 (0.00)
Toe walking	1	1 (5.56)	0	0 (0.00)
Nervous system disorders				
- Total	3	2 (11.11)	0	0 (0.00)
Dizziness	2	2 (11.11)	0	0 (0.00)
Headache	1	1 (5.56)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (5.56)	0	0 (0.00)
Urinary incontinence	1	1 (5.56)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	7	5 (27.78)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Cough	2	2 (11.11)	0	0 (0.00)
Rhinorrhoea	2	2 (11.11)	0	0 (0.00)
Nasal congestion	1	1 (5.56)	0	0 (0.00)
Oropharyngeal pain	1	1 (5.56)	0	0 (0.00)
Rhinitis allergic	1	1 (5.56)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	4	2 (11.11)	0	0 (0.00)
Rash	2	1 (5.56)	0	0 (0.00)
Papule	1	1 (5.56)	0	0 (0.00)
Pruritus	1	1 (5.56)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Total number of AE per patient	220	24 (77.42)	50	16 (51.61)
Blood and lymphatic system disorders				
- Total	16	9 (29.03)	12	6 (19.35)
Neutropenia	6	4 (12.90)	6	4 (12.90)
Febrile neutropenia	3	3 (9.68)	3	3 (9.68)
Anaemia	2	2 (6.45)	1	1 (3.23)
Eosinophilia	2	1 (3.23)	1	1 (3.23)
Lymphadenopathy	1	1 (3.23)	0	0 (0.00)
Lymphopenia	1	1 (3.23)	0	0 (0.00)
Thrombocytopenia	1	1 (3.23)	1	1 (3.23)
Cardiac disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Sinus tachycardia	1	1 (3.23)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Endocrine disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.23)	0	0 (0.00)
Eye disorders				
- Total	2	2 (6.45)	0	0 (0.00)
Dry eye	1	1 (3.23)	0	0 (0.00)
Ocular hyperaemia	1	1 (3.23)	0	0 (0.00)
Gastrointestinal disorders				
- Total	19	9 (29.03)	3	2 (6.45)
Vomiting	5	3 (9.68)	1	1 (3.23)
Diarrhoea	4	4 (12.90)	0	0 (0.00)
Nausea	3	2 (6.45)	1	1 (3.23)
Oral pain	3	2 (6.45)	1	1 (3.23)
Abdominal pain	2	2 (6.45)	0	0 (0.00)
Abdominal pain upper	1	1 (3.23)	0	0 (0.00)
Pigmentation lip	1	1 (3.23)	0	0 (0.00)
General disorders and administration site conditions				

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
- Total	14	7 (22.58)	1	1 (3.23)
Pyrexia	7	3 (9.68)	1	1 (3.23)
Catheter site pain	1	1 (3.23)	0	0 (0.00)
Chills	1	1 (3.23)	0	0 (0.00)
Fatigue	1	1 (3.23)	0	0 (0.00)
Generalised oedema	1	1 (3.23)	0	0 (0.00)
Influenza like illness	1	1 (3.23)	0	0 (0.00)
Oedema peripheral	1	1 (3.23)	0	0 (0.00)
Pain	1	1 (3.23)	0	0 (0.00)
Immune system disorders				
- Total	13	10 (32.26)	0	0 (0.00)
Hypogammaglobulinaemia	6	5 (16.13)	0	0 (0.00)
Graft versus host disease	3	2 (6.45)	0	0 (0.00)
Immunodeficiency common variable	2	2 (6.45)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (3.23)	0	0 (0.00)
Seasonal allergy	1	1 (3.23)	0	0 (0.00)
Infections and infestations				
- Total	33	17 (54.84)	9	6 (19.35)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Cellulitis of male external genital organ	5	1 (3.23)	2	1 (3.23)
Rhinovirus infection	4	2 (6.45)	0	0 (0.00)
Upper respiratory tract infection	4	4 (12.90)	1	1 (3.23)
Urinary tract infection	4	3 (9.68)	2	2 (6.45)
Otitis media	2	1 (3.23)	0	0 (0.00)
Escherichia urinary tract infection	1	1 (3.23)	1	1 (3.23)
Gastroenteritis	1	1 (3.23)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (3.23)	0	0 (0.00)
Herpes zoster	1	1 (3.23)	1	1 (3.23)
Influenza	1	1 (3.23)	0	0 (0.00)
Oral herpes	1	1 (3.23)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (3.23)	0	0 (0.00)
Rhinitis	1	1 (3.23)	0	0 (0.00)
Sinusitis	1	1 (3.23)	0	0 (0.00)
Subcutaneous abscess	1	1 (3.23)	0	0 (0.00)
Vascular device infection	1	1 (3.23)	1	1 (3.23)
Viral infection	1	1 (3.23)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (3.23)	1	1 (3.23)
Vulvovaginal mycotic infection	1	1 (3.23)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Injury, poisoning and procedural complications				
- Total	7	3 (9.68)	0	0 (0.00)
Arthropod bite	1	1 (3.23)	0	0 (0.00)
Contusion	1	1 (3.23)	0	0 (0.00)
Infusion related reaction	1	1 (3.23)	0	0 (0.00)
Procedural nausea	1	1 (3.23)	0	0 (0.00)
Procedural pain	1	1 (3.23)	0	0 (0.00)
Skin laceration	1	1 (3.23)	0	0 (0.00)
Sunburn	1	1 (3.23)	0	0 (0.00)
Investigations				
- Total	32	14 (45.16)	13	9 (29.03)
Neutrophil count decreased	10	6 (19.35)	6	4 (12.90)
White blood cell count decreased	5	3 (9.68)	2	1 (3.23)
Platelet count decreased	3	2 (6.45)	0	0 (0.00)
Alanine aminotransferase increased	2	2 (6.45)	2	2 (6.45)
Aspartate aminotransferase increased	2	2 (6.45)	2	2 (6.45)
Lymphocyte count decreased	2	2 (6.45)	0	0 (0.00)
Blood bilirubin increased	1	1 (3.23)	1	1 (3.23)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Blood creatinine increased	1	1 (3.23)	0	0 (0.00)
Blood magnesium decreased	1	1 (3.23)	0	0 (0.00)
Blood uric acid increased	1	1 (3.23)	0	0 (0.00)
Haemoglobin decreased	1	1 (3.23)	0	0 (0.00)
Serum ferritin increased	1	1 (3.23)	0	0 (0.00)
Weight decreased	1	1 (3.23)	0	0 (0.00)
Weight increased	1	1 (3.23)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	9	6 (19.35)	4	2 (6.45)
Hyperphosphataemia	2	2 (6.45)	0	0 (0.00)
Hypokalaemia	2	2 (6.45)	1	1 (3.23)
Decreased appetite	1	1 (3.23)	0	0 (0.00)
Hyperglycaemia	1	1 (3.23)	1	1 (3.23)
Hypophosphataemia	1	1 (3.23)	1	1 (3.23)
Iron overload	1	1 (3.23)	1	1 (3.23)
Vitamin D deficiency	1	1 (3.23)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	13	8 (25.81)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Joint range of motion decreased	2	2 (6.45)	0	0 (0.00)
Muscular weakness	2	2 (6.45)	0	0 (0.00)
Pain in extremity	2	2 (6.45)	0	0 (0.00)
Arthralgia	1	1 (3.23)	0	0 (0.00)
Back pain	1	1 (3.23)	0	0 (0.00)
Flank pain	1	1 (3.23)	0	0 (0.00)
Muscle spasms	1	1 (3.23)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.23)	0	0 (0.00)
Osteonecrosis	1	1 (3.23)	0	0 (0.00)
Pain in jaw	1	1 (3.23)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.23)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (3.23)	0	0 (0.00)
Nervous system disorders				
- Total	6	4 (12.90)	0	0 (0.00)
Headache	5	3 (9.68)	0	0 (0.00)
Peroneal nerve palsy	1	1 (3.23)	0	0 (0.00)
Psychiatric disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
- Total	4	2 (6.45)	0	0 (0.00)
Depression	2	2 (6.45)	0	0 (0.00)
Anxiety	1	1 (3.23)	0	0 (0.00)
Sleep disorder	1	1 (3.23)	0	0 (0.00)
Renal and urinary disorders				
- Total	4	2 (6.45)	3	2 (6.45)
Acute kidney injury	1	1 (3.23)	1	1 (3.23)
Calculus urinary	1	1 (3.23)	0	0 (0.00)
Haematuria	1	1 (3.23)	1	1 (3.23)
Nephrolithiasis	1	1 (3.23)	1	1 (3.23)
Reproductive system and breast disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Scrotal pain	1	1 (3.23)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	22	12 (38.71)	4	3 (9.68)
Cough	7	5 (16.13)	0	0 (0.00)
Nasal congestion	3	3 (9.68)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Epistaxis	2	2 (6.45)	1	1 (3.23)
Oropharyngeal pain	2	2 (6.45)	0	0 (0.00)
Rhinorrhoea	2	2 (6.45)	0	0 (0.00)
Acute respiratory failure	1	1 (3.23)	1	1 (3.23)
Dysphonia	1	1 (3.23)	0	0 (0.00)
Pharyngeal erythema	1	1 (3.23)	0	0 (0.00)
Pharyngeal lesion	1	1 (3.23)	1	1 (3.23)
Pulmonary oedema	1	1 (3.23)	1	1 (3.23)
Rhinitis allergic	1	1 (3.23)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	19	13 (41.94)	1	1 (3.23)
Rash	3	3 (9.68)	0	0 (0.00)
Rash erythematous	2	1 (3.23)	0	0 (0.00)
Rash maculo-papular	2	2 (6.45)	0	0 (0.00)
Alopecia	1	1 (3.23)	0	0 (0.00)
Dermatitis	1	1 (3.23)	0	0 (0.00)
Dermatitis acneiform	1	1 (3.23)	1	1 (3.23)
Dermatitis atopic	1	1 (3.23)	0	0 (0.00)
Dry skin	1	1 (3.23)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Eczema	1	1 (3.23)	0	0 (0.00)
Erythema	1	1 (3.23)	0	0 (0.00)
Ingrowing nail	1	1 (3.23)	0	0 (0.00)
Keloid scar	1	1 (3.23)	0	0 (0.00)
Macule	1	1 (3.23)	0	0 (0.00)
Petechiae	1	1 (3.23)	0	0 (0.00)
Rash pruritic	1	1 (3.23)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (6.45)	0	0 (0.00)
Hypertension	2	2 (6.45)	0	0 (0.00)
Hot flush	1	1 (3.23)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Total number of AE per patient	33	7 (100.00)	9	4 (57.14)
Gastrointestinal disorders				
- Total	6	2 (28.57)	4	1 (14.29)
Nausea	2	2 (28.57)	1	1 (14.29)
Vomiting	2	2 (28.57)	1	1 (14.29)
Abdominal pain	1	1 (14.29)	1	1 (14.29)
Diarrhoea	1	1 (14.29)	1	1 (14.29)
General disorders and administration site conditions				
- Total	3	3 (42.86)	0	0 (0.00)
Pyrexia	2	2 (28.57)	0	0 (0.00)
Influenza like illness	1	1 (14.29)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=7** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=7** **n (%)[2]**
Immune system disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (14.29)	0	0 (0.00)
Infections and infestations				
- Total	5	5 (71.43)	3	3 (42.86)
Influenza	2	2 (28.57)	0	0 (0.00)
Bacterial sepsis	1	1 (14.29)	1	1 (14.29)
Cholecystitis infective	1	1 (14.29)	1	1 (14.29)
Sepsis	1	1 (14.29)	1	1 (14.29)
Injury, poisoning and procedural complications				
- Total	1	1 (14.29)	0	0 (0.00)
Foot fracture	1	1 (14.29)	0	0 (0.00)
Investigations				
- Total	9	4 (57.14)	1	1 (14.29)
Platelet count decreased	2	1 (14.29)	0	0 (0.00)
Weight decreased	2	2 (28.57)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (14.29)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Haemoglobin decreased	1	1 (14.29)	0	0 (0.00)
Neutrophil count decreased	1	1 (14.29)	1	1 (14.29)
Transaminases increased	1	1 (14.29)	0	0 (0.00)
White blood cell count decreased	1	1 (14.29)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Arthralgia	1	1 (14.29)	0	0 (0.00)
Nervous system disorders				
- Total	3	2 (28.57)	0	0 (0.00)
Dizziness	1	1 (14.29)	0	0 (0.00)
Headache	1	1 (14.29)	0	0 (0.00)
Peroneal nerve palsy	1	1 (14.29)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (14.29)	1	1 (14.29)
Vaginal haemorrhage	1	1 (14.29)	1	1 (14.29)
Respiratory, thoracic and mediastinal disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
- Total	1	1 (14.29)	0	0 (0.00)
Rhinitis allergic	1	1 (14.29)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	1 (14.29)	0	0 (0.00)
Erythema	1	1 (14.29)	0	0 (0.00)
Hyperhidrosis	1	1 (14.29)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Total number of AE per patient	29	6 (54.55)	8	4 (36.36)
Ear and labyrinth disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Tympanic membrane perforation	1	1 (9.09)	0	0 (0.00)
Gastrointestinal disorders				
- Total	2	1 (9.09)	0	0 (0.00)
Abdominal pain	1	1 (9.09)	0	0 (0.00)
Diarrhoea	1	1 (9.09)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (9.09)	1	1 (9.09)
Cyst	1	1 (9.09)	1	1 (9.09)

Timing: >1 year post-CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Immune system disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Chronic graft versus host disease	1	1 (9.09)	0	0 (0.00)
Infections and infestations				
- Total	17	5 (45.45)	5	3 (27.27)
Otitis media acute	4	2 (18.18)	0	0 (0.00)
Otitis media	3	1 (9.09)	1	1 (9.09)
Campylobacter infection	1	1 (9.09)	1	1 (9.09)
Clostridium difficile infection	1	1 (9.09)	1	1 (9.09)
Haemophilus infection	1	1 (9.09)	0	0 (0.00)
Pneumonia	1	1 (9.09)	0	0 (0.00)
Respiratory tract infection	1	1 (9.09)	1	1 (9.09)
Respiratory tract infection viral	1	1 (9.09)	1	1 (9.09)
Sinusitis	1	1 (9.09)	0	0 (0.00)
Skin infection	1	1 (9.09)	0	0 (0.00)
Urinary tract infection	1	1 (9.09)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (9.09)	0	0 (0.00)
Metabolism and nutrition disorders				

Timing: >1 year post-CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
- Total	1	1 (9.09)	0	0 (0.00)
Vitamin D deficiency	1	1 (9.09)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (9.09)	1	1 (9.09)
Glioblastoma multiforme	1	1 (9.09)	1	1 (9.09)
Nervous system disorders				
- Total	3	2 (18.18)	1	1 (9.09)
Dizziness	1	1 (9.09)	0	0 (0.00)
Headache	1	1 (9.09)	0	0 (0.00)
Seizure	1	1 (9.09)	1	1 (9.09)
Respiratory, thoracic and mediastinal disorders				
- Total	2	1 (9.09)	0	0 (0.00)
Oropharyngeal pain	1	1 (9.09)	0	0 (0.00)
Rhinorrhoea	1	1 (9.09)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Total number of AE per patient	55	15 (68.18)	13	7 (31.82)
Blood and lymphatic system disorders				
- Total	2	2 (9.09)	1	1 (4.55)
Febrile neutropenia	1	1 (4.55)	1	1 (4.55)
Thrombocytopenia	1	1 (4.55)	0	0 (0.00)
Gastrointestinal disorders				
- Total	2	2 (9.09)	0	0 (0.00)
Diarrhoea	1	1 (4.55)	0	0 (0.00)
Nausea	1	1 (4.55)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	1 (4.55)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Pyrexia	2	1 (4.55)	0	0 (0.00)
Chills	1	1 (4.55)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (4.55)	0	0 (0.00)
Immunodeficiency	1	1 (4.55)	0	0 (0.00)
Infections and infestations				
- Total	11	5 (22.73)	2	1 (4.55)
Otitis media	2	2 (9.09)	0	0 (0.00)
Urinary tract infection	2	1 (4.55)	1	1 (4.55)
Cellulitis of male external genital organ	1	1 (4.55)	1	1 (4.55)
Gingivitis	1	1 (4.55)	0	0 (0.00)
Meningitis aseptic	1	1 (4.55)	0	0 (0.00)
Pneumonia	1	1 (4.55)	0	0 (0.00)
Sinusitis	1	1 (4.55)	0	0 (0.00)
Upper respiratory tract infection	1	1 (4.55)	0	0 (0.00)
Viral infection	1	1 (4.55)	0	0 (0.00)
Injury, poisoning and procedural complications				

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
- Total	1	1 (4.55)	1	1 (4.55)
Procedural pain	1	1 (4.55)	1	1 (4.55)
Investigations				
- Total	20	7 (31.82)	6	4 (18.18)
Lymphocyte count decreased	5	3 (13.64)	1	1 (4.55)
White blood cell count decreased	5	4 (18.18)	3	3 (13.64)
Neutrophil count decreased	3	2 (9.09)	0	0 (0.00)
Alanine aminotransferase increased	2	2 (9.09)	1	1 (4.55)
Aspartate aminotransferase increased	1	1 (4.55)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (4.55)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (4.55)	0	0 (0.00)
C-reactive protein increased	1	1 (4.55)	0	0 (0.00)
Platelet count decreased	1	1 (4.55)	1	1 (4.55)
Metabolism and nutrition disorders				
- Total	1	1 (4.55)	1	1 (4.55)
Hypokalaemia	1	1 (4.55)	1	1 (4.55)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	1	1 (4.55)	0	0 (0.00)
Neck pain	1	1 (4.55)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (4.55)	0	0 (0.00)
Disturbance in attention	1	1 (4.55)	0	0 (0.00)
Renal and urinary disorders				
- Total	3	2 (9.09)	1	1 (4.55)
Acute kidney injury	2	1 (4.55)	1	1 (4.55)
Haematuria	1	1 (4.55)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (4.55)	1	1 (4.55)
Ovarian failure	1	1 (4.55)	1	1 (4.55)
Respiratory, thoracic and mediastinal disorders				
- Total	5	3 (13.64)	0	0 (0.00)
Cough	3	2 (9.09)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Epistaxis	1	1 (4.55)	0	0 (0.00)
Rhinitis allergic	1	1 (4.55)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (13.64)	0	0 (0.00)
Acne	1	1 (4.55)	0	0 (0.00)
Papule	1	1 (4.55)	0	0 (0.00)
Pruritus	1	1 (4.55)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	6	1 (100.00)	2	1 (100.00)
Infections and infestations				
- Total	4	1 (100.00)	0	0 (0.00)
Upper respiratory tract infection	3	1 (100.00)	0	0 (0.00)
Sinusitis	1	1 (100.00)	0	0 (0.00)
Investigations				
- Total	2	1 (100.00)	2	1 (100.00)
Alanine aminotransferase increased	1	1 (100.00)	1	1 (100.00)
Aspartate aminotransferase increased	1	1 (100.00)	1	1 (100.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	543	20 (100.00)	175	17 (85.00)
Blood and lymphatic system disorders				
- Total	30	13 (65.00)	24	10 (50.00)
Thrombocytopenia	10	2 (10.00)	8	1 (5.00)
Anaemia	8	6 (30.00)	6	4 (20.00)
Febrile neutropenia	8	6 (30.00)	8	6 (30.00)
Disseminated intravascular coagulation	2	1 (5.00)	1	1 (5.00)
Coagulopathy	1	1 (5.00)	0	0 (0.00)
Leukopenia	1	1 (5.00)	1	1 (5.00)
Cardiac disorders				
- Total	11	8 (40.00)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Sinus tachycardia	3	3 (15.00)	0	0 (0.00)
Tachycardia	3	2 (10.00)	0	0 (0.00)
Atrioventricular block second degree	1	1 (5.00)	0	0 (0.00)
Bradycardia	1	1 (5.00)	0	0 (0.00)
Cardiac dysfunction	1	1 (5.00)	0	0 (0.00)
Palpitations	1	1 (5.00)	0	0 (0.00)
Pericardial effusion	1	1 (5.00)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (10.00)	0	0 (0.00)
Ear pain	1	1 (5.00)	0	0 (0.00)
Tympanic membrane perforation	1	1 (5.00)	0	0 (0.00)
Eye disorders				
- Total	10	7 (35.00)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (10.00)	0	0 (0.00)
Periorbital oedema	2	2 (10.00)	0	0 (0.00)
Photophobia	2	1 (5.00)	0	0 (0.00)
Conjunctivitis allergic	1	1 (5.00)	0	0 (0.00)
Dry eye	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Retinal haemorrhage	1	1 (5.00)	0	0 (0.00)
Vision blurred	1	1 (5.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	59	13 (65.00)	7	6 (30.00)
Vomiting	18	9 (45.00)	0	0 (0.00)
Nausea	12	9 (45.00)	2	2 (10.00)
Diarrhoea	10	8 (40.00)	0	0 (0.00)
Abdominal pain	7	4 (20.00)	0	0 (0.00)
Constipation	3	3 (15.00)	0	0 (0.00)
Pancreatitis	2	2 (10.00)	1	1 (5.00)
Abdominal distension	1	1 (5.00)	0	0 (0.00)
Abdominal tenderness	1	1 (5.00)	0	0 (0.00)
Ascites	1	1 (5.00)	1	1 (5.00)
Dysphagia	1	1 (5.00)	1	1 (5.00)
Enterocolitis	1	1 (5.00)	1	1 (5.00)
Ileus	1	1 (5.00)	1	1 (5.00)
Tooth socket haemorrhage	1	1 (5.00)	0	0 (0.00)
General disorders and administration site conditions				

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	30	12 (60.00)	7	4 (20.00)
Pyrexia	12	7 (35.00)	2	2 (10.00)
Fatigue	4	4 (20.00)	0	0 (0.00)
Catheter site pain	2	2 (10.00)	0	0 (0.00)
Oedema peripheral	2	2 (10.00)	1	1 (5.00)
Acquired gene mutation	1	1 (5.00)	0	0 (0.00)
Chills	1	1 (5.00)	0	0 (0.00)
Crying	1	1 (5.00)	0	0 (0.00)
Cyst	1	1 (5.00)	1	1 (5.00)
Face oedema	1	1 (5.00)	1	1 (5.00)
Generalised oedema	1	1 (5.00)	0	0 (0.00)
Localised oedema	1	1 (5.00)	1	1 (5.00)
Malaise	1	1 (5.00)	0	0 (0.00)
Mucosal haemorrhage	1	1 (5.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (5.00)	1	1 (5.00)
Hepatobiliary disorders				
- Total	2	2 (10.00)	1	1 (5.00)
Hepatosplenomegaly	1	1 (5.00)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (5.00)	1	1 (5.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Immune system disorders				
- Total	42	19 (95.00)	12	6 (30.00)
Cytokine release syndrome	28	16 (80.00)	10	6 (30.00)
Hypogammaglobulinaemia	11	11 (55.00)	2	2 (10.00)
Chronic graft versus host disease	1	1 (5.00)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (5.00)	0	0 (0.00)
Seasonal allergy	1	1 (5.00)	0	0 (0.00)
Infections and infestations				
- Total	57	17 (85.00)	14	8 (40.00)
Otitis media acute	5	2 (10.00)	0	0 (0.00)
Clostridium difficile infection	4	4 (20.00)	1	1 (5.00)
Gastroenteritis	3	3 (15.00)	0	0 (0.00)
Otitis media	3	1 (5.00)	1	1 (5.00)
Rhinovirus infection	3	3 (15.00)	0	0 (0.00)
Upper respiratory tract infection	3	3 (15.00)	0	0 (0.00)
Clostridium difficile colitis	2	2 (10.00)	1	1 (5.00)
Ear infection	2	2 (10.00)	0	0 (0.00)
Pneumonia	2	2 (10.00)	1	1 (5.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Sinusitis	2	2 (10.00)	0	0 (0.00)
Urinary tract infection	2	2 (10.00)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (10.00)	0	0 (0.00)
Vulvovaginal candidiasis	2	2 (10.00)	0	0 (0.00)
Campylobacter infection	1	1 (5.00)	1	1 (5.00)
Catheter site infection	1	1 (5.00)	1	1 (5.00)
Corona virus infection	1	1 (5.00)	1	1 (5.00)
Cytomegalovirus infection	1	1 (5.00)	0	0 (0.00)
Enterovirus infection	1	1 (5.00)	1	1 (5.00)
Gastroenteritis viral	1	1 (5.00)	0	0 (0.00)
Haemophilus infection	1	1 (5.00)	0	0 (0.00)
Molluscum contagiosum	1	1 (5.00)	0	0 (0.00)
Oral candidiasis	1	1 (5.00)	0	0 (0.00)
Otitis externa	1	1 (5.00)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (5.00)	1	1 (5.00)
Paronychia	1	1 (5.00)	0	0 (0.00)
Rash pustular	1	1 (5.00)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (5.00)	1	1 (5.00)
Respiratory tract infection	1	1 (5.00)	1	1 (5.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Respiratory tract infection viral	1	1 (5.00)	1	1 (5.00)
Rotavirus infection	1	1 (5.00)	1	1 (5.00)
Septic embolus	1	1 (5.00)	1	1 (5.00)
Skin infection	1	1 (5.00)	0	0 (0.00)
Staphylococcal infection	1	1 (5.00)	0	0 (0.00)
Tinea capitis	1	1 (5.00)	0	0 (0.00)
Viral infection	1	1 (5.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	14	8 (40.00)	0	0 (0.00)
Procedural pain	3	3 (15.00)	0	0 (0.00)
Infusion related reaction	2	2 (10.00)	0	0 (0.00)
Transfusion reaction	2	1 (5.00)	0	0 (0.00)
Contusion	1	1 (5.00)	0	0 (0.00)
Procedural complication	1	1 (5.00)	0	0 (0.00)
Procedural site reaction	1	1 (5.00)	0	0 (0.00)
Radius fracture	1	1 (5.00)	0	0 (0.00)
Skin abrasion	1	1 (5.00)	0	0 (0.00)
Stoma site irritation	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Tibia fracture	1	1 (5.00)	0	0 (0.00)
Investigations				
- Total	118	16 (80.00)	65	14 (70.00)
White blood cell count decreased	21	10 (50.00)	15	8 (40.00)
Neutrophil count decreased	19	8 (40.00)	17	7 (35.00)
Aspartate aminotransferase increased	13	7 (35.00)	8	5 (25.00)
Platelet count decreased	10	3 (15.00)	9	3 (15.00)
Alanine aminotransferase increased	7	6 (30.00)	4	4 (20.00)
Blood bilirubin increased	7	3 (15.00)	1	1 (5.00)
Blood fibrinogen decreased	6	2 (10.00)	2	2 (10.00)
Blood urea increased	4	2 (10.00)	1	1 (5.00)
Lymphocyte count decreased	4	4 (20.00)	2	2 (10.00)
Prothrombin time prolonged	4	2 (10.00)	0	0 (0.00)
Blood sodium increased	2	1 (5.00)	0	0 (0.00)
Blood uric acid increased	2	1 (5.00)	0	0 (0.00)
International normalised ratio increased	2	2 (10.00)	1	1 (5.00)
Lipase increased	2	2 (10.00)	2	2 (10.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Activated partial thromboplastin time prolonged	1	1 (5.00)	0	0 (0.00)
Blood creatinine increased	1	1 (5.00)	1	1 (5.00)
Blood immunoglobulin G decreased	1	1 (5.00)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (5.00)	0	0 (0.00)
Blood lactic acid increased	1	1 (5.00)	1	1 (5.00)
Blood phosphorus decreased	1	1 (5.00)	0	0 (0.00)
Blood phosphorus increased	1	1 (5.00)	0	0 (0.00)
Fibrin D dimer increased	1	1 (5.00)	0	0 (0.00)
Oxygen saturation decreased	1	1 (5.00)	0	0 (0.00)
Protein total decreased	1	1 (5.00)	1	1 (5.00)
Pulmonary function test decreased	1	1 (5.00)	0	0 (0.00)
Serum ferritin increased	1	1 (5.00)	0	0 (0.00)
Transaminases increased	1	1 (5.00)	0	0 (0.00)
Weight decreased	1	1 (5.00)	0	0 (0.00)
Weight increased	1	1 (5.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	57	14 (70.00)	22	8 (40.00)
Decreased appetite	9	7 (35.00)	4	3 (15.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Hypokalaemia	8	7 (35.00)	5	5 (25.00)
Hypophosphataemia	8	5 (25.00)	5	3 (15.00)
Hyperalbuminaemia	3	1 (5.00)	0	0 (0.00)
Hypercalcaemia	3	1 (5.00)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (10.00)	1	1 (5.00)
Hypoalbuminaemia	3	2 (10.00)	1	1 (5.00)
Hypocalcaemia	3	2 (10.00)	0	0 (0.00)
Hyperglycaemia	2	1 (5.00)	0	0 (0.00)
Hypernatraemia	2	1 (5.00)	0	0 (0.00)
Hyponatraemia	2	1 (5.00)	2	1 (5.00)
Acidosis	1	1 (5.00)	1	1 (5.00)
Dehydration	1	1 (5.00)	1	1 (5.00)
Fluid overload	1	1 (5.00)	0	0 (0.00)
Hyperchloraemia	1	1 (5.00)	0	0 (0.00)
Hypermagnesaemia	1	1 (5.00)	0	0 (0.00)
Hyperphosphataemia	1	1 (5.00)	0	0 (0.00)
Hypomagnesaemia	1	1 (5.00)	0	0 (0.00)
Malnutrition	1	1 (5.00)	1	1 (5.00)
Metabolic alkalosis	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Tumour lysis syndrome	1	1 (5.00)	1	1 (5.00)
Vitamin D deficiency	1	1 (5.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	10	9 (45.00)	0	0 (0.00)
Pain in extremity	8	7 (35.00)	0	0 (0.00)
Osteopenia	1	1 (5.00)	0	0 (0.00)
Toe walking	1	1 (5.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	2 (10.00)	1	1 (5.00)
Glioblastoma multiforme	1	1 (5.00)	1	1 (5.00)
Skin papilloma	1	1 (5.00)	0	0 (0.00)
Nervous system disorders				
- Total	18	10 (50.00)	3	3 (15.00)
Headache	9	7 (35.00)	0	0 (0.00)
Dizziness	4	2 (10.00)	0	0 (0.00)
Seizure	2	2 (10.00)	2	2 (10.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Depressed level of consciousness	1	1 (5.00)	0	0 (0.00)
Embolic stroke	1	1 (5.00)	1	1 (5.00)
Migraine	1	1 (5.00)	0	0 (0.00)
Psychiatric disorders				
- Total	6	4 (20.00)	0	0 (0.00)
Confusional state	2	2 (10.00)	0	0 (0.00)
Anxiety	1	1 (5.00)	0	0 (0.00)
Delirium	1	1 (5.00)	0	0 (0.00)
Insomnia	1	1 (5.00)	0	0 (0.00)
Irritability	1	1 (5.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	6	5 (25.00)	2	2 (10.00)
Acute kidney injury	2	2 (10.00)	1	1 (5.00)
Dysuria	1	1 (5.00)	0	0 (0.00)
Pollakiuria	1	1 (5.00)	0	0 (0.00)
Renal impairment	1	1 (5.00)	1	1 (5.00)
Urinary incontinence	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Reproductive system and breast disorders				
- Total	2	2 (10.00)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (10.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	31	12 (60.00)	10	5 (25.00)
Cough	6	5 (25.00)	0	0 (0.00)
Hypoxia	5	4 (20.00)	3	3 (15.00)
Pleural effusion	4	4 (20.00)	2	2 (10.00)
Rhinorrhoea	3	3 (15.00)	0	0 (0.00)
Epistaxis	2	2 (10.00)	1	1 (5.00)
Oropharyngeal pain	2	2 (10.00)	0	0 (0.00)
Pulmonary oedema	2	2 (10.00)	2	2 (10.00)
Tachypnoea	2	1 (5.00)	0	0 (0.00)
Nasal congestion	1	1 (5.00)	0	0 (0.00)
Respiratory distress	1	1 (5.00)	1	1 (5.00)
Respiratory failure	1	1 (5.00)	1	1 (5.00)
Rhinitis allergic	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Wheezing	1	1 (5.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	20	9 (45.00)	0	0 (0.00)
Rash	4	3 (15.00)	0	0 (0.00)
Hyperhidrosis	3	2 (10.00)	0	0 (0.00)
Rash maculo-papular	2	2 (10.00)	0	0 (0.00)
Rash papular	2	2 (10.00)	0	0 (0.00)
Dermatitis diaper	1	1 (5.00)	0	0 (0.00)
Erythema	1	1 (5.00)	0	0 (0.00)
Macule	1	1 (5.00)	0	0 (0.00)
Papule	1	1 (5.00)	0	0 (0.00)
Petechiae	1	1 (5.00)	0	0 (0.00)
Pruritus	1	1 (5.00)	0	0 (0.00)
Rash erythematous	1	1 (5.00)	0	0 (0.00)
Rash follicular	1	1 (5.00)	0	0 (0.00)
Rash macular	1	1 (5.00)	0	0 (0.00)
Vascular disorders				
- Total	16	8 (40.00)	7	5 (25.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Hypotension	6	5 (25.00)	5	4 (20.00)
Hypertension	5	5 (25.00)	0	0 (0.00)
Flushing	3	2 (10.00)	0	0 (0.00)
Capillary leak syndrome	1	1 (5.00)	1	1 (5.00)
Embolism	1	1 (5.00)	1	1 (5.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Total number of AE per patient	976	34 (100.00)	299	32 (94.12)
Blood and lymphatic system disorders				
- Total	85	28 (82.35)	64	26 (76.47)
Anaemia	31	18 (52.94)	20	13 (38.24)
Febrile neutropenia	20	16 (47.06)	20	16 (47.06)
Thrombocytopenia	14	5 (14.71)	9	5 (14.71)
Neutropenia	11	8 (23.53)	11	8 (23.53)
Disseminated intravascular coagulation	3	3 (8.82)	1	1 (2.94)
Lymphopenia	3	3 (8.82)	2	2 (5.88)
Eosinophilia	2	1 (2.94)	1	1 (2.94)
Lymphadenopathy	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Cardiac disorders				
- Total	17	11 (32.35)	1	1 (2.94)
Tachycardia	10	9 (26.47)	1	1 (2.94)
Sinus tachycardia	3	3 (8.82)	0	0 (0.00)
Sinus bradycardia	2	1 (2.94)	0	0 (0.00)
Pericardial effusion	1	1 (2.94)	0	0 (0.00)
Ventricular tachycardia	1	1 (2.94)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (2.94)	0	0 (0.00)
Ear pain	1	1 (2.94)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (5.88)	0	0 (0.00)
Adrenal insufficiency	2	2 (5.88)	0	0 (0.00)
Eye disorders				
- Total	17	9 (26.47)	0	0 (0.00)
Eye pain	4	3 (8.82)	0	0 (0.00)
Vision blurred	4	3 (8.82)	0	0 (0.00)
Periorbital oedema	2	2 (5.88)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Conjunctival haemorrhage	1	1 (2.94)	0	0 (0.00)
Dry eye	1	1 (2.94)	0	0 (0.00)
Ocular hyperaemia	1	1 (2.94)	0	0 (0.00)
Ocular hypertension	1	1 (2.94)	0	0 (0.00)
Photophobia	1	1 (2.94)	0	0 (0.00)
Retinal haemorrhage	1	1 (2.94)	0	0 (0.00)
Uveitis	1	1 (2.94)	0	0 (0.00)
Gastrointestinal disorders				
- Total	84	25 (73.53)	8	5 (14.71)
Vomiting	25	14 (41.18)	3	2 (5.88)
Nausea	14	12 (35.29)	1	1 (2.94)
Diarrhoea	13	11 (32.35)	1	1 (2.94)
Abdominal pain	6	6 (17.65)	0	0 (0.00)
Constipation	4	3 (8.82)	0	0 (0.00)
Oral pain	3	2 (5.88)	1	1 (2.94)
Abdominal pain upper	2	2 (5.88)	0	0 (0.00)
Anal incontinence	2	1 (2.94)	0	0 (0.00)
Haematemesis	2	2 (5.88)	0	0 (0.00)
Mouth haemorrhage	2	1 (2.94)	2	1 (2.94)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Stomatitis	2	2 (5.88)	0	0 (0.00)
Abdominal distension	1	1 (2.94)	0	0 (0.00)
Abdominal pain lower	1	1 (2.94)	0	0 (0.00)
Dysphagia	1	1 (2.94)	0	0 (0.00)
Flatulence	1	1 (2.94)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (2.94)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.94)	0	0 (0.00)
Glossodynia	1	1 (2.94)	0	0 (0.00)
Lip pain	1	1 (2.94)	0	0 (0.00)
Pigmentation lip	1	1 (2.94)	0	0 (0.00)
General disorders and administration site conditions				
- Total	58	23 (67.65)	7	6 (17.65)
Pyrexia	22	12 (35.29)	3	3 (8.82)
Fatigue	10	9 (26.47)	1	1 (2.94)
Chills	6	6 (17.65)	0	0 (0.00)
Pain	4	4 (11.76)	2	2 (5.88)
Generalised oedema	3	2 (5.88)	0	0 (0.00)
Catheter site pain	2	2 (5.88)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Malaise	2	2 (5.88)	0	0 (0.00)
Catheter site extravasation	1	1 (2.94)	0	0 (0.00)
Catheter site haemorrhage	1	1 (2.94)	0	0 (0.00)
Face oedema	1	1 (2.94)	0	0 (0.00)
Influenza like illness	1	1 (2.94)	0	0 (0.00)
Injection site haematoma	1	1 (2.94)	0	0 (0.00)
Non-cardiac chest pain	1	1 (2.94)	0	0 (0.00)
Oedema peripheral	1	1 (2.94)	0	0 (0.00)
Peripheral swelling	1	1 (2.94)	0	0 (0.00)
Physical deconditioning	1	1 (2.94)	1	1 (2.94)
Hepatobiliary disorders				
- Total	6	4 (11.76)	1	1 (2.94)
Hyperbilirubinaemia	3	2 (5.88)	1	1 (2.94)
Hepatomegaly	2	2 (5.88)	0	0 (0.00)
Gallbladder enlargement	1	1 (2.94)	0	0 (0.00)
Immune system disorders				
- Total	76	31 (91.18)	19	13 (38.24)
Cytokine release syndrome	46	26 (76.47)	16	10 (29.41)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Hypogammaglobulinaemia	20	19 (55.88)	3	3 (8.82)
Graft versus host disease	3	2 (5.88)	0	0 (0.00)
Immunodeficiency common variable	2	2 (5.88)	0	0 (0.00)
Drug hypersensitivity	1	1 (2.94)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (2.94)	0	0 (0.00)
Graft versus host disease in skin	1	1 (2.94)	0	0 (0.00)
Immunodeficiency	1	1 (2.94)	0	0 (0.00)
Seasonal allergy	1	1 (2.94)	0	0 (0.00)
Infections and infestations				
- Total	64	22 (64.71)	13	7 (20.59)
Cellulitis of male external genital organ	6	1 (2.94)	3	1 (2.94)
Upper respiratory tract infection	6	5 (14.71)	1	1 (2.94)
Urinary tract infection	6	3 (8.82)	3	2 (5.88)
Otitis media	4	3 (8.82)	0	0 (0.00)
Rhinovirus infection	4	2 (5.88)	0	0 (0.00)
Clostridium difficile colitis	2	2 (5.88)	0	0 (0.00)
Gastroenteritis	2	2 (5.88)	1	1 (2.94)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Gastroenteritis norovirus	2	1 (2.94)	0	0 (0.00)
Influenza	2	2 (5.88)	0	0 (0.00)
Sinusitis	2	1 (2.94)	0	0 (0.00)
Viral infection	2	2 (5.88)	0	0 (0.00)
Acute sinusitis	1	1 (2.94)	0	0 (0.00)
Body tinea	1	1 (2.94)	0	0 (0.00)
Catheter site cellulitis	1	1 (2.94)	0	0 (0.00)
Clostridium difficile infection	1	1 (2.94)	0	0 (0.00)
Cytomegalovirus infection	1	1 (2.94)	0	0 (0.00)
Enterococcal infection	1	1 (2.94)	0	0 (0.00)
Escherichia urinary tract infection	1	1 (2.94)	1	1 (2.94)
Fungal skin infection	1	1 (2.94)	0	0 (0.00)
Gingivitis	1	1 (2.94)	0	0 (0.00)
Herpes simplex	1	1 (2.94)	0	0 (0.00)
Herpes zoster	1	1 (2.94)	1	1 (2.94)
Hypopyon	1	1 (2.94)	0	0 (0.00)
Meningitis aseptic	1	1 (2.94)	0	0 (0.00)
Oral herpes	1	1 (2.94)	0	0 (0.00)
Orchitis	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Parainfluenzae virus infection	1	1 (2.94)	0	0 (0.00)
Pharyngitis	1	1 (2.94)	0	0 (0.00)
Pneumonia	1	1 (2.94)	0	0 (0.00)
Rhinitis	1	1 (2.94)	0	0 (0.00)
Skin infection	1	1 (2.94)	0	0 (0.00)
Staphylococcal infection	1	1 (2.94)	1	1 (2.94)
Streptococcal infection	1	1 (2.94)	0	0 (0.00)
Subcutaneous abscess	1	1 (2.94)	0	0 (0.00)
Vascular device infection	1	1 (2.94)	1	1 (2.94)
Viral upper respiratory tract infection	1	1 (2.94)	1	1 (2.94)
Vulvovaginal mycotic infection	1	1 (2.94)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	19	10 (29.41)	2	2 (5.88)
Procedural pain	3	2 (5.88)	1	1 (2.94)
Contusion	2	2 (5.88)	0	0 (0.00)
Infusion related reaction	2	2 (5.88)	0	0 (0.00)
Arthropod bite	1	1 (2.94)	0	0 (0.00)
Mouth injury	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Post procedural haemorrhage	1	1 (2.94)	0	0 (0.00)
Procedural headache	1	1 (2.94)	0	0 (0.00)
Procedural nausea	1	1 (2.94)	0	0 (0.00)
Skin abrasion	1	1 (2.94)	0	0 (0.00)
Skin laceration	1	1 (2.94)	0	0 (0.00)
Subdural haemorrhage	1	1 (2.94)	0	0 (0.00)
Sunburn	1	1 (2.94)	0	0 (0.00)
Tongue injury	1	1 (2.94)	0	0 (0.00)
Transfusion reaction	1	1 (2.94)	0	0 (0.00)
Transfusion related complication	1	1 (2.94)	1	1 (2.94)
Investigations				
- Total	236	31 (91.18)	119	26 (76.47)
Neutrophil count decreased	41	18 (52.94)	33	16 (47.06)
White blood cell count decreased	38	21 (61.76)	23	18 (52.94)
Platelet count decreased	32	14 (41.18)	26	11 (32.35)
Alanine aminotransferase increased	24	13 (38.24)	13	9 (26.47)
Aspartate aminotransferase increased	20	10 (29.41)	9	5 (14.71)
Lymphocyte count decreased	18	11 (32.35)	10	9 (26.47)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Blood creatinine increased	11	8 (23.53)	1	1 (2.94)
Activated partial thromboplastin time prolonged	7	4 (11.76)	0	0 (0.00)
Blood bilirubin increased	7	5 (14.71)	2	2 (5.88)
International normalised ratio increased	7	6 (17.65)	0	0 (0.00)
Prothrombin time prolonged	7	4 (11.76)	0	0 (0.00)
Blood immunoglobulin A decreased	3	3 (8.82)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (5.88)	0	0 (0.00)
Blood magnesium decreased	2	2 (5.88)	1	1 (2.94)
Blood phosphorus increased	2	1 (2.94)	0	0 (0.00)
Haemoglobin decreased	2	2 (5.88)	1	1 (2.94)
Blood alkaline phosphatase increased	1	1 (2.94)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (2.94)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (2.94)	0	0 (0.00)
Blood urea increased	1	1 (2.94)	0	0 (0.00)
Blood uric acid increased	1	1 (2.94)	0	0 (0.00)
C-reactive protein increased	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Cardiac murmur	1	1 (2.94)	0	0 (0.00)
Culture stool positive	1	1 (2.94)	0	0 (0.00)
Norovirus test positive	1	1 (2.94)	0	0 (0.00)
Serum ferritin increased	1	1 (2.94)	0	0 (0.00)
Transaminases increased	1	1 (2.94)	0	0 (0.00)
Weight decreased	1	1 (2.94)	0	0 (0.00)
Weight increased	1	1 (2.94)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	60	22 (64.71)	21	14 (41.18)
Decreased appetite	13	11 (32.35)	6	6 (17.65)
Hypokalaemia	11	9 (26.47)	4	4 (11.76)
Hyperphosphataemia	9	6 (17.65)	0	0 (0.00)
Hypernatraemia	5	3 (8.82)	1	1 (2.94)
Hypophosphataemia	5	4 (11.76)	4	4 (11.76)
Hyperuricaemia	3	2 (5.88)	0	0 (0.00)
Hypoalbuminaemia	3	3 (8.82)	0	0 (0.00)
Dehydration	2	2 (5.88)	1	1 (2.94)
Hyperglycaemia	2	1 (2.94)	1	1 (2.94)
Acidosis	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Fluid overload	1	1 (2.94)	0	0 (0.00)
Hypocalcaemia	1	1 (2.94)	1	1 (2.94)
Hyponatraemia	1	1 (2.94)	1	1 (2.94)
Iron overload	1	1 (2.94)	1	1 (2.94)
Tumour lysis syndrome	1	1 (2.94)	1	1 (2.94)
Vitamin D deficiency	1	1 (2.94)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	30	14 (41.18)	1	1 (2.94)
Arthralgia	5	4 (11.76)	1	1 (2.94)
Myalgia	5	5 (14.71)	0	0 (0.00)
Muscular weakness	3	3 (8.82)	0	0 (0.00)
Pain in extremity	3	3 (8.82)	0	0 (0.00)
Joint range of motion decreased	2	2 (5.88)	0	0 (0.00)
Muscle spasms	2	2 (5.88)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (5.88)	0	0 (0.00)
Musculoskeletal pain	2	2 (5.88)	0	0 (0.00)
Back pain	1	1 (2.94)	0	0 (0.00)
Coccydynia	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Flank pain	1	1 (2.94)	0	0 (0.00)
Neck pain	1	1 (2.94)	0	0 (0.00)
Osteonecrosis	1	1 (2.94)	0	0 (0.00)
Pain in jaw	1	1 (2.94)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (2.94)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (2.94)	0	0 (0.00)
Nervous system disorders				
- Total	48	20 (58.82)	4	3 (8.82)
Headache	27	15 (44.12)	2	2 (5.88)
Encephalopathy	6	4 (11.76)	2	2 (5.88)
Dysarthria	2	2 (5.88)	0	0 (0.00)
Seizure	2	2 (5.88)	0	0 (0.00)
Tremor	2	2 (5.88)	0	0 (0.00)
Asterixis	1	1 (2.94)	0	0 (0.00)
Ataxia	1	1 (2.94)	0	0 (0.00)
Disturbance in attention	1	1 (2.94)	0	0 (0.00)
Dizziness	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Myoclonus	1	1 (2.94)	0	0 (0.00)
Neuropathy peripheral	1	1 (2.94)	0	0 (0.00)
Peroneal nerve palsy	1	1 (2.94)	0	0 (0.00)
Pleocytosis	1	1 (2.94)	0	0 (0.00)
Somnolence	1	1 (2.94)	0	0 (0.00)
Product issues				
- Total	1	1 (2.94)	0	0 (0.00)
Device occlusion	1	1 (2.94)	0	0 (0.00)
Psychiatric disorders				
- Total	24	9 (26.47)	0	0 (0.00)
Anxiety	5	5 (14.71)	0	0 (0.00)
Agitation	3	2 (5.88)	0	0 (0.00)
Confusional state	3	3 (8.82)	0	0 (0.00)
Hallucination	3	2 (5.88)	0	0 (0.00)
Delirium	2	2 (5.88)	0	0 (0.00)
Depression	2	2 (5.88)	0	0 (0.00)
Adjustment disorder	1	1 (2.94)	0	0 (0.00)
Irritability	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Listless	1	1 (2.94)	0	0 (0.00)
Mental status changes	1	1 (2.94)	0	0 (0.00)
Sleep disorder	1	1 (2.94)	0	0 (0.00)
Suicidal ideation	1	1 (2.94)	0	0 (0.00)
Renal and urinary disorders				
- Total	16	8 (23.53)	10	6 (17.65)
Acute kidney injury	6	5 (14.71)	4	4 (11.76)
Haematuria	4	3 (8.82)	2	2 (5.88)
Oliguria	2	2 (5.88)	2	2 (5.88)
Calculus urinary	1	1 (2.94)	0	0 (0.00)
Dysuria	1	1 (2.94)	0	0 (0.00)
Nephrolithiasis	1	1 (2.94)	1	1 (2.94)
Renal failure	1	1 (2.94)	1	1 (2.94)
Reproductive system and breast disorders				
- Total	2	2 (5.88)	1	1 (2.94)
Ovarian failure	1	1 (2.94)	1	1 (2.94)
Scrotal pain	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	68	22 (64.71)	16	8 (23.53)
Cough	13	8 (23.53)	0	0 (0.00)
Epistaxis	11	7 (20.59)	4	4 (11.76)
Hypoxia	5	4 (11.76)	2	2 (5.88)
Nasal congestion	4	4 (11.76)	0	0 (0.00)
Oropharyngeal pain	4	4 (11.76)	0	0 (0.00)
Pulmonary oedema	4	4 (11.76)	3	3 (8.82)
Tachypnoea	4	4 (11.76)	1	1 (2.94)
Haemoptysis	3	2 (5.88)	1	1 (2.94)
Rhinitis allergic	3	2 (5.88)	0	0 (0.00)
Rhinorrhoea	3	3 (8.82)	0	0 (0.00)
Dyspnoea	2	1 (2.94)	1	1 (2.94)
Pleural effusion	2	2 (5.88)	0	0 (0.00)
Respiratory failure	2	2 (5.88)	2	2 (5.88)
Acute respiratory failure	1	1 (2.94)	1	1 (2.94)
Atelectasis	1	1 (2.94)	0	0 (0.00)
Dysphonia	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Oropharyngeal plaque	1	1 (2.94)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.94)	0	0 (0.00)
Pharyngeal lesion	1	1 (2.94)	1	1 (2.94)
Pharyngeal ulceration	1	1 (2.94)	0	0 (0.00)
Respiratory depression	1	1 (2.94)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	41	18 (52.94)	2	2 (5.88)
Dry skin	5	5 (14.71)	0	0 (0.00)
Erythema	4	3 (8.82)	0	0 (0.00)
Rash	4	4 (11.76)	0	0 (0.00)
Ingrowing nail	2	2 (5.88)	0	0 (0.00)
Petechiae	2	2 (5.88)	0	0 (0.00)
Pruritus	2	2 (5.88)	0	0 (0.00)
Rash erythematous	2	1 (2.94)	0	0 (0.00)
Rash maculo-papular	2	2 (5.88)	0	0 (0.00)
Acne	1	1 (2.94)	0	0 (0.00)
Alopecia	1	1 (2.94)	0	0 (0.00)
Dermatitis	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Dermatitis acneiform	1	1 (2.94)	1	1 (2.94)
Dermatitis atopic	1	1 (2.94)	0	0 (0.00)
Ecchymosis	1	1 (2.94)	1	1 (2.94)
Eczema	1	1 (2.94)	0	0 (0.00)
Hyperhidrosis	1	1 (2.94)	0	0 (0.00)
Keloid scar	1	1 (2.94)	0	0 (0.00)
Livedo reticularis	1	1 (2.94)	0	0 (0.00)
Macule	1	1 (2.94)	0	0 (0.00)
Night sweats	1	1 (2.94)	0	0 (0.00)
Papule	1	1 (2.94)	0	0 (0.00)
Rash pruritic	1	1 (2.94)	0	0 (0.00)
Rash vesicular	1	1 (2.94)	0	0 (0.00)
Skin exfoliation	1	1 (2.94)	0	0 (0.00)
Skin fissures	1	1 (2.94)	0	0 (0.00)
Skin irritation	1	1 (2.94)	0	0 (0.00)
Vascular disorders				
- Total	20	12 (35.29)	10	9 (26.47)
Hypotension	11	9 (26.47)	9	9 (26.47)
Hypertension	5	4 (11.76)	1	1 (2.94)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Haematoma	1	1 (2.94)	0	0 (0.00)
Hot flush	1	1 (2.94)	0	0 (0.00)
Orthostatic hypotension	1	1 (2.94)	0	0 (0.00)
Secondary hypertension	1	1 (2.94)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Total number of AE per patient	231	10 (100.00)	78	10 (100.00)
Blood and lymphatic system disorders				
- Total	27	7 (70.00)	19	7 (70.00)
Anaemia	10	3 (30.00)	6	3 (30.00)
Thrombocytopenia	9	3 (30.00)	7	3 (30.00)
Neutropenia	4	3 (30.00)	3	3 (30.00)
Febrile neutropenia	2	2 (20.00)	2	2 (20.00)
Lymphopenia	1	1 (10.00)	0	0 (0.00)
Pancytopenia	1	1 (10.00)	1	1 (10.00)
Cardiac disorders				
- Total	5	4 (40.00)	2	1 (10.00)
Tachycardia	4	4 (40.00)	1	1 (10.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Left ventricular dysfunction	1	1 (10.00)	1	1 (10.00)
Ear and labyrinth disorders				
- Total	1	1 (10.00)	0	0 (0.00)
Hypoacusis	1	1 (10.00)	0	0 (0.00)
Eye disorders				
- Total	3	2 (20.00)	0	0 (0.00)
Papilloedema	1	1 (10.00)	0	0 (0.00)
Uveitis	1	1 (10.00)	0	0 (0.00)
Visual impairment	1	1 (10.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	25	5 (50.00)	8	2 (20.00)
Nausea	8	4 (40.00)	2	2 (20.00)
Diarrhoea	5	5 (50.00)	1	1 (10.00)
Vomiting	5	4 (40.00)	2	1 (10.00)
Abdominal pain	2	1 (10.00)	2	1 (10.00)
Abdominal discomfort	1	1 (10.00)	0	0 (0.00)
Abdominal pain upper	1	1 (10.00)	0	0 (0.00)
Constipation	1	1 (10.00)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Dyspepsia	1	1 (10.00)	0	0 (0.00)
Intestinal obstruction	1	1 (10.00)	1	1 (10.00)
General disorders and administration site conditions				
- Total	19	7 (70.00)	2	2 (20.00)
Pyrexia	9	6 (60.00)	2	2 (20.00)
Chills	4	3 (30.00)	0	0 (0.00)
Fatigue	2	2 (20.00)	0	0 (0.00)
Asthenia	1	1 (10.00)	0	0 (0.00)
Facial pain	1	1 (10.00)	0	0 (0.00)
Influenza like illness	1	1 (10.00)	0	0 (0.00)
Malaise	1	1 (10.00)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (10.00)	0	0 (0.00)
Hepatomegaly	1	1 (10.00)	0	0 (0.00)
Immune system disorders				
- Total	17	8 (80.00)	3	3 (30.00)
Cytokine release syndrome	12	8 (80.00)	3	3 (30.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Hypogammaglobulinaemia	5	3 (30.00)	0	0 (0.00)
Infections and infestations				
- Total	13	7 (70.00)	4	3 (30.00)
Upper respiratory tract infection	3	1 (10.00)	0	0 (0.00)
Influenza	2	2 (20.00)	0	0 (0.00)
Bacterial sepsis	1	1 (10.00)	1	1 (10.00)
Cholecystitis infective	1	1 (10.00)	1	1 (10.00)
Folliculitis	1	1 (10.00)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (10.00)	0	0 (0.00)
Pneumonia	1	1 (10.00)	0	0 (0.00)
Sepsis	1	1 (10.00)	1	1 (10.00)
Sinusitis	1	1 (10.00)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (10.00)	1	1 (10.00)
Injury, poisoning and procedural complications				
- Total	6	4 (40.00)	1	1 (10.00)
Tracheal haemorrhage	2	1 (10.00)	1	1 (10.00)
Foot fracture	1	1 (10.00)	0	0 (0.00)
Incision site pain	1	1 (10.00)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Limb injury	1	1 (10.00)	0	0 (0.00)
Transfusion reaction	1	1 (10.00)	0	0 (0.00)
Investigations				
- Total	48	9 (90.00)	18	9 (90.00)
Blood fibrinogen decreased	9	2 (20.00)	2	1 (10.00)
White blood cell count decreased	8	4 (40.00)	5	4 (40.00)
Platelet count decreased	7	3 (30.00)	3	1 (10.00)
Prothrombin time prolonged	6	3 (30.00)	1	1 (10.00)
Aspartate aminotransferase increased	4	3 (30.00)	2	2 (20.00)
Alanine aminotransferase increased	2	2 (20.00)	1	1 (10.00)
International normalised ratio increased	2	1 (10.00)	0	0 (0.00)
Neutrophil count decreased	2	2 (20.00)	2	2 (20.00)
Weight decreased	2	2 (20.00)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (10.00)	0	0 (0.00)
C-reactive protein increased	1	1 (10.00)	1	1 (10.00)
Haemoglobin decreased	1	1 (10.00)	0	0 (0.00)
Hepatic enzyme increased	1	1 (10.00)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Lymphocyte count decreased	1	1 (10.00)	1	1 (10.00)
Transaminases increased	1	1 (10.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	16	7 (70.00)	7	5 (50.00)
Decreased appetite	4	4 (40.00)	3	3 (30.00)
Hypokalaemia	4	3 (30.00)	0	0 (0.00)
Hyperphosphataemia	2	1 (10.00)	0	0 (0.00)
Dehydration	1	1 (10.00)	1	1 (10.00)
Fluid overload	1	1 (10.00)	0	0 (0.00)
Hyperglycaemia	1	1 (10.00)	1	1 (10.00)
Hyperuricaemia	1	1 (10.00)	1	1 (10.00)
Hypophosphataemia	1	1 (10.00)	1	1 (10.00)
Metabolic acidosis	1	1 (10.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	5	2 (20.00)	0	0 (0.00)
Musculoskeletal pain	2	1 (10.00)	0	0 (0.00)
Arthralgia	1	1 (10.00)	0	0 (0.00)
Limb discomfort	1	1 (10.00)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Pain in extremity	1	1 (10.00)	0	0 (0.00)
Nervous system disorders				
- Total	8	5 (50.00)	0	0 (0.00)
Dizziness	3	3 (30.00)	0	0 (0.00)
Headache	3	2 (20.00)	0	0 (0.00)
Idiopathic intracranial hypertension	1	1 (10.00)	0	0 (0.00)
Peroneal nerve palsy	1	1 (10.00)	0	0 (0.00)
Psychiatric disorders				
- Total	4	4 (40.00)	1	1 (10.00)
Anxiety	1	1 (10.00)	1	1 (10.00)
Confusional state	1	1 (10.00)	0	0 (0.00)
Delirium	1	1 (10.00)	0	0 (0.00)
Panic attack	1	1 (10.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	4	2 (20.00)	3	2 (20.00)
Acute kidney injury	2	2 (20.00)	2	2 (20.00)
Haematuria	2	2 (20.00)	1	1 (10.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Reproductive system and breast disorders				
- Total	3	2 (20.00)	1	1 (10.00)
Oedema genital	2	1 (10.00)	0	0 (0.00)
Vaginal haemorrhage	1	1 (10.00)	1	1 (10.00)
Respiratory, thoracic and mediastinal disorders				
- Total	11	4 (40.00)	6	2 (20.00)
Hypoxia	3	2 (20.00)	3	2 (20.00)
Pleural effusion	2	2 (20.00)	0	0 (0.00)
Cough	1	1 (10.00)	0	0 (0.00)
Dyspnoea	1	1 (10.00)	1	1 (10.00)
Epistaxis	1	1 (10.00)	0	0 (0.00)
Interstitial lung disease	1	1 (10.00)	1	1 (10.00)
Pulmonary oedema	1	1 (10.00)	1	1 (10.00)
Rhinitis allergic	1	1 (10.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	8	3 (30.00)	1	1 (10.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Ingrowing nail	2	1 (10.00)	0	0 (0.00)
Erythema	1	1 (10.00)	0	0 (0.00)
Hyperhidrosis	1	1 (10.00)	0	0 (0.00)
Petechiae	1	1 (10.00)	0	0 (0.00)
Pruritus	1	1 (10.00)	0	0 (0.00)
Rash	1	1 (10.00)	0	0 (0.00)
Rash maculo-papular	1	1 (10.00)	1	1 (10.00)
Vascular disorders				
- Total	7	5 (50.00)	2	2 (20.00)
Hypertension	4	3 (30.00)	0	0 (0.00)
Hypotension	2	2 (20.00)	2	2 (20.00)
Orthostatic hypotension	1	1 (10.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Total number of AE per patient	558	29 (96.67)	214	23 (76.67)
Blood and lymphatic system disorders				
- Total	54	18 (60.00)	40	17 (56.67)
Anaemia	25	13 (43.33)	17	8 (26.67)
Febrile neutropenia	11	10 (33.33)	11	10 (33.33)
Thrombocytopenia	10	4 (13.33)	6	4 (13.33)
Neutropenia	4	4 (13.33)	4	4 (13.33)
Disseminated intravascular coagulation	3	2 (6.67)	1	1 (3.33)
Lymphopenia	1	1 (3.33)	1	1 (3.33)
Cardiac disorders				
- Total	15	9 (30.00)	3	2 (6.67)
Tachycardia	9	7 (23.33)	2	2 (6.67)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Sinus bradycardia	2	1 (3.33)	0	0 (0.00)
Bradycardia	1	1 (3.33)	0	0 (0.00)
Left ventricular dysfunction	1	1 (3.33)	1	1 (3.33)
Palpitations	1	1 (3.33)	0	0 (0.00)
Pericardial effusion	1	1 (3.33)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.33)	0	0 (0.00)
Hypoacusis	1	1 (3.33)	0	0 (0.00)
Eye disorders				
- Total	8	5 (16.67)	0	0 (0.00)
Eye pain	3	2 (6.67)	0	0 (0.00)
Periorbital oedema	2	2 (6.67)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (3.33)	0	0 (0.00)
Retinal haemorrhage	1	1 (3.33)	0	0 (0.00)
Vision blurred	1	1 (3.33)	0	0 (0.00)
Gastrointestinal disorders				
- Total	37	12 (40.00)	5	4 (13.33)
Vomiting	9	7 (23.33)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Nausea	7	5 (16.67)	1	1 (3.33)
Diarrhoea	6	6 (20.00)	0	0 (0.00)
Abdominal pain	2	2 (6.67)	0	0 (0.00)
Anal incontinence	2	1 (3.33)	0	0 (0.00)
Haematemesis	2	2 (6.67)	0	0 (0.00)
Mouth haemorrhage	2	1 (3.33)	2	1 (3.33)
Abdominal distension	1	1 (3.33)	0	0 (0.00)
Constipation	1	1 (3.33)	0	0 (0.00)
Dysphagia	1	1 (3.33)	1	1 (3.33)
Gastrointestinal haemorrhage	1	1 (3.33)	0	0 (0.00)
Ileus	1	1 (3.33)	1	1 (3.33)
Pancreatitis	1	1 (3.33)	0	0 (0.00)
Stomatitis	1	1 (3.33)	0	0 (0.00)
General disorders and administration site conditions				
- Total	36	12 (40.00)	10	6 (20.00)
Pyrexia	10	6 (20.00)	3	3 (10.00)
Chills	4	4 (13.33)	0	0 (0.00)
Fatigue	4	3 (10.00)	1	1 (3.33)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Generalised oedema	3	2 (6.67)	0	0 (0.00)
Pain	3	3 (10.00)	2	2 (6.67)
Face oedema	2	2 (6.67)	1	1 (3.33)
Asthenia	1	1 (3.33)	0	0 (0.00)
Catheter site extravasation	1	1 (3.33)	0	0 (0.00)
Catheter site pain	1	1 (3.33)	0	0 (0.00)
Localised oedema	1	1 (3.33)	1	1 (3.33)
Malaise	1	1 (3.33)	0	0 (0.00)
Mucosal haemorrhage	1	1 (3.33)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (3.33)	1	1 (3.33)
Non-cardiac chest pain	1	1 (3.33)	0	0 (0.00)
Oedema peripheral	1	1 (3.33)	1	1 (3.33)
Peripheral swelling	1	1 (3.33)	0	0 (0.00)
Hepatobiliary disorders				
- Total	7	5 (16.67)	2	2 (6.67)
Hyperbilirubinaemia	4	3 (10.00)	2	2 (6.67)
Hepatomegaly	3	3 (10.00)	0	0 (0.00)
Immune system disorders				

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
- Total	60	26 (86.67)	17	10 (33.33)
Cytokine release syndrome	45	23 (76.67)	16	9 (30.00)
Hypogammaglobulinaemia	13	12 (40.00)	1	1 (3.33)
Drug hypersensitivity	1	1 (3.33)	0	0 (0.00)
Graft versus host disease in skin	1	1 (3.33)	0	0 (0.00)
Infections and infestations				
- Total	12	8 (26.67)	2	2 (6.67)
Acute sinusitis	1	1 (3.33)	0	0 (0.00)
Body tinea	1	1 (3.33)	0	0 (0.00)
Clostridium difficile colitis	1	1 (3.33)	1	1 (3.33)
Clostridium difficile infection	1	1 (3.33)	0	0 (0.00)
Fungal skin infection	1	1 (3.33)	0	0 (0.00)
Gastroenteritis	1	1 (3.33)	1	1 (3.33)
Orchitis	1	1 (3.33)	0	0 (0.00)
Pharyngitis	1	1 (3.33)	0	0 (0.00)
Skin infection	1	1 (3.33)	0	0 (0.00)
Streptococcal infection	1	1 (3.33)	0	0 (0.00)
Upper respiratory tract infection	1	1 (3.33)	0	0 (0.00)
Viral infection	1	1 (3.33)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Injury, poisoning and procedural complications				
- Total	8	4 (13.33)	1	1 (3.33)
Tracheal haemorrhage	2	1 (3.33)	1	1 (3.33)
Infusion related reaction	1	1 (3.33)	0	0 (0.00)
Mouth injury	1	1 (3.33)	0	0 (0.00)
Procedural complication	1	1 (3.33)	0	0 (0.00)
Procedural headache	1	1 (3.33)	0	0 (0.00)
Skin abrasion	1	1 (3.33)	0	0 (0.00)
Tongue injury	1	1 (3.33)	0	0 (0.00)
Investigations				
- Total	146	22 (73.33)	80	17 (56.67)
Neutrophil count decreased	26	11 (36.67)	24	10 (33.33)
White blood cell count decreased	24	12 (40.00)	14	10 (33.33)
Platelet count decreased	19	8 (26.67)	15	5 (16.67)
Aspartate aminotransferase increased	18	8 (26.67)	10	6 (20.00)
Alanine aminotransferase increased	11	7 (23.33)	6	5 (16.67)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
International normalised ratio increased	6	4 (13.33)	0	0 (0.00)
Activated partial thromboplastin time prolonged	5	3 (10.00)	0	0 (0.00)
Blood creatinine increased	5	4 (13.33)	2	2 (6.67)
Lymphocyte count decreased	5	5 (16.67)	3	3 (10.00)
Blood bilirubin increased	4	3 (10.00)	1	1 (3.33)
Blood phosphorus increased	3	2 (6.67)	0	0 (0.00)
Prothrombin time prolonged	3	2 (6.67)	0	0 (0.00)
Blood fibrinogen decreased	2	2 (6.67)	1	1 (3.33)
Blood immunoglobulin M decreased	2	2 (6.67)	0	0 (0.00)
Blood urea increased	2	2 (6.67)	1	1 (3.33)
Blood uric acid increased	2	1 (3.33)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (3.33)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (3.33)	0	0 (0.00)
Blood phosphorus decreased	1	1 (3.33)	0	0 (0.00)
C-reactive protein increased	1	1 (3.33)	1	1 (3.33)
Cardiac murmur	1	1 (3.33)	0	0 (0.00)
Fibrin D dimer increased	1	1 (3.33)	0	0 (0.00)
Lipase increased	1	1 (3.33)	1	1 (3.33)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Norovirus test positive	1	1 (3.33)	0	0 (0.00)
Protein total decreased	1	1 (3.33)	1	1 (3.33)
Metabolism and nutrition disorders				
- Total	48	14 (46.67)	19	11 (36.67)
Decreased appetite	10	9 (30.00)	6	6 (20.00)
Hypokalaemia	10	7 (23.33)	3	3 (10.00)
Hypophosphataemia	5	5 (16.67)	4	4 (13.33)
Hypercalcaemia	2	1 (3.33)	0	0 (0.00)
Hyperglycaemia	2	1 (3.33)	0	0 (0.00)
Hypernatraemia	2	1 (3.33)	0	0 (0.00)
Hyperphosphataemia	2	2 (6.67)	0	0 (0.00)
Hypertriglyceridaemia	2	1 (3.33)	1	1 (3.33)
Hypoalbuminaemia	2	2 (6.67)	0	0 (0.00)
Hypocalcaemia	2	2 (6.67)	1	1 (3.33)
Acidosis	1	1 (3.33)	1	1 (3.33)
Dehydration	1	1 (3.33)	1	1 (3.33)
Fluid overload	1	1 (3.33)	0	0 (0.00)
Hyperalbuminaemia	1	1 (3.33)	0	0 (0.00)
Hyperchloraemia	1	1 (3.33)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Hypermagnesaemia	1	1 (3.33)	0	0 (0.00)
Hyperuricaemia	1	1 (3.33)	1	1 (3.33)
Hyponatraemia	1	1 (3.33)	1	1 (3.33)
Metabolic alkalosis	1	1 (3.33)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	7	5 (16.67)	1	1 (3.33)
Arthralgia	2	2 (6.67)	1	1 (3.33)
Myalgia	2	2 (6.67)	0	0 (0.00)
Muscle spasms	1	1 (3.33)	0	0 (0.00)
Muscular weakness	1	1 (3.33)	0	0 (0.00)
Musculoskeletal pain	1	1 (3.33)	0	0 (0.00)
Nervous system disorders				
- Total	19	15 (50.00)	2	1 (3.33)
Headache	13	11 (36.67)	1	1 (3.33)
Encephalopathy	2	2 (6.67)	1	1 (3.33)
Dizziness	1	1 (3.33)	0	0 (0.00)
Dysarthria	1	1 (3.33)	0	0 (0.00)
Seizure	1	1 (3.33)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Somnolence	1	1 (3.33)	0	0 (0.00)
Psychiatric disorders				
- Total	17	7 (23.33)	0	0 (0.00)
Confusional state	4	4 (13.33)	0	0 (0.00)
Agitation	2	1 (3.33)	0	0 (0.00)
Anxiety	2	2 (6.67)	0	0 (0.00)
Delirium	2	2 (6.67)	0	0 (0.00)
Hallucination	2	1 (3.33)	0	0 (0.00)
Irritability	2	2 (6.67)	0	0 (0.00)
Insomnia	1	1 (3.33)	0	0 (0.00)
Listless	1	1 (3.33)	0	0 (0.00)
Mental status changes	1	1 (3.33)	0	0 (0.00)
Renal and urinary disorders				
- Total	8	5 (16.67)	5	3 (10.00)
Acute kidney injury	3	3 (10.00)	2	2 (6.67)
Haematuria	2	2 (6.67)	1	1 (3.33)
Dysuria	1	1 (3.33)	0	0 (0.00)
Oliguria	1	1 (3.33)	1	1 (3.33)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Renal impairment	1	1 (3.33)	1	1 (3.33)
Respiratory, thoracic and mediastinal disorders				
- Total	36	13 (43.33)	14	4 (13.33)
Hypoxia	6	5 (16.67)	4	3 (10.00)
Pleural effusion	5	5 (16.67)	1	1 (3.33)
Cough	4	4 (13.33)	0	0 (0.00)
Epistaxis	4	4 (13.33)	2	2 (6.67)
Dyspnoea	3	2 (6.67)	2	2 (6.67)
Pulmonary oedema	3	3 (10.00)	3	3 (10.00)
Tachypnoea	3	2 (6.67)	0	0 (0.00)
Atelectasis	1	1 (3.33)	0	0 (0.00)
Interstitial lung disease	1	1 (3.33)	1	1 (3.33)
Nasal congestion	1	1 (3.33)	0	0 (0.00)
Oropharyngeal plaque	1	1 (3.33)	0	0 (0.00)
Pharyngeal ulceration	1	1 (3.33)	0	0 (0.00)
Respiratory depression	1	1 (3.33)	0	0 (0.00)
Respiratory distress	1	1 (3.33)	1	1 (3.33)
Rhinitis allergic	1	1 (3.33)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	17	11 (36.67)	1	1 (3.33)
Erythema	2	2 (6.67)	0	0 (0.00)
Hyperhidrosis	2	1 (3.33)	0	0 (0.00)
Ingrowing nail	2	1 (3.33)	0	0 (0.00)
Rash	2	2 (6.67)	0	0 (0.00)
Rash maculo-papular	2	2 (6.67)	1	1 (3.33)
Dermatitis diaper	1	1 (3.33)	0	0 (0.00)
Dry skin	1	1 (3.33)	0	0 (0.00)
Livedo reticularis	1	1 (3.33)	0	0 (0.00)
Night sweats	1	1 (3.33)	0	0 (0.00)
Pruritus	1	1 (3.33)	0	0 (0.00)
Rash papular	1	1 (3.33)	0	0 (0.00)
Skin irritation	1	1 (3.33)	0	0 (0.00)
Vascular disorders				
- Total	22	10 (33.33)	12	9 (30.00)
Hypotension	12	9 (30.00)	10	9 (30.00)
Hypertension	7	6 (20.00)	1	1 (3.33)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Flushing	2	1 (3.33)	0	0 (0.00)
Capillary leak syndrome	1	1 (3.33)	1	1 (3.33)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Total number of AE per patient	756	34 (100.00)	244	31 (91.18)
Blood and lymphatic system disorders				
- Total	68	25 (73.53)	53	21 (61.76)
Anaemia	22	14 (41.18)	14	11 (32.35)
Thrombocytopenia	20	4 (11.76)	17	4 (11.76)
Febrile neutropenia	15	12 (35.29)	15	12 (35.29)
Neutropenia	5	4 (11.76)	4	4 (11.76)
Disseminated intravascular coagulation	2	2 (5.88)	1	1 (2.94)
Lymphopenia	2	2 (5.88)	1	1 (2.94)
Coagulopathy	1	1 (2.94)	0	0 (0.00)
Pancytopenia	1	1 (2.94)	1	1 (2.94)
Cardiac disorders				

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
- Total	17	13 (38.24)	0	0 (0.00)
Tachycardia	8	8 (23.53)	0	0 (0.00)
Sinus tachycardia	5	5 (14.71)	0	0 (0.00)
Atrioventricular block second degree	1	1 (2.94)	0	0 (0.00)
Cardiac dysfunction	1	1 (2.94)	0	0 (0.00)
Pericardial effusion	1	1 (2.94)	0	0 (0.00)
Ventricular tachycardia	1	1 (2.94)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (5.88)	0	0 (0.00)
Ear pain	2	2 (5.88)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.94)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.94)	0	0 (0.00)
Eye disorders				
- Total	17	8 (23.53)	0	0 (0.00)
Photophobia	3	2 (5.88)	0	0 (0.00)
Vision blurred	3	2 (5.88)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (5.88)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Periorbital oedema	2	2 (5.88)	0	0 (0.00)
Uveitis	2	2 (5.88)	0	0 (0.00)
Eye pain	1	1 (2.94)	0	0 (0.00)
Ocular hypertension	1	1 (2.94)	0	0 (0.00)
Papilloedema	1	1 (2.94)	0	0 (0.00)
Retinal haemorrhage	1	1 (2.94)	0	0 (0.00)
Visual impairment	1	1 (2.94)	0	0 (0.00)
Gastrointestinal disorders				
- Total	89	24 (70.59)	10	7 (20.59)
Vomiting	26	15 (44.12)	3	3 (8.82)
Nausea	19	16 (47.06)	2	2 (5.88)
Diarrhoea	12	12 (35.29)	1	1 (2.94)
Abdominal pain	8	7 (20.59)	1	1 (2.94)
Constipation	7	6 (17.65)	0	0 (0.00)
Abdominal pain upper	2	2 (5.88)	0	0 (0.00)
Abdominal discomfort	1	1 (2.94)	0	0 (0.00)
Abdominal distension	1	1 (2.94)	0	0 (0.00)
Abdominal pain lower	1	1 (2.94)	0	0 (0.00)
Abdominal tenderness	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Ascites	1	1 (2.94)	1	1 (2.94)
Dyspepsia	1	1 (2.94)	0	0 (0.00)
Dysphagia	1	1 (2.94)	0	0 (0.00)
Flatulence	1	1 (2.94)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.94)	0	0 (0.00)
Glossodynia	1	1 (2.94)	0	0 (0.00)
Intestinal obstruction	1	1 (2.94)	1	1 (2.94)
Lip pain	1	1 (2.94)	0	0 (0.00)
Pancreatitis	1	1 (2.94)	1	1 (2.94)
Stomatitis	1	1 (2.94)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (2.94)	0	0 (0.00)
General disorders and administration site conditions				
- Total	41	20 (58.82)	4	4 (11.76)
Pyrexia	17	10 (29.41)	3	3 (8.82)
Fatigue	10	10 (29.41)	0	0 (0.00)
Chills	5	4 (11.76)	0	0 (0.00)
Catheter site pain	2	2 (5.88)	0	0 (0.00)
Malaise	2	2 (5.88)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Catheter site haemorrhage	1	1 (2.94)	0	0 (0.00)
Facial pain	1	1 (2.94)	0	0 (0.00)
Injection site haematoma	1	1 (2.94)	0	0 (0.00)
Oedema peripheral	1	1 (2.94)	0	0 (0.00)
Physical deconditioning	1	1 (2.94)	1	1 (2.94)
Hepatobiliary disorders				
- Total	2	2 (5.88)	0	0 (0.00)
Gallbladder enlargement	1	1 (2.94)	0	0 (0.00)
Hepatosplenomegaly	1	1 (2.94)	0	0 (0.00)
Immune system disorders				
- Total	56	31 (91.18)	16	12 (35.29)
Cytokine release syndrome	41	27 (79.41)	13	10 (29.41)
Hypogammaglobulinaemia	14	14 (41.18)	3	3 (8.82)
Haemophagocytic lymphohistiocytosis	1	1 (2.94)	0	0 (0.00)
Infections and infestations				
- Total	29	18 (52.94)	5	5 (14.71)
Clostridium difficile colitis	3	3 (8.82)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Clostridium difficile infection	3	3 (8.82)	0	0 (0.00)
Rhinovirus infection	3	3 (8.82)	0	0 (0.00)
Pneumonia	2	2 (5.88)	1	1 (2.94)
Staphylococcal infection	2	2 (5.88)	1	1 (2.94)
Catheter site cellulitis	1	1 (2.94)	0	0 (0.00)
Catheter site infection	1	1 (2.94)	1	1 (2.94)
Cytomegalovirus infection	1	1 (2.94)	0	0 (0.00)
Enterococcal infection	1	1 (2.94)	0	0 (0.00)
Folliculitis	1	1 (2.94)	0	0 (0.00)
Gastroenteritis	1	1 (2.94)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (2.94)	0	0 (0.00)
Herpes simplex	1	1 (2.94)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (2.94)	0	0 (0.00)
Hypopyon	1	1 (2.94)	0	0 (0.00)
Influenza	1	1 (2.94)	0	0 (0.00)
Oral candidiasis	1	1 (2.94)	0	0 (0.00)
Septic embolus	1	1 (2.94)	1	1 (2.94)
Urinary tract infection enterococcal	1	1 (2.94)	1	1 (2.94)
Viral upper respiratory tract infection	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Vulvovaginal candidiasis	1	1 (2.94)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	17	11 (32.35)	1	1 (2.94)
Transfusion reaction	4	3 (8.82)	0	0 (0.00)
Procedural pain	3	3 (8.82)	0	0 (0.00)
Contusion	1	1 (2.94)	0	0 (0.00)
Incision site pain	1	1 (2.94)	0	0 (0.00)
Infusion related reaction	1	1 (2.94)	0	0 (0.00)
Limb injury	1	1 (2.94)	0	0 (0.00)
Post procedural haemorrhage	1	1 (2.94)	0	0 (0.00)
Procedural site reaction	1	1 (2.94)	0	0 (0.00)
Stoma site irritation	1	1 (2.94)	0	0 (0.00)
Subdural haemorrhage	1	1 (2.94)	0	0 (0.00)
Tibia fracture	1	1 (2.94)	0	0 (0.00)
Transfusion related complication	1	1 (2.94)	1	1 (2.94)
Investigations				
- Total	186	30 (88.24)	98	27 (79.41)
White blood cell count decreased	31	18 (52.94)	23	16 (47.06)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Platelet count decreased	24	11 (32.35)	22	9 (26.47)
Neutrophil count decreased	21	14 (41.18)	20	13 (38.24)
Alanine aminotransferase increased	17	12 (35.29)	8	6 (17.65)
Aspartate aminotransferase increased	14	10 (29.41)	6	5 (14.71)
Prothrombin time prolonged	14	7 (20.59)	1	1 (2.94)
Blood fibrinogen decreased	13	2 (5.88)	3	2 (5.88)
Lymphocyte count decreased	11	9 (26.47)	9	8 (23.53)
Blood bilirubin increased	9	4 (11.76)	1	1 (2.94)
Blood creatinine increased	6	5 (14.71)	0	0 (0.00)
International normalised ratio increased	5	5 (14.71)	1	1 (2.94)
Activated partial thromboplastin time prolonged	3	2 (5.88)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (5.88)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (5.88)	0	0 (0.00)
Blood sodium increased	2	1 (2.94)	0	0 (0.00)
Transaminases increased	2	2 (5.88)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.94)	0	0 (0.00)
Blood lactic acid increased	1	1 (2.94)	1	1 (2.94)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Blood magnesium decreased	1	1 (2.94)	1	1 (2.94)
Blood urea increased	1	1 (2.94)	0	0 (0.00)
Culture stool positive	1	1 (2.94)	0	0 (0.00)
Haemoglobin decreased	1	1 (2.94)	1	1 (2.94)
Hepatic enzyme increased	1	1 (2.94)	0	0 (0.00)
Lipase increased	1	1 (2.94)	1	1 (2.94)
Pulmonary function test decreased	1	1 (2.94)	0	0 (0.00)
Serum ferritin increased	1	1 (2.94)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	68	25 (73.53)	24	13 (38.24)
Decreased appetite	14	11 (32.35)	7	6 (17.65)
Hypokalaemia	10	9 (26.47)	4	4 (11.76)
Hyperphosphataemia	8	6 (17.65)	0	0 (0.00)
Hypophosphataemia	8	4 (11.76)	5	3 (8.82)
Hypernatraemia	5	3 (8.82)	1	1 (2.94)
Hypoalbuminaemia	4	3 (8.82)	1	1 (2.94)
Hyperuricaemia	3	2 (5.88)	0	0 (0.00)
Dehydration	2	2 (5.88)	1	1 (2.94)
Fluid overload	2	2 (5.88)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Hyperglycaemia	2	2 (5.88)	1	1 (2.94)
Hypocalcaemia	2	1 (2.94)	0	0 (0.00)
Hyponatraemia	2	1 (2.94)	2	1 (2.94)
Acidosis	1	1 (2.94)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (2.94)	0	0 (0.00)
Hypomagnesaemia	1	1 (2.94)	0	0 (0.00)
Malnutrition	1	1 (2.94)	1	1 (2.94)
Metabolic acidosis	1	1 (2.94)	0	0 (0.00)
Tumour lysis syndrome	1	1 (2.94)	1	1 (2.94)
Musculoskeletal and connective tissue disorders				
- Total	16	10 (29.41)	0	0 (0.00)
Pain in extremity	4	4 (11.76)	0	0 (0.00)
Musculoskeletal pain	3	2 (5.88)	0	0 (0.00)
Myalgia	3	3 (8.82)	0	0 (0.00)
Arthralgia	2	2 (5.88)	0	0 (0.00)
Coccydynia	1	1 (2.94)	0	0 (0.00)
Limb discomfort	1	1 (2.94)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Osteopenia	1	1 (2.94)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (2.94)	0	0 (0.00)
Skin papilloma	1	1 (2.94)	0	0 (0.00)
Nervous system disorders				
- Total	39	18 (52.94)	4	4 (11.76)
Headache	18	13 (38.24)	1	1 (2.94)
Encephalopathy	4	2 (5.88)	1	1 (2.94)
Dizziness	3	3 (8.82)	0	0 (0.00)
Seizure	2	2 (5.88)	1	1 (2.94)
Tremor	2	2 (5.88)	0	0 (0.00)
Asterixis	1	1 (2.94)	0	0 (0.00)
Ataxia	1	1 (2.94)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.94)	0	0 (0.00)
Dysarthria	1	1 (2.94)	0	0 (0.00)
Embolic stroke	1	1 (2.94)	1	1 (2.94)
Idiopathic intracranial hypertension	1	1 (2.94)	0	0 (0.00)
Migraine	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Myoclonus	1	1 (2.94)	0	0 (0.00)
Neuropathy peripheral	1	1 (2.94)	0	0 (0.00)
Pleocytosis	1	1 (2.94)	0	0 (0.00)
Product issues				
- Total	1	1 (2.94)	0	0 (0.00)
Device occlusion	1	1 (2.94)	0	0 (0.00)
Psychiatric disorders				
- Total	13	9 (26.47)	1	1 (2.94)
Anxiety	4	4 (11.76)	1	1 (2.94)
Confusional state	2	2 (5.88)	0	0 (0.00)
Delirium	2	2 (5.88)	0	0 (0.00)
Adjustment disorder	1	1 (2.94)	0	0 (0.00)
Agitation	1	1 (2.94)	0	0 (0.00)
Hallucination	1	1 (2.94)	0	0 (0.00)
Panic attack	1	1 (2.94)	0	0 (0.00)
Suicidal ideation	1	1 (2.94)	0	0 (0.00)
Renal and urinary disorders				
- Total	10	6 (17.65)	6	4 (11.76)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Acute kidney injury	4	4 (11.76)	3	3 (8.82)
Haematuria	2	2 (5.88)	1	1 (2.94)
Dysuria	1	1 (2.94)	0	0 (0.00)
Oliguria	1	1 (2.94)	1	1 (2.94)
Pollakiuria	1	1 (2.94)	0	0 (0.00)
Renal failure	1	1 (2.94)	1	1 (2.94)
Reproductive system and breast disorders				
- Total	4	3 (8.82)	0	0 (0.00)
Oedema genital	2	1 (2.94)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (5.88)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	37	15 (44.12)	14	8 (23.53)
Epistaxis	7	3 (8.82)	2	2 (5.88)
Hypoxia	7	5 (14.71)	4	4 (11.76)
Cough	4	4 (11.76)	0	0 (0.00)
Haemoptysis	3	2 (5.88)	1	1 (2.94)
Pleural effusion	3	3 (8.82)	1	1 (2.94)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Pulmonary oedema	3	3 (8.82)	2	2 (5.88)
Respiratory failure	3	3 (8.82)	3	3 (8.82)
Tachypnoea	3	3 (8.82)	1	1 (2.94)
Oropharyngeal pain	2	2 (5.88)	0	0 (0.00)
Rhinorrhoea	1	1 (2.94)	0	0 (0.00)
Wheezing	1	1 (2.94)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	24	10 (29.41)	1	1 (2.94)
Dry skin	3	3 (8.82)	0	0 (0.00)
Petechiae	3	3 (8.82)	0	0 (0.00)
Erythema	2	1 (2.94)	0	0 (0.00)
Hyperhidrosis	2	2 (5.88)	0	0 (0.00)
Rash	2	2 (5.88)	0	0 (0.00)
Ecchymosis	1	1 (2.94)	1	1 (2.94)
Ingrowing nail	1	1 (2.94)	0	0 (0.00)
Macule	1	1 (2.94)	0	0 (0.00)
Pruritus	1	1 (2.94)	0	0 (0.00)
Rash erythematous	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Rash follicular	1	1 (2.94)	0	0 (0.00)
Rash macular	1	1 (2.94)	0	0 (0.00)
Rash maculo-papular	1	1 (2.94)	0	0 (0.00)
Rash papular	1	1 (2.94)	0	0 (0.00)
Rash vesicular	1	1 (2.94)	0	0 (0.00)
Skin exfoliation	1	1 (2.94)	0	0 (0.00)
Skin fissures	1	1 (2.94)	0	0 (0.00)
Vascular disorders				
- Total	18	14 (41.18)	7	7 (20.59)
Hypotension	7	7 (20.59)	6	6 (17.65)
Hypertension	5	4 (11.76)	0	0 (0.00)
Orthostatic hypotension	2	2 (5.88)	0	0 (0.00)
Embolism	1	1 (2.94)	1	1 (2.94)
Flushing	1	1 (2.94)	0	0 (0.00)
Haematoma	1	1 (2.94)	0	0 (0.00)
Secondary hypertension	1	1 (2.94)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Total number of AE per patient	163	20 (74.07)	34	12 (44.44)
Blood and lymphatic system disorders				
- Total	13	7 (25.93)	11	6 (22.22)
Neutropenia	6	4 (14.81)	6	4 (14.81)
Eosinophilia	2	1 (3.70)	1	1 (3.70)
Febrile neutropenia	2	2 (7.41)	2	2 (7.41)
Anaemia	1	1 (3.70)	0	0 (0.00)
Leukopenia	1	1 (3.70)	1	1 (3.70)
Thrombocytopenia	1	1 (3.70)	1	1 (3.70)
Cardiac disorders				
- Total	1	1 (3.70)	0	0 (0.00)
Sinus tachycardia	1	1 (3.70)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Endocrine disorders				
- Total	1	1 (3.70)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.70)	0	0 (0.00)
Eye disorders				
- Total	2	2 (7.41)	0	0 (0.00)
Ocular hyperaemia	1	1 (3.70)	0	0 (0.00)
Vision blurred	1	1 (3.70)	0	0 (0.00)
Gastrointestinal disorders				
- Total	13	6 (22.22)	2	2 (7.41)
Vomiting	4	3 (11.11)	0	0 (0.00)
Oral pain	3	2 (7.41)	1	1 (3.70)
Abdominal pain	1	1 (3.70)	0	0 (0.00)
Abdominal pain upper	1	1 (3.70)	0	0 (0.00)
Diarrhoea	1	1 (3.70)	0	0 (0.00)
Enterocolitis	1	1 (3.70)	1	1 (3.70)
Nausea	1	1 (3.70)	0	0 (0.00)
Pigmentation lip	1	1 (3.70)	0	0 (0.00)
General disorders and administration site conditions				

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
- Total	12	6 (22.22)	0	0 (0.00)
Pyrexia	6	2 (7.41)	0	0 (0.00)
Acquired gene mutation	1	1 (3.70)	0	0 (0.00)
Catheter site pain	1	1 (3.70)	0	0 (0.00)
Chills	1	1 (3.70)	0	0 (0.00)
Fatigue	1	1 (3.70)	0	0 (0.00)
Influenza like illness	1	1 (3.70)	0	0 (0.00)
Pain	1	1 (3.70)	0	0 (0.00)
Immune system disorders				
- Total	8	7 (25.93)	1	1 (3.70)
Hypogammaglobulinaemia	4	4 (14.81)	1	1 (3.70)
Graft versus host disease	3	2 (7.41)	0	0 (0.00)
Seasonal allergy	1	1 (3.70)	0	0 (0.00)
Infections and infestations				
- Total	28	14 (51.85)	8	5 (18.52)
Cellulitis of male external genital organ	5	1 (3.70)	2	1 (3.70)
Upper respiratory tract infection	4	4 (14.81)	0	0 (0.00)
Rhinovirus infection	3	1 (3.70)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Gastroenteritis	2	2 (7.41)	0	0 (0.00)
Influenza	2	2 (7.41)	0	0 (0.00)
Otitis media	2	1 (3.70)	0	0 (0.00)
Urinary tract infection	2	1 (3.70)	1	1 (3.70)
Cholecystitis infective	1	1 (3.70)	1	1 (3.70)
Corona virus infection	1	1 (3.70)	1	1 (3.70)
Herpes zoster	1	1 (3.70)	1	1 (3.70)
Rash pustular	1	1 (3.70)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (3.70)	1	1 (3.70)
Subcutaneous abscess	1	1 (3.70)	0	0 (0.00)
Viral infection	1	1 (3.70)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (3.70)	1	1 (3.70)
Injury, poisoning and procedural complications				
- Total	6	3 (11.11)	0	0 (0.00)
Contusion	1	1 (3.70)	0	0 (0.00)
Foot fracture	1	1 (3.70)	0	0 (0.00)
Infusion related reaction	1	1 (3.70)	0	0 (0.00)
Procedural nausea	1	1 (3.70)	0	0 (0.00)
Skin laceration	1	1 (3.70)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Sunburn	1	1 (3.70)	0	0 (0.00)
Investigations				
- Total	22	11 (40.74)	7	5 (18.52)
Neutrophil count decreased	6	3 (11.11)	3	2 (7.41)
White blood cell count decreased	5	3 (11.11)	2	1 (3.70)
Blood urea increased	2	1 (3.70)	0	0 (0.00)
Platelet count decreased	2	1 (3.70)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (3.70)	1	1 (3.70)
Blood bilirubin increased	1	1 (3.70)	1	1 (3.70)
Blood magnesium decreased	1	1 (3.70)	0	0 (0.00)
Lymphocyte count decreased	1	1 (3.70)	0	0 (0.00)
Serum ferritin increased	1	1 (3.70)	0	0 (0.00)
Transaminases increased	1	1 (3.70)	0	0 (0.00)
Weight decreased	1	1 (3.70)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	6	4 (14.81)	1	1 (3.70)
Hyperalbuminaemia	2	1 (3.70)	0	0 (0.00)
Hypercalcaemia	1	1 (3.70)	0	0 (0.00)
Hyperphosphataemia	1	1 (3.70)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Iron overload	1	1 (3.70)	1	1 (3.70)
Vitamin D deficiency	1	1 (3.70)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	9	5 (18.52)	0	0 (0.00)
Pain in extremity	2	2 (7.41)	0	0 (0.00)
Arthralgia	1	1 (3.70)	0	0 (0.00)
Back pain	1	1 (3.70)	0	0 (0.00)
Joint range of motion decreased	1	1 (3.70)	0	0 (0.00)
Muscle spasms	1	1 (3.70)	0	0 (0.00)
Muscular weakness	1	1 (3.70)	0	0 (0.00)
Osteonecrosis	1	1 (3.70)	0	0 (0.00)
Pain in jaw	1	1 (3.70)	0	0 (0.00)
Nervous system disorders				
- Total	7	5 (18.52)	0	0 (0.00)
Headache	5	3 (11.11)	0	0 (0.00)
Peroneal nerve palsy	2	2 (7.41)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (7.41)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Depression	2	2 (7.41)	0	0 (0.00)
Anxiety	1	1 (3.70)	0	0 (0.00)
Sleep disorder	1	1 (3.70)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.70)	0	0 (0.00)
Scrotal pain	1	1 (3.70)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	13	7 (25.93)	3	2 (7.41)
Cough	3	2 (7.41)	0	0 (0.00)
Nasal congestion	2	2 (7.41)	0	0 (0.00)
Rhinorrhoea	2	2 (7.41)	0	0 (0.00)
Dysphonia	1	1 (3.70)	0	0 (0.00)
Epistaxis	1	1 (3.70)	1	1 (3.70)
Oropharyngeal pain	1	1 (3.70)	0	0 (0.00)
Pharyngeal erythema	1	1 (3.70)	0	0 (0.00)
Pharyngeal lesion	1	1 (3.70)	1	1 (3.70)
Pulmonary oedema	1	1 (3.70)	1	1 (3.70)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	14	9 (33.33)	1	1 (3.70)
Erythema	2	2 (7.41)	0	0 (0.00)
Rash erythematous	2	1 (3.70)	0	0 (0.00)
Rash maculo-papular	2	2 (7.41)	0	0 (0.00)
Alopecia	1	1 (3.70)	0	0 (0.00)
Dermatitis acneiform	1	1 (3.70)	1	1 (3.70)
Hyperhidrosis	1	1 (3.70)	0	0 (0.00)
Ingrowing nail	1	1 (3.70)	0	0 (0.00)
Keloid scar	1	1 (3.70)	0	0 (0.00)
Macule	1	1 (3.70)	0	0 (0.00)
Papule	1	1 (3.70)	0	0 (0.00)
Rash	1	1 (3.70)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (7.41)	0	0 (0.00)
Hypertension	2	2 (7.41)	0	0 (0.00)
Hot flush	1	1 (3.70)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Total number of AE per patient	183	26 (89.66)	37	14 (48.28)
Blood and lymphatic system disorders				
- Total	5	4 (13.79)	2	1 (3.45)
Anaemia	1	1 (3.45)	1	1 (3.45)
Febrile neutropenia	1	1 (3.45)	1	1 (3.45)
Lymphadenopathy	1	1 (3.45)	0	0 (0.00)
Lymphopenia	1	1 (3.45)	0	0 (0.00)
Thrombocytopenia	1	1 (3.45)	0	0 (0.00)
Eye disorders				
- Total	3	3 (10.34)	0	0 (0.00)
Dry eye	2	2 (6.90)	0	0 (0.00)
Conjunctivitis allergic	1	1 (3.45)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Gastrointestinal disorders				
- Total	25	10 (34.48)	6	2 (6.90)
Vomiting	9	6 (20.69)	2	2 (6.90)
Diarrhoea	7	7 (24.14)	1	1 (3.45)
Nausea	6	5 (17.24)	2	2 (6.90)
Abdominal pain	3	3 (10.34)	1	1 (3.45)
General disorders and administration site conditions				
- Total	14	11 (37.93)	1	1 (3.45)
Pyrexia	8	8 (27.59)	1	1 (3.45)
Crying	1	1 (3.45)	0	0 (0.00)
Fatigue	1	1 (3.45)	0	0 (0.00)
Generalised oedema	1	1 (3.45)	0	0 (0.00)
Influenza like illness	1	1 (3.45)	0	0 (0.00)
Malaise	1	1 (3.45)	0	0 (0.00)
Oedema peripheral	1	1 (3.45)	0	0 (0.00)
Immune system disorders				
- Total	9	7 (24.14)	0	0 (0.00)
Hypogammaglobulinaemia	5	4 (13.79)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Immunodeficiency common variable	2	2 (6.90)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (3.45)	0	0 (0.00)
Seasonal allergy	1	1 (3.45)	0	0 (0.00)
Infections and infestations				
- Total	33	19 (65.52)	9	7 (24.14)
Upper respiratory tract infection	3	3 (10.34)	1	1 (3.45)
Urinary tract infection	3	3 (10.34)	1	1 (3.45)
Ear infection	2	2 (6.90)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (6.90)	1	1 (3.45)
Sinusitis	2	2 (6.90)	0	0 (0.00)
Bacterial sepsis	1	1 (3.45)	1	1 (3.45)
Cytomegalovirus infection	1	1 (3.45)	0	0 (0.00)
Enterovirus infection	1	1 (3.45)	1	1 (3.45)
Escherichia urinary tract infection	1	1 (3.45)	1	1 (3.45)
Gastroenteritis	1	1 (3.45)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (3.45)	0	0 (0.00)
Gastroenteritis viral	1	1 (3.45)	0	0 (0.00)
Influenza	1	1 (3.45)	0	0 (0.00)
Molluscum contagiosum	1	1 (3.45)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Oral herpes	1	1 (3.45)	0	0 (0.00)
Otitis externa	1	1 (3.45)	0	0 (0.00)
Otitis media acute	1	1 (3.45)	0	0 (0.00)
Paronychia	1	1 (3.45)	0	0 (0.00)
Rhinitis	1	1 (3.45)	0	0 (0.00)
Rhinovirus infection	1	1 (3.45)	0	0 (0.00)
Rotavirus infection	1	1 (3.45)	1	1 (3.45)
Sepsis	1	1 (3.45)	1	1 (3.45)
Tinea capitis	1	1 (3.45)	0	0 (0.00)
Vascular device infection	1	1 (3.45)	1	1 (3.45)
Viral upper respiratory tract infection	1	1 (3.45)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (3.45)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	7	5 (17.24)	0	0 (0.00)
Procedural pain	2	2 (6.90)	0	0 (0.00)
Arthropod bite	1	1 (3.45)	0	0 (0.00)
Contusion	1	1 (3.45)	0	0 (0.00)
Infusion related reaction	1	1 (3.45)	0	0 (0.00)
Radius fracture	1	1 (3.45)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Skin abrasion	1	1 (3.45)	0	0 (0.00)
Investigations				
- Total	26	12 (41.38)	9	7 (24.14)
Neutrophil count decreased	6	5 (17.24)	5	4 (13.79)
Aspartate aminotransferase increased	3	3 (10.34)	2	2 (6.90)
Platelet count decreased	3	2 (6.90)	0	0 (0.00)
Weight decreased	3	3 (10.34)	0	0 (0.00)
Haemoglobin decreased	2	2 (6.90)	0	0 (0.00)
Weight increased	2	2 (6.90)	0	0 (0.00)
White blood cell count decreased	2	2 (6.90)	1	1 (3.45)
Alanine aminotransferase increased	1	1 (3.45)	1	1 (3.45)
Blood creatinine increased	1	1 (3.45)	0	0 (0.00)
Blood uric acid increased	1	1 (3.45)	0	0 (0.00)
Lymphocyte count decreased	1	1 (3.45)	0	0 (0.00)
Oxygen saturation decreased	1	1 (3.45)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	9	6 (20.69)	5	3 (10.34)
Decreased appetite	2	2 (6.90)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Hypokalaemia	2	2 (6.90)	1	1 (3.45)
Dehydration	1	1 (3.45)	1	1 (3.45)
Hyperglycaemia	1	1 (3.45)	1	1 (3.45)
Hyperphosphataemia	1	1 (3.45)	0	0 (0.00)
Hypophosphataemia	1	1 (3.45)	1	1 (3.45)
Tumour lysis syndrome	1	1 (3.45)	1	1 (3.45)
Musculoskeletal and connective tissue disorders				
- Total	12	11 (37.93)	0	0 (0.00)
Pain in extremity	6	6 (20.69)	0	0 (0.00)
Arthralgia	1	1 (3.45)	0	0 (0.00)
Flank pain	1	1 (3.45)	0	0 (0.00)
Joint range of motion decreased	1	1 (3.45)	0	0 (0.00)
Muscular weakness	1	1 (3.45)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.45)	0	0 (0.00)
Toe walking	1	1 (3.45)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.45)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (3.45)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Nervous system disorders				
- Total	5	3 (10.34)	0	0 (0.00)
Dizziness	3	3 (10.34)	0	0 (0.00)
Headache	2	2 (6.90)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	3 (10.34)	3	2 (6.90)
Acute kidney injury	1	1 (3.45)	1	1 (3.45)
Calculus urinary	1	1 (3.45)	0	0 (0.00)
Haematuria	1	1 (3.45)	1	1 (3.45)
Nephrolithiasis	1	1 (3.45)	1	1 (3.45)
Urinary incontinence	1	1 (3.45)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.45)	1	1 (3.45)
Vaginal haemorrhage	1	1 (3.45)	1	1 (3.45)
Respiratory, thoracic and mediastinal disorders				
- Total	17	11 (37.93)	1	1 (3.45)
Cough	6	5 (17.24)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Rhinitis allergic	3	3 (10.34)	0	0 (0.00)
Nasal congestion	2	2 (6.90)	0	0 (0.00)
Oropharyngeal pain	2	2 (6.90)	0	0 (0.00)
Rhinorrhoea	2	2 (6.90)	0	0 (0.00)
Acute respiratory failure	1	1 (3.45)	1	1 (3.45)
Epistaxis	1	1 (3.45)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	11	7 (24.14)	0	0 (0.00)
Rash	4	3 (10.34)	0	0 (0.00)
Dermatitis	1	1 (3.45)	0	0 (0.00)
Dermatitis atopic	1	1 (3.45)	0	0 (0.00)
Dry skin	1	1 (3.45)	0	0 (0.00)
Eczema	1	1 (3.45)	0	0 (0.00)
Petechiae	1	1 (3.45)	0	0 (0.00)
Pruritus	1	1 (3.45)	0	0 (0.00)
Rash pruritic	1	1 (3.45)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	39	12 (60.00)	10	6 (30.00)
Blood and lymphatic system disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Thrombocytopenia	1	1 (5.00)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Tympanic membrane perforation	1	1 (5.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Diarrhoea	1	1 (5.00)	0	0 (0.00)
Immune system disorders				

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	1	1 (5.00)	0	0 (0.00)
Chronic graft versus host disease	1	1 (5.00)	0	0 (0.00)
Infections and infestations				
- Total	19	4 (20.00)	3	2 (10.00)
Otitis media	4	2 (10.00)	1	1 (5.00)
Otitis media acute	3	1 (5.00)	0	0 (0.00)
Upper respiratory tract infection	3	1 (5.00)	0	0 (0.00)
Sinusitis	2	2 (10.00)	0	0 (0.00)
Urinary tract infection	2	1 (5.00)	1	1 (5.00)
Cellulitis of male external genital organ	1	1 (5.00)	1	1 (5.00)
Gingivitis	1	1 (5.00)	0	0 (0.00)
Haemophilus infection	1	1 (5.00)	0	0 (0.00)
Pneumonia	1	1 (5.00)	0	0 (0.00)
Viral infection	1	1 (5.00)	0	0 (0.00)
Investigations				
- Total	9	6 (30.00)	5	4 (20.00)
Lymphocyte count decreased	3	2 (10.00)	1	1 (5.00)
Alanine aminotransferase increased	2	2 (10.00)	1	1 (5.00)

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
White blood cell count decreased	2	2 (10.00)	2	2 (10.00)
Aspartate aminotransferase increased	1	1 (5.00)	1	1 (5.00)
Neutrophil count decreased	1	1 (5.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Vitamin D deficiency	1	1 (5.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Neck pain	1	1 (5.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (5.00)	1	1 (5.00)
Glioblastoma multiforme	1	1 (5.00)	1	1 (5.00)
Nervous system disorders				
- Total	2	2 (10.00)	1	1 (5.00)
Disturbance in attention	1	1 (5.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Seizure	1	1 (5.00)	1	1 (5.00)
Skin and subcutaneous tissue disorders				
- Total	2	2 (10.00)	0	0 (0.00)
Acne	1	1 (5.00)	0	0 (0.00)
Papule	1	1 (5.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Total number of AE per patient	51	10 (71.43)	13	6 (42.86)
Blood and lymphatic system disorders				
- Total	1	1 (7.14)	1	1 (7.14)
Febrile neutropenia	1	1 (7.14)	1	1 (7.14)
Gastrointestinal disorders				
- Total	3	2 (14.29)	0	0 (0.00)
Abdominal pain	1	1 (7.14)	0	0 (0.00)
Diarrhoea	1	1 (7.14)	0	0 (0.00)
Nausea	1	1 (7.14)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	2 (14.29)	1	1 (7.14)

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Pyrexia	2	1 (7.14)	0	0 (0.00)
Chills	1	1 (7.14)	0	0 (0.00)
Cyst	1	1 (7.14)	1	1 (7.14)
Immune system disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Immunodeficiency	1	1 (7.14)	0	0 (0.00)
Infections and infestations				
- Total	13	7 (50.00)	4	2 (14.29)
Campylobacter infection	1	1 (7.14)	1	1 (7.14)
Clostridium difficile infection	1	1 (7.14)	1	1 (7.14)
Meningitis aseptic	1	1 (7.14)	0	0 (0.00)
Otitis media	1	1 (7.14)	0	0 (0.00)
Otitis media acute	1	1 (7.14)	0	0 (0.00)
Pneumonia	1	1 (7.14)	0	0 (0.00)
Respiratory tract infection	1	1 (7.14)	1	1 (7.14)
Respiratory tract infection viral	1	1 (7.14)	1	1 (7.14)
Sinusitis	1	1 (7.14)	0	0 (0.00)
Skin infection	1	1 (7.14)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Upper respiratory tract infection	1	1 (7.14)	0	0 (0.00)
Urinary tract infection	1	1 (7.14)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (7.14)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (7.14)	1	1 (7.14)
Procedural pain	1	1 (7.14)	1	1 (7.14)
Investigations				
- Total	13	2 (14.29)	3	1 (7.14)
White blood cell count decreased	3	2 (14.29)	1	1 (7.14)
Lymphocyte count decreased	2	1 (7.14)	0	0 (0.00)
Neutrophil count decreased	2	1 (7.14)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (7.14)	1	1 (7.14)
Aspartate aminotransferase increased	1	1 (7.14)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (7.14)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (7.14)	0	0 (0.00)
C-reactive protein increased	1	1 (7.14)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Platelet count decreased	1	1 (7.14)	1	1 (7.14)
Metabolism and nutrition disorders				
- Total	1	1 (7.14)	1	1 (7.14)
Hypokalaemia	1	1 (7.14)	1	1 (7.14)
Nervous system disorders				
- Total	2	1 (7.14)	0	0 (0.00)
Dizziness	1	1 (7.14)	0	0 (0.00)
Headache	1	1 (7.14)	0	0 (0.00)
Renal and urinary disorders				
- Total	3	2 (14.29)	1	1 (7.14)
Acute kidney injury	2	1 (7.14)	1	1 (7.14)
Haematuria	1	1 (7.14)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (7.14)	1	1 (7.14)
Ovarian failure	1	1 (7.14)	1	1 (7.14)
Respiratory, thoracic and mediastinal disorders				

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
- Total	7	4 (28.57)	0	0 (0.00)
Cough	3	2 (14.29)	0	0 (0.00)
Epistaxis	1	1 (7.14)	0	0 (0.00)
Oropharyngeal pain	1	1 (7.14)	0	0 (0.00)
Rhinitis allergic	1	1 (7.14)	0	0 (0.00)
Rhinorrhoea	1	1 (7.14)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Pruritus	1	1 (7.14)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Total number of AE per patient	760	30 (100.00)	258	26 (86.67)
Blood and lymphatic system disorders				
- Total	68	22 (73.33)	51	21 (70.00)
Anaemia	26	13 (43.33)	17	8 (26.67)
Febrile neutropenia	13	10 (33.33)	13	10 (33.33)
Thrombocytopenia	12	5 (16.67)	7	5 (16.67)
Neutropenia	10	7 (23.33)	10	7 (23.33)
Disseminated intravascular coagulation	3	2 (6.67)	1	1 (3.33)
Eosinophilia	2	1 (3.33)	1	1 (3.33)
Leukopenia	1	1 (3.33)	1	1 (3.33)
Lymphopenia	1	1 (3.33)	1	1 (3.33)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Cardiac disorders				
- Total	16	10 (33.33)	3	2 (6.67)
Tachycardia	9	7 (23.33)	2	2 (6.67)
Sinus bradycardia	2	1 (3.33)	0	0 (0.00)
Bradycardia	1	1 (3.33)	0	0 (0.00)
Left ventricular dysfunction	1	1 (3.33)	1	1 (3.33)
Palpitations	1	1 (3.33)	0	0 (0.00)
Pericardial effusion	1	1 (3.33)	0	0 (0.00)
Sinus tachycardia	1	1 (3.33)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (6.67)	0	0 (0.00)
Hypoacusis	1	1 (3.33)	0	0 (0.00)
Tympanic membrane perforation	1	1 (3.33)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (3.33)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.33)	0	0 (0.00)
Eye disorders				
- Total	10	7 (23.33)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Eye pain	3	2 (6.67)	0	0 (0.00)
Periorbital oedema	2	2 (6.67)	0	0 (0.00)
Vision blurred	2	2 (6.67)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (3.33)	0	0 (0.00)
Ocular hyperaemia	1	1 (3.33)	0	0 (0.00)
Retinal haemorrhage	1	1 (3.33)	0	0 (0.00)
Gastrointestinal disorders				
- Total	51	17 (56.67)	7	6 (20.00)
Vomiting	13	10 (33.33)	0	0 (0.00)
Diarrhoea	8	7 (23.33)	0	0 (0.00)
Nausea	8	6 (20.00)	1	1 (3.33)
Abdominal pain	3	3 (10.00)	0	0 (0.00)
Oral pain	3	2 (6.67)	1	1 (3.33)
Anal incontinence	2	1 (3.33)	0	0 (0.00)
Haematemesis	2	2 (6.67)	0	0 (0.00)
Mouth haemorrhage	2	1 (3.33)	2	1 (3.33)
Abdominal distension	1	1 (3.33)	0	0 (0.00)
Abdominal pain upper	1	1 (3.33)	0	0 (0.00)
Constipation	1	1 (3.33)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Dysphagia	1	1 (3.33)	1	1 (3.33)
Enterocolitis	1	1 (3.33)	1	1 (3.33)
Gastrointestinal haemorrhage	1	1 (3.33)	0	0 (0.00)
Ileus	1	1 (3.33)	1	1 (3.33)
Pancreatitis	1	1 (3.33)	0	0 (0.00)
Pigmentation lip	1	1 (3.33)	0	0 (0.00)
Stomatitis	1	1 (3.33)	0	0 (0.00)
General disorders and administration site conditions				
- Total	48	17 (56.67)	10	6 (20.00)
Pyrexia	16	8 (26.67)	3	3 (10.00)
Chills	5	5 (16.67)	0	0 (0.00)
Fatigue	5	4 (13.33)	1	1 (3.33)
Pain	4	4 (13.33)	2	2 (6.67)
Generalised oedema	3	2 (6.67)	0	0 (0.00)
Catheter site pain	2	2 (6.67)	0	0 (0.00)
Face oedema	2	2 (6.67)	1	1 (3.33)
Acquired gene mutation	1	1 (3.33)	0	0 (0.00)
Asthenia	1	1 (3.33)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Catheter site extravasation	1	1 (3.33)	0	0 (0.00)
Influenza like illness	1	1 (3.33)	0	0 (0.00)
Localised oedema	1	1 (3.33)	1	1 (3.33)
Malaise	1	1 (3.33)	0	0 (0.00)
Mucosal haemorrhage	1	1 (3.33)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (3.33)	1	1 (3.33)
Non-cardiac chest pain	1	1 (3.33)	0	0 (0.00)
Oedema peripheral	1	1 (3.33)	1	1 (3.33)
Peripheral swelling	1	1 (3.33)	0	0 (0.00)
Hepatobiliary disorders				
- Total	7	5 (16.67)	2	2 (6.67)
Hyperbilirubinaemia	4	3 (10.00)	2	2 (6.67)
Hepatomegaly	3	3 (10.00)	0	0 (0.00)
Immune system disorders				
- Total	69	27 (90.00)	18	10 (33.33)
Cytokine release syndrome	45	23 (76.67)	16	9 (30.00)
Hypogammaglobulinaemia	17	16 (53.33)	2	2 (6.67)
Graft versus host disease	3	2 (6.67)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Chronic graft versus host disease	1	1 (3.33)	0	0 (0.00)
Drug hypersensitivity	1	1 (3.33)	0	0 (0.00)
Graft versus host disease in skin	1	1 (3.33)	0	0 (0.00)
Seasonal allergy	1	1 (3.33)	0	0 (0.00)
Infections and infestations				
- Total	59	20 (66.67)	13	7 (23.33)
Upper respiratory tract infection	8	5 (16.67)	0	0 (0.00)
Cellulitis of male external genital organ	6	1 (3.33)	3	1 (3.33)
Otitis media	6	3 (10.00)	1	1 (3.33)
Urinary tract infection	4	1 (3.33)	2	1 (3.33)
Gastroenteritis	3	3 (10.00)	1	1 (3.33)
Otitis media acute	3	1 (3.33)	0	0 (0.00)
Rhinovirus infection	3	1 (3.33)	0	0 (0.00)
Viral infection	3	3 (10.00)	0	0 (0.00)
Influenza	2	2 (6.67)	0	0 (0.00)
Sinusitis	2	2 (6.67)	0	0 (0.00)
Acute sinusitis	1	1 (3.33)	0	0 (0.00)
Body tinea	1	1 (3.33)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Cholecystitis infective	1	1 (3.33)	1	1 (3.33)
Clostridium difficile colitis	1	1 (3.33)	1	1 (3.33)
Clostridium difficile infection	1	1 (3.33)	0	0 (0.00)
Corona virus infection	1	1 (3.33)	1	1 (3.33)
Fungal skin infection	1	1 (3.33)	0	0 (0.00)
Gingivitis	1	1 (3.33)	0	0 (0.00)
Haemophilus infection	1	1 (3.33)	0	0 (0.00)
Herpes zoster	1	1 (3.33)	1	1 (3.33)
Orchitis	1	1 (3.33)	0	0 (0.00)
Pharyngitis	1	1 (3.33)	0	0 (0.00)
Pneumonia	1	1 (3.33)	0	0 (0.00)
Rash pustular	1	1 (3.33)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (3.33)	1	1 (3.33)
Skin infection	1	1 (3.33)	0	0 (0.00)
Streptococcal infection	1	1 (3.33)	0	0 (0.00)
Subcutaneous abscess	1	1 (3.33)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (3.33)	1	1 (3.33)
Injury, poisoning and procedural complications				

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
- Total	14	7 (23.33)	1	1 (3.33)
Infusion related reaction	2	2 (6.67)	0	0 (0.00)
Tracheal haemorrhage	2	1 (3.33)	1	1 (3.33)
Contusion	1	1 (3.33)	0	0 (0.00)
Foot fracture	1	1 (3.33)	0	0 (0.00)
Mouth injury	1	1 (3.33)	0	0 (0.00)
Procedural complication	1	1 (3.33)	0	0 (0.00)
Procedural headache	1	1 (3.33)	0	0 (0.00)
Procedural nausea	1	1 (3.33)	0	0 (0.00)
Skin abrasion	1	1 (3.33)	0	0 (0.00)
Skin laceration	1	1 (3.33)	0	0 (0.00)
Sunburn	1	1 (3.33)	0	0 (0.00)
Tongue injury	1	1 (3.33)	0	0 (0.00)
Investigations				
- Total	177	25 (83.33)	92	21 (70.00)
Neutrophil count decreased	33	13 (43.33)	27	11 (36.67)
White blood cell count decreased	31	15 (50.00)	18	12 (40.00)
Platelet count decreased	21	8 (26.67)	15	5 (16.67)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Aspartate aminotransferase increased	19	9 (30.00)	11	7 (23.33)
Alanine aminotransferase increased	14	8 (26.67)	8	6 (20.00)
Lymphocyte count decreased	9	7 (23.33)	4	4 (13.33)
International normalised ratio increased	6	4 (13.33)	0	0 (0.00)
Activated partial thromboplastin time prolonged	5	3 (10.00)	0	0 (0.00)
Blood bilirubin increased	5	4 (13.33)	2	2 (6.67)
Blood creatinine increased	5	4 (13.33)	2	2 (6.67)
Blood urea increased	4	2 (6.67)	1	1 (3.33)
Blood phosphorus increased	3	2 (6.67)	0	0 (0.00)
Prothrombin time prolonged	3	2 (6.67)	0	0 (0.00)
Blood fibrinogen decreased	2	2 (6.67)	1	1 (3.33)
Blood immunoglobulin M decreased	2	2 (6.67)	0	0 (0.00)
Blood uric acid increased	2	1 (3.33)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (3.33)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (3.33)	0	0 (0.00)
Blood magnesium decreased	1	1 (3.33)	0	0 (0.00)
Blood phosphorus decreased	1	1 (3.33)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
C-reactive protein increased	1	1 (3.33)	1	1 (3.33)
Cardiac murmur	1	1 (3.33)	0	0 (0.00)
Fibrin D dimer increased	1	1 (3.33)	0	0 (0.00)
Lipase increased	1	1 (3.33)	1	1 (3.33)
Norovirus test positive	1	1 (3.33)	0	0 (0.00)
Protein total decreased	1	1 (3.33)	1	1 (3.33)
Serum ferritin increased	1	1 (3.33)	0	0 (0.00)
Transaminases increased	1	1 (3.33)	0	0 (0.00)
Weight decreased	1	1 (3.33)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	55	16 (53.33)	20	11 (36.67)
Decreased appetite	10	9 (30.00)	6	6 (20.00)
Hypokalaemia	10	7 (23.33)	3	3 (10.00)
Hypophosphataemia	5	5 (16.67)	4	4 (13.33)
Hyperalbuminaemia	3	1 (3.33)	0	0 (0.00)
Hypercalcaemia	3	1 (3.33)	0	0 (0.00)
Hyperphosphataemia	3	2 (6.67)	0	0 (0.00)
Hyperglycaemia	2	1 (3.33)	0	0 (0.00)
Hypernatraemia	2	1 (3.33)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Hypertriglyceridaemia	2	1 (3.33)	1	1 (3.33)
Hypoalbuminaemia	2	2 (6.67)	0	0 (0.00)
Hypocalcaemia	2	2 (6.67)	1	1 (3.33)
Vitamin D deficiency	2	2 (6.67)	0	0 (0.00)
Acidosis	1	1 (3.33)	1	1 (3.33)
Dehydration	1	1 (3.33)	1	1 (3.33)
Fluid overload	1	1 (3.33)	0	0 (0.00)
Hyperchloraemia	1	1 (3.33)	0	0 (0.00)
Hypermagnesaemia	1	1 (3.33)	0	0 (0.00)
Hyperuricaemia	1	1 (3.33)	1	1 (3.33)
Hyponatraemia	1	1 (3.33)	1	1 (3.33)
Iron overload	1	1 (3.33)	1	1 (3.33)
Metabolic alkalosis	1	1 (3.33)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	17	9 (30.00)	1	1 (3.33)
Arthralgia	3	2 (6.67)	1	1 (3.33)
Muscle spasms	2	2 (6.67)	0	0 (0.00)
Muscular weakness	2	2 (6.67)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Myalgia	2	2 (6.67)	0	0 (0.00)
Pain in extremity	2	2 (6.67)	0	0 (0.00)
Back pain	1	1 (3.33)	0	0 (0.00)
Joint range of motion decreased	1	1 (3.33)	0	0 (0.00)
Musculoskeletal pain	1	1 (3.33)	0	0 (0.00)
Neck pain	1	1 (3.33)	0	0 (0.00)
Osteonecrosis	1	1 (3.33)	0	0 (0.00)
Pain in jaw	1	1 (3.33)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.33)	1	1 (3.33)
Glioblastoma multiforme	1	1 (3.33)	1	1 (3.33)
Nervous system disorders				
- Total	28	17 (56.67)	3	2 (6.67)
Headache	18	11 (36.67)	1	1 (3.33)
Encephalopathy	2	2 (6.67)	1	1 (3.33)
Peroneal nerve palsy	2	2 (6.67)	0	0 (0.00)
Seizure	2	2 (6.67)	1	1 (3.33)
Disturbance in attention	1	1 (3.33)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Dizziness	1	1 (3.33)	0	0 (0.00)
Dysarthria	1	1 (3.33)	0	0 (0.00)
Somnolence	1	1 (3.33)	0	0 (0.00)
Psychiatric disorders				
- Total	21	8 (26.67)	0	0 (0.00)
Confusional state	4	4 (13.33)	0	0 (0.00)
Anxiety	3	3 (10.00)	0	0 (0.00)
Agitation	2	1 (3.33)	0	0 (0.00)
Delirium	2	2 (6.67)	0	0 (0.00)
Depression	2	2 (6.67)	0	0 (0.00)
Hallucination	2	1 (3.33)	0	0 (0.00)
Irritability	2	2 (6.67)	0	0 (0.00)
Insomnia	1	1 (3.33)	0	0 (0.00)
Listless	1	1 (3.33)	0	0 (0.00)
Mental status changes	1	1 (3.33)	0	0 (0.00)
Sleep disorder	1	1 (3.33)	0	0 (0.00)
Renal and urinary disorders				
- Total	8	5 (16.67)	5	3 (10.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Acute kidney injury	3	3 (10.00)	2	2 (6.67)
Haematuria	2	2 (6.67)	1	1 (3.33)
Dysuria	1	1 (3.33)	0	0 (0.00)
Oliguria	1	1 (3.33)	1	1 (3.33)
Renal impairment	1	1 (3.33)	1	1 (3.33)
Reproductive system and breast disorders				
- Total	1	1 (3.33)	0	0 (0.00)
Scrotal pain	1	1 (3.33)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	49	16 (53.33)	17	6 (20.00)
Cough	7	6 (20.00)	0	0 (0.00)
Hypoxia	6	5 (16.67)	4	3 (10.00)
Epistaxis	5	5 (16.67)	3	3 (10.00)
Pleural effusion	5	5 (16.67)	1	1 (3.33)
Pulmonary oedema	4	4 (13.33)	4	4 (13.33)
Dyspnoea	3	2 (6.67)	2	2 (6.67)
Nasal congestion	3	3 (10.00)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Tachypnoea	3	2 (6.67)	0	0 (0.00)
Rhinorrhoea	2	2 (6.67)	0	0 (0.00)
Atelectasis	1	1 (3.33)	0	0 (0.00)
Dysphonia	1	1 (3.33)	0	0 (0.00)
Interstitial lung disease	1	1 (3.33)	1	1 (3.33)
Oropharyngeal pain	1	1 (3.33)	0	0 (0.00)
Oropharyngeal plaque	1	1 (3.33)	0	0 (0.00)
Pharyngeal erythema	1	1 (3.33)	0	0 (0.00)
Pharyngeal lesion	1	1 (3.33)	1	1 (3.33)
Pharyngeal ulceration	1	1 (3.33)	0	0 (0.00)
Respiratory depression	1	1 (3.33)	0	0 (0.00)
Respiratory distress	1	1 (3.33)	1	1 (3.33)
Rhinitis allergic	1	1 (3.33)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	33	16 (53.33)	2	2 (6.67)
Erythema	4	4 (13.33)	0	0 (0.00)
Rash maculo-papular	4	4 (13.33)	1	1 (3.33)
Hyperhidrosis	3	2 (6.67)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Ingrowing nail	3	2 (6.67)	0	0 (0.00)
Rash	3	3 (10.00)	0	0 (0.00)
Papule	2	2 (6.67)	0	0 (0.00)
Rash erythematous	2	1 (3.33)	0	0 (0.00)
Acne	1	1 (3.33)	0	0 (0.00)
Alopecia	1	1 (3.33)	0	0 (0.00)
Dermatitis acneiform	1	1 (3.33)	1	1 (3.33)
Dermatitis diaper	1	1 (3.33)	0	0 (0.00)
Dry skin	1	1 (3.33)	0	0 (0.00)
Keloid scar	1	1 (3.33)	0	0 (0.00)
Livedo reticularis	1	1 (3.33)	0	0 (0.00)
Macule	1	1 (3.33)	0	0 (0.00)
Night sweats	1	1 (3.33)	0	0 (0.00)
Pruritus	1	1 (3.33)	0	0 (0.00)
Rash papular	1	1 (3.33)	0	0 (0.00)
Skin irritation	1	1 (3.33)	0	0 (0.00)
Vascular disorders				
- Total	25	11 (36.67)	12	9 (30.00)
Hypotension	12	9 (30.00)	10	9 (30.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Hypertension	9	8 (26.67)	1	1 (3.33)
Flushing	2	1 (3.33)	0	0 (0.00)
Capillary leak syndrome	1	1 (3.33)	1	1 (3.33)
Hot flush	1	1 (3.33)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Total number of AE per patient	990	34 (100.00)	294	33 (97.06)
Blood and lymphatic system disorders				
- Total	74	26 (76.47)	56	22 (64.71)
Anaemia	23	14 (41.18)	15	12 (35.29)
Thrombocytopenia	21	5 (14.71)	17	4 (11.76)
Febrile neutropenia	17	14 (41.18)	17	14 (41.18)
Neutropenia	5	4 (11.76)	4	4 (11.76)
Lymphopenia	3	3 (8.82)	1	1 (2.94)
Disseminated intravascular coagulation	2	2 (5.88)	1	1 (2.94)
Coagulopathy	1	1 (2.94)	0	0 (0.00)
Lymphadenopathy	1	1 (2.94)	0	0 (0.00)
Pancytopenia	1	1 (2.94)	1	1 (2.94)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Cardiac disorders				
- Total	17	13 (38.24)	0	0 (0.00)
Tachycardia	8	8 (23.53)	0	0 (0.00)
Sinus tachycardia	5	5 (14.71)	0	0 (0.00)
Atrioventricular block second degree	1	1 (2.94)	0	0 (0.00)
Cardiac dysfunction	1	1 (2.94)	0	0 (0.00)
Pericardial effusion	1	1 (2.94)	0	0 (0.00)
Ventricular tachycardia	1	1 (2.94)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (5.88)	0	0 (0.00)
Ear pain	2	2 (5.88)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.94)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.94)	0	0 (0.00)
Eye disorders				
- Total	20	11 (32.35)	0	0 (0.00)
Photophobia	3	2 (5.88)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Vision blurred	3	2 (5.88)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (5.88)	0	0 (0.00)
Dry eye	2	2 (5.88)	0	0 (0.00)
Periorbital oedema	2	2 (5.88)	0	0 (0.00)
Uveitis	2	2 (5.88)	0	0 (0.00)
Conjunctivitis allergic	1	1 (2.94)	0	0 (0.00)
Eye pain	1	1 (2.94)	0	0 (0.00)
Ocular hypertension	1	1 (2.94)	0	0 (0.00)
Papilloedema	1	1 (2.94)	0	0 (0.00)
Retinal haemorrhage	1	1 (2.94)	0	0 (0.00)
Visual impairment	1	1 (2.94)	0	0 (0.00)
Gastrointestinal disorders				
- Total	117	26 (76.47)	16	7 (20.59)
Vomiting	35	17 (50.00)	5	3 (8.82)
Nausea	26	19 (55.88)	4	4 (11.76)
Diarrhoea	20	17 (50.00)	2	2 (5.88)
Abdominal pain	12	8 (23.53)	2	1 (2.94)
Constipation	7	6 (17.65)	0	0 (0.00)
Abdominal pain upper	2	2 (5.88)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Abdominal discomfort	1	1 (2.94)	0	0 (0.00)
Abdominal distension	1	1 (2.94)	0	0 (0.00)
Abdominal pain lower	1	1 (2.94)	0	0 (0.00)
Abdominal tenderness	1	1 (2.94)	0	0 (0.00)
Ascites	1	1 (2.94)	1	1 (2.94)
Dyspepsia	1	1 (2.94)	0	0 (0.00)
Dysphagia	1	1 (2.94)	0	0 (0.00)
Flatulence	1	1 (2.94)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.94)	0	0 (0.00)
Glossodynia	1	1 (2.94)	0	0 (0.00)
Intestinal obstruction	1	1 (2.94)	1	1 (2.94)
Lip pain	1	1 (2.94)	0	0 (0.00)
Pancreatitis	1	1 (2.94)	1	1 (2.94)
Stomatitis	1	1 (2.94)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (2.94)	0	0 (0.00)
General disorders and administration site conditions				
- Total	59	25 (73.53)	6	6 (17.65)
Pyrexia	27	17 (50.00)	4	4 (11.76)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Fatigue	11	11 (32.35)	0	0 (0.00)
Chills	6	5 (14.71)	0	0 (0.00)
Malaise	3	3 (8.82)	0	0 (0.00)
Catheter site pain	2	2 (5.88)	0	0 (0.00)
Oedema peripheral	2	2 (5.88)	0	0 (0.00)
Catheter site haemorrhage	1	1 (2.94)	0	0 (0.00)
Crying	1	1 (2.94)	0	0 (0.00)
Cyst	1	1 (2.94)	1	1 (2.94)
Facial pain	1	1 (2.94)	0	0 (0.00)
Generalised oedema	1	1 (2.94)	0	0 (0.00)
Influenza like illness	1	1 (2.94)	0	0 (0.00)
Injection site haematoma	1	1 (2.94)	0	0 (0.00)
Physical deconditioning	1	1 (2.94)	1	1 (2.94)
Hepatobiliary disorders				
- Total	2	2 (5.88)	0	0 (0.00)
Gallbladder enlargement	1	1 (2.94)	0	0 (0.00)
Hepatosplenomegaly	1	1 (2.94)	0	0 (0.00)
Immune system disorders				

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
- Total	66	31 (91.18)	16	12 (35.29)
Cytokine release syndrome	41	27 (79.41)	13	10 (29.41)
Hypogammaglobulinaemia	19	17 (50.00)	3	3 (8.82)
Immunodeficiency common variable	2	2 (5.88)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (2.94)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (2.94)	0	0 (0.00)
Immunodeficiency	1	1 (2.94)	0	0 (0.00)
Seasonal allergy	1	1 (2.94)	0	0 (0.00)
Infections and infestations				
- Total	75	26 (76.47)	18	11 (32.35)
Clostridium difficile infection	4	4 (11.76)	1	1 (2.94)
Rhinovirus infection	4	4 (11.76)	0	0 (0.00)
Upper respiratory tract infection	4	4 (11.76)	1	1 (2.94)
Urinary tract infection	4	4 (11.76)	1	1 (2.94)
Clostridium difficile colitis	3	3 (8.82)	0	0 (0.00)
Pneumonia	3	3 (8.82)	1	1 (2.94)
Sinusitis	3	2 (5.88)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Cytomegalovirus infection	2	2 (5.88)	0	0 (0.00)
Ear infection	2	2 (5.88)	0	0 (0.00)
Gastroenteritis	2	2 (5.88)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (2.94)	0	0 (0.00)
Influenza	2	2 (5.88)	0	0 (0.00)
Otitis media acute	2	1 (2.94)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (5.88)	1	1 (2.94)
Staphylococcal infection	2	2 (5.88)	1	1 (2.94)
Viral upper respiratory tract infection	2	2 (5.88)	0	0 (0.00)
Vulvovaginal candidiasis	2	2 (5.88)	0	0 (0.00)
Bacterial sepsis	1	1 (2.94)	1	1 (2.94)
Campylobacter infection	1	1 (2.94)	1	1 (2.94)
Catheter site cellulitis	1	1 (2.94)	0	0 (0.00)
Catheter site infection	1	1 (2.94)	1	1 (2.94)
Enterococcal infection	1	1 (2.94)	0	0 (0.00)
Enterovirus infection	1	1 (2.94)	1	1 (2.94)
Escherichia urinary tract infection	1	1 (2.94)	1	1 (2.94)
Folliculitis	1	1 (2.94)	0	0 (0.00)
Gastroenteritis viral	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Herpes simplex	1	1 (2.94)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (2.94)	0	0 (0.00)
Hypopyon	1	1 (2.94)	0	0 (0.00)
Meningitis aseptic	1	1 (2.94)	0	0 (0.00)
Molluscum contagiosum	1	1 (2.94)	0	0 (0.00)
Oral candidiasis	1	1 (2.94)	0	0 (0.00)
Oral herpes	1	1 (2.94)	0	0 (0.00)
Otitis externa	1	1 (2.94)	0	0 (0.00)
Otitis media	1	1 (2.94)	0	0 (0.00)
Paronychia	1	1 (2.94)	0	0 (0.00)
Respiratory tract infection	1	1 (2.94)	1	1 (2.94)
Respiratory tract infection viral	1	1 (2.94)	1	1 (2.94)
Rhinitis	1	1 (2.94)	0	0 (0.00)
Rotavirus infection	1	1 (2.94)	1	1 (2.94)
Sepsis	1	1 (2.94)	1	1 (2.94)
Septic embolus	1	1 (2.94)	1	1 (2.94)
Skin infection	1	1 (2.94)	0	0 (0.00)
Tinea capitis	1	1 (2.94)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (2.94)	1	1 (2.94)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Vascular device infection	1	1 (2.94)	1	1 (2.94)
Vulvovaginal mycotic infection	1	1 (2.94)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	25	15 (44.12)	2	2 (5.88)
Procedural pain	6	5 (14.71)	1	1 (2.94)
Transfusion reaction	4	3 (8.82)	0	0 (0.00)
Contusion	2	2 (5.88)	0	0 (0.00)
Infusion related reaction	2	2 (5.88)	0	0 (0.00)
Arthropod bite	1	1 (2.94)	0	0 (0.00)
Incision site pain	1	1 (2.94)	0	0 (0.00)
Limb injury	1	1 (2.94)	0	0 (0.00)
Post procedural haemorrhage	1	1 (2.94)	0	0 (0.00)
Procedural site reaction	1	1 (2.94)	0	0 (0.00)
Radius fracture	1	1 (2.94)	0	0 (0.00)
Skin abrasion	1	1 (2.94)	0	0 (0.00)
Stoma site irritation	1	1 (2.94)	0	0 (0.00)
Subdural haemorrhage	1	1 (2.94)	0	0 (0.00)
Tibia fracture	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Transfusion related complication	1	1 (2.94)	1	1 (2.94)
Investigations				
- Total	225	31 (91.18)	110	28 (82.35)
White blood cell count decreased	36	20 (58.82)	25	18 (52.94)
Neutrophil count decreased	29	15 (44.12)	25	14 (41.18)
Platelet count decreased	28	12 (35.29)	23	10 (29.41)
Alanine aminotransferase increased	19	13 (38.24)	10	8 (23.53)
Aspartate aminotransferase increased	18	11 (32.35)	8	5 (14.71)
Lymphocyte count decreased	14	9 (26.47)	9	8 (23.53)
Prothrombin time prolonged	14	7 (20.59)	1	1 (2.94)
Blood fibrinogen decreased	13	2 (5.88)	3	2 (5.88)
Blood bilirubin increased	9	4 (11.76)	1	1 (2.94)
Blood creatinine increased	7	5 (14.71)	0	0 (0.00)
International normalised ratio increased	5	5 (14.71)	1	1 (2.94)
Activated partial thromboplastin time prolonged	3	2 (5.88)	0	0 (0.00)
Haemoglobin decreased	3	3 (8.82)	1	1 (2.94)
Weight decreased	3	3 (8.82)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Blood immunoglobulin A decreased	2	2 (5.88)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (5.88)	0	0 (0.00)
Blood sodium increased	2	1 (2.94)	0	0 (0.00)
Transaminases increased	2	2 (5.88)	0	0 (0.00)
Weight increased	2	2 (5.88)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (2.94)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.94)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (2.94)	0	0 (0.00)
Blood lactic acid increased	1	1 (2.94)	1	1 (2.94)
Blood magnesium decreased	1	1 (2.94)	1	1 (2.94)
Blood urea increased	1	1 (2.94)	0	0 (0.00)
Blood uric acid increased	1	1 (2.94)	0	0 (0.00)
C-reactive protein increased	1	1 (2.94)	0	0 (0.00)
Culture stool positive	1	1 (2.94)	0	0 (0.00)
Hepatic enzyme increased	1	1 (2.94)	0	0 (0.00)
Lipase increased	1	1 (2.94)	1	1 (2.94)
Oxygen saturation decreased	1	1 (2.94)	0	0 (0.00)
Pulmonary function test decreased	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Serum ferritin increased	1	1 (2.94)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	78	27 (79.41)	30	16 (47.06)
Decreased appetite	16	13 (38.24)	7	6 (17.65)
Hypokalaemia	13	12 (35.29)	6	6 (17.65)
Hyperphosphataemia	9	6 (17.65)	0	0 (0.00)
Hypophosphataemia	9	5 (14.71)	6	4 (11.76)
Hypernatraemia	5	3 (8.82)	1	1 (2.94)
Hypoalbuminaemia	4	3 (8.82)	1	1 (2.94)
Dehydration	3	3 (8.82)	2	2 (5.88)
Hyperglycaemia	3	2 (5.88)	2	2 (5.88)
Hyperuricaemia	3	2 (5.88)	0	0 (0.00)
Fluid overload	2	2 (5.88)	0	0 (0.00)
Hypocalcaemia	2	1 (2.94)	0	0 (0.00)
Hyponatraemia	2	1 (2.94)	2	1 (2.94)
Tumour lysis syndrome	2	2 (5.88)	2	2 (5.88)
Acidosis	1	1 (2.94)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (2.94)	0	0 (0.00)
Hypomagnesaemia	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Malnutrition	1	1 (2.94)	1	1 (2.94)
Metabolic acidosis	1	1 (2.94)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	28	16 (47.06)	0	0 (0.00)
Pain in extremity	10	9 (26.47)	0	0 (0.00)
Arthralgia	3	3 (8.82)	0	0 (0.00)
Musculoskeletal pain	3	2 (5.88)	0	0 (0.00)
Myalgia	3	3 (8.82)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (5.88)	0	0 (0.00)
Coccydynia	1	1 (2.94)	0	0 (0.00)
Flank pain	1	1 (2.94)	0	0 (0.00)
Joint range of motion decreased	1	1 (2.94)	0	0 (0.00)
Limb discomfort	1	1 (2.94)	0	0 (0.00)
Muscular weakness	1	1 (2.94)	0	0 (0.00)
Osteopenia	1	1 (2.94)	0	0 (0.00)
Toe walking	1	1 (2.94)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
- Total	2	2 (5.88)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (2.94)	0	0 (0.00)
Skin papilloma	1	1 (2.94)	0	0 (0.00)
Nervous system disorders				
- Total	46	18 (52.94)	4	4 (11.76)
Headache	21	13 (38.24)	1	1 (2.94)
Dizziness	7	5 (14.71)	0	0 (0.00)
Encephalopathy	4	2 (5.88)	1	1 (2.94)
Seizure	2	2 (5.88)	1	1 (2.94)
Tremor	2	2 (5.88)	0	0 (0.00)
Asterixis	1	1 (2.94)	0	0 (0.00)
Ataxia	1	1 (2.94)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.94)	0	0 (0.00)
Dysarthria	1	1 (2.94)	0	0 (0.00)
Embolic stroke	1	1 (2.94)	1	1 (2.94)
Idiopathic intracranial hypertension	1	1 (2.94)	0	0 (0.00)
Migraine	1	1 (2.94)	0	0 (0.00)
Myoclonus	1	1 (2.94)	0	0 (0.00)
Neuropathy peripheral	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Pleocytosis	1	1 (2.94)	0	0 (0.00)
Product issues				
- Total	1	1 (2.94)	0	0 (0.00)
Device occlusion	1	1 (2.94)	0	0 (0.00)
Psychiatric disorders				
- Total	13	9 (26.47)	1	1 (2.94)
Anxiety	4	4 (11.76)	1	1 (2.94)
Confusional state	2	2 (5.88)	0	0 (0.00)
Delirium	2	2 (5.88)	0	0 (0.00)
Adjustment disorder	1	1 (2.94)	0	0 (0.00)
Agitation	1	1 (2.94)	0	0 (0.00)
Hallucination	1	1 (2.94)	0	0 (0.00)
Panic attack	1	1 (2.94)	0	0 (0.00)
Suicidal ideation	1	1 (2.94)	0	0 (0.00)
Renal and urinary disorders				
- Total	18	10 (29.41)	10	7 (20.59)
Acute kidney injury	7	6 (17.65)	5	5 (14.71)
Haematuria	4	3 (8.82)	2	2 (5.88)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Calculus urinary	1	1 (2.94)	0	0 (0.00)
Dysuria	1	1 (2.94)	0	0 (0.00)
Nephrolithiasis	1	1 (2.94)	1	1 (2.94)
Oliguria	1	1 (2.94)	1	1 (2.94)
Pollakiuria	1	1 (2.94)	0	0 (0.00)
Renal failure	1	1 (2.94)	1	1 (2.94)
Urinary incontinence	1	1 (2.94)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	6	5 (14.71)	2	2 (5.88)
Oedema genital	2	1 (2.94)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (5.88)	0	0 (0.00)
Ovarian failure	1	1 (2.94)	1	1 (2.94)
Vaginal haemorrhage	1	1 (2.94)	1	1 (2.94)
Respiratory, thoracic and mediastinal disorders				
- Total	61	22 (64.71)	15	9 (26.47)
Cough	13	8 (23.53)	0	0 (0.00)
Epistaxis	9	5 (14.71)	2	2 (5.88)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Hypoxia	7	5 (14.71)	4	4 (11.76)
Oropharyngeal pain	5	5 (14.71)	0	0 (0.00)
Rhinitis allergic	4	3 (8.82)	0	0 (0.00)
Rhinorrhoea	4	4 (11.76)	0	0 (0.00)
Haemoptysis	3	2 (5.88)	1	1 (2.94)
Pleural effusion	3	3 (8.82)	1	1 (2.94)
Pulmonary oedema	3	3 (8.82)	2	2 (5.88)
Respiratory failure	3	3 (8.82)	3	3 (8.82)
Tachypnoea	3	3 (8.82)	1	1 (2.94)
Nasal congestion	2	2 (5.88)	0	0 (0.00)
Acute respiratory failure	1	1 (2.94)	1	1 (2.94)
Wheezing	1	1 (2.94)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	36	14 (41.18)	1	1 (2.94)
Rash	6	5 (14.71)	0	0 (0.00)
Dry skin	4	4 (11.76)	0	0 (0.00)
Petechiae	4	4 (11.76)	0	0 (0.00)
Pruritus	3	3 (8.82)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Erythema	2	1 (2.94)	0	0 (0.00)
Hyperhidrosis	2	2 (5.88)	0	0 (0.00)
Dermatitis	1	1 (2.94)	0	0 (0.00)
Dermatitis atopic	1	1 (2.94)	0	0 (0.00)
Ecchymosis	1	1 (2.94)	1	1 (2.94)
Eczema	1	1 (2.94)	0	0 (0.00)
Ingrowing nail	1	1 (2.94)	0	0 (0.00)
Macule	1	1 (2.94)	0	0 (0.00)
Rash erythematous	1	1 (2.94)	0	0 (0.00)
Rash follicular	1	1 (2.94)	0	0 (0.00)
Rash macular	1	1 (2.94)	0	0 (0.00)
Rash maculo-papular	1	1 (2.94)	0	0 (0.00)
Rash papular	1	1 (2.94)	0	0 (0.00)
Rash pruritic	1	1 (2.94)	0	0 (0.00)
Rash vesicular	1	1 (2.94)	0	0 (0.00)
Skin exfoliation	1	1 (2.94)	0	0 (0.00)
Skin fissures	1	1 (2.94)	0	0 (0.00)
Vascular disorders				
- Total	18	14 (41.18)	7	7 (20.59)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Hypotension	7	7 (20.59)	6	6 (17.65)
Hypertension	5	4 (11.76)	0	0 (0.00)
Orthostatic hypotension	2	2 (5.88)	0	0 (0.00)
Embolism	1	1 (2.94)	1	1 (2.94)
Flushing	1	1 (2.94)	0	0 (0.00)
Haematoma	1	1 (2.94)	0	0 (0.00)
Secondary hypertension	1	1 (2.94)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Total number of AE per patient	1111	51 (98.08)	409	44 (84.62)
Blood and lymphatic system disorders				
- Total	111	35 (67.31)	85	33 (63.46)
Anaemia	41	21 (40.38)	27	15 (28.85)
Thrombocytopenia	30	8 (15.38)	23	8 (15.38)
Febrile neutropenia	23	19 (36.54)	23	19 (36.54)
Neutropenia	9	8 (15.38)	8	8 (15.38)
Disseminated intravascular coagulation	4	3 (5.77)	2	2 (3.85)
Lymphopenia	2	2 (3.85)	1	1 (1.92)
Coagulopathy	1	1 (1.92)	0	0 (0.00)
Pancytopenia	1	1 (1.92)	1	1 (1.92)
Cardiac disorders				

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
- Total	27	18 (34.62)	3	2 (3.85)
Tachycardia	14	12 (23.08)	2	2 (3.85)
Sinus tachycardia	5	5 (9.62)	0	0 (0.00)
Pericardial effusion	2	2 (3.85)	0	0 (0.00)
Sinus bradycardia	2	1 (1.92)	0	0 (0.00)
Bradycardia	1	1 (1.92)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.92)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.92)	1	1 (1.92)
Palpitations	1	1 (1.92)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (5.77)	0	0 (0.00)
Ear pain	2	2 (3.85)	0	0 (0.00)
Hypoacusis	1	1 (1.92)	0	0 (0.00)
Eye disorders				
- Total	20	11 (21.15)	0	0 (0.00)
Eye pain	4	3 (5.77)	0	0 (0.00)
Periorbital oedema	3	3 (5.77)	0	0 (0.00)
Photophobia	3	2 (3.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Conjunctival haemorrhage	2	2 (3.85)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.85)	0	0 (0.00)
Vision blurred	2	2 (3.85)	0	0 (0.00)
Ocular hypertension	1	1 (1.92)	0	0 (0.00)
Papilloedema	1	1 (1.92)	0	0 (0.00)
Uveitis	1	1 (1.92)	0	0 (0.00)
Visual impairment	1	1 (1.92)	0	0 (0.00)
Gastrointestinal disorders				
- Total	105	29 (55.77)	15	11 (21.15)
Vomiting	28	17 (32.69)	3	3 (5.77)
Nausea	20	16 (30.77)	3	3 (5.77)
Diarrhoea	16	16 (30.77)	1	1 (1.92)
Abdominal pain	9	8 (15.38)	1	1 (1.92)
Constipation	7	6 (11.54)	0	0 (0.00)
Abdominal distension	2	2 (3.85)	0	0 (0.00)
Anal incontinence	2	1 (1.92)	0	0 (0.00)
Haematemesis	2	2 (3.85)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.92)	2	1 (1.92)
Pancreatitis	2	2 (3.85)	1	1 (1.92)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Stomatitis	2	2 (3.85)	0	0 (0.00)
Abdominal discomfort	1	1 (1.92)	0	0 (0.00)
Abdominal pain lower	1	1 (1.92)	0	0 (0.00)
Abdominal pain upper	1	1 (1.92)	0	0 (0.00)
Abdominal tenderness	1	1 (1.92)	0	0 (0.00)
Ascites	1	1 (1.92)	1	1 (1.92)
Dyspepsia	1	1 (1.92)	0	0 (0.00)
Dysphagia	1	1 (1.92)	1	1 (1.92)
Gastrointestinal haemorrhage	1	1 (1.92)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.92)	0	0 (0.00)
Glossodynia	1	1 (1.92)	0	0 (0.00)
Ileus	1	1 (1.92)	1	1 (1.92)
Intestinal obstruction	1	1 (1.92)	1	1 (1.92)
Tooth socket haemorrhage	1	1 (1.92)	0	0 (0.00)
General disorders and administration site conditions				
- Total	65	24 (46.15)	13	9 (17.31)
Pyrexia	25	14 (26.92)	6	6 (11.54)
Fatigue	10	9 (17.31)	1	1 (1.92)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Chills	9	8 (15.38)	0	0 (0.00)
Generalised oedema	3	2 (3.85)	0	0 (0.00)
Catheter site pain	2	2 (3.85)	0	0 (0.00)
Face oedema	2	2 (3.85)	1	1 (1.92)
Malaise	2	2 (3.85)	0	0 (0.00)
Oedema peripheral	2	2 (3.85)	1	1 (1.92)
Pain	2	2 (3.85)	2	2 (3.85)
Asthenia	1	1 (1.92)	0	0 (0.00)
Catheter site extravasation	1	1 (1.92)	0	0 (0.00)
Facial pain	1	1 (1.92)	0	0 (0.00)
Localised oedema	1	1 (1.92)	1	1 (1.92)
Mucosal haemorrhage	1	1 (1.92)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.92)	1	1 (1.92)
Non-cardiac chest pain	1	1 (1.92)	0	0 (0.00)
Peripheral swelling	1	1 (1.92)	0	0 (0.00)
Hepatobiliary disorders				
- Total	8	6 (11.54)	2	2 (3.85)
Hyperbilirubinaemia	4	3 (5.77)	2	2 (3.85)
Hepatomegaly	3	3 (5.77)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Hepatosplenomegaly	1	1 (1.92)	0	0 (0.00)
Immune system disorders				
- Total	98	46 (88.46)	30	20 (38.46)
Cytokine release syndrome	73	40 (76.92)	26	17 (32.69)
Hypogammaglobulinaemia	22	21 (40.38)	4	4 (7.69)
Drug hypersensitivity	1	1 (1.92)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.92)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.92)	0	0 (0.00)
Infections and infestations				
- Total	32	21 (40.38)	6	6 (11.54)
Clostridium difficile colitis	3	3 (5.77)	1	1 (1.92)
Clostridium difficile infection	3	3 (5.77)	0	0 (0.00)
Rhinovirus infection	3	3 (5.77)	0	0 (0.00)
Pneumonia	2	2 (3.85)	1	1 (1.92)
Staphylococcal infection	2	2 (3.85)	1	1 (1.92)
Acute sinusitis	1	1 (1.92)	0	0 (0.00)
Body tinea	1	1 (1.92)	0	0 (0.00)
Catheter site infection	1	1 (1.92)	1	1 (1.92)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Enterococcal infection	1	1 (1.92)	0	0 (0.00)
Folliculitis	1	1 (1.92)	0	0 (0.00)
Fungal skin infection	1	1 (1.92)	0	0 (0.00)
Gastroenteritis	1	1 (1.92)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.92)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (1.92)	0	0 (0.00)
Hypopyon	1	1 (1.92)	0	0 (0.00)
Influenza	1	1 (1.92)	0	0 (0.00)
Oral candidiasis	1	1 (1.92)	0	0 (0.00)
Orchitis	1	1 (1.92)	0	0 (0.00)
Septic embolus	1	1 (1.92)	1	1 (1.92)
Skin infection	1	1 (1.92)	0	0 (0.00)
Upper respiratory tract infection	1	1 (1.92)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.92)	1	1 (1.92)
Viral infection	1	1 (1.92)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (1.92)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	21	12 (23.08)	1	1 (1.92)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Transfusion reaction	3	2 (3.85)	0	0 (0.00)
Infusion related reaction	2	2 (3.85)	0	0 (0.00)
Procedural pain	2	2 (3.85)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.92)	1	1 (1.92)
Contusion	1	1 (1.92)	0	0 (0.00)
Incision site pain	1	1 (1.92)	0	0 (0.00)
Limb injury	1	1 (1.92)	0	0 (0.00)
Mouth injury	1	1 (1.92)	0	0 (0.00)
Procedural complication	1	1 (1.92)	0	0 (0.00)
Procedural headache	1	1 (1.92)	0	0 (0.00)
Procedural site reaction	1	1 (1.92)	0	0 (0.00)
Skin abrasion	1	1 (1.92)	0	0 (0.00)
Stoma site irritation	1	1 (1.92)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.92)	0	0 (0.00)
Tibia fracture	1	1 (1.92)	0	0 (0.00)
Tongue injury	1	1 (1.92)	0	0 (0.00)
Investigations				
- Total	281	43 (82.69)	153	36 (69.23)
White blood cell count decreased	46	23 (44.23)	30	20 (38.46)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Platelet count decreased	41	17 (32.69)	35	12 (23.08)
Neutrophil count decreased	37	20 (38.46)	35	19 (36.54)
Aspartate aminotransferase increased	25	14 (26.92)	14	9 (17.31)
Alanine aminotransferase increased	23	16 (30.77)	12	10 (19.23)
Blood fibrinogen decreased	15	4 (7.69)	4	3 (5.77)
Blood bilirubin increased	13	7 (13.46)	2	2 (3.85)
Lymphocyte count decreased	13	11 (21.15)	10	9 (17.31)
Prothrombin time prolonged	13	7 (13.46)	1	1 (1.92)
Blood creatinine increased	9	7 (13.46)	2	2 (3.85)
International normalised ratio increased	9	7 (13.46)	1	1 (1.92)
Activated partial thromboplastin time prolonged	7	4 (7.69)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (5.77)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.85)	0	0 (0.00)
Blood urea increased	3	3 (5.77)	1	1 (1.92)
Blood sodium increased	2	1 (1.92)	0	0 (0.00)
Blood uric acid increased	2	1 (1.92)	0	0 (0.00)
Lipase increased	2	2 (3.85)	2	2 (3.85)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Transaminases increased	2	2 (3.85)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.92)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (1.92)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.92)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.92)	1	1 (1.92)
Blood magnesium decreased	1	1 (1.92)	1	1 (1.92)
Blood phosphorus decreased	1	1 (1.92)	0	0 (0.00)
C-reactive protein increased	1	1 (1.92)	1	1 (1.92)
Cardiac murmur	1	1 (1.92)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.92)	0	0 (0.00)
Norovirus test positive	1	1 (1.92)	0	0 (0.00)
Protein total decreased	1	1 (1.92)	1	1 (1.92)
Pulmonary function test decreased	1	1 (1.92)	0	0 (0.00)
Serum ferritin increased	1	1 (1.92)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	106	33 (63.46)	40	21 (40.38)
Decreased appetite	21	18 (34.62)	12	11 (21.15)
Hypokalaemia	20	16 (30.77)	7	7 (13.46)
Hypophosphataemia	13	9 (17.31)	9	7 (13.46)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Hyperphosphataemia	8	6 (11.54)	0	0 (0.00)
Hypernatraemia	6	3 (5.77)	1	1 (1.92)
Hypoalbuminaemia	6	5 (9.62)	1	1 (1.92)
Hyperglycaemia	4	3 (5.77)	1	1 (1.92)
Hypocalcaemia	4	3 (5.77)	1	1 (1.92)
Fluid overload	3	3 (5.77)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.85)	1	1 (1.92)
Hyperuricaemia	3	2 (3.85)	1	1 (1.92)
Hyponatraemia	3	2 (3.85)	3	2 (3.85)
Dehydration	2	2 (3.85)	1	1 (1.92)
Hypercalcaemia	2	1 (1.92)	0	0 (0.00)
Acidosis	1	1 (1.92)	1	1 (1.92)
Hyperalbuminaemia	1	1 (1.92)	0	0 (0.00)
Hyperchloraemia	1	1 (1.92)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.92)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.92)	0	0 (0.00)
Malnutrition	1	1 (1.92)	1	1 (1.92)
Metabolic acidosis	1	1 (1.92)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.92)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	17	11 (21.15)	1	1 (1.92)
Musculoskeletal pain	4	3 (5.77)	0	0 (0.00)
Arthralgia	3	3 (5.77)	1	1 (1.92)
Myalgia	3	3 (5.77)	0	0 (0.00)
Pain in extremity	2	2 (3.85)	0	0 (0.00)
Limb discomfort	1	1 (1.92)	0	0 (0.00)
Muscle spasms	1	1 (1.92)	0	0 (0.00)
Muscular weakness	1	1 (1.92)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.92)	0	0 (0.00)
Osteopenia	1	1 (1.92)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.92)	0	0 (0.00)
Skin papilloma	1	1 (1.92)	0	0 (0.00)
Nervous system disorders				
- Total	43	27 (51.92)	6	5 (9.62)
Headache	25	19 (36.54)	2	2 (3.85)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Encephalopathy	5	3 (5.77)	2	2 (3.85)
Dizziness	4	4 (7.69)	0	0 (0.00)
Seizure	2	2 (3.85)	1	1 (1.92)
Depressed level of consciousness	1	1 (1.92)	0	0 (0.00)
Dysarthria	1	1 (1.92)	0	0 (0.00)
Embolic stroke	1	1 (1.92)	1	1 (1.92)
Idiopathic intracranial hypertension	1	1 (1.92)	0	0 (0.00)
Migraine	1	1 (1.92)	0	0 (0.00)
Somnolence	1	1 (1.92)	0	0 (0.00)
Tremor	1	1 (1.92)	0	0 (0.00)
Product issues				
- Total	1	1 (1.92)	0	0 (0.00)
Device occlusion	1	1 (1.92)	0	0 (0.00)
Psychiatric disorders				
- Total	25	15 (28.85)	1	1 (1.92)
Confusional state	6	6 (11.54)	0	0 (0.00)
Anxiety	5	5 (9.62)	1	1 (1.92)
Delirium	3	3 (5.77)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Hallucination	3	2 (3.85)	0	0 (0.00)
Agitation	2	1 (1.92)	0	0 (0.00)
Irritability	2	2 (3.85)	0	0 (0.00)
Insomnia	1	1 (1.92)	0	0 (0.00)
Listless	1	1 (1.92)	0	0 (0.00)
Mental status changes	1	1 (1.92)	0	0 (0.00)
Panic attack	1	1 (1.92)	0	0 (0.00)
Renal and urinary disorders				
- Total	14	8 (15.38)	10	6 (11.54)
Acute kidney injury	5	5 (9.62)	4	4 (7.69)
Haematuria	4	4 (7.69)	2	2 (3.85)
Oliguria	2	2 (3.85)	2	2 (3.85)
Dysuria	1	1 (1.92)	0	0 (0.00)
Renal failure	1	1 (1.92)	1	1 (1.92)
Renal impairment	1	1 (1.92)	1	1 (1.92)
Reproductive system and breast disorders				
- Total	4	3 (5.77)	0	0 (0.00)
Oedema genital	2	1 (1.92)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Vulvovaginal adhesion	2	2 (3.85)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	63	26 (50.00)	25	10 (19.23)
Hypoxia	13	10 (19.23)	8	7 (13.46)
Cough	8	8 (15.38)	0	0 (0.00)
Pleural effusion	8	8 (15.38)	2	2 (3.85)
Epistaxis	6	6 (11.54)	3	3 (5.77)
Tachypnoea	6	5 (9.62)	1	1 (1.92)
Pulmonary oedema	5	5 (9.62)	4	4 (7.69)
Dyspnoea	3	2 (3.85)	2	2 (3.85)
Respiratory failure	2	2 (3.85)	2	2 (3.85)
Atelectasis	1	1 (1.92)	0	0 (0.00)
Haemoptysis	1	1 (1.92)	1	1 (1.92)
Interstitial lung disease	1	1 (1.92)	1	1 (1.92)
Nasal congestion	1	1 (1.92)	0	0 (0.00)
Oropharyngeal pain	1	1 (1.92)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.92)	0	0 (0.00)
Pharyngeal ulceration	1	1 (1.92)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Respiratory depression	1	1 (1.92)	0	0 (0.00)
Respiratory distress	1	1 (1.92)	1	1 (1.92)
Rhinitis allergic	1	1 (1.92)	0	0 (0.00)
Rhinorrhoea	1	1 (1.92)	0	0 (0.00)
Wheezing	1	1 (1.92)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	31	19 (36.54)	1	1 (1.92)
Rash	4	4 (7.69)	0	0 (0.00)
Hyperhidrosis	3	2 (3.85)	0	0 (0.00)
Ingrowing nail	3	2 (3.85)	0	0 (0.00)
Petechiae	3	3 (5.77)	0	0 (0.00)
Rash maculo-papular	3	3 (5.77)	1	1 (1.92)
Dry skin	2	2 (3.85)	0	0 (0.00)
Erythema	2	2 (3.85)	0	0 (0.00)
Rash papular	2	2 (3.85)	0	0 (0.00)
Dermatitis diaper	1	1 (1.92)	0	0 (0.00)
Livedo reticularis	1	1 (1.92)	0	0 (0.00)
Macule	1	1 (1.92)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Night sweats	1	1 (1.92)	0	0 (0.00)
Pruritus	1	1 (1.92)	0	0 (0.00)
Rash erythematous	1	1 (1.92)	0	0 (0.00)
Rash follicular	1	1 (1.92)	0	0 (0.00)
Rash macular	1	1 (1.92)	0	0 (0.00)
Skin irritation	1	1 (1.92)	0	0 (0.00)
Vascular disorders				
- Total	35	20 (38.46)	17	14 (26.92)
Hypotension	18	15 (28.85)	15	14 (26.92)
Hypertension	11	9 (17.31)	1	1 (1.92)
Flushing	3	2 (3.85)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.92)	1	1 (1.92)
Haematoma	1	1 (1.92)	0	0 (0.00)
Orthostatic hypotension	1	1 (1.92)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	50	5 (100.00)	12	3 (60.00)
Blood and lymphatic system disorders				
- Total	4	3 (60.00)	3	2 (40.00)
Anaemia	3	3 (60.00)	2	2 (40.00)
Febrile neutropenia	1	1 (20.00)	1	1 (20.00)
Cardiac disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Atrioventricular block second degree	1	1 (20.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	2 (40.00)	0	0 (0.00)
Diarrhoea	1	1 (20.00)	0	0 (0.00)
Nausea	1	1 (20.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Vomiting	1	1 (20.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	5	4 (80.00)	0	0 (0.00)
Fatigue	3	3 (60.00)	0	0 (0.00)
Pain	1	1 (20.00)	0	0 (0.00)
Pyrexia	1	1 (20.00)	0	0 (0.00)
Immune system disorders				
- Total	8	5 (100.00)	0	0 (0.00)
Cytokine release syndrome	5	4 (80.00)	0	0 (0.00)
Hypogammaglobulinaemia	3	3 (60.00)	0	0 (0.00)
Infections and infestations				
- Total	4	2 (40.00)	1	1 (20.00)
Gastroenteritis	1	1 (20.00)	1	1 (20.00)
Pharyngitis	1	1 (20.00)	0	0 (0.00)
Streptococcal infection	1	1 (20.00)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (20.00)	0	0 (0.00)
Investigations				

Timing: within 8 weeks post infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
- Total	11	3 (60.00)	6	2 (40.00)
Neutrophil count decreased	5	2 (40.00)	4	1 (20.00)
White blood cell count decreased	2	2 (40.00)	1	1 (20.00)
Aspartate aminotransferase increased	1	1 (20.00)	1	1 (20.00)
Blood immunoglobulin A decreased	1	1 (20.00)	0	0 (0.00)
International normalised ratio increased	1	1 (20.00)	0	0 (0.00)
Lymphocyte count decreased	1	1 (20.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	4	3 (60.00)	1	1 (20.00)
Decreased appetite	1	1 (20.00)	0	0 (0.00)
Dehydration	1	1 (20.00)	1	1 (20.00)
Hyperphosphataemia	1	1 (20.00)	0	0 (0.00)
Hyperuricaemia	1	1 (20.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	4	2 (40.00)	0	0 (0.00)
Pain in extremity	2	2 (40.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Arthralgia	1	1 (20.00)	0	0 (0.00)
Myalgia	1	1 (20.00)	0	0 (0.00)
Nervous system disorders				
- Total	2	2 (40.00)	0	0 (0.00)
Headache	2	2 (40.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	2	1 (20.00)	0	0 (0.00)
Dysuria	1	1 (20.00)	0	0 (0.00)
Pollakiuria	1	1 (20.00)	0	0 (0.00)
Vascular disorders				
- Total	2	1 (20.00)	1	1 (20.00)
Embolism	1	1 (20.00)	1	1 (20.00)
Hypertension	1	1 (20.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Total number of AE per patient	153	7 (100.00)	37	7 (100.00)
Blood and lymphatic system disorders				
- Total	7	5 (71.43)	5	3 (42.86)
Anaemia	3	3 (42.86)	2	2 (28.57)
Febrile neutropenia	2	2 (28.57)	2	2 (28.57)
Disseminated intravascular coagulation	1	1 (14.29)	0	0 (0.00)
Lymphopenia	1	1 (14.29)	1	1 (14.29)
Cardiac disorders				
- Total	4	3 (42.86)	0	0 (0.00)
Tachycardia	3	3 (42.86)	0	0 (0.00)
Ventricular tachycardia	1	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Endocrine disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Adrenal insufficiency	1	1 (14.29)	0	0 (0.00)
Eye disorders				
- Total	5	2 (28.57)	0	0 (0.00)
Vision blurred	2	1 (14.29)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (14.29)	0	0 (0.00)
Periorbital oedema	1	1 (14.29)	0	0 (0.00)
Uveitis	1	1 (14.29)	0	0 (0.00)
Gastrointestinal disorders				
- Total	18	5 (71.43)	0	0 (0.00)
Vomiting	6	4 (57.14)	0	0 (0.00)
Nausea	5	4 (57.14)	0	0 (0.00)
Abdominal pain	1	1 (14.29)	0	0 (0.00)
Abdominal pain upper	1	1 (14.29)	0	0 (0.00)
Constipation	1	1 (14.29)	0	0 (0.00)
Diarrhoea	1	1 (14.29)	0	0 (0.00)
Dysphagia	1	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Flatulence	1	1 (14.29)	0	0 (0.00)
Lip pain	1	1 (14.29)	0	0 (0.00)
General disorders and administration site conditions				
- Total	7	4 (57.14)	1	1 (14.29)
Catheter site haemorrhage	1	1 (14.29)	0	0 (0.00)
Catheter site pain	1	1 (14.29)	0	0 (0.00)
Fatigue	1	1 (14.29)	0	0 (0.00)
Injection site haematoma	1	1 (14.29)	0	0 (0.00)
Malaise	1	1 (14.29)	0	0 (0.00)
Physical deconditioning	1	1 (14.29)	1	1 (14.29)
Pyrexia	1	1 (14.29)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Gallbladder enlargement	1	1 (14.29)	0	0 (0.00)
Immune system disorders				
- Total	10	6 (85.71)	3	2 (28.57)
Cytokine release syndrome	8	6 (85.71)	3	2 (28.57)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Hypogammaglobulinaemia	2	2 (28.57)	0	0 (0.00)
Infections and infestations				
- Total	5	3 (42.86)	0	0 (0.00)
Catheter site cellulitis	1	1 (14.29)	0	0 (0.00)
Clostridium difficile colitis	1	1 (14.29)	0	0 (0.00)
Clostridium difficile infection	1	1 (14.29)	0	0 (0.00)
Cytomegalovirus infection	1	1 (14.29)	0	0 (0.00)
Herpes simplex	1	1 (14.29)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	4	3 (42.86)	1	1 (14.29)
Post procedural haemorrhage	1	1 (14.29)	0	0 (0.00)
Procedural pain	1	1 (14.29)	0	0 (0.00)
Transfusion reaction	1	1 (14.29)	0	0 (0.00)
Transfusion related complication	1	1 (14.29)	1	1 (14.29)
Investigations				
- Total	40	6 (85.71)	19	6 (85.71)
White blood cell count decreased	7	5 (71.43)	6	5 (71.43)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Aspartate aminotransferase increased	6	3 (42.86)	1	1 (14.29)
Alanine aminotransferase increased	5	3 (42.86)	2	1 (14.29)
Neutrophil count decreased	5	3 (42.86)	5	3 (42.86)
Prothrombin time prolonged	4	2 (28.57)	0	0 (0.00)
Blood creatinine increased	2	2 (28.57)	0	0 (0.00)
Lymphocyte count decreased	2	2 (28.57)	2	2 (28.57)
Platelet count decreased	2	2 (28.57)	2	2 (28.57)
Activated partial thromboplastin time prolonged	1	1 (14.29)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (14.29)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (14.29)	0	0 (0.00)
Culture stool positive	1	1 (14.29)	0	0 (0.00)
Haemoglobin decreased	1	1 (14.29)	1	1 (14.29)
Hepatic enzyme increased	1	1 (14.29)	0	0 (0.00)
International normalised ratio increased	1	1 (14.29)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	6	3 (42.86)	2	2 (28.57)
Decreased appetite	2	1 (14.29)	1	1 (14.29)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Acidosis	1	1 (14.29)	0	0 (0.00)
Hypernatraemia	1	1 (14.29)	0	0 (0.00)
Hyperphosphataemia	1	1 (14.29)	0	0 (0.00)
Tumour lysis syndrome	1	1 (14.29)	1	1 (14.29)
Musculoskeletal and connective tissue disorders				
- Total	2	2 (28.57)	0	0 (0.00)
Coccydynia	1	1 (14.29)	0	0 (0.00)
Myalgia	1	1 (14.29)	0	0 (0.00)
Nervous system disorders				
- Total	13	4 (57.14)	0	0 (0.00)
Headache	4	3 (42.86)	0	0 (0.00)
Asterixis	1	1 (14.29)	0	0 (0.00)
Ataxia	1	1 (14.29)	0	0 (0.00)
Dysarthria	1	1 (14.29)	0	0 (0.00)
Encephalopathy	1	1 (14.29)	0	0 (0.00)
Myoclonus	1	1 (14.29)	0	0 (0.00)
Neuropathy peripheral	1	1 (14.29)	0	0 (0.00)
Pleocytosis	1	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Seizure	1	1 (14.29)	0	0 (0.00)
Tremor	1	1 (14.29)	0	0 (0.00)
Psychiatric disorders				
- Total	5	1 (14.29)	0	0 (0.00)
Adjustment disorder	1	1 (14.29)	0	0 (0.00)
Agitation	1	1 (14.29)	0	0 (0.00)
Anxiety	1	1 (14.29)	0	0 (0.00)
Delirium	1	1 (14.29)	0	0 (0.00)
Suicidal ideation	1	1 (14.29)	0	0 (0.00)
Renal and urinary disorders				
- Total	2	2 (28.57)	1	1 (14.29)
Acute kidney injury	2	2 (28.57)	1	1 (14.29)
Respiratory, thoracic and mediastinal disorders				
- Total	10	2 (28.57)	3	2 (28.57)
Epistaxis	5	1 (14.29)	1	1 (14.29)
Haemoptysis	2	1 (14.29)	0	0 (0.00)
Oropharyngeal pain	1	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Pulmonary oedema	1	1 (14.29)	1	1 (14.29)
Respiratory failure	1	1 (14.29)	1	1 (14.29)
Skin and subcutaneous tissue disorders				
- Total	10	2 (28.57)	1	1 (14.29)
Dry skin	2	2 (28.57)	0	0 (0.00)
Erythema	2	1 (14.29)	0	0 (0.00)
Ecchymosis	1	1 (14.29)	1	1 (14.29)
Hyperhidrosis	1	1 (14.29)	0	0 (0.00)
Pruritus	1	1 (14.29)	0	0 (0.00)
Rash vesicular	1	1 (14.29)	0	0 (0.00)
Skin exfoliation	1	1 (14.29)	0	0 (0.00)
Skin fissures	1	1 (14.29)	0	0 (0.00)
Vascular disorders				
- Total	3	3 (42.86)	1	1 (14.29)
Hypotension	1	1 (14.29)	1	1 (14.29)
Orthostatic hypotension	1	1 (14.29)	0	0 (0.00)
Secondary hypertension	1	1 (14.29)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Total number of AE per patient	283	36 (81.82)	57	22 (50.00)
Blood and lymphatic system disorders				
- Total	10	7 (15.91)	7	5 (11.36)
Neutropenia	3	3 (6.82)	3	3 (6.82)
Eosinophilia	2	1 (2.27)	1	1 (2.27)
Thrombocytopenia	2	2 (4.55)	1	1 (2.27)
Anaemia	1	1 (2.27)	0	0 (0.00)
Febrile neutropenia	1	1 (2.27)	1	1 (2.27)
Leukopenia	1	1 (2.27)	1	1 (2.27)
Cardiac disorders				
- Total	1	1 (2.27)	0	0 (0.00)
Sinus tachycardia	1	1 (2.27)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Endocrine disorders				
- Total	1	1 (2.27)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.27)	0	0 (0.00)
Eye disorders				
- Total	4	4 (9.09)	0	0 (0.00)
Conjunctivitis allergic	1	1 (2.27)	0	0 (0.00)
Dry eye	1	1 (2.27)	0	0 (0.00)
Ocular hyperaemia	1	1 (2.27)	0	0 (0.00)
Vision blurred	1	1 (2.27)	0	0 (0.00)
Gastrointestinal disorders				
- Total	35	14 (31.82)	8	4 (9.09)
Vomiting	13	9 (20.45)	2	2 (4.55)
Diarrhoea	7	7 (15.91)	1	1 (2.27)
Nausea	5	5 (11.36)	2	2 (4.55)
Abdominal pain	4	4 (9.09)	1	1 (2.27)
Oral pain	3	2 (4.55)	1	1 (2.27)
Abdominal pain upper	1	1 (2.27)	0	0 (0.00)
Enterocolitis	1	1 (2.27)	1	1 (2.27)
Pigmentation lip	1	1 (2.27)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
General disorders and administration site conditions				
- Total	23	14 (31.82)	1	1 (2.27)
Pyrexia	11	7 (15.91)	1	1 (2.27)
Fatigue	2	2 (4.55)	0	0 (0.00)
Influenza like illness	2	2 (4.55)	0	0 (0.00)
Acquired gene mutation	1	1 (2.27)	0	0 (0.00)
Catheter site pain	1	1 (2.27)	0	0 (0.00)
Chills	1	1 (2.27)	0	0 (0.00)
Crying	1	1 (2.27)	0	0 (0.00)
Generalised oedema	1	1 (2.27)	0	0 (0.00)
Malaise	1	1 (2.27)	0	0 (0.00)
Oedema peripheral	1	1 (2.27)	0	0 (0.00)
Pain	1	1 (2.27)	0	0 (0.00)
Immune system disorders				
- Total	13	10 (22.73)	1	1 (2.27)
Hypogammaglobulinaemia	8	7 (15.91)	1	1 (2.27)
Graft versus host disease	3	2 (4.55)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (2.27)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Seasonal allergy	1	1 (2.27)	0	0 (0.00)
Infections and infestations				
- Total	53	26 (59.09)	14	9 (20.45)
Upper respiratory tract infection	7	7 (15.91)	1	1 (2.27)
Cellulitis of male external genital organ	5	1 (2.27)	2	1 (2.27)
Rhinovirus infection	4	2 (4.55)	0	0 (0.00)
Urinary tract infection	4	3 (6.82)	2	2 (4.55)
Gastroenteritis	3	3 (6.82)	0	0 (0.00)
Influenza	3	3 (6.82)	0	0 (0.00)
Ear infection	2	2 (4.55)	0	0 (0.00)
Otitis media	2	1 (2.27)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (4.55)	1	1 (2.27)
Sinusitis	2	2 (4.55)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (4.55)	1	1 (2.27)
Bacterial sepsis	1	1 (2.27)	1	1 (2.27)
Cholecystitis infective	1	1 (2.27)	1	1 (2.27)
Corona virus infection	1	1 (2.27)	1	1 (2.27)
Cytomegalovirus infection	1	1 (2.27)	0	0 (0.00)
Enterovirus infection	1	1 (2.27)	1	1 (2.27)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Escherichia urinary tract infection	1	1 (2.27)	1	1 (2.27)
Gastroenteritis norovirus	1	1 (2.27)	0	0 (0.00)
Gastroenteritis viral	1	1 (2.27)	0	0 (0.00)
Otitis externa	1	1 (2.27)	0	0 (0.00)
Otitis media acute	1	1 (2.27)	0	0 (0.00)
Paronychia	1	1 (2.27)	0	0 (0.00)
Rash pustular	1	1 (2.27)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (2.27)	1	1 (2.27)
Rotavirus infection	1	1 (2.27)	1	1 (2.27)
Subcutaneous abscess	1	1 (2.27)	0	0 (0.00)
Tinea capitis	1	1 (2.27)	0	0 (0.00)
Viral infection	1	1 (2.27)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	11	7 (15.91)	0	0 (0.00)
Contusion	2	2 (4.55)	0	0 (0.00)
Infusion related reaction	2	2 (4.55)	0	0 (0.00)
Foot fracture	1	1 (2.27)	0	0 (0.00)
Procedural nausea	1	1 (2.27)	0	0 (0.00)
Procedural pain	1	1 (2.27)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Radius fracture	1	1 (2.27)	0	0 (0.00)
Skin abrasion	1	1 (2.27)	0	0 (0.00)
Skin laceration	1	1 (2.27)	0	0 (0.00)
Sunburn	1	1 (2.27)	0	0 (0.00)
Investigations				
- Total	39	19 (43.18)	12	10 (22.73)
Neutrophil count decreased	7	5 (11.36)	4	4 (9.09)
White blood cell count decreased	7	5 (11.36)	3	2 (4.55)
Platelet count decreased	5	3 (6.82)	0	0 (0.00)
Weight decreased	4	4 (9.09)	0	0 (0.00)
Aspartate aminotransferase increased	3	3 (6.82)	2	2 (4.55)
Alanine aminotransferase increased	2	2 (4.55)	2	2 (4.55)
Blood urea increased	2	1 (2.27)	0	0 (0.00)
Weight increased	2	2 (4.55)	0	0 (0.00)
Blood bilirubin increased	1	1 (2.27)	1	1 (2.27)
Blood magnesium decreased	1	1 (2.27)	0	0 (0.00)
Haemoglobin decreased	1	1 (2.27)	0	0 (0.00)
Lymphocyte count decreased	1	1 (2.27)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.27)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Serum ferritin increased	1	1 (2.27)	0	0 (0.00)
Transaminases increased	1	1 (2.27)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	13	8 (18.18)	6	4 (9.09)
Hyperalbuminaemia	2	1 (2.27)	0	0 (0.00)
Hyperphosphataemia	2	2 (4.55)	0	0 (0.00)
Decreased appetite	1	1 (2.27)	0	0 (0.00)
Dehydration	1	1 (2.27)	1	1 (2.27)
Hypercalcaemia	1	1 (2.27)	0	0 (0.00)
Hyperglycaemia	1	1 (2.27)	1	1 (2.27)
Hypokalaemia	1	1 (2.27)	1	1 (2.27)
Hypophosphataemia	1	1 (2.27)	1	1 (2.27)
Iron overload	1	1 (2.27)	1	1 (2.27)
Tumour lysis syndrome	1	1 (2.27)	1	1 (2.27)
Vitamin D deficiency	1	1 (2.27)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	14	10 (22.73)	0	0 (0.00)
Pain in extremity	5	5 (11.36)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Arthralgia	2	2 (4.55)	0	0 (0.00)
Back pain	1	1 (2.27)	0	0 (0.00)
Flank pain	1	1 (2.27)	0	0 (0.00)
Joint range of motion decreased	1	1 (2.27)	0	0 (0.00)
Muscle spasms	1	1 (2.27)	0	0 (0.00)
Muscular weakness	1	1 (2.27)	0	0 (0.00)
Pain in jaw	1	1 (2.27)	0	0 (0.00)
Toe walking	1	1 (2.27)	0	0 (0.00)
Nervous system disorders				
- Total	12	8 (18.18)	0	0 (0.00)
Headache	7	5 (11.36)	0	0 (0.00)
Dizziness	3	3 (6.82)	0	0 (0.00)
Peroneal nerve palsy	2	2 (4.55)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (4.55)	0	0 (0.00)
Depression	2	2 (4.55)	0	0 (0.00)
Anxiety	1	1 (2.27)	0	0 (0.00)
Sleep disorder	1	1 (2.27)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Renal and urinary disorders				
- Total	5	3 (6.82)	3	2 (4.55)
Acute kidney injury	1	1 (2.27)	1	1 (2.27)
Calculus urinary	1	1 (2.27)	0	0 (0.00)
Haematuria	1	1 (2.27)	1	1 (2.27)
Nephrolithiasis	1	1 (2.27)	1	1 (2.27)
Urinary incontinence	1	1 (2.27)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	2 (4.55)	1	1 (2.27)
Scrotal pain	1	1 (2.27)	0	0 (0.00)
Vaginal haemorrhage	1	1 (2.27)	1	1 (2.27)
Respiratory, thoracic and mediastinal disorders				
- Total	22	13 (29.55)	3	2 (4.55)
Cough	5	4 (9.09)	0	0 (0.00)
Nasal congestion	3	3 (6.82)	0	0 (0.00)
Oropharyngeal pain	3	3 (6.82)	0	0 (0.00)
Rhinorrhoea	3	3 (6.82)	0	0 (0.00)
Epistaxis	2	2 (4.55)	1	1 (2.27)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Rhinitis allergic	2	2 (4.55)	0	0 (0.00)
Acute respiratory failure	1	1 (2.27)	1	1 (2.27)
Dysphonia	1	1 (2.27)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.27)	0	0 (0.00)
Pharyngeal lesion	1	1 (2.27)	1	1 (2.27)
Skin and subcutaneous tissue disorders				
- Total	18	10 (22.73)	1	1 (2.27)
Erythema	2	2 (4.55)	0	0 (0.00)
Rash	2	1 (2.27)	0	0 (0.00)
Rash erythematous	2	1 (2.27)	0	0 (0.00)
Rash maculo-papular	2	2 (4.55)	0	0 (0.00)
Alopecia	1	1 (2.27)	0	0 (0.00)
Dermatitis acneiform	1	1 (2.27)	1	1 (2.27)
Hyperhidrosis	1	1 (2.27)	0	0 (0.00)
Ingrowing nail	1	1 (2.27)	0	0 (0.00)
Keloid scar	1	1 (2.27)	0	0 (0.00)
Macule	1	1 (2.27)	0	0 (0.00)
Papule	1	1 (2.27)	0	0 (0.00)
Petechiae	1	1 (2.27)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Pruritus	1	1 (2.27)	0	0 (0.00)
Rash pruritic	1	1 (2.27)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (4.55)	0	0 (0.00)
Hypertension	2	2 (4.55)	0	0 (0.00)
Hot flush	1	1 (2.27)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	18	4 (80.00)	8	1 (20.00)
Blood and lymphatic system disorders				
- Total	5	2 (40.00)	4	1 (20.00)
Neutropenia	3	1 (20.00)	3	1 (20.00)
Febrile neutropenia	1	1 (20.00)	1	1 (20.00)
Lymphopenia	1	1 (20.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	2	2 (40.00)	0	0 (0.00)
Pyrexia	2	2 (40.00)	0	0 (0.00)
Infections and infestations				
- Total	2	2 (40.00)	1	1 (20.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Herpes zoster	1	1 (20.00)	1	1 (20.00)
Molluscum contagiosum	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	4	2 (40.00)	2	1 (20.00)
Neutrophil count decreased	3	2 (40.00)	2	1 (20.00)
Blood uric acid increased	1	1 (20.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	3	3 (60.00)	0	0 (0.00)
Joint range of motion decreased	1	1 (20.00)	0	0 (0.00)
Osteonecrosis	1	1 (20.00)	0	0 (0.00)
Pain in extremity	1	1 (20.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	1	1 (20.00)	1	1 (20.00)
Pulmonary oedema	1	1 (20.00)	1	1 (20.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (20.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Rash	1	1 (20.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Total number of AE per patient	45	6 (85.71)	6	3 (42.86)
Blood and lymphatic system disorders				
- Total	3	2 (28.57)	2	1 (14.29)
Anaemia	1	1 (14.29)	1	1 (14.29)
Febrile neutropenia	1	1 (14.29)	1	1 (14.29)
Lymphadenopathy	1	1 (14.29)	0	0 (0.00)
Eye disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Dry eye	1	1 (14.29)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	2 (28.57)	0	0 (0.00)
Nausea	2	1 (14.29)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Diarrhoea	1	1 (14.29)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (14.29)	0	0 (0.00)
Pyrexia	1	1 (14.29)	0	0 (0.00)
Immune system disorders				
- Total	4	4 (57.14)	0	0 (0.00)
Immunodeficiency common variable	2	2 (28.57)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (14.29)	0	0 (0.00)
Seasonal allergy	1	1 (14.29)	0	0 (0.00)
Infections and infestations				
- Total	6	5 (71.43)	2	2 (28.57)
Oral herpes	1	1 (14.29)	0	0 (0.00)
Rhinitis	1	1 (14.29)	0	0 (0.00)
Sepsis	1	1 (14.29)	1	1 (14.29)
Urinary tract infection	1	1 (14.29)	0	0 (0.00)
Vascular device infection	1	1 (14.29)	1	1 (14.29)
Vulvovaginal mycotic infection	1	1 (14.29)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Injury, poisoning and procedural complications				
- Total	2	1 (14.29)	0	0 (0.00)
Arthropod bite	1	1 (14.29)	0	0 (0.00)
Procedural pain	1	1 (14.29)	0	0 (0.00)
Investigations				
- Total	5	2 (28.57)	2	1 (14.29)
Neutrophil count decreased	2	1 (14.29)	2	1 (14.29)
Blood creatinine increased	1	1 (14.29)	0	0 (0.00)
Haemoglobin decreased	1	1 (14.29)	0	0 (0.00)
Lymphocyte count decreased	1	1 (14.29)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	2	2 (28.57)	0	0 (0.00)
Decreased appetite	1	1 (14.29)	0	0 (0.00)
Hypokalaemia	1	1 (14.29)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	4	3 (42.86)	0	0 (0.00)
Pain in extremity	2	2 (28.57)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Muscular weakness	1	1 (14.29)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (14.29)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (14.29)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (14.29)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	7	4 (57.14)	0	0 (0.00)
Cough	4	3 (42.86)	0	0 (0.00)
Nasal congestion	1	1 (14.29)	0	0 (0.00)
Rhinitis allergic	1	1 (14.29)	0	0 (0.00)
Rhinorrhoea	1	1 (14.29)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	6	5 (71.43)	0	0 (0.00)
Rash	2	2 (28.57)	0	0 (0.00)
Dermatitis	1	1 (14.29)	0	0 (0.00)
Dermatitis atopic	1	1 (14.29)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Dry skin	1	1 (14.29)	0	0 (0.00)
Eczema	1	1 (14.29)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Total number of AE per patient	56	16 (57.14)	15	8 (28.57)
Blood and lymphatic system disorders				
- Total	1	1 (3.57)	0	0 (0.00)
Thrombocytopenia	1	1 (3.57)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.57)	0	0 (0.00)
Tympanic membrane perforation	1	1 (3.57)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	2 (7.14)	0	0 (0.00)
Diarrhoea	2	2 (7.14)	0	0 (0.00)
Abdominal pain	1	1 (3.57)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
General disorders and administration site conditions				
- Total	1	1 (3.57)	1	1 (3.57)
Cyst	1	1 (3.57)	1	1 (3.57)
Immune system disorders				
- Total	1	1 (3.57)	0	0 (0.00)
Chronic graft versus host disease	1	1 (3.57)	0	0 (0.00)
Infections and infestations				
- Total	26	7 (25.00)	6	3 (10.71)
Otitis media	4	2 (7.14)	1	1 (3.57)
Otitis media acute	4	2 (7.14)	0	0 (0.00)
Sinusitis	3	3 (10.71)	0	0 (0.00)
Upper respiratory tract infection	3	1 (3.57)	0	0 (0.00)
Urinary tract infection	3	2 (7.14)	1	1 (3.57)
Pneumonia	2	2 (7.14)	0	0 (0.00)
Campylobacter infection	1	1 (3.57)	1	1 (3.57)
Cellulitis of male external genital organ	1	1 (3.57)	1	1 (3.57)
Clostridium difficile infection	1	1 (3.57)	1	1 (3.57)

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Haemophilus infection	1	1 (3.57)	0	0 (0.00)
Respiratory tract infection viral	1	1 (3.57)	1	1 (3.57)
Skin infection	1	1 (3.57)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (3.57)	0	0 (0.00)
Investigations				
- Total	8	5 (17.86)	4	3 (10.71)
Lymphocyte count decreased	3	2 (7.14)	1	1 (3.57)
Alanine aminotransferase increased	2	2 (7.14)	1	1 (3.57)
Aspartate aminotransferase increased	1	1 (3.57)	1	1 (3.57)
Neutrophil count decreased	1	1 (3.57)	0	0 (0.00)
White blood cell count decreased	1	1 (3.57)	1	1 (3.57)
Metabolism and nutrition disorders				
- Total	2	2 (7.14)	1	1 (3.57)
Hypokalaemia	1	1 (3.57)	1	1 (3.57)
Vitamin D deficiency	1	1 (3.57)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
- Total	1	1 (3.57)	0	0 (0.00)
Neck pain	1	1 (3.57)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.57)	1	1 (3.57)
Glioblastoma multiforme	1	1 (3.57)	1	1 (3.57)
Nervous system disorders				
- Total	4	3 (10.71)	1	1 (3.57)
Disturbance in attention	1	1 (3.57)	0	0 (0.00)
Dizziness	1	1 (3.57)	0	0 (0.00)
Headache	1	1 (3.57)	0	0 (0.00)
Seizure	1	1 (3.57)	1	1 (3.57)
Renal and urinary disorders				
- Total	3	2 (7.14)	1	1 (3.57)
Acute kidney injury	2	1 (3.57)	1	1 (3.57)
Haematuria	1	1 (3.57)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
- Total	2	1 (3.57)	0	0 (0.00)
Oropharyngeal pain	1	1 (3.57)	0	0 (0.00)
Rhinorrhoea	1	1 (3.57)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	2 (7.14)	0	0 (0.00)
Acne	1	1 (3.57)	0	0 (0.00)
Papule	1	1 (3.57)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Total number of AE per patient	4	2 (100.00)	2	2 (100.00)
Infections and infestations				
- Total	3	2 (100.00)	1	1 (50.00)
Gingivitis	1	1 (50.00)	0	0 (0.00)
Respiratory tract infection	1	1 (50.00)	1	1 (50.00)
Viral infection	1	1 (50.00)	0	0 (0.00)
Investigations				
- Total	1	1 (50.00)	1	1 (50.00)
White blood cell count decreased	1	1 (50.00)	1	1 (50.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.

1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Total number of AE per patient	30	4 (100.00)	6	2 (50.00)
Blood and lymphatic system disorders				
- Total	1	1 (25.00)	1	1 (25.00)
Febrile neutropenia	1	1 (25.00)	1	1 (25.00)
Gastrointestinal disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Nausea	1	1 (25.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	1 (25.00)	0	0 (0.00)
Pyrexia	2	1 (25.00)	0	0 (0.00)
Chills	1	1 (25.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Immune system disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Immunodeficiency	1	1 (25.00)	0	0 (0.00)
Infections and infestations				
- Total	3	2 (50.00)	0	0 (0.00)
Meningitis aseptic	1	1 (25.00)	0	0 (0.00)
Otitis media	1	1 (25.00)	0	0 (0.00)
Upper respiratory tract infection	1	1 (25.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (25.00)	1	1 (25.00)
Procedural pain	1	1 (25.00)	1	1 (25.00)
Investigations				
- Total	13	2 (50.00)	3	1 (25.00)
White blood cell count decreased	3	2 (50.00)	1	1 (25.00)
Lymphocyte count decreased	2	1 (25.00)	0	0 (0.00)
Neutrophil count decreased	2	1 (25.00)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (25.00)	1	1 (25.00)

Timing: >1 year post-CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Aspartate aminotransferase increased	1	1 (25.00)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (25.00)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (25.00)	0	0 (0.00)
C-reactive protein increased	1	1 (25.00)	0	0 (0.00)
Platelet count decreased	1	1 (25.00)	1	1 (25.00)
Reproductive system and breast disorders				
- Total	1	1 (25.00)	1	1 (25.00)
Ovarian failure	1	1 (25.00)	1	1 (25.00)
Respiratory, thoracic and mediastinal disorders				
- Total	5	3 (75.00)	0	0 (0.00)
Cough	3	2 (50.00)	0	0 (0.00)
Epistaxis	1	1 (25.00)	0	0 (0.00)
Rhinitis allergic	1	1 (25.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: >1 year post-CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
- Total	1	1 (25.00)	0	0 (0.00)
Pruritus	1	1 (25.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Total number of AE per patient	1450	52 (100.00)	481	48 (92.31)
Blood and lymphatic system disorders				
- Total	122	40 (76.92)	92	37 (71.15)
Anaemia	42	21 (40.38)	27	15 (28.85)
Thrombocytopenia	33	10 (19.23)	24	9 (17.31)
Febrile neutropenia	24	19 (36.54)	24	19 (36.54)
Neutropenia	12	10 (19.23)	11	10 (19.23)
Disseminated intravascular coagulation	4	3 (5.77)	2	2 (3.85)
Eosinophilia	2	1 (1.92)	1	1 (1.92)
Lymphopenia	2	2 (3.85)	1	1 (1.92)
Coagulopathy	1	1 (1.92)	0	0 (0.00)
Leukopenia	1	1 (1.92)	1	1 (1.92)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Pancytopenia	1	1 (1.92)	1	1 (1.92)
Cardiac disorders				
- Total	28	19 (36.54)	3	2 (3.85)
Tachycardia	14	12 (23.08)	2	2 (3.85)
Sinus tachycardia	6	6 (11.54)	0	0 (0.00)
Pericardial effusion	2	2 (3.85)	0	0 (0.00)
Sinus bradycardia	2	1 (1.92)	0	0 (0.00)
Bradycardia	1	1 (1.92)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.92)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.92)	1	1 (1.92)
Palpitations	1	1 (1.92)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	4	4 (7.69)	0	0 (0.00)
Ear pain	2	2 (3.85)	0	0 (0.00)
Hypoacusis	1	1 (1.92)	0	0 (0.00)
Tympanic membrane perforation	1	1 (1.92)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.92)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Adrenal insufficiency	1	1 (1.92)	0	0 (0.00)
Eye disorders				
- Total	24	15 (28.85)	0	0 (0.00)
Eye pain	4	3 (5.77)	0	0 (0.00)
Periorbital oedema	3	3 (5.77)	0	0 (0.00)
Photophobia	3	2 (3.85)	0	0 (0.00)
Vision blurred	3	3 (5.77)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (3.85)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.85)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.92)	0	0 (0.00)
Dry eye	1	1 (1.92)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.92)	0	0 (0.00)
Ocular hypertension	1	1 (1.92)	0	0 (0.00)
Papilloedema	1	1 (1.92)	0	0 (0.00)
Uveitis	1	1 (1.92)	0	0 (0.00)
Visual impairment	1	1 (1.92)	0	0 (0.00)
Gastrointestinal disorders				
- Total	143	35 (67.31)	23	13 (25.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Vomiting	41	22 (42.31)	5	3 (5.77)
Diarrhoea	25	21 (40.38)	2	2 (3.85)
Nausea	25	18 (34.62)	5	5 (9.62)
Abdominal pain	14	10 (19.23)	2	1 (1.92)
Constipation	7	6 (11.54)	0	0 (0.00)
Oral pain	3	2 (3.85)	1	1 (1.92)
Abdominal distension	2	2 (3.85)	0	0 (0.00)
Abdominal pain upper	2	2 (3.85)	0	0 (0.00)
Anal incontinence	2	1 (1.92)	0	0 (0.00)
Haematemesis	2	2 (3.85)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.92)	2	1 (1.92)
Pancreatitis	2	2 (3.85)	1	1 (1.92)
Stomatitis	2	2 (3.85)	0	0 (0.00)
Abdominal discomfort	1	1 (1.92)	0	0 (0.00)
Abdominal pain lower	1	1 (1.92)	0	0 (0.00)
Abdominal tenderness	1	1 (1.92)	0	0 (0.00)
Ascites	1	1 (1.92)	1	1 (1.92)
Dyspepsia	1	1 (1.92)	0	0 (0.00)
Dysphagia	1	1 (1.92)	1	1 (1.92)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Enterocolitis	1	1 (1.92)	1	1 (1.92)
Gastrointestinal haemorrhage	1	1 (1.92)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.92)	0	0 (0.00)
Glossodynia	1	1 (1.92)	0	0 (0.00)
Ileus	1	1 (1.92)	1	1 (1.92)
Intestinal obstruction	1	1 (1.92)	1	1 (1.92)
Pigmentation lip	1	1 (1.92)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.92)	0	0 (0.00)
General disorders and administration site conditions				
- Total	89	32 (61.54)	15	11 (21.15)
Pyrexia	36	20 (38.46)	7	7 (13.46)
Fatigue	12	11 (21.15)	1	1 (1.92)
Chills	10	9 (17.31)	0	0 (0.00)
Generalised oedema	4	3 (5.77)	0	0 (0.00)
Catheter site pain	3	3 (5.77)	0	0 (0.00)
Malaise	3	3 (5.77)	0	0 (0.00)
Oedema peripheral	3	3 (5.77)	1	1 (1.92)
Pain	3	3 (5.77)	2	2 (3.85)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Face oedema	2	2 (3.85)	1	1 (1.92)
Influenza like illness	2	2 (3.85)	0	0 (0.00)
Acquired gene mutation	1	1 (1.92)	0	0 (0.00)
Asthenia	1	1 (1.92)	0	0 (0.00)
Catheter site extravasation	1	1 (1.92)	0	0 (0.00)
Crying	1	1 (1.92)	0	0 (0.00)
Cyst	1	1 (1.92)	1	1 (1.92)
Facial pain	1	1 (1.92)	0	0 (0.00)
Localised oedema	1	1 (1.92)	1	1 (1.92)
Mucosal haemorrhage	1	1 (1.92)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.92)	1	1 (1.92)
Non-cardiac chest pain	1	1 (1.92)	0	0 (0.00)
Peripheral swelling	1	1 (1.92)	0	0 (0.00)
Hepatobiliary disorders				
- Total	8	6 (11.54)	2	2 (3.85)
Hyperbilirubinaemia	4	3 (5.77)	2	2 (3.85)
Hepatomegaly	3	3 (5.77)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.92)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Immune system disorders				
- Total	112	47 (90.38)	31	20 (38.46)
Cytokine release syndrome	73	40 (76.92)	26	17 (32.69)
Hypogammaglobulinaemia	30	27 (51.92)	5	5 (9.62)
Graft versus host disease	3	2 (3.85)	0	0 (0.00)
Chronic graft versus host disease	1	1 (1.92)	0	0 (0.00)
Drug hypersensitivity	1	1 (1.92)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.92)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.92)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.92)	0	0 (0.00)
Seasonal allergy	1	1 (1.92)	0	0 (0.00)
Infections and infestations				
- Total	111	38 (73.08)	26	14 (26.92)
Upper respiratory tract infection	11	8 (15.38)	1	1 (1.92)
Rhinovirus infection	7	5 (9.62)	0	0 (0.00)
Urinary tract infection	7	4 (7.69)	3	2 (3.85)
Cellulitis of male external genital organ	6	1 (1.92)	3	1 (1.92)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Otitis media	6	3 (5.77)	1	1 (1.92)
Otitis media acute	5	2 (3.85)	0	0 (0.00)
Sinusitis	5	4 (7.69)	0	0 (0.00)
Clostridium difficile infection	4	4 (7.69)	1	1 (1.92)
Gastroenteritis	4	4 (7.69)	0	0 (0.00)
Influenza	4	4 (7.69)	0	0 (0.00)
Pneumonia	4	4 (7.69)	1	1 (1.92)
Clostridium difficile colitis	3	3 (5.77)	1	1 (1.92)
Ear infection	2	2 (3.85)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (1.92)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.85)	1	1 (1.92)
Skin infection	2	2 (3.85)	0	0 (0.00)
Staphylococcal infection	2	2 (3.85)	1	1 (1.92)
Viral infection	2	2 (3.85)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (3.85)	1	1 (1.92)
Vulvovaginal candidiasis	2	2 (3.85)	0	0 (0.00)
Acute sinusitis	1	1 (1.92)	0	0 (0.00)
Bacterial sepsis	1	1 (1.92)	1	1 (1.92)
Body tinea	1	1 (1.92)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Campylobacter infection	1	1 (1.92)	1	1 (1.92)
Catheter site infection	1	1 (1.92)	1	1 (1.92)
Cholecystitis infective	1	1 (1.92)	1	1 (1.92)
Corona virus infection	1	1 (1.92)	1	1 (1.92)
Cytomegalovirus infection	1	1 (1.92)	0	0 (0.00)
Enterococcal infection	1	1 (1.92)	0	0 (0.00)
Enterovirus infection	1	1 (1.92)	1	1 (1.92)
Escherichia urinary tract infection	1	1 (1.92)	1	1 (1.92)
Folliculitis	1	1 (1.92)	0	0 (0.00)
Fungal skin infection	1	1 (1.92)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.92)	0	0 (0.00)
Haemophilus infection	1	1 (1.92)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (1.92)	0	0 (0.00)
Hypopyon	1	1 (1.92)	0	0 (0.00)
Oral candidiasis	1	1 (1.92)	0	0 (0.00)
Orchitis	1	1 (1.92)	0	0 (0.00)
Otitis externa	1	1 (1.92)	0	0 (0.00)
Paronychia	1	1 (1.92)	0	0 (0.00)
Rash pustular	1	1 (1.92)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Respiratory syncytial virus infection	1	1 (1.92)	1	1 (1.92)
Respiratory tract infection viral	1	1 (1.92)	1	1 (1.92)
Rotavirus infection	1	1 (1.92)	1	1 (1.92)
Septic embolus	1	1 (1.92)	1	1 (1.92)
Subcutaneous abscess	1	1 (1.92)	0	0 (0.00)
Tinea capitis	1	1 (1.92)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.92)	1	1 (1.92)
Injury, poisoning and procedural complications				
- Total	32	18 (34.62)	1	1 (1.92)
Infusion related reaction	4	4 (7.69)	0	0 (0.00)
Contusion	3	3 (5.77)	0	0 (0.00)
Procedural pain	3	3 (5.77)	0	0 (0.00)
Transfusion reaction	3	2 (3.85)	0	0 (0.00)
Skin abrasion	2	2 (3.85)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.92)	1	1 (1.92)
Foot fracture	1	1 (1.92)	0	0 (0.00)
Incision site pain	1	1 (1.92)	0	0 (0.00)
Limb injury	1	1 (1.92)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Mouth injury	1	1 (1.92)	0	0 (0.00)
Procedural complication	1	1 (1.92)	0	0 (0.00)
Procedural headache	1	1 (1.92)	0	0 (0.00)
Procedural nausea	1	1 (1.92)	0	0 (0.00)
Procedural site reaction	1	1 (1.92)	0	0 (0.00)
Radius fracture	1	1 (1.92)	0	0 (0.00)
Skin laceration	1	1 (1.92)	0	0 (0.00)
Stoma site irritation	1	1 (1.92)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.92)	0	0 (0.00)
Sunburn	1	1 (1.92)	0	0 (0.00)
Tibia fracture	1	1 (1.92)	0	0 (0.00)
Tongue injury	1	1 (1.92)	0	0 (0.00)
Investigations				
- Total	328	46 (88.46)	169	40 (76.92)
White blood cell count decreased	54	26 (50.00)	34	22 (42.31)
Platelet count decreased	46	17 (32.69)	35	12 (23.08)
Neutrophil count decreased	45	22 (42.31)	39	20 (38.46)
Aspartate aminotransferase increased	29	15 (28.85)	17	10 (19.23)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Alanine aminotransferase increased	27	17 (32.69)	15	12 (23.08)
Lymphocyte count decreased	17	13 (25.00)	11	10 (19.23)
Blood fibrinogen decreased	15	4 (7.69)	4	3 (5.77)
Blood bilirubin increased	14	8 (15.38)	3	3 (5.77)
Prothrombin time prolonged	13	7 (13.46)	1	1 (1.92)
Blood creatinine increased	9	7 (13.46)	2	2 (3.85)
International normalised ratio increased	9	7 (13.46)	1	1 (1.92)
Activated partial thromboplastin time prolonged	7	4 (7.69)	0	0 (0.00)
Blood urea increased	5	3 (5.77)	1	1 (1.92)
Weight decreased	4	4 (7.69)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (5.77)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.85)	0	0 (0.00)
Transaminases increased	3	3 (5.77)	0	0 (0.00)
Blood magnesium decreased	2	2 (3.85)	1	1 (1.92)
Blood sodium increased	2	1 (1.92)	0	0 (0.00)
Blood uric acid increased	2	1 (1.92)	0	0 (0.00)
Lipase increased	2	2 (3.85)	2	2 (3.85)
Serum ferritin increased	2	2 (3.85)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Weight increased	2	2 (3.85)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.92)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (1.92)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.92)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.92)	1	1 (1.92)
Blood phosphorus decreased	1	1 (1.92)	0	0 (0.00)
C-reactive protein increased	1	1 (1.92)	1	1 (1.92)
Cardiac murmur	1	1 (1.92)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.92)	0	0 (0.00)
Haemoglobin decreased	1	1 (1.92)	0	0 (0.00)
Norovirus test positive	1	1 (1.92)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.92)	0	0 (0.00)
Protein total decreased	1	1 (1.92)	1	1 (1.92)
Pulmonary function test decreased	1	1 (1.92)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	121	36 (69.23)	47	24 (46.15)
Decreased appetite	22	19 (36.54)	12	11 (21.15)
Hypokalaemia	22	18 (34.62)	9	9 (17.31)
Hypophosphataemia	14	10 (19.23)	10	8 (15.38)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Hyperphosphataemia	10	6 (11.54)	0	0 (0.00)
Hypernatraemia	6	3 (5.77)	1	1 (1.92)
Hypoalbuminaemia	6	5 (9.62)	1	1 (1.92)
Hyperglycaemia	5	3 (5.77)	2	2 (3.85)
Hypocalcaemia	4	3 (5.77)	1	1 (1.92)
Dehydration	3	3 (5.77)	2	2 (3.85)
Fluid overload	3	3 (5.77)	0	0 (0.00)
Hyperalbuminaemia	3	1 (1.92)	0	0 (0.00)
Hypercalcaemia	3	1 (1.92)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.85)	1	1 (1.92)
Hyperuricaemia	3	2 (3.85)	1	1 (1.92)
Hyponatraemia	3	2 (3.85)	3	2 (3.85)
Vitamin D deficiency	2	2 (3.85)	0	0 (0.00)
Acidosis	1	1 (1.92)	1	1 (1.92)
Hyperchloraemia	1	1 (1.92)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.92)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.92)	0	0 (0.00)
Iron overload	1	1 (1.92)	1	1 (1.92)
Malnutrition	1	1 (1.92)	1	1 (1.92)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Metabolic acidosis	1	1 (1.92)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.92)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.92)	1	1 (1.92)
Musculoskeletal and connective tissue disorders				
- Total	32	18 (34.62)	1	1 (1.92)
Pain in extremity	7	6 (11.54)	0	0 (0.00)
Arthralgia	5	4 (7.69)	1	1 (1.92)
Musculoskeletal pain	4	3 (5.77)	0	0 (0.00)
Myalgia	3	3 (5.77)	0	0 (0.00)
Muscle spasms	2	2 (3.85)	0	0 (0.00)
Muscular weakness	2	2 (3.85)	0	0 (0.00)
Back pain	1	1 (1.92)	0	0 (0.00)
Flank pain	1	1 (1.92)	0	0 (0.00)
Joint range of motion decreased	1	1 (1.92)	0	0 (0.00)
Limb discomfort	1	1 (1.92)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.92)	0	0 (0.00)
Neck pain	1	1 (1.92)	0	0 (0.00)
Osteopenia	1	1 (1.92)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Pain in jaw	1	1 (1.92)	0	0 (0.00)
Toe walking	1	1 (1.92)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	2 (3.85)	1	1 (1.92)
Glioblastoma multiforme	1	1 (1.92)	1	1 (1.92)
Skin papilloma	1	1 (1.92)	0	0 (0.00)
Nervous system disorders				
- Total	59	29 (55.77)	7	6 (11.54)
Headache	33	19 (36.54)	2	2 (3.85)
Dizziness	8	6 (11.54)	0	0 (0.00)
Encephalopathy	5	3 (5.77)	2	2 (3.85)
Seizure	3	3 (5.77)	2	2 (3.85)
Peroneal nerve palsy	2	2 (3.85)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.92)	0	0 (0.00)
Disturbance in attention	1	1 (1.92)	0	0 (0.00)
Dysarthria	1	1 (1.92)	0	0 (0.00)
Embolic stroke	1	1 (1.92)	1	1 (1.92)
Idiopathic intracranial hypertension	1	1 (1.92)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Migraine	1	1 (1.92)	0	0 (0.00)
Somnolence	1	1 (1.92)	0	0 (0.00)
Tremor	1	1 (1.92)	0	0 (0.00)
Product issues				
- Total	1	1 (1.92)	0	0 (0.00)
Device occlusion	1	1 (1.92)	0	0 (0.00)
Psychiatric disorders				
- Total	29	16 (30.77)	1	1 (1.92)
Anxiety	6	6 (11.54)	1	1 (1.92)
Confusional state	6	6 (11.54)	0	0 (0.00)
Delirium	3	3 (5.77)	0	0 (0.00)
Hallucination	3	2 (3.85)	0	0 (0.00)
Agitation	2	1 (1.92)	0	0 (0.00)
Depression	2	2 (3.85)	0	0 (0.00)
Irritability	2	2 (3.85)	0	0 (0.00)
Insomnia	1	1 (1.92)	0	0 (0.00)
Listless	1	1 (1.92)	0	0 (0.00)
Mental status changes	1	1 (1.92)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Panic attack	1	1 (1.92)	0	0 (0.00)
Sleep disorder	1	1 (1.92)	0	0 (0.00)
Renal and urinary disorders				
- Total	22	12 (23.08)	14	9 (17.31)
Acute kidney injury	8	7 (13.46)	6	6 (11.54)
Haematuria	6	5 (9.62)	3	3 (5.77)
Oliguria	2	2 (3.85)	2	2 (3.85)
Calculus urinary	1	1 (1.92)	0	0 (0.00)
Dysuria	1	1 (1.92)	0	0 (0.00)
Nephrolithiasis	1	1 (1.92)	1	1 (1.92)
Renal failure	1	1 (1.92)	1	1 (1.92)
Renal impairment	1	1 (1.92)	1	1 (1.92)
Urinary incontinence	1	1 (1.92)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	6	5 (9.62)	1	1 (1.92)
Oedema genital	2	1 (1.92)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.85)	0	0 (0.00)
Scrotal pain	1	1 (1.92)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Vaginal haemorrhage	1	1 (1.92)	1	1 (1.92)
Respiratory, thoracic and mediastinal disorders				
- Total	87	32 (61.54)	28	12 (23.08)
Cough	13	11 (21.15)	0	0 (0.00)
Hypoxia	13	10 (19.23)	8	7 (13.46)
Epistaxis	8	8 (15.38)	4	4 (7.69)
Pleural effusion	8	8 (15.38)	2	2 (3.85)
Tachypnoea	6	5 (9.62)	1	1 (1.92)
Oropharyngeal pain	5	5 (9.62)	0	0 (0.00)
Pulmonary oedema	5	5 (9.62)	4	4 (7.69)
Rhinorrhoea	5	5 (9.62)	0	0 (0.00)
Nasal congestion	4	4 (7.69)	0	0 (0.00)
Dyspnoea	3	2 (3.85)	2	2 (3.85)
Rhinitis allergic	3	3 (5.77)	0	0 (0.00)
Respiratory failure	2	2 (3.85)	2	2 (3.85)
Acute respiratory failure	1	1 (1.92)	1	1 (1.92)
Atelectasis	1	1 (1.92)	0	0 (0.00)
Dysphonia	1	1 (1.92)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Haemoptysis	1	1 (1.92)	1	1 (1.92)
Interstitial lung disease	1	1 (1.92)	1	1 (1.92)
Oropharyngeal plaque	1	1 (1.92)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.92)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.92)	1	1 (1.92)
Pharyngeal ulceration	1	1 (1.92)	0	0 (0.00)
Respiratory depression	1	1 (1.92)	0	0 (0.00)
Respiratory distress	1	1 (1.92)	1	1 (1.92)
Wheezing	1	1 (1.92)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	51	24 (46.15)	2	2 (3.85)
Rash	6	5 (9.62)	0	0 (0.00)
Rash maculo-papular	5	5 (9.62)	1	1 (1.92)
Erythema	4	4 (7.69)	0	0 (0.00)
Hyperhidrosis	4	3 (5.77)	0	0 (0.00)
Ingrowing nail	4	3 (5.77)	0	0 (0.00)
Petechiae	4	4 (7.69)	0	0 (0.00)
Rash erythematous	3	2 (3.85)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Dry skin	2	2 (3.85)	0	0 (0.00)
Macule	2	2 (3.85)	0	0 (0.00)
Papule	2	2 (3.85)	0	0 (0.00)
Pruritus	2	2 (3.85)	0	0 (0.00)
Rash papular	2	2 (3.85)	0	0 (0.00)
Acne	1	1 (1.92)	0	0 (0.00)
Alopecia	1	1 (1.92)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.92)	1	1 (1.92)
Dermatitis diaper	1	1 (1.92)	0	0 (0.00)
Keloid scar	1	1 (1.92)	0	0 (0.00)
Livedo reticularis	1	1 (1.92)	0	0 (0.00)
Night sweats	1	1 (1.92)	0	0 (0.00)
Rash follicular	1	1 (1.92)	0	0 (0.00)
Rash macular	1	1 (1.92)	0	0 (0.00)
Rash pruritic	1	1 (1.92)	0	0 (0.00)
Skin irritation	1	1 (1.92)	0	0 (0.00)
Vascular disorders				
- Total	38	21 (40.38)	17	14 (26.92)
Hypotension	18	15 (28.85)	15	14 (26.92)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Hypertension	13	11 (21.15)	1	1 (1.92)
Flushing	3	2 (3.85)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.92)	1	1 (1.92)
Haematoma	1	1 (1.92)	0	0 (0.00)
Hot flush	1	1 (1.92)	0	0 (0.00)
Orthostatic hypotension	1	1 (1.92)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	72	5 (100.00)	22	4 (80.00)
Blood and lymphatic system disorders				
- Total	9	3 (60.00)	7	2 (40.00)
Anaemia	3	3 (60.00)	2	2 (40.00)
Neutropenia	3	1 (20.00)	3	1 (20.00)
Febrile neutropenia	2	1 (20.00)	2	1 (20.00)
Lymphopenia	1	1 (20.00)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Atrioventricular block second degree	1	1 (20.00)	0	0 (0.00)
Gastrointestinal disorders				

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
- Total	3	2 (40.00)	0	0 (0.00)
Diarrhoea	1	1 (20.00)	0	0 (0.00)
Nausea	1	1 (20.00)	0	0 (0.00)
Vomiting	1	1 (20.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	7	5 (100.00)	0	0 (0.00)
Fatigue	3	3 (60.00)	0	0 (0.00)
Pyrexia	3	2 (40.00)	0	0 (0.00)
Pain	1	1 (20.00)	0	0 (0.00)
Immune system disorders				
- Total	8	5 (100.00)	0	0 (0.00)
Cytokine release syndrome	5	4 (80.00)	0	0 (0.00)
Hypogammaglobulinaemia	3	3 (60.00)	0	0 (0.00)
Infections and infestations				
- Total	9	3 (60.00)	3	2 (40.00)
Gastroenteritis	1	1 (20.00)	1	1 (20.00)
Gingivitis	1	1 (20.00)	0	0 (0.00)

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Herpes zoster	1	1 (20.00)	1	1 (20.00)
Molluscum contagiosum	1	1 (20.00)	0	0 (0.00)
Pharyngitis	1	1 (20.00)	0	0 (0.00)
Respiratory tract infection	1	1 (20.00)	1	1 (20.00)
Streptococcal infection	1	1 (20.00)	0	0 (0.00)
Viral infection	1	1 (20.00)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	16	4 (80.00)	9	3 (60.00)
Neutrophil count decreased	8	3 (60.00)	6	2 (40.00)
White blood cell count decreased	3	3 (60.00)	2	2 (40.00)
Aspartate aminotransferase increased	1	1 (20.00)	1	1 (20.00)
Blood immunoglobulin A decreased	1	1 (20.00)	0	0 (0.00)
Blood uric acid increased	1	1 (20.00)	0	0 (0.00)
International normalised ratio increased	1	1 (20.00)	0	0 (0.00)
Lymphocyte count decreased	1	1 (20.00)	0	0 (0.00)
Metabolism and nutrition disorders				

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
- Total	4	3 (60.00)	1	1 (20.00)
Decreased appetite	1	1 (20.00)	0	0 (0.00)
Dehydration	1	1 (20.00)	1	1 (20.00)
Hyperphosphataemia	1	1 (20.00)	0	0 (0.00)
Hyperuricaemia	1	1 (20.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	7	4 (80.00)	0	0 (0.00)
Pain in extremity	3	3 (60.00)	0	0 (0.00)
Arthralgia	1	1 (20.00)	0	0 (0.00)
Joint range of motion decreased	1	1 (20.00)	0	0 (0.00)
Myalgia	1	1 (20.00)	0	0 (0.00)
Osteonecrosis	1	1 (20.00)	0	0 (0.00)
Nervous system disorders				
- Total	2	2 (40.00)	0	0 (0.00)
Headache	2	2 (40.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	2	1 (20.00)	0	0 (0.00)

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Dysuria	1	1 (20.00)	0	0 (0.00)
Pollakiuria	1	1 (20.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	1	1 (20.00)	1	1 (20.00)
Pulmonary oedema	1	1 (20.00)	1	1 (20.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Rash	1	1 (20.00)	0	0 (0.00)
Vascular disorders				
- Total	2	1 (20.00)	1	1 (20.00)
Embolism	1	1 (20.00)	1	1 (20.00)
Hypertension	1	1 (20.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Total number of AE per patient	228	7 (100.00)	49	7 (100.00)
Blood and lymphatic system disorders				
- Total	11	5 (71.43)	8	4 (57.14)
Anaemia	4	3 (42.86)	3	3 (42.86)
Febrile neutropenia	4	4 (57.14)	4	4 (57.14)
Disseminated intravascular coagulation	1	1 (14.29)	0	0 (0.00)
Lymphadenopathy	1	1 (14.29)	0	0 (0.00)
Lymphopenia	1	1 (14.29)	1	1 (14.29)
Cardiac disorders				
- Total	4	3 (42.86)	0	0 (0.00)
Tachycardia	3	3 (42.86)	0	0 (0.00)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Ventricular tachycardia	1	1 (14.29)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Adrenal insufficiency	1	1 (14.29)	0	0 (0.00)
Eye disorders				
- Total	6	3 (42.86)	0	0 (0.00)
Vision blurred	2	1 (14.29)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (14.29)	0	0 (0.00)
Dry eye	1	1 (14.29)	0	0 (0.00)
Periorbital oedema	1	1 (14.29)	0	0 (0.00)
Uveitis	1	1 (14.29)	0	0 (0.00)
Gastrointestinal disorders				
- Total	22	6 (85.71)	0	0 (0.00)
Nausea	8	6 (85.71)	0	0 (0.00)
Vomiting	6	4 (57.14)	0	0 (0.00)
Diarrhoea	2	2 (28.57)	0	0 (0.00)
Abdominal pain	1	1 (14.29)	0	0 (0.00)
Abdominal pain upper	1	1 (14.29)	0	0 (0.00)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Constipation	1	1 (14.29)	0	0 (0.00)
Dysphagia	1	1 (14.29)	0	0 (0.00)
Flatulence	1	1 (14.29)	0	0 (0.00)
Lip pain	1	1 (14.29)	0	0 (0.00)
General disorders and administration site conditions				
- Total	11	5 (71.43)	1	1 (14.29)
Pyrexia	4	3 (42.86)	0	0 (0.00)
Catheter site haemorrhage	1	1 (14.29)	0	0 (0.00)
Catheter site pain	1	1 (14.29)	0	0 (0.00)
Chills	1	1 (14.29)	0	0 (0.00)
Fatigue	1	1 (14.29)	0	0 (0.00)
Injection site haematoma	1	1 (14.29)	0	0 (0.00)
Malaise	1	1 (14.29)	0	0 (0.00)
Physical deconditioning	1	1 (14.29)	1	1 (14.29)
Hepatobiliary disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Gallbladder enlargement	1	1 (14.29)	0	0 (0.00)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Immune system disorders				
- Total	15	6 (85.71)	3	2 (28.57)
Cytokine release syndrome	8	6 (85.71)	3	2 (28.57)
Hypogammaglobulinaemia	3	3 (42.86)	0	0 (0.00)
Immunodeficiency common variable	2	2 (28.57)	0	0 (0.00)
Immunodeficiency	1	1 (14.29)	0	0 (0.00)
Seasonal allergy	1	1 (14.29)	0	0 (0.00)
Infections and infestations				
- Total	14	5 (71.43)	2	2 (28.57)
Catheter site cellulitis	1	1 (14.29)	0	0 (0.00)
Clostridium difficile colitis	1	1 (14.29)	0	0 (0.00)
Clostridium difficile infection	1	1 (14.29)	0	0 (0.00)
Cytomegalovirus infection	1	1 (14.29)	0	0 (0.00)
Herpes simplex	1	1 (14.29)	0	0 (0.00)
Meningitis aseptic	1	1 (14.29)	0	0 (0.00)
Oral herpes	1	1 (14.29)	0	0 (0.00)
Otitis media	1	1 (14.29)	0	0 (0.00)
Rhinitis	1	1 (14.29)	0	0 (0.00)
Sepsis	1	1 (14.29)	1	1 (14.29)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Upper respiratory tract infection	1	1 (14.29)	0	0 (0.00)
Urinary tract infection	1	1 (14.29)	0	0 (0.00)
Vascular device infection	1	1 (14.29)	1	1 (14.29)
Vulvovaginal mycotic infection	1	1 (14.29)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	7	4 (57.14)	2	2 (28.57)
Procedural pain	3	2 (28.57)	1	1 (14.29)
Arthropod bite	1	1 (14.29)	0	0 (0.00)
Post procedural haemorrhage	1	1 (14.29)	0	0 (0.00)
Transfusion reaction	1	1 (14.29)	0	0 (0.00)
Transfusion related complication	1	1 (14.29)	1	1 (14.29)
Investigations				
- Total	58	6 (85.71)	24	6 (85.71)
White blood cell count decreased	10	6 (85.71)	7	6 (85.71)
Neutrophil count decreased	9	3 (42.86)	7	3 (42.86)
Aspartate aminotransferase increased	7	4 (57.14)	1	1 (14.29)
Alanine aminotransferase increased	6	4 (57.14)	3	2 (28.57)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Lymphocyte count decreased	5	2 (28.57)	2	2 (28.57)
Prothrombin time prolonged	4	2 (28.57)	0	0 (0.00)
Blood creatinine increased	3	2 (28.57)	0	0 (0.00)
Platelet count decreased	3	3 (42.86)	3	3 (42.86)
Haemoglobin decreased	2	2 (28.57)	1	1 (14.29)
Activated partial thromboplastin time prolonged	1	1 (14.29)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (14.29)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (14.29)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (14.29)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (14.29)	0	0 (0.00)
C-reactive protein increased	1	1 (14.29)	0	0 (0.00)
Culture stool positive	1	1 (14.29)	0	0 (0.00)
Hepatic enzyme increased	1	1 (14.29)	0	0 (0.00)
International normalised ratio increased	1	1 (14.29)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	8	4 (57.14)	2	2 (28.57)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Decreased appetite	3	2 (28.57)	1	1 (14.29)
Acidosis	1	1 (14.29)	0	0 (0.00)
Hypernatraemia	1	1 (14.29)	0	0 (0.00)
Hyperphosphataemia	1	1 (14.29)	0	0 (0.00)
Hypokalaemia	1	1 (14.29)	0	0 (0.00)
Tumour lysis syndrome	1	1 (14.29)	1	1 (14.29)
Musculoskeletal and connective tissue disorders				
- Total	6	3 (42.86)	0	0 (0.00)
Pain in extremity	2	2 (28.57)	0	0 (0.00)
Coccydynia	1	1 (14.29)	0	0 (0.00)
Muscular weakness	1	1 (14.29)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (14.29)	0	0 (0.00)
Myalgia	1	1 (14.29)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (14.29)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (14.29)	0	0 (0.00)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Nervous system disorders				
- Total	13	4 (57.14)	0	0 (0.00)
Headache	4	3 (42.86)	0	0 (0.00)
Asterixis	1	1 (14.29)	0	0 (0.00)
Ataxia	1	1 (14.29)	0	0 (0.00)
Dysarthria	1	1 (14.29)	0	0 (0.00)
Encephalopathy	1	1 (14.29)	0	0 (0.00)
Myoclonus	1	1 (14.29)	0	0 (0.00)
Neuropathy peripheral	1	1 (14.29)	0	0 (0.00)
Pleocytosis	1	1 (14.29)	0	0 (0.00)
Seizure	1	1 (14.29)	0	0 (0.00)
Tremor	1	1 (14.29)	0	0 (0.00)
Psychiatric disorders				
- Total	5	1 (14.29)	0	0 (0.00)
Adjustment disorder	1	1 (14.29)	0	0 (0.00)
Agitation	1	1 (14.29)	0	0 (0.00)
Anxiety	1	1 (14.29)	0	0 (0.00)
Delirium	1	1 (14.29)	0	0 (0.00)
Suicidal ideation	1	1 (14.29)	0	0 (0.00)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Renal and urinary disorders				
- Total	2	2 (28.57)	1	1 (14.29)
Acute kidney injury	2	2 (28.57)	1	1 (14.29)
Reproductive system and breast disorders				
- Total	1	1 (14.29)	1	1 (14.29)
Ovarian failure	1	1 (14.29)	1	1 (14.29)
Respiratory, thoracic and mediastinal disorders				
- Total	22	5 (71.43)	3	2 (28.57)
Cough	7	3 (42.86)	0	0 (0.00)
Epistaxis	6	2 (28.57)	1	1 (14.29)
Haemoptysis	2	1 (14.29)	0	0 (0.00)
Rhinitis allergic	2	1 (14.29)	0	0 (0.00)
Nasal congestion	1	1 (14.29)	0	0 (0.00)
Oropharyngeal pain	1	1 (14.29)	0	0 (0.00)
Pulmonary oedema	1	1 (14.29)	1	1 (14.29)
Respiratory failure	1	1 (14.29)	1	1 (14.29)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Rhinorrhoea	1	1 (14.29)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	17	5 (71.43)	1	1 (14.29)
Dry skin	3	3 (42.86)	0	0 (0.00)
Erythema	2	1 (14.29)	0	0 (0.00)
Pruritus	2	2 (28.57)	0	0 (0.00)
Rash	2	2 (28.57)	0	0 (0.00)
Dermatitis	1	1 (14.29)	0	0 (0.00)
Dermatitis atopic	1	1 (14.29)	0	0 (0.00)
Ecchymosis	1	1 (14.29)	1	1 (14.29)
Eczema	1	1 (14.29)	0	0 (0.00)
Hyperhidrosis	1	1 (14.29)	0	0 (0.00)
Rash vesicular	1	1 (14.29)	0	0 (0.00)
Skin exfoliation	1	1 (14.29)	0	0 (0.00)
Skin fissures	1	1 (14.29)	0	0 (0.00)
Vascular disorders				
- Total	3	3 (42.86)	1	1 (14.29)
Hypotension	1	1 (14.29)	1	1 (14.29)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Orthostatic hypotension	1	1 (14.29)	0	0 (0.00)
Secondary hypertension	1	1 (14.29)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Total number of AE per patient	446	25 (100.00)	173	22 (88.00)
Blood and lymphatic system disorders				
- Total	49	19 (76.00)	40	17 (68.00)
Anaemia	17	11 (44.00)	11	6 (24.00)
Febrile neutropenia	16	14 (56.00)	16	14 (56.00)
Thrombocytopenia	10	2 (8.00)	9	2 (8.00)
Disseminated intravascular coagulation	2	2 (8.00)	1	1 (4.00)
Lymphopenia	2	2 (8.00)	1	1 (4.00)
Neutropenia	2	2 (8.00)	2	2 (8.00)
Cardiac disorders				
- Total	10	8 (32.00)	0	0 (0.00)
Tachycardia	7	7 (28.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Cardiac dysfunction	1	1 (4.00)	0	0 (0.00)
Sinus tachycardia	1	1 (4.00)	0	0 (0.00)
Ventricular tachycardia	1	1 (4.00)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (4.00)	0	0 (0.00)
Adrenal insufficiency	1	1 (4.00)	0	0 (0.00)
Eye disorders				
- Total	6	2 (8.00)	0	0 (0.00)
Eye pain	2	1 (4.00)	0	0 (0.00)
Vision blurred	2	1 (4.00)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (4.00)	0	0 (0.00)
Periorbital oedema	1	1 (4.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	41	12 (48.00)	4	3 (12.00)
Vomiting	12	6 (24.00)	1	1 (4.00)
Nausea	9	7 (28.00)	0	0 (0.00)
Diarrhoea	5	5 (20.00)	1	1 (4.00)
Abdominal pain	3	3 (12.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Constipation	3	2 (8.00)	0	0 (0.00)
Abdominal distension	1	1 (4.00)	0	0 (0.00)
Abdominal pain upper	1	1 (4.00)	0	0 (0.00)
Abdominal tenderness	1	1 (4.00)	0	0 (0.00)
Ascites	1	1 (4.00)	1	1 (4.00)
Dysphagia	1	1 (4.00)	0	0 (0.00)
Flatulence	1	1 (4.00)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (4.00)	0	0 (0.00)
Glossodynia	1	1 (4.00)	0	0 (0.00)
Pancreatitis	1	1 (4.00)	1	1 (4.00)
General disorders and administration site conditions				
- Total	11	8 (32.00)	3	3 (12.00)
Pyrexia	4	3 (12.00)	2	2 (8.00)
Chills	3	2 (8.00)	0	0 (0.00)
Fatigue	2	2 (8.00)	0	0 (0.00)
Malaise	1	1 (4.00)	0	0 (0.00)
Physical deconditioning	1	1 (4.00)	1	1 (4.00)
Hepatobiliary disorders				

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
- Total	1	1 (4.00)	0	0 (0.00)
Gallbladder enlargement	1	1 (4.00)	0	0 (0.00)
Immune system disorders				
- Total	44	23 (92.00)	9	7 (28.00)
Cytokine release syndrome	30	20 (80.00)	8	6 (24.00)
Hypogammaglobulinaemia	12	12 (48.00)	1	1 (4.00)
Drug hypersensitivity	1	1 (4.00)	0	0 (0.00)
Graft versus host disease in skin	1	1 (4.00)	0	0 (0.00)
Infections and infestations				
- Total	11	8 (32.00)	1	1 (4.00)
Clostridium difficile infection	2	2 (8.00)	0	0 (0.00)
Cytomegalovirus infection	1	1 (4.00)	0	0 (0.00)
Enterococcal infection	1	1 (4.00)	0	0 (0.00)
Fungal skin infection	1	1 (4.00)	0	0 (0.00)
Gastroenteritis	1	1 (4.00)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (4.00)	0	0 (0.00)
Influenza	1	1 (4.00)	0	0 (0.00)
Skin infection	1	1 (4.00)	0	0 (0.00)
Staphylococcal infection	1	1 (4.00)	1	1 (4.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Viral infection	1	1 (4.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	8	6 (24.00)	0	0 (0.00)
Procedural pain	2	2 (8.00)	0	0 (0.00)
Contusion	1	1 (4.00)	0	0 (0.00)
Infusion related reaction	1	1 (4.00)	0	0 (0.00)
Post procedural haemorrhage	1	1 (4.00)	0	0 (0.00)
Procedural site reaction	1	1 (4.00)	0	0 (0.00)
Skin abrasion	1	1 (4.00)	0	0 (0.00)
Subdural haemorrhage	1	1 (4.00)	0	0 (0.00)
Investigations				
- Total	137	22 (88.00)	90	20 (80.00)
White blood cell count decreased	32	15 (60.00)	25	15 (60.00)
Neutrophil count decreased	31	13 (52.00)	31	13 (52.00)
Platelet count decreased	18	9 (36.00)	13	4 (16.00)
Alanine aminotransferase increased	11	7 (28.00)	9	6 (24.00)
Lymphocyte count decreased	7	7 (28.00)	6	6 (24.00)
Aspartate aminotransferase increased	6	4 (16.00)	3	3 (12.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Blood creatinine increased	6	4 (16.00)	0	0 (0.00)
Blood fibrinogen decreased	5	1 (4.00)	1	1 (4.00)
Activated partial thromboplastin time prolonged	4	3 (12.00)	0	0 (0.00)
Blood bilirubin increased	3	2 (8.00)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (8.00)	0	0 (0.00)
Blood sodium increased	2	1 (4.00)	0	0 (0.00)
Prothrombin time prolonged	2	2 (8.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (4.00)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (4.00)	0	0 (0.00)
Blood urea increased	1	1 (4.00)	0	0 (0.00)
C-reactive protein increased	1	1 (4.00)	1	1 (4.00)
Fibrin D dimer increased	1	1 (4.00)	0	0 (0.00)
International normalised ratio increased	1	1 (4.00)	0	0 (0.00)
Lipase increased	1	1 (4.00)	1	1 (4.00)
Pulmonary function test decreased	1	1 (4.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	38	15 (60.00)	12	8 (32.00)
Decreased appetite	8	7 (28.00)	3	3 (12.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Hyperphosphataemia	6	4 (16.00)	0	0 (0.00)
Hypokalaemia	6	6 (24.00)	2	2 (8.00)
Hypernatraemia	4	2 (8.00)	1	1 (4.00)
Hyperuricaemia	3	2 (8.00)	1	1 (4.00)
Hypophosphataemia	3	1 (4.00)	3	1 (4.00)
Hypoalbuminaemia	2	1 (4.00)	1	1 (4.00)
Acidosis	1	1 (4.00)	0	0 (0.00)
Dehydration	1	1 (4.00)	0	0 (0.00)
Hyperglycaemia	1	1 (4.00)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (4.00)	0	0 (0.00)
Hypomagnesaemia	1	1 (4.00)	0	0 (0.00)
Tumour lysis syndrome	1	1 (4.00)	1	1 (4.00)
Musculoskeletal and connective tissue disorders				
- Total	5	2 (8.00)	0	0 (0.00)
Arthralgia	2	2 (8.00)	0	0 (0.00)
Muscular weakness	1	1 (4.00)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (4.00)	0	0 (0.00)
Musculoskeletal pain	1	1 (4.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (4.00)	0	0 (0.00)
Skin papilloma	1	1 (4.00)	0	0 (0.00)
Nervous system disorders				
- Total	27	13 (52.00)	1	1 (4.00)
Headache	13	10 (40.00)	0	0 (0.00)
Encephalopathy	3	1 (4.00)	1	1 (4.00)
Dysarthria	2	2 (8.00)	0	0 (0.00)
Seizure	2	2 (8.00)	0	0 (0.00)
Asterixis	1	1 (4.00)	0	0 (0.00)
Ataxia	1	1 (4.00)	0	0 (0.00)
Dizziness	1	1 (4.00)	0	0 (0.00)
Neuropathy peripheral	1	1 (4.00)	0	0 (0.00)
Pleocytosis	1	1 (4.00)	0	0 (0.00)
Somnolence	1	1 (4.00)	0	0 (0.00)
Tremor	1	1 (4.00)	0	0 (0.00)
Product issues				
- Total	1	1 (4.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Device occlusion	1	1 (4.00)	0	0 (0.00)
Psychiatric disorders				
- Total	7	3 (12.00)	0	0 (0.00)
Adjustment disorder	1	1 (4.00)	0	0 (0.00)
Agitation	1	1 (4.00)	0	0 (0.00)
Anxiety	1	1 (4.00)	0	0 (0.00)
Confusional state	1	1 (4.00)	0	0 (0.00)
Delirium	1	1 (4.00)	0	0 (0.00)
Hallucination	1	1 (4.00)	0	0 (0.00)
Suicidal ideation	1	1 (4.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	3	3 (12.00)	2	2 (8.00)
Acute kidney injury	2	2 (8.00)	2	2 (8.00)
Dysuria	1	1 (4.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	19	11 (44.00)	5	2 (8.00)
Pulmonary oedema	3	3 (12.00)	2	2 (8.00)
Tachypnoea	3	3 (12.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Haemoptysis	2	1 (4.00)	0	0 (0.00)
Respiratory failure	2	2 (8.00)	2	2 (8.00)
Cough	1	1 (4.00)	0	0 (0.00)
Epistaxis	1	1 (4.00)	0	0 (0.00)
Hypoxia	1	1 (4.00)	0	0 (0.00)
Nasal congestion	1	1 (4.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (4.00)	0	0 (0.00)
Oropharyngeal plaque	1	1 (4.00)	0	0 (0.00)
Pleural effusion	1	1 (4.00)	1	1 (4.00)
Rhinorrhoea	1	1 (4.00)	0	0 (0.00)
Wheezing	1	1 (4.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	14	9 (36.00)	1	1 (4.00)
Dry skin	2	2 (8.00)	0	0 (0.00)
Dermatitis diaper	1	1 (4.00)	0	0 (0.00)
Ecchymosis	1	1 (4.00)	1	1 (4.00)
Erythema	1	1 (4.00)	0	0 (0.00)
Ingrowing nail	1	1 (4.00)	0	0 (0.00)
Petechiae	1	1 (4.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Pruritus	1	1 (4.00)	0	0 (0.00)
Rash	1	1 (4.00)	0	0 (0.00)
Rash follicular	1	1 (4.00)	0	0 (0.00)
Rash papular	1	1 (4.00)	0	0 (0.00)
Skin exfoliation	1	1 (4.00)	0	0 (0.00)
Skin fissures	1	1 (4.00)	0	0 (0.00)
Skin irritation	1	1 (4.00)	0	0 (0.00)
Vascular disorders				
- Total	12	10 (40.00)	5	5 (20.00)
Hypotension	7	5 (20.00)	5	5 (20.00)
Hypertension	2	2 (8.00)	0	0 (0.00)
Orthostatic hypotension	2	2 (8.00)	0	0 (0.00)
Secondary hypertension	1	1 (4.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Total number of AE per patient	868	38 (97.44)	285	32 (82.05)
Blood and lymphatic system disorders				
- Total	73	24 (61.54)	53	21 (53.85)
Anaemia	30	16 (41.03)	20	13 (33.33)
Thrombocytopenia	20	6 (15.38)	14	6 (15.38)
Febrile neutropenia	10	8 (20.51)	10	8 (20.51)
Neutropenia	7	6 (15.38)	6	6 (15.38)
Disseminated intravascular coagulation	3	2 (5.13)	1	1 (2.56)
Coagulopathy	1	1 (2.56)	0	0 (0.00)
Lymphopenia	1	1 (2.56)	1	1 (2.56)
Pancytopenia	1	1 (2.56)	1	1 (2.56)
Cardiac disorders				

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
- Total	22	14 (35.90)	3	2 (5.13)
Tachycardia	10	8 (20.51)	2	2 (5.13)
Sinus tachycardia	4	4 (10.26)	0	0 (0.00)
Pericardial effusion	2	2 (5.13)	0	0 (0.00)
Sinus bradycardia	2	1 (2.56)	0	0 (0.00)
Atrioventricular block second degree	1	1 (2.56)	0	0 (0.00)
Bradycardia	1	1 (2.56)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.56)	1	1 (2.56)
Palpitations	1	1 (2.56)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (7.69)	0	0 (0.00)
Ear pain	2	2 (5.13)	0	0 (0.00)
Hypoacusis	1	1 (2.56)	0	0 (0.00)
Eye disorders				
- Total	19	11 (28.21)	0	0 (0.00)
Periorbital oedema	3	3 (7.69)	0	0 (0.00)
Photophobia	3	2 (5.13)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (5.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Eye pain	2	2 (5.13)	0	0 (0.00)
Retinal haemorrhage	2	2 (5.13)	0	0 (0.00)
Uveitis	2	2 (5.13)	0	0 (0.00)
Vision blurred	2	2 (5.13)	0	0 (0.00)
Ocular hypertension	1	1 (2.56)	0	0 (0.00)
Papilloedema	1	1 (2.56)	0	0 (0.00)
Visual impairment	1	1 (2.56)	0	0 (0.00)
Gastrointestinal disorders				
- Total	85	24 (61.54)	11	8 (20.51)
Vomiting	23	16 (41.03)	2	2 (5.13)
Nausea	17	14 (35.90)	3	3 (7.69)
Diarrhoea	13	13 (33.33)	0	0 (0.00)
Abdominal pain	7	6 (15.38)	1	1 (2.56)
Constipation	5	5 (12.82)	0	0 (0.00)
Anal incontinence	2	1 (2.56)	0	0 (0.00)
Haematemesis	2	2 (5.13)	0	0 (0.00)
Mouth haemorrhage	2	1 (2.56)	2	1 (2.56)
Stomatitis	2	2 (5.13)	0	0 (0.00)
Abdominal discomfort	1	1 (2.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Abdominal distension	1	1 (2.56)	0	0 (0.00)
Abdominal pain lower	1	1 (2.56)	0	0 (0.00)
Abdominal pain upper	1	1 (2.56)	0	0 (0.00)
Dyspepsia	1	1 (2.56)	0	0 (0.00)
Dysphagia	1	1 (2.56)	1	1 (2.56)
Gastrointestinal haemorrhage	1	1 (2.56)	0	0 (0.00)
Ileus	1	1 (2.56)	1	1 (2.56)
Intestinal obstruction	1	1 (2.56)	1	1 (2.56)
Lip pain	1	1 (2.56)	0	0 (0.00)
Pancreatitis	1	1 (2.56)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (2.56)	0	0 (0.00)
General disorders and administration site conditions				
- Total	66	24 (61.54)	11	7 (17.95)
Pyrexia	23	13 (33.33)	4	4 (10.26)
Fatigue	12	11 (28.21)	1	1 (2.56)
Chills	6	6 (15.38)	0	0 (0.00)
Catheter site pain	3	3 (7.69)	0	0 (0.00)
Generalised oedema	3	2 (5.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Pain	3	3 (7.69)	2	2 (5.13)
Face oedema	2	2 (5.13)	1	1 (2.56)
Malaise	2	2 (5.13)	0	0 (0.00)
Oedema peripheral	2	2 (5.13)	1	1 (2.56)
Asthenia	1	1 (2.56)	0	0 (0.00)
Catheter site extravasation	1	1 (2.56)	0	0 (0.00)
Catheter site haemorrhage	1	1 (2.56)	0	0 (0.00)
Facial pain	1	1 (2.56)	0	0 (0.00)
Injection site haematoma	1	1 (2.56)	0	0 (0.00)
Localised oedema	1	1 (2.56)	1	1 (2.56)
Mucosal haemorrhage	1	1 (2.56)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.56)	1	1 (2.56)
Non-cardiac chest pain	1	1 (2.56)	0	0 (0.00)
Peripheral swelling	1	1 (2.56)	0	0 (0.00)
Hepatobiliary disorders				
- Total	8	6 (15.38)	2	2 (5.13)
Hyperbilirubinaemia	4	3 (7.69)	2	2 (5.13)
Hepatomegaly	3	3 (7.69)	0	0 (0.00)
Hepatosplenomegaly	1	1 (2.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Immune system disorders				
- Total	72	34 (87.18)	24	15 (38.46)
Cytokine release syndrome	56	30 (76.92)	21	13 (33.33)
Hypogammaglobulinaemia	15	14 (35.90)	3	3 (7.69)
Haemophagocytic lymphohistiocytosis	1	1 (2.56)	0	0 (0.00)
Infections and infestations				
- Total	30	18 (46.15)	6	6 (15.38)
Clostridium difficile colitis	4	4 (10.26)	1	1 (2.56)
Rhinovirus infection	3	3 (7.69)	0	0 (0.00)
Clostridium difficile infection	2	2 (5.13)	0	0 (0.00)
Pneumonia	2	2 (5.13)	1	1 (2.56)
Acute sinusitis	1	1 (2.56)	0	0 (0.00)
Body tinea	1	1 (2.56)	0	0 (0.00)
Catheter site cellulitis	1	1 (2.56)	0	0 (0.00)
Catheter site infection	1	1 (2.56)	1	1 (2.56)
Folliculitis	1	1 (2.56)	0	0 (0.00)
Gastroenteritis	1	1 (2.56)	1	1 (2.56)
Herpes simplex	1	1 (2.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Human herpesvirus 6 infection	1	1 (2.56)	0	0 (0.00)
Hypopyon	1	1 (2.56)	0	0 (0.00)
Oral candidiasis	1	1 (2.56)	0	0 (0.00)
Orchitis	1	1 (2.56)	0	0 (0.00)
Pharyngitis	1	1 (2.56)	0	0 (0.00)
Septic embolus	1	1 (2.56)	1	1 (2.56)
Staphylococcal infection	1	1 (2.56)	0	0 (0.00)
Streptococcal infection	1	1 (2.56)	0	0 (0.00)
Upper respiratory tract infection	1	1 (2.56)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (2.56)	1	1 (2.56)
Viral upper respiratory tract infection	1	1 (2.56)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (2.56)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	17	9 (23.08)	2	2 (5.13)
Transfusion reaction	4	3 (7.69)	0	0 (0.00)
Tracheal haemorrhage	2	1 (2.56)	1	1 (2.56)
Incision site pain	1	1 (2.56)	0	0 (0.00)
Infusion related reaction	1	1 (2.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Limb injury	1	1 (2.56)	0	0 (0.00)
Mouth injury	1	1 (2.56)	0	0 (0.00)
Procedural complication	1	1 (2.56)	0	0 (0.00)
Procedural headache	1	1 (2.56)	0	0 (0.00)
Procedural pain	1	1 (2.56)	0	0 (0.00)
Stoma site irritation	1	1 (2.56)	0	0 (0.00)
Tibia fracture	1	1 (2.56)	0	0 (0.00)
Tongue injury	1	1 (2.56)	0	0 (0.00)
Transfusion related complication	1	1 (2.56)	1	1 (2.56)
Investigations				
- Total	195	30 (76.92)	88	24 (61.54)
Aspartate aminotransferase increased	26	14 (35.90)	13	8 (20.51)
Platelet count decreased	25	10 (25.64)	24	10 (25.64)
White blood cell count decreased	23	15 (38.46)	12	11 (28.21)
Alanine aminotransferase increased	17	12 (30.77)	5	5 (12.82)
Neutrophil count decreased	16	12 (30.77)	13	10 (25.64)
Prothrombin time prolonged	15	7 (17.95)	1	1 (2.56)
Blood bilirubin increased	10	5 (12.82)	2	2 (5.13)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Blood fibrinogen decreased	10	3 (7.69)	3	2 (5.13)
International normalised ratio increased	10	8 (20.51)	1	1 (2.56)
Lymphocyte count decreased	9	7 (17.95)	6	5 (12.82)
Blood creatinine increased	5	5 (12.82)	2	2 (5.13)
Activated partial thromboplastin time prolonged	4	2 (5.13)	0	0 (0.00)
Blood phosphorus increased	3	2 (5.13)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (5.13)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (5.13)	0	0 (0.00)
Blood urea increased	2	2 (5.13)	1	1 (2.56)
Blood uric acid increased	2	1 (2.56)	0	0 (0.00)
Transaminases increased	2	2 (5.13)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (2.56)	0	0 (0.00)
Blood lactic acid increased	1	1 (2.56)	1	1 (2.56)
Blood magnesium decreased	1	1 (2.56)	1	1 (2.56)
Blood phosphorus decreased	1	1 (2.56)	0	0 (0.00)
Cardiac murmur	1	1 (2.56)	0	0 (0.00)
Culture stool positive	1	1 (2.56)	0	0 (0.00)
Haemoglobin decreased	1	1 (2.56)	1	1 (2.56)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Hepatic enzyme increased	1	1 (2.56)	0	0 (0.00)
Lipase increased	1	1 (2.56)	1	1 (2.56)
Norovirus test positive	1	1 (2.56)	0	0 (0.00)
Protein total decreased	1	1 (2.56)	1	1 (2.56)
Serum ferritin increased	1	1 (2.56)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	78	24 (61.54)	31	16 (41.03)
Decreased appetite	16	13 (33.33)	10	9 (23.08)
Hypokalaemia	14	10 (25.64)	5	5 (12.82)
Hypophosphataemia	10	8 (20.51)	6	6 (15.38)
Hyperphosphataemia	4	4 (10.26)	0	0 (0.00)
Hypoalbuminaemia	4	4 (10.26)	0	0 (0.00)
Hypocalcaemia	4	3 (7.69)	1	1 (2.56)
Fluid overload	3	3 (7.69)	0	0 (0.00)
Hyperglycaemia	3	2 (5.13)	1	1 (2.56)
Hypernatraemia	3	2 (5.13)	0	0 (0.00)
Hyponatraemia	3	2 (5.13)	3	2 (5.13)
Dehydration	2	2 (5.13)	2	2 (5.13)
Hypercalcaemia	2	1 (2.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Hypertriglyceridaemia	2	1 (2.56)	1	1 (2.56)
Acidosis	1	1 (2.56)	1	1 (2.56)
Hyperalbuminaemia	1	1 (2.56)	0	0 (0.00)
Hyperchloraemia	1	1 (2.56)	0	0 (0.00)
Hypermagnesaemia	1	1 (2.56)	0	0 (0.00)
Hyperuricaemia	1	1 (2.56)	0	0 (0.00)
Malnutrition	1	1 (2.56)	1	1 (2.56)
Metabolic acidosis	1	1 (2.56)	0	0 (0.00)
Metabolic alkalosis	1	1 (2.56)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	18	13 (33.33)	1	1 (2.56)
Myalgia	5	5 (12.82)	0	0 (0.00)
Pain in extremity	4	4 (10.26)	0	0 (0.00)
Musculoskeletal pain	3	2 (5.13)	0	0 (0.00)
Arthralgia	2	2 (5.13)	1	1 (2.56)
Coccydynia	1	1 (2.56)	0	0 (0.00)
Limb discomfort	1	1 (2.56)	0	0 (0.00)
Muscle spasms	1	1 (2.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Osteopenia	1	1 (2.56)	0	0 (0.00)
Nervous system disorders				
- Total	31	20 (51.28)	5	4 (10.26)
Headache	18	14 (35.90)	2	2 (5.13)
Dizziness	3	3 (7.69)	0	0 (0.00)
Encephalopathy	3	3 (7.69)	1	1 (2.56)
Depressed level of consciousness	1	1 (2.56)	0	0 (0.00)
Embolic stroke	1	1 (2.56)	1	1 (2.56)
Idiopathic intracranial hypertension	1	1 (2.56)	0	0 (0.00)
Migraine	1	1 (2.56)	0	0 (0.00)
Myoclonus	1	1 (2.56)	0	0 (0.00)
Seizure	1	1 (2.56)	1	1 (2.56)
Tremor	1	1 (2.56)	0	0 (0.00)
Psychiatric disorders				
- Total	23	13 (33.33)	1	1 (2.56)
Anxiety	5	5 (12.82)	1	1 (2.56)
Confusional state	5	5 (12.82)	0	0 (0.00)
Delirium	3	3 (7.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Agitation	2	1 (2.56)	0	0 (0.00)
Hallucination	2	1 (2.56)	0	0 (0.00)
Irritability	2	2 (5.13)	0	0 (0.00)
Insomnia	1	1 (2.56)	0	0 (0.00)
Listless	1	1 (2.56)	0	0 (0.00)
Mental status changes	1	1 (2.56)	0	0 (0.00)
Panic attack	1	1 (2.56)	0	0 (0.00)
Renal and urinary disorders				
- Total	15	8 (20.51)	9	5 (12.82)
Acute kidney injury	5	5 (12.82)	3	3 (7.69)
Haematuria	4	4 (10.26)	2	2 (5.13)
Oliguria	2	2 (5.13)	2	2 (5.13)
Dysuria	1	1 (2.56)	0	0 (0.00)
Pollakiuria	1	1 (2.56)	0	0 (0.00)
Renal failure	1	1 (2.56)	1	1 (2.56)
Renal impairment	1	1 (2.56)	1	1 (2.56)
Reproductive system and breast disorders				
- Total	4	3 (7.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Oedema genital	2	1 (2.56)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (5.13)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	54	17 (43.59)	23	10 (25.64)
Hypoxia	12	9 (23.08)	8	7 (17.95)
Epistaxis	10	6 (15.38)	4	4 (10.26)
Cough	7	7 (17.95)	0	0 (0.00)
Pleural effusion	7	7 (17.95)	1	1 (2.56)
Dyspnoea	3	2 (5.13)	2	2 (5.13)
Pulmonary oedema	3	3 (7.69)	3	3 (7.69)
Tachypnoea	3	2 (5.13)	1	1 (2.56)
Atelectasis	1	1 (2.56)	0	0 (0.00)
Haemoptysis	1	1 (2.56)	1	1 (2.56)
Interstitial lung disease	1	1 (2.56)	1	1 (2.56)
Oropharyngeal pain	1	1 (2.56)	0	0 (0.00)
Pharyngeal ulceration	1	1 (2.56)	0	0 (0.00)
Respiratory depression	1	1 (2.56)	0	0 (0.00)
Respiratory distress	1	1 (2.56)	1	1 (2.56)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Respiratory failure	1	1 (2.56)	1	1 (2.56)
Rhinitis allergic	1	1 (2.56)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	27	12 (30.77)	1	1 (2.56)
Hyperhidrosis	4	3 (7.69)	0	0 (0.00)
Erythema	3	2 (5.13)	0	0 (0.00)
Rash	3	3 (7.69)	0	0 (0.00)
Rash maculo-papular	3	3 (7.69)	1	1 (2.56)
Dry skin	2	2 (5.13)	0	0 (0.00)
Ingrowing nail	2	1 (2.56)	0	0 (0.00)
Petechiae	2	2 (5.13)	0	0 (0.00)
Livedo reticularis	1	1 (2.56)	0	0 (0.00)
Macule	1	1 (2.56)	0	0 (0.00)
Night sweats	1	1 (2.56)	0	0 (0.00)
Pruritus	1	1 (2.56)	0	0 (0.00)
Rash erythematous	1	1 (2.56)	0	0 (0.00)
Rash macular	1	1 (2.56)	0	0 (0.00)
Rash papular	1	1 (2.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Rash vesicular	1	1 (2.56)	0	0 (0.00)
Vascular disorders				
- Total	28	14 (35.90)	14	11 (28.21)
Hypotension	12	11 (28.21)	11	10 (25.64)
Hypertension	10	8 (20.51)	1	1 (2.56)
Flushing	3	2 (5.13)	0	0 (0.00)
Capillary leak syndrome	1	1 (2.56)	1	1 (2.56)
Embolism	1	1 (2.56)	1	1 (2.56)
Haematoma	1	1 (2.56)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Total number of AE per patient	188	22 (95.65)	34	13 (56.52)
Blood and lymphatic system disorders				
- Total	9	5 (21.74)	6	3 (13.04)
Anaemia	2	2 (8.70)	1	1 (4.35)
Eosinophilia	2	1 (4.35)	1	1 (4.35)
Febrile neutropenia	2	2 (8.70)	2	2 (8.70)
Neutropenia	2	2 (8.70)	2	2 (8.70)
Lymphadenopathy	1	1 (4.35)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (4.35)	0	0 (0.00)
Sinus tachycardia	1	1 (4.35)	0	0 (0.00)
Eye disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
- Total	4	4 (17.39)	0	0 (0.00)
Dry eye	2	2 (8.70)	0	0 (0.00)
Conjunctivitis allergic	1	1 (4.35)	0	0 (0.00)
Ocular hyperaemia	1	1 (4.35)	0	0 (0.00)
Gastrointestinal disorders				
- Total	20	9 (39.13)	3	2 (8.70)
Vomiting	9	6 (26.09)	1	1 (4.35)
Diarrhoea	3	3 (13.04)	0	0 (0.00)
Nausea	3	3 (13.04)	1	1 (4.35)
Oral pain	2	1 (4.35)	0	0 (0.00)
Abdominal pain	1	1 (4.35)	0	0 (0.00)
Enterocolitis	1	1 (4.35)	1	1 (4.35)
Pigmentation lip	1	1 (4.35)	0	0 (0.00)
General disorders and administration site conditions				
- Total	15	7 (30.43)	0	0 (0.00)
Pyrexia	7	3 (13.04)	0	0 (0.00)
Influenza like illness	2	2 (8.70)	0	0 (0.00)
Catheter site pain	1	1 (4.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Chills	1	1 (4.35)	0	0 (0.00)
Fatigue	1	1 (4.35)	0	0 (0.00)
Generalised oedema	1	1 (4.35)	0	0 (0.00)
Oedema peripheral	1	1 (4.35)	0	0 (0.00)
Pain	1	1 (4.35)	0	0 (0.00)
Immune system disorders				
- Total	10	8 (34.78)	0	0 (0.00)
Hypogammaglobulinaemia	5	4 (17.39)	0	0 (0.00)
Immunodeficiency common variable	2	2 (8.70)	0	0 (0.00)
Graft versus host disease	1	1 (4.35)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (4.35)	0	0 (0.00)
Seasonal allergy	1	1 (4.35)	0	0 (0.00)
Infections and infestations				
- Total	36	16 (69.57)	8	4 (17.39)
Cellulitis of male external genital organ	5	1 (4.35)	2	1 (4.35)
Urinary tract infection	5	4 (17.39)	2	2 (8.70)
Upper respiratory tract infection	4	4 (17.39)	0	0 (0.00)
Influenza	3	3 (13.04)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Otitis media	2	1 (4.35)	0	0 (0.00)
Corona virus infection	1	1 (4.35)	1	1 (4.35)
Cytomegalovirus infection	1	1 (4.35)	0	0 (0.00)
Ear infection	1	1 (4.35)	0	0 (0.00)
Escherichia urinary tract infection	1	1 (4.35)	1	1 (4.35)
Gastroenteritis	1	1 (4.35)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (4.35)	0	0 (0.00)
Otitis externa	1	1 (4.35)	0	0 (0.00)
Otitis media acute	1	1 (4.35)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (4.35)	0	0 (0.00)
Paronychia	1	1 (4.35)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (4.35)	1	1 (4.35)
Rhinovirus infection	1	1 (4.35)	0	0 (0.00)
Sinusitis	1	1 (4.35)	0	0 (0.00)
Subcutaneous abscess	1	1 (4.35)	0	0 (0.00)
Tinea capitis	1	1 (4.35)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (4.35)	1	1 (4.35)
Vulvovaginal mycotic infection	1	1 (4.35)	0	0 (0.00)
Injury, poisoning and procedural complications				

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
- Total	4	3 (13.04)	0	0 (0.00)
Arthropod bite	1	1 (4.35)	0	0 (0.00)
Procedural pain	1	1 (4.35)	0	0 (0.00)
Skin abrasion	1	1 (4.35)	0	0 (0.00)
Skin laceration	1	1 (4.35)	0	0 (0.00)
Investigations				
- Total	25	10 (43.48)	7	6 (26.09)
Neutrophil count decreased	7	5 (21.74)	4	4 (17.39)
Platelet count decreased	5	3 (13.04)	0	0 (0.00)
Aspartate aminotransferase increased	3	3 (13.04)	2	2 (8.70)
White blood cell count decreased	3	3 (13.04)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (4.35)	1	1 (4.35)
Blood magnesium decreased	1	1 (4.35)	0	0 (0.00)
Haemoglobin decreased	1	1 (4.35)	0	0 (0.00)
Lymphocyte count decreased	1	1 (4.35)	0	0 (0.00)
Serum ferritin increased	1	1 (4.35)	0	0 (0.00)
Weight decreased	1	1 (4.35)	0	0 (0.00)
Weight increased	1	1 (4.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Metabolism and nutrition disorders				
- Total	10	7 (30.43)	5	3 (13.04)
Hyperphosphataemia	2	2 (8.70)	0	0 (0.00)
Hypokalaemia	2	2 (8.70)	1	1 (4.35)
Decreased appetite	1	1 (4.35)	0	0 (0.00)
Hyperglycaemia	1	1 (4.35)	1	1 (4.35)
Hypophosphataemia	1	1 (4.35)	1	1 (4.35)
Iron overload	1	1 (4.35)	1	1 (4.35)
Tumour lysis syndrome	1	1 (4.35)	1	1 (4.35)
Vitamin D deficiency	1	1 (4.35)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	9	7 (30.43)	0	0 (0.00)
Pain in extremity	3	3 (13.04)	0	0 (0.00)
Back pain	1	1 (4.35)	0	0 (0.00)
Flank pain	1	1 (4.35)	0	0 (0.00)
Joint range of motion decreased	1	1 (4.35)	0	0 (0.00)
Muscle spasms	1	1 (4.35)	0	0 (0.00)
Muscular weakness	1	1 (4.35)	0	0 (0.00)
Toe walking	1	1 (4.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (4.35)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (4.35)	0	0 (0.00)
Nervous system disorders				
- Total	6	3 (13.04)	0	0 (0.00)
Headache	5	3 (13.04)	0	0 (0.00)
Dizziness	1	1 (4.35)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (4.35)	0	0 (0.00)
Depression	1	1 (4.35)	0	0 (0.00)
Renal and urinary disorders				
- Total	4	2 (8.70)	3	2 (8.70)
Acute kidney injury	1	1 (4.35)	1	1 (4.35)
Calculus urinary	1	1 (4.35)	0	0 (0.00)
Haematuria	1	1 (4.35)	1	1 (4.35)
Nephrolithiasis	1	1 (4.35)	1	1 (4.35)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Reproductive system and breast disorders				
- Total	1	1 (4.35)	0	0 (0.00)
Scrotal pain	1	1 (4.35)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	19	12 (52.17)	1	1 (4.35)
Cough	5	4 (17.39)	0	0 (0.00)
Nasal congestion	4	4 (17.39)	0	0 (0.00)
Rhinorrhoea	4	4 (17.39)	0	0 (0.00)
Oropharyngeal pain	2	2 (8.70)	0	0 (0.00)
Rhinitis allergic	2	2 (8.70)	0	0 (0.00)
Acute respiratory failure	1	1 (4.35)	1	1 (4.35)
Epistaxis	1	1 (4.35)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	12	9 (39.13)	1	1 (4.35)
Rash maculo-papular	2	2 (8.70)	0	0 (0.00)
Dermatitis	1	1 (4.35)	0	0 (0.00)
Dermatitis acneiform	1	1 (4.35)	1	1 (4.35)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Dry skin	1	1 (4.35)	0	0 (0.00)
Eczema	1	1 (4.35)	0	0 (0.00)
Ingrowing nail	1	1 (4.35)	0	0 (0.00)
Keloid scar	1	1 (4.35)	0	0 (0.00)
Macule	1	1 (4.35)	0	0 (0.00)
Petechiae	1	1 (4.35)	0	0 (0.00)
Rash	1	1 (4.35)	0	0 (0.00)
Rash pruritic	1	1 (4.35)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (4.35)	0	0 (0.00)
Hypertension	1	1 (4.35)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Total number of AE per patient	158	24 (72.73)	37	13 (39.39)
Blood and lymphatic system disorders				
- Total	9	6 (18.18)	7	4 (12.12)
Neutropenia	4	2 (6.06)	4	2 (6.06)
Thrombocytopenia	2	2 (6.06)	1	1 (3.03)
Febrile neutropenia	1	1 (3.03)	1	1 (3.03)
Leukopenia	1	1 (3.03)	1	1 (3.03)
Lymphopenia	1	1 (3.03)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.03)	0	0 (0.00)
Eye disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
- Total	1	1 (3.03)	0	0 (0.00)
Vision blurred	1	1 (3.03)	0	0 (0.00)
Gastrointestinal disorders				
- Total	18	7 (21.21)	5	2 (6.06)
Diarrhoea	5	5 (15.15)	1	1 (3.03)
Nausea	4	3 (9.09)	1	1 (3.03)
Vomiting	4	3 (9.09)	1	1 (3.03)
Abdominal pain	3	3 (9.09)	1	1 (3.03)
Abdominal pain upper	1	1 (3.03)	0	0 (0.00)
Oral pain	1	1 (3.03)	1	1 (3.03)
General disorders and administration site conditions				
- Total	11	10 (30.30)	1	1 (3.03)
Pyrexia	7	7 (21.21)	1	1 (3.03)
Acquired gene mutation	1	1 (3.03)	0	0 (0.00)
Crying	1	1 (3.03)	0	0 (0.00)
Fatigue	1	1 (3.03)	0	0 (0.00)
Malaise	1	1 (3.03)	0	0 (0.00)
Immune system disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
- Total	7	6 (18.18)	1	1 (3.03)
Hypogammaglobulinaemia	4	4 (12.12)	1	1 (3.03)
Graft versus host disease	2	1 (3.03)	0	0 (0.00)
Seasonal allergy	1	1 (3.03)	0	0 (0.00)
Infections and infestations				
- Total	25	17 (51.52)	9	8 (24.24)
Rhinovirus infection	3	1 (3.03)	0	0 (0.00)
Upper respiratory tract infection	3	3 (9.09)	1	1 (3.03)
Gastroenteritis	2	2 (6.06)	0	0 (0.00)
Bacterial sepsis	1	1 (3.03)	1	1 (3.03)
Cholecystitis infective	1	1 (3.03)	1	1 (3.03)
Ear infection	1	1 (3.03)	0	0 (0.00)
Enterovirus infection	1	1 (3.03)	1	1 (3.03)
Gastroenteritis viral	1	1 (3.03)	0	0 (0.00)
Herpes zoster	1	1 (3.03)	1	1 (3.03)
Molluscum contagiosum	1	1 (3.03)	0	0 (0.00)
Oral herpes	1	1 (3.03)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (3.03)	1	1 (3.03)
Rash pustular	1	1 (3.03)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Rhinitis	1	1 (3.03)	0	0 (0.00)
Rotavirus infection	1	1 (3.03)	1	1 (3.03)
Sepsis	1	1 (3.03)	1	1 (3.03)
Sinusitis	1	1 (3.03)	0	0 (0.00)
Vascular device infection	1	1 (3.03)	1	1 (3.03)
Viral infection	1	1 (3.03)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (3.03)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	9	5 (15.15)	0	0 (0.00)
Contusion	2	2 (6.06)	0	0 (0.00)
Infusion related reaction	2	2 (6.06)	0	0 (0.00)
Foot fracture	1	1 (3.03)	0	0 (0.00)
Procedural nausea	1	1 (3.03)	0	0 (0.00)
Procedural pain	1	1 (3.03)	0	0 (0.00)
Radius fracture	1	1 (3.03)	0	0 (0.00)
Sunburn	1	1 (3.03)	0	0 (0.00)
Investigations				
- Total	23	13 (39.39)	9	6 (18.18)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Neutrophil count decreased	5	3 (9.09)	4	2 (6.06)
White blood cell count decreased	4	2 (6.06)	3	2 (6.06)
Weight decreased	3	3 (9.09)	0	0 (0.00)
Blood urea increased	2	1 (3.03)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (3.03)	1	1 (3.03)
Blood bilirubin increased	1	1 (3.03)	1	1 (3.03)
Blood creatinine increased	1	1 (3.03)	0	0 (0.00)
Blood uric acid increased	1	1 (3.03)	0	0 (0.00)
Haemoglobin decreased	1	1 (3.03)	0	0 (0.00)
Lymphocyte count decreased	1	1 (3.03)	0	0 (0.00)
Oxygen saturation decreased	1	1 (3.03)	0	0 (0.00)
Transaminases increased	1	1 (3.03)	0	0 (0.00)
Weight increased	1	1 (3.03)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	5	3 (9.09)	1	1 (3.03)
Hyperalbuminaemia	2	1 (3.03)	0	0 (0.00)
Decreased appetite	1	1 (3.03)	0	0 (0.00)
Dehydration	1	1 (3.03)	1	1 (3.03)
Hypercalcaemia	1	1 (3.03)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	12	9 (27.27)	0	0 (0.00)
Pain in extremity	5	5 (15.15)	0	0 (0.00)
Arthralgia	2	2 (6.06)	0	0 (0.00)
Joint range of motion decreased	1	1 (3.03)	0	0 (0.00)
Muscular weakness	1	1 (3.03)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.03)	0	0 (0.00)
Osteonecrosis	1	1 (3.03)	0	0 (0.00)
Pain in jaw	1	1 (3.03)	0	0 (0.00)
Nervous system disorders				
- Total	6	5 (15.15)	0	0 (0.00)
Dizziness	2	2 (6.06)	0	0 (0.00)
Headache	2	2 (6.06)	0	0 (0.00)
Peroneal nerve palsy	2	2 (6.06)	0	0 (0.00)
Psychiatric disorders				
- Total	3	1 (3.03)	0	0 (0.00)
Anxiety	1	1 (3.03)	0	0 (0.00)
Depression	1	1 (3.03)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Sleep disorder	1	1 (3.03)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Urinary incontinence	1	1 (3.03)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.03)	1	1 (3.03)
Vaginal haemorrhage	1	1 (3.03)	1	1 (3.03)
Respiratory, thoracic and mediastinal disorders				
- Total	11	6 (18.18)	3	2 (6.06)
Cough	4	3 (9.09)	0	0 (0.00)
Dysphonia	1	1 (3.03)	0	0 (0.00)
Epistaxis	1	1 (3.03)	1	1 (3.03)
Oropharyngeal pain	1	1 (3.03)	0	0 (0.00)
Pharyngeal erythema	1	1 (3.03)	0	0 (0.00)
Pharyngeal lesion	1	1 (3.03)	1	1 (3.03)
Pulmonary oedema	1	1 (3.03)	1	1 (3.03)
Rhinitis allergic	1	1 (3.03)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	13	7 (21.21)	0	0 (0.00)
Rash	4	3 (9.09)	0	0 (0.00)
Erythema	2	2 (6.06)	0	0 (0.00)
Rash erythematous	2	1 (3.03)	0	0 (0.00)
Alopecia	1	1 (3.03)	0	0 (0.00)
Dermatitis atopic	1	1 (3.03)	0	0 (0.00)
Hyperhidrosis	1	1 (3.03)	0	0 (0.00)
Papule	1	1 (3.03)	0	0 (0.00)
Pruritus	1	1 (3.03)	0	0 (0.00)
Vascular disorders				
- Total	2	1 (3.03)	0	0 (0.00)
Hot flush	1	1 (3.03)	0	0 (0.00)
Hypertension	1	1 (3.03)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Total number of AE per patient	34	11 (64.71)	10	5 (29.41)
Blood and lymphatic system disorders				
- Total	1	1 (5.88)	1	1 (5.88)
Febrile neutropenia	1	1 (5.88)	1	1 (5.88)
Gastrointestinal disorders				
- Total	2	2 (11.76)	0	0 (0.00)
Diarrhoea	1	1 (5.88)	0	0 (0.00)
Nausea	1	1 (5.88)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	2 (11.76)	1	1 (5.88)
Pyrexia	2	1 (5.88)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Chills	1	1 (5.88)	0	0 (0.00)
Cyst	1	1 (5.88)	1	1 (5.88)
Immune system disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Immunodeficiency	1	1 (5.88)	0	0 (0.00)
Infections and infestations				
- Total	8	4 (23.53)	2	1 (5.88)
Otitis media	2	2 (11.76)	0	0 (0.00)
Urinary tract infection	2	1 (5.88)	1	1 (5.88)
Cellulitis of male external genital organ	1	1 (5.88)	1	1 (5.88)
Meningitis aseptic	1	1 (5.88)	0	0 (0.00)
Otitis media acute	1	1 (5.88)	0	0 (0.00)
Skin infection	1	1 (5.88)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (5.88)	1	1 (5.88)
Procedural pain	1	1 (5.88)	1	1 (5.88)
Investigations				

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
- Total	11	4 (23.53)	4	2 (11.76)
Alanine aminotransferase increased	2	2 (11.76)	1	1 (5.88)
White blood cell count decreased	2	2 (11.76)	2	2 (11.76)
Aspartate aminotransferase increased	1	1 (5.88)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (5.88)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (5.88)	0	0 (0.00)
C-reactive protein increased	1	1 (5.88)	0	0 (0.00)
Lymphocyte count decreased	1	1 (5.88)	0	0 (0.00)
Neutrophil count decreased	1	1 (5.88)	0	0 (0.00)
Platelet count decreased	1	1 (5.88)	1	1 (5.88)
Renal and urinary disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Haematuria	1	1 (5.88)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (5.88)	1	1 (5.88)
Ovarian failure	1	1 (5.88)	1	1 (5.88)

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	2	2 (11.76)	0	0 (0.00)
Cough	1	1 (5.88)	0	0 (0.00)
Epistaxis	1	1 (5.88)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	2 (11.76)	0	0 (0.00)
Papule	1	1 (5.88)	0	0 (0.00)
Pruritus	1	1 (5.88)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Total number of AE per patient	56	11 (64.71)	13	7 (41.18)
Blood and lymphatic system disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Thrombocytopenia	1	1 (5.88)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Tympanic membrane perforation	1	1 (5.88)	0	0 (0.00)
Gastrointestinal disorders				
- Total	2	1 (5.88)	0	0 (0.00)
Abdominal pain	1	1 (5.88)	0	0 (0.00)
Diarrhoea	1	1 (5.88)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Immune system disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Chronic graft versus host disease	1	1 (5.88)	0	0 (0.00)
Infections and infestations				
- Total	24	7 (41.18)	5	3 (17.65)
Upper respiratory tract infection	4	2 (11.76)	0	0 (0.00)
Otitis media	3	1 (5.88)	1	1 (5.88)
Otitis media acute	3	1 (5.88)	0	0 (0.00)
Sinusitis	3	3 (17.65)	0	0 (0.00)
Pneumonia	2	2 (11.76)	0	0 (0.00)
Campylobacter infection	1	1 (5.88)	1	1 (5.88)
Clostridium difficile infection	1	1 (5.88)	1	1 (5.88)
Gingivitis	1	1 (5.88)	0	0 (0.00)
Haemophilus infection	1	1 (5.88)	0	0 (0.00)
Respiratory tract infection	1	1 (5.88)	1	1 (5.88)
Respiratory tract infection viral	1	1 (5.88)	1	1 (5.88)
Urinary tract infection	1	1 (5.88)	0	0 (0.00)
Viral infection	1	1 (5.88)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (5.88)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Investigations				
- Total	11	4 (23.53)	4	3 (17.65)
Lymphocyte count decreased	4	2 (11.76)	1	1 (5.88)
White blood cell count decreased	3	2 (11.76)	1	1 (5.88)
Neutrophil count decreased	2	1 (5.88)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (5.88)	1	1 (5.88)
Aspartate aminotransferase increased	1	1 (5.88)	1	1 (5.88)
Metabolism and nutrition disorders				
- Total	2	2 (11.76)	1	1 (5.88)
Hypokalaemia	1	1 (5.88)	1	1 (5.88)
Vitamin D deficiency	1	1 (5.88)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Neck pain	1	1 (5.88)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
- Total	1	1 (5.88)	1	1 (5.88)
Glioblastoma multiforme	1	1 (5.88)	1	1 (5.88)
Nervous system disorders				
- Total	4	3 (17.65)	1	1 (5.88)
Disturbance in attention	1	1 (5.88)	0	0 (0.00)
Dizziness	1	1 (5.88)	0	0 (0.00)
Headache	1	1 (5.88)	0	0 (0.00)
Seizure	1	1 (5.88)	1	1 (5.88)
Renal and urinary disorders				
- Total	2	1 (5.88)	1	1 (5.88)
Acute kidney injury	2	1 (5.88)	1	1 (5.88)
Respiratory, thoracic and mediastinal disorders				
- Total	5	2 (11.76)	0	0 (0.00)
Cough	2	1 (5.88)	0	0 (0.00)
Oropharyngeal pain	1	1 (5.88)	0	0 (0.00)
Rhinitis allergic	1	1 (5.88)	0	0 (0.00)
Rhinorrhoea	1	1 (5.88)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Acne	1	1 (5.88)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Total number of AE per patient	668	25 (100.00)	217	24 (96.00)
Blood and lymphatic system disorders				
- Total	59	20 (80.00)	47	19 (76.00)
Anaemia	19	11 (44.00)	12	7 (28.00)
Febrile neutropenia	19	16 (64.00)	19	16 (64.00)
Thrombocytopenia	10	2 (8.00)	9	2 (8.00)
Neutropenia	4	3 (12.00)	4	3 (12.00)
Disseminated intravascular coagulation	2	2 (8.00)	1	1 (4.00)
Eosinophilia	2	1 (4.00)	1	1 (4.00)
Lymphopenia	2	2 (8.00)	1	1 (4.00)
Lymphadenopathy	1	1 (4.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Cardiac disorders				
- Total	11	9 (36.00)	0	0 (0.00)
Tachycardia	7	7 (28.00)	0	0 (0.00)
Sinus tachycardia	2	2 (8.00)	0	0 (0.00)
Cardiac dysfunction	1	1 (4.00)	0	0 (0.00)
Ventricular tachycardia	1	1 (4.00)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (4.00)	0	0 (0.00)
Adrenal insufficiency	1	1 (4.00)	0	0 (0.00)
Eye disorders				
- Total	10	6 (24.00)	0	0 (0.00)
Dry eye	2	2 (8.00)	0	0 (0.00)
Eye pain	2	1 (4.00)	0	0 (0.00)
Vision blurred	2	1 (4.00)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (4.00)	0	0 (0.00)
Conjunctivitis allergic	1	1 (4.00)	0	0 (0.00)
Ocular hyperaemia	1	1 (4.00)	0	0 (0.00)
Periorbital oedema	1	1 (4.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Gastrointestinal disorders				
- Total	63	17 (68.00)	7	4 (16.00)
Vomiting	21	11 (44.00)	2	1 (4.00)
Nausea	13	10 (40.00)	1	1 (4.00)
Diarrhoea	9	8 (32.00)	1	1 (4.00)
Abdominal pain	4	4 (16.00)	0	0 (0.00)
Constipation	3	2 (8.00)	0	0 (0.00)
Oral pain	2	1 (4.00)	0	0 (0.00)
Abdominal distension	1	1 (4.00)	0	0 (0.00)
Abdominal pain upper	1	1 (4.00)	0	0 (0.00)
Abdominal tenderness	1	1 (4.00)	0	0 (0.00)
Ascites	1	1 (4.00)	1	1 (4.00)
Dysphagia	1	1 (4.00)	0	0 (0.00)
Enterocolitis	1	1 (4.00)	1	1 (4.00)
Flatulence	1	1 (4.00)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (4.00)	0	0 (0.00)
Glossodynia	1	1 (4.00)	0	0 (0.00)
Pancreatitis	1	1 (4.00)	1	1 (4.00)
Pigmentation lip	1	1 (4.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
General disorders and administration site conditions				
- Total	30	14 (56.00)	4	4 (16.00)
Pyrexia	13	7 (28.00)	2	2 (8.00)
Chills	5	4 (16.00)	0	0 (0.00)
Fatigue	3	3 (12.00)	0	0 (0.00)
Influenza like illness	2	2 (8.00)	0	0 (0.00)
Catheter site pain	1	1 (4.00)	0	0 (0.00)
Cyst	1	1 (4.00)	1	1 (4.00)
Generalised oedema	1	1 (4.00)	0	0 (0.00)
Malaise	1	1 (4.00)	0	0 (0.00)
Oedema peripheral	1	1 (4.00)	0	0 (0.00)
Pain	1	1 (4.00)	0	0 (0.00)
Physical deconditioning	1	1 (4.00)	1	1 (4.00)
Hepatobiliary disorders				
- Total	1	1 (4.00)	0	0 (0.00)
Gallbladder enlargement	1	1 (4.00)	0	0 (0.00)
Immune system disorders				
- Total	55	24 (96.00)	9	7 (28.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Cytokine release syndrome	30	20 (80.00)	8	6 (24.00)
Hypogammaglobulinaemia	17	15 (60.00)	1	1 (4.00)
Immunodeficiency common variable	2	2 (8.00)	0	0 (0.00)
Drug hypersensitivity	1	1 (4.00)	0	0 (0.00)
Graft versus host disease	1	1 (4.00)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (4.00)	0	0 (0.00)
Graft versus host disease in skin	1	1 (4.00)	0	0 (0.00)
Immunodeficiency	1	1 (4.00)	0	0 (0.00)
Seasonal allergy	1	1 (4.00)	0	0 (0.00)
Infections and infestations				
- Total	55	18 (72.00)	11	5 (20.00)
Urinary tract infection	7	4 (16.00)	3	2 (8.00)
Cellulitis of male external genital organ	6	1 (4.00)	3	1 (4.00)
Influenza	4	4 (16.00)	0	0 (0.00)
Otitis media	4	3 (12.00)	0	0 (0.00)
Upper respiratory tract infection	4	4 (16.00)	0	0 (0.00)
Clostridium difficile infection	2	2 (8.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Cytomegalovirus infection	2	2 (8.00)	0	0 (0.00)
Gastroenteritis	2	2 (8.00)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (4.00)	0	0 (0.00)
Otitis media acute	2	1 (4.00)	0	0 (0.00)
Skin infection	2	2 (8.00)	0	0 (0.00)
Corona virus infection	1	1 (4.00)	1	1 (4.00)
Ear infection	1	1 (4.00)	0	0 (0.00)
Enterococcal infection	1	1 (4.00)	0	0 (0.00)
Escherichia urinary tract infection	1	1 (4.00)	1	1 (4.00)
Fungal skin infection	1	1 (4.00)	0	0 (0.00)
Meningitis aseptic	1	1 (4.00)	0	0 (0.00)
Otitis externa	1	1 (4.00)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (4.00)	0	0 (0.00)
Paronychia	1	1 (4.00)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (4.00)	1	1 (4.00)
Rhinovirus infection	1	1 (4.00)	0	0 (0.00)
Sinusitis	1	1 (4.00)	0	0 (0.00)
Staphylococcal infection	1	1 (4.00)	1	1 (4.00)
Subcutaneous abscess	1	1 (4.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Tinea capitis	1	1 (4.00)	0	0 (0.00)
Viral infection	1	1 (4.00)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (4.00)	1	1 (4.00)
Vulvovaginal mycotic infection	1	1 (4.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	13	9 (36.00)	1	1 (4.00)
Procedural pain	4	3 (12.00)	1	1 (4.00)
Skin abrasion	2	2 (8.00)	0	0 (0.00)
Arthropod bite	1	1 (4.00)	0	0 (0.00)
Contusion	1	1 (4.00)	0	0 (0.00)
Infusion related reaction	1	1 (4.00)	0	0 (0.00)
Post procedural haemorrhage	1	1 (4.00)	0	0 (0.00)
Procedural site reaction	1	1 (4.00)	0	0 (0.00)
Skin laceration	1	1 (4.00)	0	0 (0.00)
Subdural haemorrhage	1	1 (4.00)	0	0 (0.00)
Investigations				
- Total	173	22 (88.00)	101	20 (80.00)
Neutrophil count decreased	39	15 (60.00)	35	14 (56.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
White blood cell count decreased	37	17 (68.00)	27	16 (64.00)
Platelet count decreased	24	10 (40.00)	14	5 (20.00)
Alanine aminotransferase increased	14	8 (32.00)	11	7 (28.00)
Aspartate aminotransferase increased	10	5 (20.00)	5	3 (12.00)
Lymphocyte count decreased	9	8 (32.00)	6	6 (24.00)
Blood creatinine increased	6	4 (16.00)	0	0 (0.00)
Blood fibrinogen decreased	5	1 (4.00)	1	1 (4.00)
Activated partial thromboplastin time prolonged	4	3 (12.00)	0	0 (0.00)
Blood bilirubin increased	3	2 (8.00)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (8.00)	0	0 (0.00)
Blood sodium increased	2	1 (4.00)	0	0 (0.00)
C-reactive protein increased	2	2 (8.00)	1	1 (4.00)
Prothrombin time prolonged	2	2 (8.00)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (4.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (4.00)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (4.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Blood lactate dehydrogenase increased	1	1 (4.00)	0	0 (0.00)
Blood magnesium decreased	1	1 (4.00)	0	0 (0.00)
Blood urea increased	1	1 (4.00)	0	0 (0.00)
Fibrin D dimer increased	1	1 (4.00)	0	0 (0.00)
Haemoglobin decreased	1	1 (4.00)	0	0 (0.00)
International normalised ratio increased	1	1 (4.00)	0	0 (0.00)
Lipase increased	1	1 (4.00)	1	1 (4.00)
Pulmonary function test decreased	1	1 (4.00)	0	0 (0.00)
Serum ferritin increased	1	1 (4.00)	0	0 (0.00)
Weight decreased	1	1 (4.00)	0	0 (0.00)
Weight increased	1	1 (4.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	48	17 (68.00)	17	9 (36.00)
Decreased appetite	9	8 (32.00)	3	3 (12.00)
Hyperphosphataemia	8	4 (16.00)	0	0 (0.00)
Hypokalaemia	8	8 (32.00)	3	3 (12.00)
Hypernatraemia	4	2 (8.00)	1	1 (4.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Hypophosphataemia	4	2 (8.00)	4	2 (8.00)
Hyperuricaemia	3	2 (8.00)	1	1 (4.00)
Hyperglycaemia	2	1 (4.00)	1	1 (4.00)
Hypoalbuminaemia	2	1 (4.00)	1	1 (4.00)
Tumour lysis syndrome	2	2 (8.00)	2	2 (8.00)
Acidosis	1	1 (4.00)	0	0 (0.00)
Dehydration	1	1 (4.00)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (4.00)	0	0 (0.00)
Hypomagnesaemia	1	1 (4.00)	0	0 (0.00)
Iron overload	1	1 (4.00)	1	1 (4.00)
Vitamin D deficiency	1	1 (4.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	14	9 (36.00)	0	0 (0.00)
Pain in extremity	3	3 (12.00)	0	0 (0.00)
Arthralgia	2	2 (8.00)	0	0 (0.00)
Muscular weakness	2	2 (8.00)	0	0 (0.00)
Back pain	1	1 (4.00)	0	0 (0.00)
Flank pain	1	1 (4.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Joint range of motion decreased	1	1 (4.00)	0	0 (0.00)
Muscle spasms	1	1 (4.00)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (4.00)	0	0 (0.00)
Musculoskeletal pain	1	1 (4.00)	0	0 (0.00)
Toe walking	1	1 (4.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	2 (8.00)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (4.00)	0	0 (0.00)
Skin papilloma	1	1 (4.00)	0	0 (0.00)
Nervous system disorders				
- Total	33	13 (52.00)	1	1 (4.00)
Headache	18	10 (40.00)	0	0 (0.00)
Encephalopathy	3	1 (4.00)	1	1 (4.00)
Dizziness	2	2 (8.00)	0	0 (0.00)
Dysarthria	2	2 (8.00)	0	0 (0.00)
Seizure	2	2 (8.00)	0	0 (0.00)
Asterixis	1	1 (4.00)	0	0 (0.00)
Ataxia	1	1 (4.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Neuropathy peripheral	1	1 (4.00)	0	0 (0.00)
Pleocytosis	1	1 (4.00)	0	0 (0.00)
Somnolence	1	1 (4.00)	0	0 (0.00)
Tremor	1	1 (4.00)	0	0 (0.00)
Product issues				
- Total	1	1 (4.00)	0	0 (0.00)
Device occlusion	1	1 (4.00)	0	0 (0.00)
Psychiatric disorders				
- Total	8	4 (16.00)	0	0 (0.00)
Adjustment disorder	1	1 (4.00)	0	0 (0.00)
Agitation	1	1 (4.00)	0	0 (0.00)
Anxiety	1	1 (4.00)	0	0 (0.00)
Confusional state	1	1 (4.00)	0	0 (0.00)
Delirium	1	1 (4.00)	0	0 (0.00)
Depression	1	1 (4.00)	0	0 (0.00)
Hallucination	1	1 (4.00)	0	0 (0.00)
Suicidal ideation	1	1 (4.00)	0	0 (0.00)
Renal and urinary disorders				

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
- Total	8	5 (20.00)	5	4 (16.00)
Acute kidney injury	3	3 (12.00)	3	3 (12.00)
Haematuria	2	1 (4.00)	1	1 (4.00)
Calculus urinary	1	1 (4.00)	0	0 (0.00)
Dysuria	1	1 (4.00)	0	0 (0.00)
Nephrolithiasis	1	1 (4.00)	1	1 (4.00)
Reproductive system and breast disorders				
- Total	2	2 (8.00)	1	1 (4.00)
Ovarian failure	1	1 (4.00)	1	1 (4.00)
Scrotal pain	1	1 (4.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	40	19 (76.00)	6	3 (12.00)
Cough	7	5 (20.00)	0	0 (0.00)
Nasal congestion	5	5 (20.00)	0	0 (0.00)
Rhinorrhoea	5	5 (20.00)	0	0 (0.00)
Epistaxis	3	3 (12.00)	0	0 (0.00)
Oropharyngeal pain	3	3 (12.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Pulmonary oedema	3	3 (12.00)	2	2 (8.00)
Tachypnoea	3	3 (12.00)	0	0 (0.00)
Haemoptysis	2	1 (4.00)	0	0 (0.00)
Respiratory failure	2	2 (8.00)	2	2 (8.00)
Rhinitis allergic	2	2 (8.00)	0	0 (0.00)
Acute respiratory failure	1	1 (4.00)	1	1 (4.00)
Hypoxia	1	1 (4.00)	0	0 (0.00)
Oropharyngeal plaque	1	1 (4.00)	0	0 (0.00)
Pleural effusion	1	1 (4.00)	1	1 (4.00)
Wheezing	1	1 (4.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	28	15 (60.00)	2	2 (8.00)
Dry skin	3	3 (12.00)	0	0 (0.00)
Ingrowing nail	2	2 (8.00)	0	0 (0.00)
Petechiae	2	2 (8.00)	0	0 (0.00)
Pruritus	2	2 (8.00)	0	0 (0.00)
Rash	2	2 (8.00)	0	0 (0.00)
Rash maculo-papular	2	2 (8.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Dermatitis	1	1 (4.00)	0	0 (0.00)
Dermatitis acneiform	1	1 (4.00)	1	1 (4.00)
Dermatitis diaper	1	1 (4.00)	0	0 (0.00)
Ecchymosis	1	1 (4.00)	1	1 (4.00)
Eczema	1	1 (4.00)	0	0 (0.00)
Erythema	1	1 (4.00)	0	0 (0.00)
Keloid scar	1	1 (4.00)	0	0 (0.00)
Macule	1	1 (4.00)	0	0 (0.00)
Papule	1	1 (4.00)	0	0 (0.00)
Rash follicular	1	1 (4.00)	0	0 (0.00)
Rash papular	1	1 (4.00)	0	0 (0.00)
Rash pruritic	1	1 (4.00)	0	0 (0.00)
Skin exfoliation	1	1 (4.00)	0	0 (0.00)
Skin fissures	1	1 (4.00)	0	0 (0.00)
Skin irritation	1	1 (4.00)	0	0 (0.00)
Vascular disorders				
- Total	13	11 (44.00)	5	5 (20.00)
Hypotension	7	5 (20.00)	5	5 (20.00)
Hypertension	3	3 (12.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Orthostatic hypotension	2	2 (8.00)	0	0 (0.00)
Secondary hypertension	1	1 (4.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Total number of AE per patient	1082	39 (100.00)	335	35 (89.74)
Blood and lymphatic system disorders				
- Total	83	28 (71.79)	60	24 (61.54)
Anaemia	30	16 (41.03)	20	13 (33.33)
Thrombocytopenia	23	8 (20.51)	15	7 (17.95)
Febrile neutropenia	11	8 (20.51)	11	8 (20.51)
Neutropenia	11	8 (20.51)	10	8 (20.51)
Disseminated intravascular coagulation	3	2 (5.13)	1	1 (2.56)
Lymphopenia	2	2 (5.13)	1	1 (2.56)
Coagulopathy	1	1 (2.56)	0	0 (0.00)
Leukopenia	1	1 (2.56)	1	1 (2.56)
Pancytopenia	1	1 (2.56)	1	1 (2.56)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Cardiac disorders				
- Total	22	14 (35.90)	3	2 (5.13)
Tachycardia	10	8 (20.51)	2	2 (5.13)
Sinus tachycardia	4	4 (10.26)	0	0 (0.00)
Pericardial effusion	2	2 (5.13)	0	0 (0.00)
Sinus bradycardia	2	1 (2.56)	0	0 (0.00)
Atrioventricular block second degree	1	1 (2.56)	0	0 (0.00)
Bradycardia	1	1 (2.56)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.56)	1	1 (2.56)
Palpitations	1	1 (2.56)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	4	4 (10.26)	0	0 (0.00)
Ear pain	2	2 (5.13)	0	0 (0.00)
Hypoacusis	1	1 (2.56)	0	0 (0.00)
Tympanic membrane perforation	1	1 (2.56)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.56)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.56)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Eye disorders				
- Total	20	12 (30.77)	0	0 (0.00)
Periorbital oedema	3	3 (7.69)	0	0 (0.00)
Photophobia	3	2 (5.13)	0	0 (0.00)
Vision blurred	3	3 (7.69)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (5.13)	0	0 (0.00)
Eye pain	2	2 (5.13)	0	0 (0.00)
Retinal haemorrhage	2	2 (5.13)	0	0 (0.00)
Uveitis	2	2 (5.13)	0	0 (0.00)
Ocular hypertension	1	1 (2.56)	0	0 (0.00)
Papilloedema	1	1 (2.56)	0	0 (0.00)
Visual impairment	1	1 (2.56)	0	0 (0.00)
Gastrointestinal disorders				
- Total	105	26 (66.67)	16	9 (23.08)
Vomiting	27	16 (41.03)	3	2 (5.13)
Nausea	21	15 (38.46)	4	4 (10.26)
Diarrhoea	19	16 (41.03)	1	1 (2.56)
Abdominal pain	11	7 (17.95)	2	1 (2.56)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Constipation	5	5 (12.82)	0	0 (0.00)
Abdominal pain upper	2	2 (5.13)	0	0 (0.00)
Anal incontinence	2	1 (2.56)	0	0 (0.00)
Haematemesis	2	2 (5.13)	0	0 (0.00)
Mouth haemorrhage	2	1 (2.56)	2	1 (2.56)
Stomatitis	2	2 (5.13)	0	0 (0.00)
Abdominal discomfort	1	1 (2.56)	0	0 (0.00)
Abdominal distension	1	1 (2.56)	0	0 (0.00)
Abdominal pain lower	1	1 (2.56)	0	0 (0.00)
Dyspepsia	1	1 (2.56)	0	0 (0.00)
Dysphagia	1	1 (2.56)	1	1 (2.56)
Gastrointestinal haemorrhage	1	1 (2.56)	0	0 (0.00)
Ileus	1	1 (2.56)	1	1 (2.56)
Intestinal obstruction	1	1 (2.56)	1	1 (2.56)
Lip pain	1	1 (2.56)	0	0 (0.00)
Oral pain	1	1 (2.56)	1	1 (2.56)
Pancreatitis	1	1 (2.56)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (2.56)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
General disorders and administration site conditions				
- Total	77	28 (71.79)	12	8 (20.51)
Pyrexia	30	18 (46.15)	5	5 (12.82)
Fatigue	13	12 (30.77)	1	1 (2.56)
Chills	6	6 (15.38)	0	0 (0.00)
Catheter site pain	3	3 (7.69)	0	0 (0.00)
Generalised oedema	3	2 (5.13)	0	0 (0.00)
Malaise	3	3 (7.69)	0	0 (0.00)
Pain	3	3 (7.69)	2	2 (5.13)
Face oedema	2	2 (5.13)	1	1 (2.56)
Oedema peripheral	2	2 (5.13)	1	1 (2.56)
Acquired gene mutation	1	1 (2.56)	0	0 (0.00)
Asthenia	1	1 (2.56)	0	0 (0.00)
Catheter site extravasation	1	1 (2.56)	0	0 (0.00)
Catheter site haemorrhage	1	1 (2.56)	0	0 (0.00)
Crying	1	1 (2.56)	0	0 (0.00)
Facial pain	1	1 (2.56)	0	0 (0.00)
Injection site haematoma	1	1 (2.56)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Localised oedema	1	1 (2.56)	1	1 (2.56)
Mucosal haemorrhage	1	1 (2.56)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.56)	1	1 (2.56)
Non-cardiac chest pain	1	1 (2.56)	0	0 (0.00)
Peripheral swelling	1	1 (2.56)	0	0 (0.00)
Hepatobiliary disorders				
- Total	8	6 (15.38)	2	2 (5.13)
Hyperbilirubinaemia	4	3 (7.69)	2	2 (5.13)
Hepatomegaly	3	3 (7.69)	0	0 (0.00)
Hepatosplenomegaly	1	1 (2.56)	0	0 (0.00)
Immune system disorders				
- Total	80	34 (87.18)	25	15 (38.46)
Cytokine release syndrome	56	30 (76.92)	21	13 (33.33)
Hypogammaglobulinaemia	19	18 (46.15)	4	4 (10.26)
Graft versus host disease	2	1 (2.56)	0	0 (0.00)
Chronic graft versus host disease	1	1 (2.56)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (2.56)	0	0 (0.00)
Seasonal allergy	1	1 (2.56)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Infections and infestations				
- Total	79	28 (71.79)	20	13 (33.33)
Upper respiratory tract infection	8	5 (12.82)	1	1 (2.56)
Rhinovirus infection	6	4 (10.26)	0	0 (0.00)
Clostridium difficile colitis	4	4 (10.26)	1	1 (2.56)
Pneumonia	4	4 (10.26)	1	1 (2.56)
Sinusitis	4	3 (7.69)	0	0 (0.00)
Clostridium difficile infection	3	3 (7.69)	1	1 (2.56)
Gastroenteritis	3	3 (7.69)	1	1 (2.56)
Otitis media	3	1 (2.56)	1	1 (2.56)
Otitis media acute	3	1 (2.56)	0	0 (0.00)
Viral infection	2	2 (5.13)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (5.13)	0	0 (0.00)
Vulvovaginal candidiasis	2	2 (5.13)	0	0 (0.00)
Acute sinusitis	1	1 (2.56)	0	0 (0.00)
Bacterial sepsis	1	1 (2.56)	1	1 (2.56)
Body tinea	1	1 (2.56)	0	0 (0.00)
Campylobacter infection	1	1 (2.56)	1	1 (2.56)
Catheter site cellulitis	1	1 (2.56)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Catheter site infection	1	1 (2.56)	1	1 (2.56)
Cholecystitis infective	1	1 (2.56)	1	1 (2.56)
Ear infection	1	1 (2.56)	0	0 (0.00)
Enterovirus infection	1	1 (2.56)	1	1 (2.56)
Folliculitis	1	1 (2.56)	0	0 (0.00)
Gastroenteritis viral	1	1 (2.56)	0	0 (0.00)
Gingivitis	1	1 (2.56)	0	0 (0.00)
Haemophilus infection	1	1 (2.56)	0	0 (0.00)
Herpes simplex	1	1 (2.56)	0	0 (0.00)
Herpes zoster	1	1 (2.56)	1	1 (2.56)
Human herpesvirus 6 infection	1	1 (2.56)	0	0 (0.00)
Hypopyon	1	1 (2.56)	0	0 (0.00)
Molluscum contagiosum	1	1 (2.56)	0	0 (0.00)
Oral candidiasis	1	1 (2.56)	0	0 (0.00)
Oral herpes	1	1 (2.56)	0	0 (0.00)
Orchitis	1	1 (2.56)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.56)	1	1 (2.56)
Pharyngitis	1	1 (2.56)	0	0 (0.00)
Rash pustular	1	1 (2.56)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Respiratory tract infection	1	1 (2.56)	1	1 (2.56)
Respiratory tract infection viral	1	1 (2.56)	1	1 (2.56)
Rhinitis	1	1 (2.56)	0	0 (0.00)
Rotavirus infection	1	1 (2.56)	1	1 (2.56)
Sepsis	1	1 (2.56)	1	1 (2.56)
Septic embolus	1	1 (2.56)	1	1 (2.56)
Staphylococcal infection	1	1 (2.56)	0	0 (0.00)
Streptococcal infection	1	1 (2.56)	0	0 (0.00)
Urinary tract infection	1	1 (2.56)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (2.56)	1	1 (2.56)
Vascular device infection	1	1 (2.56)	1	1 (2.56)
Injury, poisoning and procedural complications				
- Total	26	13 (33.33)	2	2 (5.13)
Transfusion reaction	4	3 (7.69)	0	0 (0.00)
Infusion related reaction	3	3 (7.69)	0	0 (0.00)
Contusion	2	2 (5.13)	0	0 (0.00)
Procedural pain	2	2 (5.13)	0	0 (0.00)
Tracheal haemorrhage	2	1 (2.56)	1	1 (2.56)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Foot fracture	1	1 (2.56)	0	0 (0.00)
Incision site pain	1	1 (2.56)	0	0 (0.00)
Limb injury	1	1 (2.56)	0	0 (0.00)
Mouth injury	1	1 (2.56)	0	0 (0.00)
Procedural complication	1	1 (2.56)	0	0 (0.00)
Procedural headache	1	1 (2.56)	0	0 (0.00)
Procedural nausea	1	1 (2.56)	0	0 (0.00)
Radius fracture	1	1 (2.56)	0	0 (0.00)
Stoma site irritation	1	1 (2.56)	0	0 (0.00)
Sunburn	1	1 (2.56)	0	0 (0.00)
Tibia fracture	1	1 (2.56)	0	0 (0.00)
Tongue injury	1	1 (2.56)	0	0 (0.00)
Transfusion related complication	1	1 (2.56)	1	1 (2.56)
Investigations				
- Total	229	34 (87.18)	101	29 (74.36)
White blood cell count decreased	30	18 (46.15)	16	14 (35.90)
Aspartate aminotransferase increased	27	15 (38.46)	14	9 (23.08)
Platelet count decreased	25	10 (25.64)	24	10 (25.64)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Neutrophil count decreased	23	13 (33.33)	17	11 (28.21)
Alanine aminotransferase increased	19	13 (33.33)	7	7 (17.95)
Prothrombin time prolonged	15	7 (17.95)	1	1 (2.56)
Lymphocyte count decreased	14	8 (20.51)	7	6 (15.38)
Blood bilirubin increased	11	6 (15.38)	3	3 (7.69)
Blood fibrinogen decreased	10	3 (7.69)	3	2 (5.13)
International normalised ratio increased	10	8 (20.51)	1	1 (2.56)
Blood creatinine increased	6	5 (12.82)	2	2 (5.13)
Activated partial thromboplastin time prolonged	4	2 (5.13)	0	0 (0.00)
Blood urea increased	4	2 (5.13)	1	1 (2.56)
Blood phosphorus increased	3	2 (5.13)	0	0 (0.00)
Blood uric acid increased	3	2 (5.13)	0	0 (0.00)
Transaminases increased	3	3 (7.69)	0	0 (0.00)
Weight decreased	3	3 (7.69)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (5.13)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (5.13)	0	0 (0.00)
Haemoglobin decreased	2	2 (5.13)	1	1 (2.56)
Blood bicarbonate decreased	1	1 (2.56)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Blood lactic acid increased	1	1 (2.56)	1	1 (2.56)
Blood magnesium decreased	1	1 (2.56)	1	1 (2.56)
Blood phosphorus decreased	1	1 (2.56)	0	0 (0.00)
Cardiac murmur	1	1 (2.56)	0	0 (0.00)
Culture stool positive	1	1 (2.56)	0	0 (0.00)
Hepatic enzyme increased	1	1 (2.56)	0	0 (0.00)
Lipase increased	1	1 (2.56)	1	1 (2.56)
Norovirus test positive	1	1 (2.56)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.56)	0	0 (0.00)
Protein total decreased	1	1 (2.56)	1	1 (2.56)
Serum ferritin increased	1	1 (2.56)	0	0 (0.00)
Weight increased	1	1 (2.56)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	85	26 (66.67)	33	18 (46.15)
Decreased appetite	17	14 (35.90)	10	9 (23.08)
Hypokalaemia	15	11 (28.21)	6	6 (15.38)
Hypophosphataemia	10	8 (20.51)	6	6 (15.38)
Hyperphosphataemia	4	4 (10.26)	0	0 (0.00)
Hypoalbuminaemia	4	4 (10.26)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Hypocalcaemia	4	3 (7.69)	1	1 (2.56)
Dehydration	3	3 (7.69)	3	3 (7.69)
Fluid overload	3	3 (7.69)	0	0 (0.00)
Hyperalbuminaemia	3	1 (2.56)	0	0 (0.00)
Hypercalcaemia	3	1 (2.56)	0	0 (0.00)
Hyperglycaemia	3	2 (5.13)	1	1 (2.56)
Hypernatraemia	3	2 (5.13)	0	0 (0.00)
Hyponatraemia	3	2 (5.13)	3	2 (5.13)
Hypertriglyceridaemia	2	1 (2.56)	1	1 (2.56)
Acidosis	1	1 (2.56)	1	1 (2.56)
Hyperchloraemia	1	1 (2.56)	0	0 (0.00)
Hypermagnesaemia	1	1 (2.56)	0	0 (0.00)
Hyperuricaemia	1	1 (2.56)	0	0 (0.00)
Malnutrition	1	1 (2.56)	1	1 (2.56)
Metabolic acidosis	1	1 (2.56)	0	0 (0.00)
Metabolic alkalosis	1	1 (2.56)	0	0 (0.00)
Vitamin D deficiency	1	1 (2.56)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
- Total	31	16 (41.03)	1	1 (2.56)
Pain in extremity	9	8 (20.51)	0	0 (0.00)
Myalgia	5	5 (12.82)	0	0 (0.00)
Arthralgia	4	3 (7.69)	1	1 (2.56)
Musculoskeletal pain	3	2 (5.13)	0	0 (0.00)
Coccydynia	1	1 (2.56)	0	0 (0.00)
Joint range of motion decreased	1	1 (2.56)	0	0 (0.00)
Limb discomfort	1	1 (2.56)	0	0 (0.00)
Muscle spasms	1	1 (2.56)	0	0 (0.00)
Muscular weakness	1	1 (2.56)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.56)	0	0 (0.00)
Neck pain	1	1 (2.56)	0	0 (0.00)
Osteonecrosis	1	1 (2.56)	0	0 (0.00)
Osteopenia	1	1 (2.56)	0	0 (0.00)
Pain in jaw	1	1 (2.56)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (2.56)	1	1 (2.56)
Glioblastoma multiforme	1	1 (2.56)	1	1 (2.56)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Nervous system disorders				
- Total	41	22 (56.41)	6	5 (12.82)
Headache	21	14 (35.90)	2	2 (5.13)
Dizziness	6	4 (10.26)	0	0 (0.00)
Encephalopathy	3	3 (7.69)	1	1 (2.56)
Peroneal nerve palsy	2	2 (5.13)	0	0 (0.00)
Seizure	2	2 (5.13)	2	2 (5.13)
Depressed level of consciousness	1	1 (2.56)	0	0 (0.00)
Disturbance in attention	1	1 (2.56)	0	0 (0.00)
Embolic stroke	1	1 (2.56)	1	1 (2.56)
Idiopathic intracranial hypertension	1	1 (2.56)	0	0 (0.00)
Migraine	1	1 (2.56)	0	0 (0.00)
Myoclonus	1	1 (2.56)	0	0 (0.00)
Tremor	1	1 (2.56)	0	0 (0.00)
Psychiatric disorders				
- Total	26	13 (33.33)	1	1 (2.56)
Anxiety	6	6 (15.38)	1	1 (2.56)
Confusional state	5	5 (12.82)	0	0 (0.00)
Delirium	3	3 (7.69)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Agitation	2	1 (2.56)	0	0 (0.00)
Hallucination	2	1 (2.56)	0	0 (0.00)
Irritability	2	2 (5.13)	0	0 (0.00)
Depression	1	1 (2.56)	0	0 (0.00)
Insomnia	1	1 (2.56)	0	0 (0.00)
Listless	1	1 (2.56)	0	0 (0.00)
Mental status changes	1	1 (2.56)	0	0 (0.00)
Panic attack	1	1 (2.56)	0	0 (0.00)
Sleep disorder	1	1 (2.56)	0	0 (0.00)
Renal and urinary disorders				
- Total	18	10 (25.64)	10	6 (15.38)
Acute kidney injury	7	6 (15.38)	4	4 (10.26)
Haematuria	4	4 (10.26)	2	2 (5.13)
Oliguria	2	2 (5.13)	2	2 (5.13)
Dysuria	1	1 (2.56)	0	0 (0.00)
Pollakiuria	1	1 (2.56)	0	0 (0.00)
Renal failure	1	1 (2.56)	1	1 (2.56)
Renal impairment	1	1 (2.56)	1	1 (2.56)
Urinary incontinence	1	1 (2.56)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Reproductive system and breast disorders				
- Total	5	4 (10.26)	1	1 (2.56)
Oedema genital	2	1 (2.56)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (5.13)	0	0 (0.00)
Vaginal haemorrhage	1	1 (2.56)	1	1 (2.56)
Respiratory, thoracic and mediastinal disorders				
- Total	70	19 (48.72)	26	12 (30.77)
Cough	13	9 (23.08)	0	0 (0.00)
Hypoxia	12	9 (23.08)	8	7 (17.95)
Epistaxis	11	7 (17.95)	5	5 (12.82)
Pleural effusion	7	7 (17.95)	1	1 (2.56)
Pulmonary oedema	4	4 (10.26)	4	4 (10.26)
Dyspnoea	3	2 (5.13)	2	2 (5.13)
Oropharyngeal pain	3	3 (7.69)	0	0 (0.00)
Rhinitis allergic	3	2 (5.13)	0	0 (0.00)
Tachypnoea	3	2 (5.13)	1	1 (2.56)
Atelectasis	1	1 (2.56)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Dysphonia	1	1 (2.56)	0	0 (0.00)
Haemoptysis	1	1 (2.56)	1	1 (2.56)
Interstitial lung disease	1	1 (2.56)	1	1 (2.56)
Pharyngeal erythema	1	1 (2.56)	0	0 (0.00)
Pharyngeal lesion	1	1 (2.56)	1	1 (2.56)
Pharyngeal ulceration	1	1 (2.56)	0	0 (0.00)
Respiratory depression	1	1 (2.56)	0	0 (0.00)
Respiratory distress	1	1 (2.56)	1	1 (2.56)
Respiratory failure	1	1 (2.56)	1	1 (2.56)
Rhinorrhoea	1	1 (2.56)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	41	15 (38.46)	1	1 (2.56)
Rash	7	6 (15.38)	0	0 (0.00)
Erythema	5	4 (10.26)	0	0 (0.00)
Hyperhidrosis	5	4 (10.26)	0	0 (0.00)
Rash erythematous	3	2 (5.13)	0	0 (0.00)
Rash maculo-papular	3	3 (7.69)	1	1 (2.56)
Dry skin	2	2 (5.13)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Ingrowing nail	2	1 (2.56)	0	0 (0.00)
Petechiae	2	2 (5.13)	0	0 (0.00)
Pruritus	2	2 (5.13)	0	0 (0.00)
Acne	1	1 (2.56)	0	0 (0.00)
Alopecia	1	1 (2.56)	0	0 (0.00)
Dermatitis atopic	1	1 (2.56)	0	0 (0.00)
Livedo reticularis	1	1 (2.56)	0	0 (0.00)
Macule	1	1 (2.56)	0	0 (0.00)
Night sweats	1	1 (2.56)	0	0 (0.00)
Papule	1	1 (2.56)	0	0 (0.00)
Rash macular	1	1 (2.56)	0	0 (0.00)
Rash papular	1	1 (2.56)	0	0 (0.00)
Rash vesicular	1	1 (2.56)	0	0 (0.00)
Vascular disorders				
- Total	30	14 (35.90)	14	11 (28.21)
Hypotension	12	11 (28.21)	11	10 (25.64)
Hypertension	11	9 (23.08)	1	1 (2.56)
Flushing	3	2 (5.13)	0	0 (0.00)
Capillary leak syndrome	1	1 (2.56)	1	1 (2.56)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Embolism	1	1 (2.56)	1	1 (2.56)
Haematoma	1	1 (2.56)	0	0 (0.00)
Hot flush	1	1 (2.56)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Total number of AE per patient	140	7 (100.00)	58	6 (85.71)
Blood and lymphatic system disorders				
- Total	11	5 (71.43)	9	4 (57.14)
Anaemia	5	4 (57.14)	3	2 (28.57)
Febrile neutropenia	2	2 (28.57)	2	2 (28.57)
Neutropenia	2	2 (28.57)	2	2 (28.57)
Thrombocytopenia	2	2 (28.57)	2	2 (28.57)
Cardiac disorders				
- Total	5	3 (42.86)	2	1 (14.29)
Tachycardia	2	2 (28.57)	1	1 (14.29)
Left ventricular dysfunction	1	1 (14.29)	1	1 (14.29)
Palpitations	1	1 (14.29)	0	0 (0.00)
Pericardial effusion	1	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Eye disorders				
- Total	2	1 (14.29)	0	0 (0.00)
Eye pain	2	1 (14.29)	0	0 (0.00)
Gastrointestinal disorders				
- Total	13	4 (57.14)	1	1 (14.29)
Nausea	5	3 (42.86)	1	1 (14.29)
Vomiting	4	3 (42.86)	0	0 (0.00)
Diarrhoea	3	3 (42.86)	0	0 (0.00)
Constipation	1	1 (14.29)	0	0 (0.00)
General disorders and administration site conditions				
- Total	8	3 (42.86)	3	3 (42.86)
Pyrexia	5	3 (42.86)	2	2 (28.57)
Asthenia	1	1 (14.29)	0	0 (0.00)
Chills	1	1 (14.29)	0	0 (0.00)
Pain	1	1 (14.29)	1	1 (14.29)
Hepatobiliary disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Hepatomegaly	1	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Immune system disorders				
- Total	15	7 (100.00)	6	3 (42.86)
Cytokine release syndrome	11	5 (71.43)	6	3 (42.86)
Hypogammaglobulinaemia	4	4 (57.14)	0	0 (0.00)
Infections and infestations				
- Total	2	2 (28.57)	0	0 (0.00)
Gastroenteritis	1	1 (14.29)	0	0 (0.00)
Viral infection	1	1 (14.29)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	1 (14.29)	1	1 (14.29)
Tracheal haemorrhage	2	1 (14.29)	1	1 (14.29)
Investigations				
- Total	35	7 (100.00)	15	5 (71.43)
White blood cell count decreased	10	4 (57.14)	6	3 (42.86)
Neutrophil count decreased	9	4 (57.14)	7	3 (42.86)
Blood uric acid increased	2	1 (14.29)	0	0 (0.00)
International normalised ratio increased	2	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Lymphocyte count decreased	2	2 (28.57)	0	0 (0.00)
Activated partial thromboplastin time prolonged	1	1 (14.29)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (14.29)	1	1 (14.29)
Blood creatinine increased	1	1 (14.29)	0	0 (0.00)
Blood fibrinogen decreased	1	1 (14.29)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (14.29)	0	0 (0.00)
Blood magnesium decreased	1	1 (14.29)	1	1 (14.29)
Blood phosphorus increased	1	1 (14.29)	0	0 (0.00)
Cardiac murmur	1	1 (14.29)	0	0 (0.00)
Fibrin D dimer increased	1	1 (14.29)	0	0 (0.00)
Prothrombin time prolonged	1	1 (14.29)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	9	4 (57.14)	2	1 (14.29)
Decreased appetite	3	3 (42.86)	1	1 (14.29)
Hypokalaemia	3	2 (28.57)	0	0 (0.00)
Hypernatraemia	1	1 (14.29)	0	0 (0.00)
Hypoalbuminaemia	1	1 (14.29)	0	0 (0.00)
Hypophosphataemia	1	1 (14.29)	1	1 (14.29)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	1	1 (14.29)	1	1 (14.29)
Arthralgia	1	1 (14.29)	1	1 (14.29)
Nervous system disorders				
- Total	4	4 (57.14)	0	0 (0.00)
Headache	3	3 (42.86)	0	0 (0.00)
Dizziness	1	1 (14.29)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (42.86)	0	0 (0.00)
Confusional state	2	2 (28.57)	0	0 (0.00)
Delirium	1	1 (14.29)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	2 (28.57)	5	2 (28.57)
Haematuria	2	2 (28.57)	2	2 (28.57)
Acute kidney injury	1	1 (14.29)	1	1 (14.29)
Oliguria	1	1 (14.29)	1	1 (14.29)
Renal failure	1	1 (14.29)	1	1 (14.29)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	13	3 (42.86)	9	2 (28.57)
Hypoxia	4	2 (28.57)	3	2 (28.57)
Cough	2	2 (28.57)	0	0 (0.00)
Dyspnoea	1	1 (14.29)	1	1 (14.29)
Epistaxis	1	1 (14.29)	1	1 (14.29)
Haemoptysis	1	1 (14.29)	1	1 (14.29)
Interstitial lung disease	1	1 (14.29)	1	1 (14.29)
Pleural effusion	1	1 (14.29)	0	0 (0.00)
Pulmonary oedema	1	1 (14.29)	1	1 (14.29)
Respiratory failure	1	1 (14.29)	1	1 (14.29)
Skin and subcutaneous tissue disorders				
- Total	5	4 (57.14)	0	0 (0.00)
Dermatitis diaper	1	1 (14.29)	0	0 (0.00)
Dry skin	1	1 (14.29)	0	0 (0.00)
Erythema	1	1 (14.29)	0	0 (0.00)
Livedo reticularis	1	1 (14.29)	0	0 (0.00)
Rash maculo-papular	1	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Vascular disorders				
- Total	6	4 (57.14)	4	4 (57.14)
Hypotension	4	4 (57.14)	4	4 (57.14)
Haematoma	1	1 (14.29)	0	0 (0.00)
Hypertension	1	1 (14.29)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Total number of AE per patient	1174	56 (98.25)	400	48 (84.21)
Blood and lymphatic system disorders				
- Total	111	38 (66.67)	84	34 (59.65)
Anaemia	42	23 (40.35)	28	17 (29.82)
Thrombocytopenia	28	6 (10.53)	21	6 (10.53)
Febrile neutropenia	24	20 (35.09)	24	20 (35.09)
Neutropenia	7	6 (10.53)	6	6 (10.53)
Disseminated intravascular coagulation	5	4 (7.02)	2	2 (3.51)
Lymphopenia	3	3 (5.26)	2	2 (3.51)
Coagulopathy	1	1 (1.75)	0	0 (0.00)
Pancytopenia	1	1 (1.75)	1	1 (1.75)
Cardiac disorders				
- Total	27	19 (33.33)	1	1 (1.75)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Tachycardia	15	13 (22.81)	1	1 (1.75)
Sinus tachycardia	5	5 (8.77)	0	0 (0.00)
Sinus bradycardia	2	1 (1.75)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.75)	0	0 (0.00)
Bradycardia	1	1 (1.75)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.75)	0	0 (0.00)
Pericardial effusion	1	1 (1.75)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.75)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (5.26)	0	0 (0.00)
Ear pain	2	2 (3.51)	0	0 (0.00)
Hypoacusis	1	1 (1.75)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.75)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.75)	0	0 (0.00)
Eye disorders				
- Total	23	12 (21.05)	0	0 (0.00)
Periorbital oedema	4	4 (7.02)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Vision blurred	4	3 (5.26)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (5.26)	0	0 (0.00)
Photophobia	3	2 (3.51)	0	0 (0.00)
Eye pain	2	2 (3.51)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.51)	0	0 (0.00)
Uveitis	2	2 (3.51)	0	0 (0.00)
Ocular hypertension	1	1 (1.75)	0	0 (0.00)
Papilloedema	1	1 (1.75)	0	0 (0.00)
Visual impairment	1	1 (1.75)	0	0 (0.00)
Gastrointestinal disorders				
- Total	113	32 (56.14)	14	10 (17.54)
Vomiting	31	19 (33.33)	3	3 (5.26)
Nausea	21	18 (31.58)	2	2 (3.51)
Diarrhoea	15	15 (26.32)	1	1 (1.75)
Abdominal pain	10	9 (15.79)	1	1 (1.75)
Constipation	7	6 (10.53)	0	0 (0.00)
Abdominal distension	2	2 (3.51)	0	0 (0.00)
Abdominal pain upper	2	2 (3.51)	0	0 (0.00)
Anal incontinence	2	1 (1.75)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Dysphagia	2	2 (3.51)	1	1 (1.75)
Haematemesis	2	2 (3.51)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.75)	2	1 (1.75)
Pancreatitis	2	2 (3.51)	1	1 (1.75)
Stomatitis	2	2 (3.51)	0	0 (0.00)
Abdominal discomfort	1	1 (1.75)	0	0 (0.00)
Abdominal pain lower	1	1 (1.75)	0	0 (0.00)
Abdominal tenderness	1	1 (1.75)	0	0 (0.00)
Ascites	1	1 (1.75)	1	1 (1.75)
Dyspepsia	1	1 (1.75)	0	0 (0.00)
Flatulence	1	1 (1.75)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.75)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.75)	0	0 (0.00)
Glossodynia	1	1 (1.75)	0	0 (0.00)
Ileus	1	1 (1.75)	1	1 (1.75)
Intestinal obstruction	1	1 (1.75)	1	1 (1.75)
Lip pain	1	1 (1.75)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.75)	0	0 (0.00)
General disorders and administration site conditions				

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
- Total	69	29 (50.88)	11	7 (12.28)
Pyrexia	22	13 (22.81)	4	4 (7.02)
Fatigue	14	13 (22.81)	1	1 (1.75)
Chills	8	7 (12.28)	0	0 (0.00)
Catheter site pain	3	3 (5.26)	0	0 (0.00)
Generalised oedema	3	2 (3.51)	0	0 (0.00)
Malaise	3	3 (5.26)	0	0 (0.00)
Face oedema	2	2 (3.51)	1	1 (1.75)
Oedema peripheral	2	2 (3.51)	1	1 (1.75)
Pain	2	2 (3.51)	1	1 (1.75)
Catheter site extravasation	1	1 (1.75)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.75)	0	0 (0.00)
Facial pain	1	1 (1.75)	0	0 (0.00)
Injection site haematoma	1	1 (1.75)	0	0 (0.00)
Localised oedema	1	1 (1.75)	1	1 (1.75)
Mucosal haemorrhage	1	1 (1.75)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.75)	1	1 (1.75)
Non-cardiac chest pain	1	1 (1.75)	0	0 (0.00)
Peripheral swelling	1	1 (1.75)	0	0 (0.00)
Physical deconditioning	1	1 (1.75)	1	1 (1.75)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Hepatobiliary disorders				
- Total	8	6 (10.53)	2	2 (3.51)
Hyperbilirubinaemia	4	3 (5.26)	2	2 (3.51)
Hepatomegaly	2	2 (3.51)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.75)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.75)	0	0 (0.00)
Immune system disorders				
- Total	101	50 (87.72)	27	19 (33.33)
Cytokine release syndrome	75	45 (78.95)	23	16 (28.07)
Hypogammaglobulinaemia	23	22 (38.60)	4	4 (7.02)
Drug hypersensitivity	1	1 (1.75)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.75)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.75)	0	0 (0.00)
Infections and infestations				
- Total	39	24 (42.11)	7	7 (12.28)
Clostridium difficile colitis	4	4 (7.02)	1	1 (1.75)
Clostridium difficile infection	4	4 (7.02)	0	0 (0.00)
Rhinovirus infection	3	3 (5.26)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Pneumonia	2	2 (3.51)	1	1 (1.75)
Staphylococcal infection	2	2 (3.51)	1	1 (1.75)
Acute sinusitis	1	1 (1.75)	0	0 (0.00)
Body tinea	1	1 (1.75)	0	0 (0.00)
Catheter site cellulitis	1	1 (1.75)	0	0 (0.00)
Catheter site infection	1	1 (1.75)	1	1 (1.75)
Cytomegalovirus infection	1	1 (1.75)	0	0 (0.00)
Enterococcal infection	1	1 (1.75)	0	0 (0.00)
Folliculitis	1	1 (1.75)	0	0 (0.00)
Fungal skin infection	1	1 (1.75)	0	0 (0.00)
Gastroenteritis	1	1 (1.75)	1	1 (1.75)
Gastroenteritis norovirus	1	1 (1.75)	0	0 (0.00)
Herpes simplex	1	1 (1.75)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (1.75)	0	0 (0.00)
Hypopyon	1	1 (1.75)	0	0 (0.00)
Influenza	1	1 (1.75)	0	0 (0.00)
Oral candidiasis	1	1 (1.75)	0	0 (0.00)
Orchitis	1	1 (1.75)	0	0 (0.00)
Pharyngitis	1	1 (1.75)	0	0 (0.00)
Septic embolus	1	1 (1.75)	1	1 (1.75)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Skin infection	1	1 (1.75)	0	0 (0.00)
Streptococcal infection	1	1 (1.75)	0	0 (0.00)
Upper respiratory tract infection	1	1 (1.75)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.75)	1	1 (1.75)
Viral upper respiratory tract infection	1	1 (1.75)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (1.75)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	23	14 (24.56)	1	1 (1.75)
Transfusion reaction	4	3 (5.26)	0	0 (0.00)
Procedural pain	3	3 (5.26)	0	0 (0.00)
Infusion related reaction	2	2 (3.51)	0	0 (0.00)
Contusion	1	1 (1.75)	0	0 (0.00)
Incision site pain	1	1 (1.75)	0	0 (0.00)
Limb injury	1	1 (1.75)	0	0 (0.00)
Mouth injury	1	1 (1.75)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.75)	0	0 (0.00)
Procedural complication	1	1 (1.75)	0	0 (0.00)
Procedural headache	1	1 (1.75)	0	0 (0.00)
Procedural site reaction	1	1 (1.75)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Skin abrasion	1	1 (1.75)	0	0 (0.00)
Stoma site irritation	1	1 (1.75)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.75)	0	0 (0.00)
Tibia fracture	1	1 (1.75)	0	0 (0.00)
Tongue injury	1	1 (1.75)	0	0 (0.00)
Transfusion related complication	1	1 (1.75)	1	1 (1.75)
Investigations				
- Total	297	45 (78.95)	163	39 (68.42)
White blood cell count decreased	45	26 (45.61)	31	23 (40.35)
Platelet count decreased	43	19 (33.33)	37	14 (24.56)
Neutrophil count decreased	38	21 (36.84)	37	20 (35.09)
Aspartate aminotransferase increased	31	17 (29.82)	15	10 (17.54)
Alanine aminotransferase increased	28	19 (33.33)	14	11 (19.30)
Prothrombin time prolonged	16	8 (14.04)	1	1 (1.75)
Blood fibrinogen decreased	14	3 (5.26)	4	3 (5.26)
Lymphocyte count decreased	14	12 (21.05)	12	11 (19.30)
Blood bilirubin increased	13	7 (12.28)	2	2 (3.51)
Blood creatinine increased	10	8 (14.04)	2	2 (3.51)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
International normalised ratio increased	9	8 (14.04)	1	1 (1.75)
Activated partial thromboplastin time prolonged	7	4 (7.02)	0	0 (0.00)
Blood immunoglobulin A decreased	3	3 (5.26)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (5.26)	0	0 (0.00)
Blood urea increased	3	3 (5.26)	1	1 (1.75)
Blood phosphorus increased	2	1 (1.75)	0	0 (0.00)
Blood sodium increased	2	1 (1.75)	0	0 (0.00)
Lipase increased	2	2 (3.51)	2	2 (3.51)
Transaminases increased	2	2 (3.51)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.75)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.75)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.75)	1	1 (1.75)
Blood phosphorus decreased	1	1 (1.75)	0	0 (0.00)
C-reactive protein increased	1	1 (1.75)	1	1 (1.75)
Culture stool positive	1	1 (1.75)	0	0 (0.00)
Haemoglobin decreased	1	1 (1.75)	1	1 (1.75)
Hepatic enzyme increased	1	1 (1.75)	0	0 (0.00)
Norovirus test positive	1	1 (1.75)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Protein total decreased	1	1 (1.75)	1	1 (1.75)
Pulmonary function test decreased	1	1 (1.75)	0	0 (0.00)
Serum ferritin increased	1	1 (1.75)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	107	35 (61.40)	41	23 (40.35)
Decreased appetite	21	17 (29.82)	12	11 (19.30)
Hypokalaemia	17	14 (24.56)	7	7 (12.28)
Hypophosphataemia	12	8 (14.04)	8	6 (10.53)
Hyperphosphataemia	10	8 (14.04)	0	0 (0.00)
Hypernatraemia	6	3 (5.26)	1	1 (1.75)
Hypoalbuminaemia	5	4 (7.02)	1	1 (1.75)
Hyperglycaemia	4	3 (5.26)	1	1 (1.75)
Hyperuricaemia	4	3 (5.26)	1	1 (1.75)
Hypocalcaemia	4	3 (5.26)	1	1 (1.75)
Dehydration	3	3 (5.26)	2	2 (3.51)
Fluid overload	3	3 (5.26)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.51)	1	1 (1.75)
Hyponatraemia	3	2 (3.51)	3	2 (3.51)
Acidosis	2	2 (3.51)	1	1 (1.75)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Hypercalcaemia	2	1 (1.75)	0	0 (0.00)
Hyperalbuminaemia	1	1 (1.75)	0	0 (0.00)
Hyperchloraemia	1	1 (1.75)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.75)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.75)	0	0 (0.00)
Malnutrition	1	1 (1.75)	1	1 (1.75)
Metabolic acidosis	1	1 (1.75)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.75)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.75)	1	1 (1.75)
Musculoskeletal and connective tissue disorders				
- Total	22	14 (24.56)	0	0 (0.00)
Myalgia	5	5 (8.77)	0	0 (0.00)
Musculoskeletal pain	4	3 (5.26)	0	0 (0.00)
Pain in extremity	4	4 (7.02)	0	0 (0.00)
Arthralgia	3	3 (5.26)	0	0 (0.00)
Coccydynia	1	1 (1.75)	0	0 (0.00)
Limb discomfort	1	1 (1.75)	0	0 (0.00)
Muscle spasms	1	1 (1.75)	0	0 (0.00)
Muscular weakness	1	1 (1.75)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Musculoskeletal chest pain	1	1 (1.75)	0	0 (0.00)
Osteopenia	1	1 (1.75)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.75)	0	0 (0.00)
Skin papilloma	1	1 (1.75)	0	0 (0.00)
Nervous system disorders				
- Total	54	29 (50.88)	6	5 (8.77)
Headache	28	21 (36.84)	2	2 (3.51)
Encephalopathy	6	4 (7.02)	2	2 (3.51)
Dizziness	3	3 (5.26)	0	0 (0.00)
Seizure	3	3 (5.26)	1	1 (1.75)
Dysarthria	2	2 (3.51)	0	0 (0.00)
Tremor	2	2 (3.51)	0	0 (0.00)
Asterixis	1	1 (1.75)	0	0 (0.00)
Ataxia	1	1 (1.75)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.75)	0	0 (0.00)
Embolic stroke	1	1 (1.75)	1	1 (1.75)
Idiopathic intracranial hypertension	1	1 (1.75)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Migraine	1	1 (1.75)	0	0 (0.00)
Myoclonus	1	1 (1.75)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.75)	0	0 (0.00)
Pleocytosis	1	1 (1.75)	0	0 (0.00)
Somnolence	1	1 (1.75)	0	0 (0.00)
Product issues				
- Total	1	1 (1.75)	0	0 (0.00)
Device occlusion	1	1 (1.75)	0	0 (0.00)
Psychiatric disorders				
- Total	27	13 (22.81)	1	1 (1.75)
Anxiety	6	6 (10.53)	1	1 (1.75)
Confusional state	4	4 (7.02)	0	0 (0.00)
Agitation	3	2 (3.51)	0	0 (0.00)
Delirium	3	3 (5.26)	0	0 (0.00)
Hallucination	3	2 (3.51)	0	0 (0.00)
Irritability	2	2 (3.51)	0	0 (0.00)
Adjustment disorder	1	1 (1.75)	0	0 (0.00)
Insomnia	1	1 (1.75)	0	0 (0.00)
Listless	1	1 (1.75)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Mental status changes	1	1 (1.75)	0	0 (0.00)
Panic attack	1	1 (1.75)	0	0 (0.00)
Suicidal ideation	1	1 (1.75)	0	0 (0.00)
Renal and urinary disorders				
- Total	13	9 (15.79)	6	5 (8.77)
Acute kidney injury	6	6 (10.53)	4	4 (7.02)
Dysuria	2	2 (3.51)	0	0 (0.00)
Haematuria	2	2 (3.51)	0	0 (0.00)
Oliguria	1	1 (1.75)	1	1 (1.75)
Pollakiuria	1	1 (1.75)	0	0 (0.00)
Renal impairment	1	1 (1.75)	1	1 (1.75)
Reproductive system and breast disorders				
- Total	4	3 (5.26)	0	0 (0.00)
Oedema genital	2	1 (1.75)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.51)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	60	25 (43.86)	19	10 (17.54)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Epistaxis	10	6 (10.53)	3	3 (5.26)
Hypoxia	9	8 (14.04)	5	5 (8.77)
Pleural effusion	7	7 (12.28)	2	2 (3.51)
Cough	6	6 (10.53)	0	0 (0.00)
Tachypnoea	6	5 (8.77)	1	1 (1.75)
Pulmonary oedema	5	5 (8.77)	4	4 (7.02)
Dyspnoea	2	1 (1.75)	1	1 (1.75)
Haemoptysis	2	1 (1.75)	0	0 (0.00)
Oropharyngeal pain	2	2 (3.51)	0	0 (0.00)
Respiratory failure	2	2 (3.51)	2	2 (3.51)
Atelectasis	1	1 (1.75)	0	0 (0.00)
Nasal congestion	1	1 (1.75)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.75)	0	0 (0.00)
Pharyngeal ulceration	1	1 (1.75)	0	0 (0.00)
Respiratory depression	1	1 (1.75)	0	0 (0.00)
Respiratory distress	1	1 (1.75)	1	1 (1.75)
Rhinitis allergic	1	1 (1.75)	0	0 (0.00)
Rhinorrhoea	1	1 (1.75)	0	0 (0.00)
Wheezing	1	1 (1.75)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	36	17 (29.82)	2	2 (3.51)
Hyperhidrosis	4	3 (5.26)	0	0 (0.00)
Rash	4	4 (7.02)	0	0 (0.00)
Dry skin	3	3 (5.26)	0	0 (0.00)
Erythema	3	2 (3.51)	0	0 (0.00)
Ingrowing nail	3	2 (3.51)	0	0 (0.00)
Petechiae	3	3 (5.26)	0	0 (0.00)
Pruritus	2	2 (3.51)	0	0 (0.00)
Rash maculo-papular	2	2 (3.51)	1	1 (1.75)
Rash papular	2	2 (3.51)	0	0 (0.00)
Ecchymosis	1	1 (1.75)	1	1 (1.75)
Macule	1	1 (1.75)	0	0 (0.00)
Night sweats	1	1 (1.75)	0	0 (0.00)
Rash erythematous	1	1 (1.75)	0	0 (0.00)
Rash follicular	1	1 (1.75)	0	0 (0.00)
Rash macular	1	1 (1.75)	0	0 (0.00)
Rash vesicular	1	1 (1.75)	0	0 (0.00)
Skin exfoliation	1	1 (1.75)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Skin fissures	1	1 (1.75)	0	0 (0.00)
Skin irritation	1	1 (1.75)	0	0 (0.00)
Vascular disorders				
- Total	34	20 (35.09)	15	12 (21.05)
Hypotension	15	12 (21.05)	12	11 (19.30)
Hypertension	11	9 (15.79)	1	1 (1.75)
Flushing	3	2 (3.51)	0	0 (0.00)
Orthostatic hypotension	2	2 (3.51)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.75)	1	1 (1.75)
Embolism	1	1 (1.75)	1	1 (1.75)
Secondary hypertension	1	1 (1.75)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	59	4 (80.00)	7	2 (40.00)
Endocrine disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Adrenal insufficiency	1	1 (20.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	11	4 (80.00)	2	2 (40.00)
Oral pain	3	2 (40.00)	1	1 (20.00)
Vomiting	3	2 (40.00)	0	0 (0.00)
Diarrhoea	2	2 (40.00)	0	0 (0.00)
Abdominal pain	1	1 (20.00)	0	0 (0.00)
Enterocolitis	1	1 (20.00)	1	1 (20.00)
Nausea	1	1 (20.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
General disorders and administration site conditions				
- Total	3	3 (60.00)	0	0 (0.00)
Catheter site pain	1	1 (20.00)	0	0 (0.00)
Fatigue	1	1 (20.00)	0	0 (0.00)
Pyrexia	1	1 (20.00)	0	0 (0.00)
Immune system disorders				
- Total	2	1 (20.00)	0	0 (0.00)
Graft versus host disease	2	1 (20.00)	0	0 (0.00)
Infections and infestations				
- Total	10	4 (80.00)	2	1 (20.00)
Rhinovirus infection	3	1 (20.00)	0	0 (0.00)
Upper respiratory tract infection	2	2 (40.00)	0	0 (0.00)
Corona virus infection	1	1 (20.00)	1	1 (20.00)
Ear infection	1	1 (20.00)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (20.00)	1	1 (20.00)
Tinea capitis	1	1 (20.00)	0	0 (0.00)
Viral infection	1	1 (20.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Injury, poisoning and procedural complications				
- Total	4	1 (20.00)	0	0 (0.00)
Contusion	1	1 (20.00)	0	0 (0.00)
Infusion related reaction	1	1 (20.00)	0	0 (0.00)
Procedural nausea	1	1 (20.00)	0	0 (0.00)
Sunburn	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	3	2 (40.00)	1	1 (20.00)
Blood bilirubin increased	1	1 (20.00)	1	1 (20.00)
Blood magnesium decreased	1	1 (20.00)	0	0 (0.00)
Weight decreased	1	1 (20.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	5	3 (60.00)	0	0 (0.00)
Pain in extremity	2	2 (40.00)	0	0 (0.00)
Arthralgia	1	1 (20.00)	0	0 (0.00)
Muscular weakness	1	1 (20.00)	0	0 (0.00)
Pain in jaw	1	1 (20.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Nervous system disorders				
- Total	2	2 (40.00)	0	0 (0.00)
Headache	1	1 (20.00)	0	0 (0.00)
Peroneal nerve palsy	1	1 (20.00)	0	0 (0.00)
Psychiatric disorders				
- Total	3	1 (20.00)	0	0 (0.00)
Anxiety	1	1 (20.00)	0	0 (0.00)
Depression	1	1 (20.00)	0	0 (0.00)
Sleep disorder	1	1 (20.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	8	4 (80.00)	2	1 (20.00)
Rhinorrhoea	2	2 (40.00)	0	0 (0.00)
Cough	1	1 (20.00)	0	0 (0.00)
Epistaxis	1	1 (20.00)	1	1 (20.00)
Nasal congestion	1	1 (20.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (20.00)	0	0 (0.00)
Pharyngeal erythema	1	1 (20.00)	0	0 (0.00)
Pharyngeal lesion	1	1 (20.00)	1	1 (20.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	4	1 (20.00)	0	0 (0.00)
Rash erythematous	2	1 (20.00)	0	0 (0.00)
Alopecia	1	1 (20.00)	0	0 (0.00)
Erythema	1	1 (20.00)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (40.00)	0	0 (0.00)
Hypertension	2	2 (40.00)	0	0 (0.00)
Hot flush	1	1 (20.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Total number of AE per patient	287	42 (82.35)	64	24 (47.06)
Blood and lymphatic system disorders				
- Total	18	11 (21.57)	13	7 (13.73)
Neutropenia	6	4 (7.84)	6	4 (7.84)
Febrile neutropenia	3	3 (5.88)	3	3 (5.88)
Anaemia	2	2 (3.92)	1	1 (1.96)
Eosinophilia	2	1 (1.96)	1	1 (1.96)
Thrombocytopenia	2	2 (3.92)	1	1 (1.96)
Leukopenia	1	1 (1.96)	1	1 (1.96)
Lymphadenopathy	1	1 (1.96)	0	0 (0.00)
Lymphopenia	1	1 (1.96)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (1.96)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Sinus tachycardia	1	1 (1.96)	0	0 (0.00)
Eye disorders				
- Total	5	5 (9.80)	0	0 (0.00)
Dry eye	2	2 (3.92)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.96)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.96)	0	0 (0.00)
Vision blurred	1	1 (1.96)	0	0 (0.00)
Gastrointestinal disorders				
- Total	27	12 (23.53)	6	2 (3.92)
Vomiting	10	7 (13.73)	2	2 (3.92)
Diarrhoea	6	6 (11.76)	1	1 (1.96)
Nausea	6	5 (9.80)	2	2 (3.92)
Abdominal pain	3	3 (5.88)	1	1 (1.96)
Abdominal pain upper	1	1 (1.96)	0	0 (0.00)
Pigmentation lip	1	1 (1.96)	0	0 (0.00)
General disorders and administration site conditions				
- Total	23	14 (27.45)	1	1 (1.96)
Pyrexia	13	9 (17.65)	1	1 (1.96)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Influenza like illness	2	2 (3.92)	0	0 (0.00)
Acquired gene mutation	1	1 (1.96)	0	0 (0.00)
Chills	1	1 (1.96)	0	0 (0.00)
Crying	1	1 (1.96)	0	0 (0.00)
Fatigue	1	1 (1.96)	0	0 (0.00)
Generalised oedema	1	1 (1.96)	0	0 (0.00)
Malaise	1	1 (1.96)	0	0 (0.00)
Oedema peripheral	1	1 (1.96)	0	0 (0.00)
Pain	1	1 (1.96)	0	0 (0.00)
Immune system disorders				
- Total	15	13 (25.49)	1	1 (1.96)
Hypogammaglobulinaemia	9	8 (15.69)	1	1 (1.96)
Immunodeficiency common variable	2	2 (3.92)	0	0 (0.00)
Seasonal allergy	2	2 (3.92)	0	0 (0.00)
Graft versus host disease	1	1 (1.96)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.96)	0	0 (0.00)
Infections and infestations				
- Total	51	29 (56.86)	15	11 (21.57)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Cellulitis of male external genital organ	5	1 (1.96)	2	1 (1.96)
Upper respiratory tract infection	5	5 (9.80)	1	1 (1.96)
Urinary tract infection	5	4 (7.84)	2	2 (3.92)
Gastroenteritis	3	3 (5.88)	0	0 (0.00)
Influenza	3	3 (5.88)	0	0 (0.00)
Otitis media	2	1 (1.96)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.92)	1	1 (1.96)
Sinusitis	2	2 (3.92)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (3.92)	1	1 (1.96)
Bacterial sepsis	1	1 (1.96)	1	1 (1.96)
Cholecystitis infective	1	1 (1.96)	1	1 (1.96)
Cytomegalovirus infection	1	1 (1.96)	0	0 (0.00)
Ear infection	1	1 (1.96)	0	0 (0.00)
Enterovirus infection	1	1 (1.96)	1	1 (1.96)
Escherichia urinary tract infection	1	1 (1.96)	1	1 (1.96)
Gastroenteritis norovirus	1	1 (1.96)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.96)	0	0 (0.00)
Herpes zoster	1	1 (1.96)	1	1 (1.96)
Molluscum contagiosum	1	1 (1.96)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Oral herpes	1	1 (1.96)	0	0 (0.00)
Otitis externa	1	1 (1.96)	0	0 (0.00)
Otitis media acute	1	1 (1.96)	0	0 (0.00)
Paronychia	1	1 (1.96)	0	0 (0.00)
Rash pustular	1	1 (1.96)	0	0 (0.00)
Rhinitis	1	1 (1.96)	0	0 (0.00)
Rhinovirus infection	1	1 (1.96)	0	0 (0.00)
Rotavirus infection	1	1 (1.96)	1	1 (1.96)
Sepsis	1	1 (1.96)	1	1 (1.96)
Subcutaneous abscess	1	1 (1.96)	0	0 (0.00)
Vascular device infection	1	1 (1.96)	1	1 (1.96)
Vulvovaginal mycotic infection	1	1 (1.96)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	9	7 (13.73)	0	0 (0.00)
Procedural pain	2	2 (3.92)	0	0 (0.00)
Arthropod bite	1	1 (1.96)	0	0 (0.00)
Contusion	1	1 (1.96)	0	0 (0.00)
Foot fracture	1	1 (1.96)	0	0 (0.00)
Infusion related reaction	1	1 (1.96)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Radius fracture	1	1 (1.96)	0	0 (0.00)
Skin abrasion	1	1 (1.96)	0	0 (0.00)
Skin laceration	1	1 (1.96)	0	0 (0.00)
Investigations				
- Total	45	21 (41.18)	15	11 (21.57)
Neutrophil count decreased	12	8 (15.69)	8	6 (11.76)
White blood cell count decreased	7	5 (9.80)	3	2 (3.92)
Platelet count decreased	5	3 (5.88)	0	0 (0.00)
Aspartate aminotransferase increased	3	3 (5.88)	2	2 (3.92)
Weight decreased	3	3 (5.88)	0	0 (0.00)
Alanine aminotransferase increased	2	2 (3.92)	2	2 (3.92)
Blood urea increased	2	1 (1.96)	0	0 (0.00)
Haemoglobin decreased	2	2 (3.92)	0	0 (0.00)
Lymphocyte count decreased	2	2 (3.92)	0	0 (0.00)
Weight increased	2	2 (3.92)	0	0 (0.00)
Blood creatinine increased	1	1 (1.96)	0	0 (0.00)
Blood uric acid increased	1	1 (1.96)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.96)	0	0 (0.00)
Serum ferritin increased	1	1 (1.96)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Transaminases increased	1	1 (1.96)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	15	10 (19.61)	6	4 (7.84)
Decreased appetite	2	2 (3.92)	0	0 (0.00)
Hyperalbuminaemia	2	1 (1.96)	0	0 (0.00)
Hyperphosphataemia	2	2 (3.92)	0	0 (0.00)
Hypokalaemia	2	2 (3.92)	1	1 (1.96)
Dehydration	1	1 (1.96)	1	1 (1.96)
Hypercalcaemia	1	1 (1.96)	0	0 (0.00)
Hyperglycaemia	1	1 (1.96)	1	1 (1.96)
Hypophosphataemia	1	1 (1.96)	1	1 (1.96)
Iron overload	1	1 (1.96)	1	1 (1.96)
Tumour lysis syndrome	1	1 (1.96)	1	1 (1.96)
Vitamin D deficiency	1	1 (1.96)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	16	13 (25.49)	0	0 (0.00)
Pain in extremity	6	6 (11.76)	0	0 (0.00)
Joint range of motion decreased	2	2 (3.92)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Arthralgia	1	1 (1.96)	0	0 (0.00)
Back pain	1	1 (1.96)	0	0 (0.00)
Flank pain	1	1 (1.96)	0	0 (0.00)
Muscle spasms	1	1 (1.96)	0	0 (0.00)
Muscular weakness	1	1 (1.96)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.96)	0	0 (0.00)
Osteonecrosis	1	1 (1.96)	0	0 (0.00)
Toe walking	1	1 (1.96)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.96)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.96)	0	0 (0.00)
Nervous system disorders				
- Total	10	6 (11.76)	0	0 (0.00)
Headache	6	4 (7.84)	0	0 (0.00)
Dizziness	3	3 (5.88)	0	0 (0.00)
Peroneal nerve palsy	1	1 (1.96)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (1.96)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Depression	1	1 (1.96)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	3 (5.88)	3	2 (3.92)
Acute kidney injury	1	1 (1.96)	1	1 (1.96)
Calculus urinary	1	1 (1.96)	0	0 (0.00)
Haematuria	1	1 (1.96)	1	1 (1.96)
Nephrolithiasis	1	1 (1.96)	1	1 (1.96)
Urinary incontinence	1	1 (1.96)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	2 (3.92)	1	1 (1.96)
Scrotal pain	1	1 (1.96)	0	0 (0.00)
Vaginal haemorrhage	1	1 (1.96)	1	1 (1.96)
Respiratory, thoracic and mediastinal disorders				
- Total	22	14 (27.45)	2	2 (3.92)
Cough	8	6 (11.76)	0	0 (0.00)
Nasal congestion	3	3 (5.88)	0	0 (0.00)
Rhinitis allergic	3	3 (5.88)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Oropharyngeal pain	2	2 (3.92)	0	0 (0.00)
Rhinorrhoea	2	2 (3.92)	0	0 (0.00)
Acute respiratory failure	1	1 (1.96)	1	1 (1.96)
Dysphonia	1	1 (1.96)	0	0 (0.00)
Epistaxis	1	1 (1.96)	0	0 (0.00)
Pulmonary oedema	1	1 (1.96)	1	1 (1.96)
Skin and subcutaneous tissue disorders				
- Total	21	15 (29.41)	1	1 (1.96)
Rash	5	4 (7.84)	0	0 (0.00)
Rash maculo-papular	2	2 (3.92)	0	0 (0.00)
Dermatitis	1	1 (1.96)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.96)	1	1 (1.96)
Dermatitis atopic	1	1 (1.96)	0	0 (0.00)
Dry skin	1	1 (1.96)	0	0 (0.00)
Eczema	1	1 (1.96)	0	0 (0.00)
Erythema	1	1 (1.96)	0	0 (0.00)
Hyperhidrosis	1	1 (1.96)	0	0 (0.00)
Ingrowing nail	1	1 (1.96)	0	0 (0.00)
Keloid scar	1	1 (1.96)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Macule	1	1 (1.96)	0	0 (0.00)
Papule	1	1 (1.96)	0	0 (0.00)
Petechiae	1	1 (1.96)	0	0 (0.00)
Pruritus	1	1 (1.96)	0	0 (0.00)
Rash pruritic	1	1 (1.96)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	2	2 (40.00)	1	1 (20.00)
Infections and infestations				
- Total	1	1 (20.00)	0	0 (0.00)
Skin infection	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	1	1 (20.00)	1	1 (20.00)
White blood cell count decreased	1	1 (20.00)	1	1 (20.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Total number of AE per patient	88	20 (68.97)	22	11 (37.93)
Blood and lymphatic system disorders				
- Total	2	2 (6.90)	1	1 (3.45)
Febrile neutropenia	1	1 (3.45)	1	1 (3.45)
Thrombocytopenia	1	1 (3.45)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.45)	0	0 (0.00)
Tympanic membrane perforation	1	1 (3.45)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	3 (10.34)	0	0 (0.00)
Diarrhoea	2	2 (6.90)	0	0 (0.00)
Abdominal pain	1	1 (3.45)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Nausea	1	1 (3.45)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	2 (6.90)	1	1 (3.45)
Pyrexia	2	1 (3.45)	0	0 (0.00)
Chills	1	1 (3.45)	0	0 (0.00)
Cyst	1	1 (3.45)	1	1 (3.45)
Immune system disorders				
- Total	2	2 (6.90)	0	0 (0.00)
Chronic graft versus host disease	1	1 (3.45)	0	0 (0.00)
Immunodeficiency	1	1 (3.45)	0	0 (0.00)
Infections and infestations				
- Total	31	10 (34.48)	7	4 (13.79)
Otitis media	5	3 (10.34)	1	1 (3.45)
Otitis media acute	4	2 (6.90)	0	0 (0.00)
Upper respiratory tract infection	4	2 (6.90)	0	0 (0.00)
Sinusitis	3	3 (10.34)	0	0 (0.00)
Urinary tract infection	3	2 (6.90)	1	1 (3.45)
Pneumonia	2	2 (6.90)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Campylobacter infection	1	1 (3.45)	1	1 (3.45)
Cellulitis of male external genital organ	1	1 (3.45)	1	1 (3.45)
Clostridium difficile infection	1	1 (3.45)	1	1 (3.45)
Gingivitis	1	1 (3.45)	0	0 (0.00)
Haemophilus infection	1	1 (3.45)	0	0 (0.00)
Meningitis aseptic	1	1 (3.45)	0	0 (0.00)
Respiratory tract infection	1	1 (3.45)	1	1 (3.45)
Respiratory tract infection viral	1	1 (3.45)	1	1 (3.45)
Viral infection	1	1 (3.45)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (3.45)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (3.45)	1	1 (3.45)
Procedural pain	1	1 (3.45)	1	1 (3.45)
Investigations				
- Total	21	7 (24.14)	7	4 (13.79)
Lymphocyte count decreased	5	3 (10.34)	1	1 (3.45)
White blood cell count decreased	4	3 (10.34)	2	2 (6.90)
Alanine aminotransferase increased	3	3 (10.34)	2	2 (6.90)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Neutrophil count decreased	3	2 (6.90)	0	0 (0.00)
Aspartate aminotransferase increased	2	2 (6.90)	1	1 (3.45)
Blood alkaline phosphatase increased	1	1 (3.45)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (3.45)	0	0 (0.00)
C-reactive protein increased	1	1 (3.45)	0	0 (0.00)
Platelet count decreased	1	1 (3.45)	1	1 (3.45)
Metabolism and nutrition disorders				
- Total	2	2 (6.90)	1	1 (3.45)
Hypokalaemia	1	1 (3.45)	1	1 (3.45)
Vitamin D deficiency	1	1 (3.45)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (3.45)	0	0 (0.00)
Neck pain	1	1 (3.45)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.45)	1	1 (3.45)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Glioblastoma multiforme	1	1 (3.45)	1	1 (3.45)
Nervous system disorders				
- Total	4	3 (10.34)	1	1 (3.45)
Disturbance in attention	1	1 (3.45)	0	0 (0.00)
Dizziness	1	1 (3.45)	0	0 (0.00)
Headache	1	1 (3.45)	0	0 (0.00)
Seizure	1	1 (3.45)	1	1 (3.45)
Renal and urinary disorders				
- Total	3	2 (6.90)	1	1 (3.45)
Acute kidney injury	2	1 (3.45)	1	1 (3.45)
Haematuria	1	1 (3.45)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.45)	1	1 (3.45)
Ovarian failure	1	1 (3.45)	1	1 (3.45)
Respiratory, thoracic and mediastinal disorders				
- Total	7	4 (13.79)	0	0 (0.00)
Cough	3	2 (6.90)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Epistaxis	1	1 (3.45)	0	0 (0.00)
Oropharyngeal pain	1	1 (3.45)	0	0 (0.00)
Rhinitis allergic	1	1 (3.45)	0	0 (0.00)
Rhinorrhoea	1	1 (3.45)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (10.34)	0	0 (0.00)
Acne	1	1 (3.45)	0	0 (0.00)
Papule	1	1 (3.45)	0	0 (0.00)
Pruritus	1	1 (3.45)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Total number of AE per patient	201	7 (100.00)	66	6 (85.71)
Blood and lymphatic system disorders				
- Total	11	5 (71.43)	9	4 (57.14)
Anaemia	5	4 (57.14)	3	2 (28.57)
Febrile neutropenia	2	2 (28.57)	2	2 (28.57)
Neutropenia	2	2 (28.57)	2	2 (28.57)
Thrombocytopenia	2	2 (28.57)	2	2 (28.57)
Cardiac disorders				
- Total	5	3 (42.86)	2	1 (14.29)
Tachycardia	2	2 (28.57)	1	1 (14.29)
Left ventricular dysfunction	1	1 (14.29)	1	1 (14.29)
Palpitations	1	1 (14.29)	0	0 (0.00)
Pericardial effusion	1	1 (14.29)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Endocrine disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Adrenal insufficiency	1	1 (14.29)	0	0 (0.00)
Eye disorders				
- Total	2	1 (14.29)	0	0 (0.00)
Eye pain	2	1 (14.29)	0	0 (0.00)
Gastrointestinal disorders				
- Total	24	6 (85.71)	3	3 (42.86)
Vomiting	7	5 (71.43)	0	0 (0.00)
Nausea	6	4 (57.14)	1	1 (14.29)
Diarrhoea	5	4 (57.14)	0	0 (0.00)
Oral pain	3	2 (28.57)	1	1 (14.29)
Abdominal pain	1	1 (14.29)	0	0 (0.00)
Constipation	1	1 (14.29)	0	0 (0.00)
Enterocolitis	1	1 (14.29)	1	1 (14.29)
General disorders and administration site conditions				
- Total	11	5 (71.43)	3	3 (42.86)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Pyrexia	6	4 (57.14)	2	2 (28.57)
Asthenia	1	1 (14.29)	0	0 (0.00)
Catheter site pain	1	1 (14.29)	0	0 (0.00)
Chills	1	1 (14.29)	0	0 (0.00)
Fatigue	1	1 (14.29)	0	0 (0.00)
Pain	1	1 (14.29)	1	1 (14.29)
Hepatobiliary disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Hepatomegaly	1	1 (14.29)	0	0 (0.00)
Immune system disorders				
- Total	17	7 (100.00)	6	3 (42.86)
Cytokine release syndrome	11	5 (71.43)	6	3 (42.86)
Hypogammaglobulinaemia	4	4 (57.14)	0	0 (0.00)
Graft versus host disease	2	1 (14.29)	0	0 (0.00)
Infections and infestations				
- Total	13	4 (57.14)	2	1 (14.29)
Rhinovirus infection	3	1 (14.29)	0	0 (0.00)
Upper respiratory tract infection	2	2 (28.57)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Viral infection	2	2 (28.57)	0	0 (0.00)
Corona virus infection	1	1 (14.29)	1	1 (14.29)
Ear infection	1	1 (14.29)	0	0 (0.00)
Gastroenteritis	1	1 (14.29)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (14.29)	1	1 (14.29)
Skin infection	1	1 (14.29)	0	0 (0.00)
Tinea capitis	1	1 (14.29)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	6	2 (28.57)	1	1 (14.29)
Tracheal haemorrhage	2	1 (14.29)	1	1 (14.29)
Contusion	1	1 (14.29)	0	0 (0.00)
Infusion related reaction	1	1 (14.29)	0	0 (0.00)
Procedural nausea	1	1 (14.29)	0	0 (0.00)
Sunburn	1	1 (14.29)	0	0 (0.00)
Investigations				
- Total	39	7 (100.00)	17	6 (85.71)
White blood cell count decreased	11	4 (57.14)	7	3 (42.86)
Neutrophil count decreased	9	4 (57.14)	7	3 (42.86)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Blood magnesium decreased	2	2 (28.57)	1	1 (14.29)
Blood uric acid increased	2	1 (14.29)	0	0 (0.00)
International normalised ratio increased	2	1 (14.29)	0	0 (0.00)
Lymphocyte count decreased	2	2 (28.57)	0	0 (0.00)
Activated partial thromboplastin time prolonged	1	1 (14.29)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (14.29)	1	1 (14.29)
Blood bilirubin increased	1	1 (14.29)	1	1 (14.29)
Blood creatinine increased	1	1 (14.29)	0	0 (0.00)
Blood fibrinogen decreased	1	1 (14.29)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (14.29)	0	0 (0.00)
Blood phosphorus increased	1	1 (14.29)	0	0 (0.00)
Cardiac murmur	1	1 (14.29)	0	0 (0.00)
Fibrin D dimer increased	1	1 (14.29)	0	0 (0.00)
Prothrombin time prolonged	1	1 (14.29)	0	0 (0.00)
Weight decreased	1	1 (14.29)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	9	4 (57.14)	2	1 (14.29)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Decreased appetite	3	3 (42.86)	1	1 (14.29)
Hypokalaemia	3	2 (28.57)	0	0 (0.00)
Hypernatraemia	1	1 (14.29)	0	0 (0.00)
Hypoalbuminaemia	1	1 (14.29)	0	0 (0.00)
Hypophosphataemia	1	1 (14.29)	1	1 (14.29)
Musculoskeletal and connective tissue disorders				
- Total	6	3 (42.86)	1	1 (14.29)
Arthralgia	2	1 (14.29)	1	1 (14.29)
Pain in extremity	2	2 (28.57)	0	0 (0.00)
Muscular weakness	1	1 (14.29)	0	0 (0.00)
Pain in jaw	1	1 (14.29)	0	0 (0.00)
Nervous system disorders				
- Total	6	4 (57.14)	0	0 (0.00)
Headache	4	3 (42.86)	0	0 (0.00)
Dizziness	1	1 (14.29)	0	0 (0.00)
Peroneal nerve palsy	1	1 (14.29)	0	0 (0.00)
Psychiatric disorders				
- Total	6	3 (42.86)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Confusional state	2	2 (28.57)	0	0 (0.00)
Anxiety	1	1 (14.29)	0	0 (0.00)
Delirium	1	1 (14.29)	0	0 (0.00)
Depression	1	1 (14.29)	0	0 (0.00)
Sleep disorder	1	1 (14.29)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	2 (28.57)	5	2 (28.57)
Haematuria	2	2 (28.57)	2	2 (28.57)
Acute kidney injury	1	1 (14.29)	1	1 (14.29)
Oliguria	1	1 (14.29)	1	1 (14.29)
Renal failure	1	1 (14.29)	1	1 (14.29)
Respiratory, thoracic and mediastinal disorders				
- Total	21	6 (85.71)	11	3 (42.86)
Hypoxia	4	2 (28.57)	3	2 (28.57)
Cough	3	3 (42.86)	0	0 (0.00)
Epistaxis	2	2 (28.57)	2	2 (28.57)
Rhinorrhoea	2	2 (28.57)	0	0 (0.00)
Dyspnoea	1	1 (14.29)	1	1 (14.29)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Haemoptysis	1	1 (14.29)	1	1 (14.29)
Interstitial lung disease	1	1 (14.29)	1	1 (14.29)
Nasal congestion	1	1 (14.29)	0	0 (0.00)
Oropharyngeal pain	1	1 (14.29)	0	0 (0.00)
Pharyngeal erythema	1	1 (14.29)	0	0 (0.00)
Pharyngeal lesion	1	1 (14.29)	1	1 (14.29)
Pleural effusion	1	1 (14.29)	0	0 (0.00)
Pulmonary oedema	1	1 (14.29)	1	1 (14.29)
Respiratory failure	1	1 (14.29)	1	1 (14.29)
Skin and subcutaneous tissue disorders				
- Total	9	4 (57.14)	0	0 (0.00)
Erythema	2	2 (28.57)	0	0 (0.00)
Rash erythematous	2	1 (14.29)	0	0 (0.00)
Alopecia	1	1 (14.29)	0	0 (0.00)
Dermatitis diaper	1	1 (14.29)	0	0 (0.00)
Dry skin	1	1 (14.29)	0	0 (0.00)
Livedo reticularis	1	1 (14.29)	0	0 (0.00)
Rash maculo-papular	1	1 (14.29)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Vascular disorders				
- Total	9	5 (71.43)	4	4 (57.14)
Hypotension	4	4 (57.14)	4	4 (57.14)
Hypertension	3	3 (42.86)	0	0 (0.00)
Haematoma	1	1 (14.29)	0	0 (0.00)
Hot flush	1	1 (14.29)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Total number of AE per patient	1549	57 (100.00)	486	53 (92.98)
Blood and lymphatic system disorders				
- Total	131	43 (75.44)	98	39 (68.42)
Anaemia	44	23 (40.35)	29	18 (31.58)
Thrombocytopenia	31	8 (14.04)	22	7 (12.28)
Febrile neutropenia	28	22 (38.60)	28	22 (38.60)
Neutropenia	13	9 (15.79)	12	9 (15.79)
Disseminated intravascular coagulation	5	4 (7.02)	2	2 (3.51)
Lymphopenia	4	4 (7.02)	2	2 (3.51)
Eosinophilia	2	1 (1.75)	1	1 (1.75)
Coagulopathy	1	1 (1.75)	0	0 (0.00)
Leukopenia	1	1 (1.75)	1	1 (1.75)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Lymphadenopathy	1	1 (1.75)	0	0 (0.00)
Pancytopenia	1	1 (1.75)	1	1 (1.75)
Cardiac disorders				
- Total	28	20 (35.09)	1	1 (1.75)
Tachycardia	15	13 (22.81)	1	1 (1.75)
Sinus tachycardia	6	6 (10.53)	0	0 (0.00)
Sinus bradycardia	2	1 (1.75)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.75)	0	0 (0.00)
Bradycardia	1	1 (1.75)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.75)	0	0 (0.00)
Pericardial effusion	1	1 (1.75)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.75)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	4	4 (7.02)	0	0 (0.00)
Ear pain	2	2 (3.51)	0	0 (0.00)
Hypoacusis	1	1 (1.75)	0	0 (0.00)
Tympanic membrane perforation	1	1 (1.75)	0	0 (0.00)
Endocrine disorders				

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
- Total	1	1 (1.75)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.75)	0	0 (0.00)
Eye disorders				
- Total	28	17 (29.82)	0	0 (0.00)
Vision blurred	5	4 (7.02)	0	0 (0.00)
Periorbital oedema	4	4 (7.02)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (5.26)	0	0 (0.00)
Photophobia	3	2 (3.51)	0	0 (0.00)
Dry eye	2	2 (3.51)	0	0 (0.00)
Eye pain	2	2 (3.51)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.51)	0	0 (0.00)
Uveitis	2	2 (3.51)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.75)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.75)	0	0 (0.00)
Ocular hypertension	1	1 (1.75)	0	0 (0.00)
Papilloedema	1	1 (1.75)	0	0 (0.00)
Visual impairment	1	1 (1.75)	0	0 (0.00)
Gastrointestinal disorders				
- Total	144	37 (64.91)	20	10 (17.54)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Vomiting	41	22 (38.60)	5	3 (5.26)
Nausea	28	21 (36.84)	4	4 (7.02)
Diarrhoea	23	20 (35.09)	2	2 (3.51)
Abdominal pain	14	10 (17.54)	2	1 (1.75)
Constipation	7	6 (10.53)	0	0 (0.00)
Abdominal pain upper	3	3 (5.26)	0	0 (0.00)
Abdominal distension	2	2 (3.51)	0	0 (0.00)
Anal incontinence	2	1 (1.75)	0	0 (0.00)
Dysphagia	2	2 (3.51)	1	1 (1.75)
Haematemesis	2	2 (3.51)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.75)	2	1 (1.75)
Pancreatitis	2	2 (3.51)	1	1 (1.75)
Stomatitis	2	2 (3.51)	0	0 (0.00)
Abdominal discomfort	1	1 (1.75)	0	0 (0.00)
Abdominal pain lower	1	1 (1.75)	0	0 (0.00)
Abdominal tenderness	1	1 (1.75)	0	0 (0.00)
Ascites	1	1 (1.75)	1	1 (1.75)
Dyspepsia	1	1 (1.75)	0	0 (0.00)
Flatulence	1	1 (1.75)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.75)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Gastrooesophageal reflux disease	1	1 (1.75)	0	0 (0.00)
Glossodynia	1	1 (1.75)	0	0 (0.00)
Ileus	1	1 (1.75)	1	1 (1.75)
Intestinal obstruction	1	1 (1.75)	1	1 (1.75)
Lip pain	1	1 (1.75)	0	0 (0.00)
Pigmentation lip	1	1 (1.75)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.75)	0	0 (0.00)
General disorders and administration site conditions				
- Total	96	37 (64.91)	13	9 (15.79)
Pyrexia	37	21 (36.84)	5	5 (8.77)
Fatigue	15	14 (24.56)	1	1 (1.75)
Chills	10	9 (15.79)	0	0 (0.00)
Generalised oedema	4	3 (5.26)	0	0 (0.00)
Malaise	4	4 (7.02)	0	0 (0.00)
Catheter site pain	3	3 (5.26)	0	0 (0.00)
Oedema peripheral	3	3 (5.26)	1	1 (1.75)
Pain	3	3 (5.26)	1	1 (1.75)
Face oedema	2	2 (3.51)	1	1 (1.75)
Influenza like illness	2	2 (3.51)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Acquired gene mutation	1	1 (1.75)	0	0 (0.00)
Catheter site extravasation	1	1 (1.75)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.75)	0	0 (0.00)
Crying	1	1 (1.75)	0	0 (0.00)
Cyst	1	1 (1.75)	1	1 (1.75)
Facial pain	1	1 (1.75)	0	0 (0.00)
Injection site haematoma	1	1 (1.75)	0	0 (0.00)
Localised oedema	1	1 (1.75)	1	1 (1.75)
Mucosal haemorrhage	1	1 (1.75)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.75)	1	1 (1.75)
Non-cardiac chest pain	1	1 (1.75)	0	0 (0.00)
Peripheral swelling	1	1 (1.75)	0	0 (0.00)
Physical deconditioning	1	1 (1.75)	1	1 (1.75)
Hepatobiliary disorders				
- Total	8	6 (10.53)	2	2 (3.51)
Hyperbilirubinaemia	4	3 (5.26)	2	2 (3.51)
Hepatomegaly	2	2 (3.51)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.75)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.75)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Immune system disorders				
- Total	118	51 (89.47)	28	19 (33.33)
Cytokine release syndrome	75	45 (78.95)	23	16 (28.07)
Hypogammaglobulinaemia	32	29 (50.88)	5	5 (8.77)
Immunodeficiency common variable	2	2 (3.51)	0	0 (0.00)
Seasonal allergy	2	2 (3.51)	0	0 (0.00)
Chronic graft versus host disease	1	1 (1.75)	0	0 (0.00)
Drug hypersensitivity	1	1 (1.75)	0	0 (0.00)
Graft versus host disease	1	1 (1.75)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.75)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.75)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.75)	0	0 (0.00)
Immunodeficiency	1	1 (1.75)	0	0 (0.00)
Infections and infestations				
- Total	121	42 (73.68)	29	17 (29.82)
Upper respiratory tract infection	10	7 (12.28)	1	1 (1.75)
Urinary tract infection	8	5 (8.77)	3	2 (3.51)
Otitis media	7	4 (7.02)	1	1 (1.75)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Cellulitis of male external genital organ	6	1 (1.75)	3	1 (1.75)
Clostridium difficile infection	5	5 (8.77)	1	1 (1.75)
Otitis media acute	5	2 (3.51)	0	0 (0.00)
Sinusitis	5	4 (7.02)	0	0 (0.00)
Clostridium difficile colitis	4	4 (7.02)	1	1 (1.75)
Gastroenteritis	4	4 (7.02)	1	1 (1.75)
Influenza	4	4 (7.02)	0	0 (0.00)
Pneumonia	4	4 (7.02)	1	1 (1.75)
Rhinovirus infection	4	4 (7.02)	0	0 (0.00)
Viral upper respiratory tract infection	3	3 (5.26)	1	1 (1.75)
Cytomegalovirus infection	2	2 (3.51)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (1.75)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.51)	1	1 (1.75)
Staphylococcal infection	2	2 (3.51)	1	1 (1.75)
Vulvovaginal candidiasis	2	2 (3.51)	0	0 (0.00)
Acute sinusitis	1	1 (1.75)	0	0 (0.00)
Bacterial sepsis	1	1 (1.75)	1	1 (1.75)
Body tinea	1	1 (1.75)	0	0 (0.00)
Campylobacter infection	1	1 (1.75)	1	1 (1.75)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Catheter site cellulitis	1	1 (1.75)	0	0 (0.00)
Catheter site infection	1	1 (1.75)	1	1 (1.75)
Cholecystitis infective	1	1 (1.75)	1	1 (1.75)
Ear infection	1	1 (1.75)	0	0 (0.00)
Enterococcal infection	1	1 (1.75)	0	0 (0.00)
Enterovirus infection	1	1 (1.75)	1	1 (1.75)
Escherichia urinary tract infection	1	1 (1.75)	1	1 (1.75)
Folliculitis	1	1 (1.75)	0	0 (0.00)
Fungal skin infection	1	1 (1.75)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.75)	0	0 (0.00)
Gingivitis	1	1 (1.75)	0	0 (0.00)
Haemophilus infection	1	1 (1.75)	0	0 (0.00)
Herpes simplex	1	1 (1.75)	0	0 (0.00)
Herpes zoster	1	1 (1.75)	1	1 (1.75)
Human herpesvirus 6 infection	1	1 (1.75)	0	0 (0.00)
Hypopyon	1	1 (1.75)	0	0 (0.00)
Meningitis aseptic	1	1 (1.75)	0	0 (0.00)
Molluscum contagiosum	1	1 (1.75)	0	0 (0.00)
Oral candidiasis	1	1 (1.75)	0	0 (0.00)
Oral herpes	1	1 (1.75)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Orchitis	1	1 (1.75)	0	0 (0.00)
Otitis externa	1	1 (1.75)	0	0 (0.00)
Paronychia	1	1 (1.75)	0	0 (0.00)
Pharyngitis	1	1 (1.75)	0	0 (0.00)
Rash pustular	1	1 (1.75)	0	0 (0.00)
Respiratory tract infection	1	1 (1.75)	1	1 (1.75)
Respiratory tract infection viral	1	1 (1.75)	1	1 (1.75)
Rhinitis	1	1 (1.75)	0	0 (0.00)
Rotavirus infection	1	1 (1.75)	1	1 (1.75)
Sepsis	1	1 (1.75)	1	1 (1.75)
Septic embolus	1	1 (1.75)	1	1 (1.75)
Skin infection	1	1 (1.75)	0	0 (0.00)
Streptococcal infection	1	1 (1.75)	0	0 (0.00)
Subcutaneous abscess	1	1 (1.75)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.75)	1	1 (1.75)
Vascular device infection	1	1 (1.75)	1	1 (1.75)
Viral infection	1	1 (1.75)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (1.75)	0	0 (0.00)
Injury, poisoning and procedural complications				

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
- Total	33	20 (35.09)	2	2 (3.51)
Procedural pain	6	5 (8.77)	1	1 (1.75)
Transfusion reaction	4	3 (5.26)	0	0 (0.00)
Infusion related reaction	3	3 (5.26)	0	0 (0.00)
Contusion	2	2 (3.51)	0	0 (0.00)
Skin abrasion	2	2 (3.51)	0	0 (0.00)
Arthropod bite	1	1 (1.75)	0	0 (0.00)
Foot fracture	1	1 (1.75)	0	0 (0.00)
Incision site pain	1	1 (1.75)	0	0 (0.00)
Limb injury	1	1 (1.75)	0	0 (0.00)
Mouth injury	1	1 (1.75)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.75)	0	0 (0.00)
Procedural complication	1	1 (1.75)	0	0 (0.00)
Procedural headache	1	1 (1.75)	0	0 (0.00)
Procedural site reaction	1	1 (1.75)	0	0 (0.00)
Radius fracture	1	1 (1.75)	0	0 (0.00)
Skin laceration	1	1 (1.75)	0	0 (0.00)
Stoma site irritation	1	1 (1.75)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.75)	0	0 (0.00)
Tibia fracture	1	1 (1.75)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Tongue injury	1	1 (1.75)	0	0 (0.00)
Transfusion related complication	1	1 (1.75)	1	1 (1.75)
Investigations				
- Total	363	49 (85.96)	185	43 (75.44)
White blood cell count decreased	56	31 (54.39)	36	27 (47.37)
Neutrophil count decreased	53	24 (42.11)	45	22 (38.60)
Platelet count decreased	49	20 (35.09)	38	15 (26.32)
Aspartate aminotransferase increased	36	19 (33.33)	18	11 (19.30)
Alanine aminotransferase increased	33	21 (36.84)	18	14 (24.56)
Lymphocyte count decreased	21	14 (24.56)	13	12 (21.05)
Prothrombin time prolonged	16	8 (14.04)	1	1 (1.75)
Blood fibrinogen decreased	14	3 (5.26)	4	3 (5.26)
Blood bilirubin increased	13	7 (12.28)	2	2 (3.51)
Blood creatinine increased	11	8 (14.04)	2	2 (3.51)
International normalised ratio increased	9	8 (14.04)	1	1 (1.75)
Activated partial thromboplastin time prolonged	7	4 (7.02)	0	0 (0.00)
Blood urea increased	5	3 (5.26)	1	1 (1.75)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Blood immunoglobulin A decreased	3	3 (5.26)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (5.26)	0	0 (0.00)
Haemoglobin decreased	3	3 (5.26)	1	1 (1.75)
Transaminases increased	3	3 (5.26)	0	0 (0.00)
Weight decreased	3	3 (5.26)	0	0 (0.00)
Blood phosphorus increased	2	1 (1.75)	0	0 (0.00)
Blood sodium increased	2	1 (1.75)	0	0 (0.00)
C-reactive protein increased	2	2 (3.51)	1	1 (1.75)
Lipase increased	2	2 (3.51)	2	2 (3.51)
Serum ferritin increased	2	2 (3.51)	0	0 (0.00)
Weight increased	2	2 (3.51)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (1.75)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.75)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.75)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (1.75)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.75)	1	1 (1.75)
Blood phosphorus decreased	1	1 (1.75)	0	0 (0.00)
Blood uric acid increased	1	1 (1.75)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Culture stool positive	1	1 (1.75)	0	0 (0.00)
Hepatic enzyme increased	1	1 (1.75)	0	0 (0.00)
Norovirus test positive	1	1 (1.75)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.75)	0	0 (0.00)
Protein total decreased	1	1 (1.75)	1	1 (1.75)
Pulmonary function test decreased	1	1 (1.75)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	124	39 (68.42)	48	26 (45.61)
Decreased appetite	23	19 (33.33)	12	11 (19.30)
Hypokalaemia	20	17 (29.82)	9	9 (15.79)
Hypophosphataemia	13	9 (15.79)	9	7 (12.28)
Hyperphosphataemia	12	8 (14.04)	0	0 (0.00)
Hypernatraemia	6	3 (5.26)	1	1 (1.75)
Hyperglycaemia	5	3 (5.26)	2	2 (3.51)
Hypoalbuminaemia	5	4 (7.02)	1	1 (1.75)
Dehydration	4	4 (7.02)	3	3 (5.26)
Hyperuricaemia	4	3 (5.26)	1	1 (1.75)
Hypocalcaemia	4	3 (5.26)	1	1 (1.75)
Fluid overload	3	3 (5.26)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Hyperalbuminaemia	3	1 (1.75)	0	0 (0.00)
Hypercalcaemia	3	1 (1.75)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.51)	1	1 (1.75)
Hyponatraemia	3	2 (3.51)	3	2 (3.51)
Acidosis	2	2 (3.51)	1	1 (1.75)
Tumour lysis syndrome	2	2 (3.51)	2	2 (3.51)
Vitamin D deficiency	2	2 (3.51)	0	0 (0.00)
Hyperchloraemia	1	1 (1.75)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.75)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.75)	0	0 (0.00)
Iron overload	1	1 (1.75)	1	1 (1.75)
Malnutrition	1	1 (1.75)	1	1 (1.75)
Metabolic acidosis	1	1 (1.75)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.75)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	39	22 (38.60)	0	0 (0.00)
Pain in extremity	10	9 (15.79)	0	0 (0.00)
Myalgia	5	5 (8.77)	0	0 (0.00)
Arthralgia	4	4 (7.02)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Musculoskeletal pain	4	3 (5.26)	0	0 (0.00)
Joint range of motion decreased	2	2 (3.51)	0	0 (0.00)
Muscle spasms	2	2 (3.51)	0	0 (0.00)
Muscular weakness	2	2 (3.51)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (3.51)	0	0 (0.00)
Back pain	1	1 (1.75)	0	0 (0.00)
Coccydynia	1	1 (1.75)	0	0 (0.00)
Flank pain	1	1 (1.75)	0	0 (0.00)
Limb discomfort	1	1 (1.75)	0	0 (0.00)
Neck pain	1	1 (1.75)	0	0 (0.00)
Osteonecrosis	1	1 (1.75)	0	0 (0.00)
Osteopenia	1	1 (1.75)	0	0 (0.00)
Toe walking	1	1 (1.75)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (5.26)	1	1 (1.75)
Glioblastoma multiforme	1	1 (1.75)	1	1 (1.75)
Myelodysplastic syndrome	1	1 (1.75)	0	0 (0.00)
Skin papilloma	1	1 (1.75)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Nervous system disorders				
- Total	68	31 (54.39)	7	6 (10.53)
Headache	35	21 (36.84)	2	2 (3.51)
Dizziness	7	5 (8.77)	0	0 (0.00)
Encephalopathy	6	4 (7.02)	2	2 (3.51)
Seizure	4	4 (7.02)	2	2 (3.51)
Dysarthria	2	2 (3.51)	0	0 (0.00)
Tremor	2	2 (3.51)	0	0 (0.00)
Asterixis	1	1 (1.75)	0	0 (0.00)
Ataxia	1	1 (1.75)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.75)	0	0 (0.00)
Disturbance in attention	1	1 (1.75)	0	0 (0.00)
Embolic stroke	1	1 (1.75)	1	1 (1.75)
Idiopathic intracranial hypertension	1	1 (1.75)	0	0 (0.00)
Migraine	1	1 (1.75)	0	0 (0.00)
Myoclonus	1	1 (1.75)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.75)	0	0 (0.00)
Peroneal nerve palsy	1	1 (1.75)	0	0 (0.00)
Pleocytosis	1	1 (1.75)	0	0 (0.00)
Somnolence	1	1 (1.75)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Product issues				
- Total	1	1 (1.75)	0	0 (0.00)
Device occlusion	1	1 (1.75)	0	0 (0.00)
Psychiatric disorders				
- Total	28	14 (24.56)	1	1 (1.75)
Anxiety	6	6 (10.53)	1	1 (1.75)
Confusional state	4	4 (7.02)	0	0 (0.00)
Agitation	3	2 (3.51)	0	0 (0.00)
Delirium	3	3 (5.26)	0	0 (0.00)
Hallucination	3	2 (3.51)	0	0 (0.00)
Irritability	2	2 (3.51)	0	0 (0.00)
Adjustment disorder	1	1 (1.75)	0	0 (0.00)
Depression	1	1 (1.75)	0	0 (0.00)
Insomnia	1	1 (1.75)	0	0 (0.00)
Listless	1	1 (1.75)	0	0 (0.00)
Mental status changes	1	1 (1.75)	0	0 (0.00)
Panic attack	1	1 (1.75)	0	0 (0.00)
Suicidal ideation	1	1 (1.75)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Renal and urinary disorders				
- Total	21	13 (22.81)	10	8 (14.04)
Acute kidney injury	9	8 (14.04)	6	6 (10.53)
Haematuria	4	3 (5.26)	1	1 (1.75)
Dysuria	2	2 (3.51)	0	0 (0.00)
Calculus urinary	1	1 (1.75)	0	0 (0.00)
Nephrolithiasis	1	1 (1.75)	1	1 (1.75)
Oliguria	1	1 (1.75)	1	1 (1.75)
Pollakiuria	1	1 (1.75)	0	0 (0.00)
Renal impairment	1	1 (1.75)	1	1 (1.75)
Urinary incontinence	1	1 (1.75)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	7	6 (10.53)	2	2 (3.51)
Oedema genital	2	1 (1.75)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.51)	0	0 (0.00)
Ovarian failure	1	1 (1.75)	1	1 (1.75)
Scrotal pain	1	1 (1.75)	0	0 (0.00)
Vaginal haemorrhage	1	1 (1.75)	1	1 (1.75)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	89	32 (56.14)	21	12 (21.05)
Cough	17	11 (19.30)	0	0 (0.00)
Epistaxis	12	8 (14.04)	3	3 (5.26)
Hypoxia	9	8 (14.04)	5	5 (8.77)
Pleural effusion	7	7 (12.28)	2	2 (3.51)
Pulmonary oedema	6	6 (10.53)	5	5 (8.77)
Tachypnoea	6	5 (8.77)	1	1 (1.75)
Oropharyngeal pain	5	5 (8.77)	0	0 (0.00)
Rhinitis allergic	5	4 (7.02)	0	0 (0.00)
Nasal congestion	4	4 (7.02)	0	0 (0.00)
Rhinorrhoea	4	4 (7.02)	0	0 (0.00)
Dyspnoea	2	1 (1.75)	1	1 (1.75)
Haemoptysis	2	1 (1.75)	0	0 (0.00)
Respiratory failure	2	2 (3.51)	2	2 (3.51)
Acute respiratory failure	1	1 (1.75)	1	1 (1.75)
Atelectasis	1	1 (1.75)	0	0 (0.00)
Dysphonia	1	1 (1.75)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.75)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Pharyngeal ulceration	1	1 (1.75)	0	0 (0.00)
Respiratory depression	1	1 (1.75)	0	0 (0.00)
Respiratory distress	1	1 (1.75)	1	1 (1.75)
Wheezing	1	1 (1.75)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	60	26 (45.61)	3	3 (5.26)
Rash	9	8 (14.04)	0	0 (0.00)
Hyperhidrosis	5	4 (7.02)	0	0 (0.00)
Dry skin	4	4 (7.02)	0	0 (0.00)
Erythema	4	3 (5.26)	0	0 (0.00)
Ingrowing nail	4	3 (5.26)	0	0 (0.00)
Petechiae	4	4 (7.02)	0	0 (0.00)
Pruritus	4	4 (7.02)	0	0 (0.00)
Rash maculo-papular	4	4 (7.02)	1	1 (1.75)
Macule	2	2 (3.51)	0	0 (0.00)
Papule	2	2 (3.51)	0	0 (0.00)
Rash papular	2	2 (3.51)	0	0 (0.00)
Acne	1	1 (1.75)	0	0 (0.00)
Dermatitis	1	1 (1.75)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Dermatitis acneiform	1	1 (1.75)	1	1 (1.75)
Dermatitis atopic	1	1 (1.75)	0	0 (0.00)
Ecchymosis	1	1 (1.75)	1	1 (1.75)
Eczema	1	1 (1.75)	0	0 (0.00)
Keloid scar	1	1 (1.75)	0	0 (0.00)
Night sweats	1	1 (1.75)	0	0 (0.00)
Rash erythematous	1	1 (1.75)	0	0 (0.00)
Rash follicular	1	1 (1.75)	0	0 (0.00)
Rash macular	1	1 (1.75)	0	0 (0.00)
Rash pruritic	1	1 (1.75)	0	0 (0.00)
Rash vesicular	1	1 (1.75)	0	0 (0.00)
Skin exfoliation	1	1 (1.75)	0	0 (0.00)
Skin fissures	1	1 (1.75)	0	0 (0.00)
Skin irritation	1	1 (1.75)	0	0 (0.00)
Vascular disorders				
- Total	34	20 (35.09)	15	12 (21.05)
Hypotension	15	12 (21.05)	12	11 (19.30)
Hypertension	11	9 (15.79)	1	1 (1.75)
Flushing	3	2 (3.51)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=57 n (%)[1]	Grade >= 3 Total events	All patients N=57 n (%)[2]
Orthostatic hypotension	2	2 (3.51)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.75)	1	1 (1.75)
Embolism	1	1 (1.75)	1	1 (1.75)
Secondary hypertension	1	1 (1.75)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Total number of AE per patient	19	2 (100.00)	0	0 (0.00)
Blood and lymphatic system disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Anaemia	1	1 (50.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (50.00)	0	0 (0.00)
Fatigue	1	1 (50.00)	0	0 (0.00)
Immune system disorders				
- Total	2	2 (100.00)	0	0 (0.00)
Graft versus host disease in skin	1	1 (50.00)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (50.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Injury, poisoning and procedural complications				
- Total	1	1 (50.00)	0	0 (0.00)
Skin abrasion	1	1 (50.00)	0	0 (0.00)
Investigations				
- Total	5	1 (50.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (50.00)	0	0 (0.00)
International normalised ratio increased	1	1 (50.00)	0	0 (0.00)
Lymphocyte count decreased	1	1 (50.00)	0	0 (0.00)
Neutrophil count decreased	1	1 (50.00)	0	0 (0.00)
White blood cell count decreased	1	1 (50.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	2	1 (50.00)	0	0 (0.00)
Hyperphosphataemia	1	1 (50.00)	0	0 (0.00)
Hyperuricaemia	1	1 (50.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	3	1 (50.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Arthralgia	1	1 (50.00)	0	0 (0.00)
Myalgia	1	1 (50.00)	0	0 (0.00)
Pain in extremity	1	1 (50.00)	0	0 (0.00)
Nervous system disorders				
- Total	2	2 (100.00)	0	0 (0.00)
Headache	2	2 (100.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Cough	1	1 (50.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Skin irritation	1	1 (50.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Total number of AE per patient	1295	61 (98.39)	458	54 (87.10)
Blood and lymphatic system disorders				
- Total	121	42 (67.74)	93	38 (61.29)
Anaemia	46	26 (41.94)	31	19 (30.65)
Thrombocytopenia	30	8 (12.90)	23	8 (12.90)
Febrile neutropenia	26	22 (35.48)	26	22 (35.48)
Neutropenia	9	8 (12.90)	8	8 (12.90)
Disseminated intravascular coagulation	5	4 (6.45)	2	2 (3.23)
Lymphopenia	3	3 (4.84)	2	2 (3.23)
Coagulopathy	1	1 (1.61)	0	0 (0.00)
Pancytopenia	1	1 (1.61)	1	1 (1.61)
Cardiac disorders				
- Total	32	22 (35.48)	3	2 (3.23)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Tachycardia	17	15 (24.19)	2	2 (3.23)
Sinus tachycardia	5	5 (8.06)	0	0 (0.00)
Pericardial effusion	2	2 (3.23)	0	0 (0.00)
Sinus bradycardia	2	1 (1.61)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.61)	0	0 (0.00)
Bradycardia	1	1 (1.61)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.61)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.61)	1	1 (1.61)
Palpitations	1	1 (1.61)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.61)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (4.84)	0	0 (0.00)
Ear pain	2	2 (3.23)	0	0 (0.00)
Hypoacusis	1	1 (1.61)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.61)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.61)	0	0 (0.00)
Eye disorders				

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
- Total	25	13 (20.97)	0	0 (0.00)
Eye pain	4	3 (4.84)	0	0 (0.00)
Periorbital oedema	4	4 (6.45)	0	0 (0.00)
Vision blurred	4	3 (4.84)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (4.84)	0	0 (0.00)
Photophobia	3	2 (3.23)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.23)	0	0 (0.00)
Uveitis	2	2 (3.23)	0	0 (0.00)
Ocular hypertension	1	1 (1.61)	0	0 (0.00)
Papilloedema	1	1 (1.61)	0	0 (0.00)
Visual impairment	1	1 (1.61)	0	0 (0.00)
Gastrointestinal disorders				
- Total	126	36 (58.06)	15	11 (17.74)
Vomiting	35	22 (35.48)	3	3 (4.84)
Nausea	26	21 (33.87)	3	3 (4.84)
Diarrhoea	18	18 (29.03)	1	1 (1.61)
Abdominal pain	10	9 (14.52)	1	1 (1.61)
Constipation	8	7 (11.29)	0	0 (0.00)
Abdominal distension	2	2 (3.23)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Abdominal pain upper	2	2 (3.23)	0	0 (0.00)
Anal incontinence	2	1 (1.61)	0	0 (0.00)
Dysphagia	2	2 (3.23)	1	1 (1.61)
Haematemesis	2	2 (3.23)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.61)	2	1 (1.61)
Pancreatitis	2	2 (3.23)	1	1 (1.61)
Stomatitis	2	2 (3.23)	0	0 (0.00)
Abdominal discomfort	1	1 (1.61)	0	0 (0.00)
Abdominal pain lower	1	1 (1.61)	0	0 (0.00)
Abdominal tenderness	1	1 (1.61)	0	0 (0.00)
Ascites	1	1 (1.61)	1	1 (1.61)
Dyspepsia	1	1 (1.61)	0	0 (0.00)
Flatulence	1	1 (1.61)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.61)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.61)	0	0 (0.00)
Glossodynia	1	1 (1.61)	0	0 (0.00)
Ileus	1	1 (1.61)	1	1 (1.61)
Intestinal obstruction	1	1 (1.61)	1	1 (1.61)
Lip pain	1	1 (1.61)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.61)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
General disorders and administration site conditions				
- Total	76	31 (50.00)	14	10 (16.13)
Pyrexia	27	16 (25.81)	6	6 (9.68)
Fatigue	13	12 (19.35)	1	1 (1.61)
Chills	9	8 (12.90)	0	0 (0.00)
Catheter site pain	3	3 (4.84)	0	0 (0.00)
Generalised oedema	3	2 (3.23)	0	0 (0.00)
Malaise	3	3 (4.84)	0	0 (0.00)
Pain	3	3 (4.84)	2	2 (3.23)
Face oedema	2	2 (3.23)	1	1 (1.61)
Oedema peripheral	2	2 (3.23)	1	1 (1.61)
Asthenia	1	1 (1.61)	0	0 (0.00)
Catheter site extravasation	1	1 (1.61)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.61)	0	0 (0.00)
Facial pain	1	1 (1.61)	0	0 (0.00)
Injection site haematoma	1	1 (1.61)	0	0 (0.00)
Localised oedema	1	1 (1.61)	1	1 (1.61)
Mucosal haemorrhage	1	1 (1.61)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.61)	1	1 (1.61)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Non-cardiac chest pain	1	1 (1.61)	0	0 (0.00)
Peripheral swelling	1	1 (1.61)	0	0 (0.00)
Physical deconditioning	1	1 (1.61)	1	1 (1.61)
Hepatobiliary disorders				
- Total	9	7 (11.29)	2	2 (3.23)
Hyperbilirubinaemia	4	3 (4.84)	2	2 (3.23)
Hepatomegaly	3	3 (4.84)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.61)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.61)	0	0 (0.00)
Immune system disorders				
- Total	114	55 (88.71)	33	22 (35.48)
Cytokine release syndrome	86	50 (80.65)	29	19 (30.65)
Hypogammaglobulinaemia	26	25 (40.32)	4	4 (6.45)
Drug hypersensitivity	1	1 (1.61)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.61)	0	0 (0.00)
Infections and infestations				
- Total	41	26 (41.94)	7	7 (11.29)
Clostridium difficile colitis	4	4 (6.45)	1	1 (1.61)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Clostridium difficile infection	4	4 (6.45)	0	0 (0.00)
Rhinovirus infection	3	3 (4.84)	0	0 (0.00)
Gastroenteritis	2	2 (3.23)	1	1 (1.61)
Pneumonia	2	2 (3.23)	1	1 (1.61)
Staphylococcal infection	2	2 (3.23)	1	1 (1.61)
Acute sinusitis	1	1 (1.61)	0	0 (0.00)
Body tinea	1	1 (1.61)	0	0 (0.00)
Catheter site cellulitis	1	1 (1.61)	0	0 (0.00)
Catheter site infection	1	1 (1.61)	1	1 (1.61)
Cytomegalovirus infection	1	1 (1.61)	0	0 (0.00)
Enterococcal infection	1	1 (1.61)	0	0 (0.00)
Folliculitis	1	1 (1.61)	0	0 (0.00)
Fungal skin infection	1	1 (1.61)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.61)	0	0 (0.00)
Herpes simplex	1	1 (1.61)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (1.61)	0	0 (0.00)
Hypopyon	1	1 (1.61)	0	0 (0.00)
Influenza	1	1 (1.61)	0	0 (0.00)
Oral candidiasis	1	1 (1.61)	0	0 (0.00)
Orchitis	1	1 (1.61)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Pharyngitis	1	1 (1.61)	0	0 (0.00)
Septic embolus	1	1 (1.61)	1	1 (1.61)
Skin infection	1	1 (1.61)	0	0 (0.00)
Streptococcal infection	1	1 (1.61)	0	0 (0.00)
Upper respiratory tract infection	1	1 (1.61)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.61)	1	1 (1.61)
Viral infection	1	1 (1.61)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.61)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (1.61)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	24	14 (22.58)	2	2 (3.23)
Transfusion reaction	4	3 (4.84)	0	0 (0.00)
Procedural pain	3	3 (4.84)	0	0 (0.00)
Infusion related reaction	2	2 (3.23)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.61)	1	1 (1.61)
Contusion	1	1 (1.61)	0	0 (0.00)
Incision site pain	1	1 (1.61)	0	0 (0.00)
Limb injury	1	1 (1.61)	0	0 (0.00)
Mouth injury	1	1 (1.61)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Post procedural haemorrhage	1	1 (1.61)	0	0 (0.00)
Procedural complication	1	1 (1.61)	0	0 (0.00)
Procedural headache	1	1 (1.61)	0	0 (0.00)
Procedural site reaction	1	1 (1.61)	0	0 (0.00)
Stoma site irritation	1	1 (1.61)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.61)	0	0 (0.00)
Tibia fracture	1	1 (1.61)	0	0 (0.00)
Tongue injury	1	1 (1.61)	0	0 (0.00)
Transfusion related complication	1	1 (1.61)	1	1 (1.61)
Investigations				
- Total	327	51 (82.26)	178	44 (70.97)
White blood cell count decreased	54	29 (46.77)	37	26 (41.94)
Neutrophil count decreased	46	24 (38.71)	44	23 (37.10)
Platelet count decreased	43	19 (30.65)	37	14 (22.58)
Aspartate aminotransferase increased	32	18 (29.03)	16	11 (17.74)
Alanine aminotransferase increased	28	19 (30.65)	14	11 (17.74)
Prothrombin time prolonged	17	9 (14.52)	1	1 (1.61)
Blood fibrinogen decreased	15	4 (6.45)	4	3 (4.84)
Lymphocyte count decreased	15	13 (20.97)	12	11 (17.74)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Blood bilirubin increased	13	7 (11.29)	2	2 (3.23)
Blood creatinine increased	11	9 (14.52)	2	2 (3.23)
International normalised ratio increased	10	8 (12.90)	1	1 (1.61)
Activated partial thromboplastin time prolonged	8	5 (8.06)	0	0 (0.00)
Blood immunoglobulin M decreased	4	4 (6.45)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.23)	0	0 (0.00)
Blood urea increased	3	3 (4.84)	1	1 (1.61)
Blood immunoglobulin A decreased	2	2 (3.23)	0	0 (0.00)
Blood sodium increased	2	1 (1.61)	0	0 (0.00)
Blood uric acid increased	2	1 (1.61)	0	0 (0.00)
Lipase increased	2	2 (3.23)	2	2 (3.23)
Transaminases increased	2	2 (3.23)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.61)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.61)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.61)	1	1 (1.61)
Blood magnesium decreased	1	1 (1.61)	1	1 (1.61)
Blood phosphorus decreased	1	1 (1.61)	0	0 (0.00)
C-reactive protein increased	1	1 (1.61)	1	1 (1.61)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Cardiac murmur	1	1 (1.61)	0	0 (0.00)
Culture stool positive	1	1 (1.61)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.61)	0	0 (0.00)
Haemoglobin decreased	1	1 (1.61)	1	1 (1.61)
Hepatic enzyme increased	1	1 (1.61)	0	0 (0.00)
Norovirus test positive	1	1 (1.61)	0	0 (0.00)
Protein total decreased	1	1 (1.61)	1	1 (1.61)
Pulmonary function test decreased	1	1 (1.61)	0	0 (0.00)
Serum ferritin increased	1	1 (1.61)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	114	38 (61.29)	43	24 (38.71)
Decreased appetite	24	20 (32.26)	13	12 (19.35)
Hypokalaemia	20	16 (25.81)	7	7 (11.29)
Hypophosphataemia	13	9 (14.52)	9	7 (11.29)
Hyperphosphataemia	9	7 (11.29)	0	0 (0.00)
Hypernatraemia	7	4 (6.45)	1	1 (1.61)
Hypoalbuminaemia	6	5 (8.06)	1	1 (1.61)
Hyperglycaemia	4	3 (4.84)	1	1 (1.61)
Hypocalcaemia	4	3 (4.84)	1	1 (1.61)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Dehydration	3	3 (4.84)	2	2 (3.23)
Fluid overload	3	3 (4.84)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.23)	1	1 (1.61)
Hyperuricaemia	3	2 (3.23)	1	1 (1.61)
Hyponatraemia	3	2 (3.23)	3	2 (3.23)
Acidosis	2	2 (3.23)	1	1 (1.61)
Hypercalcaemia	2	1 (1.61)	0	0 (0.00)
Hyperalbuminaemia	1	1 (1.61)	0	0 (0.00)
Hyperchloraemia	1	1 (1.61)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.61)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.61)	0	0 (0.00)
Malnutrition	1	1 (1.61)	1	1 (1.61)
Metabolic acidosis	1	1 (1.61)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.61)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.61)	1	1 (1.61)
Musculoskeletal and connective tissue disorders				
- Total	20	14 (22.58)	1	1 (1.61)
Musculoskeletal pain	4	3 (4.84)	0	0 (0.00)
Myalgia	4	4 (6.45)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Arthralgia	3	3 (4.84)	1	1 (1.61)
Pain in extremity	3	3 (4.84)	0	0 (0.00)
Coccydynia	1	1 (1.61)	0	0 (0.00)
Limb discomfort	1	1 (1.61)	0	0 (0.00)
Muscle spasms	1	1 (1.61)	0	0 (0.00)
Muscular weakness	1	1 (1.61)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.61)	0	0 (0.00)
Osteopenia	1	1 (1.61)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.61)	0	0 (0.00)
Skin papilloma	1	1 (1.61)	0	0 (0.00)
Nervous system disorders				
- Total	56	31 (50.00)	6	5 (8.06)
Headache	29	22 (35.48)	2	2 (3.23)
Encephalopathy	6	4 (6.45)	2	2 (3.23)
Dizziness	4	4 (6.45)	0	0 (0.00)
Seizure	3	3 (4.84)	1	1 (1.61)
Dysarthria	2	2 (3.23)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Tremor	2	2 (3.23)	0	0 (0.00)
Asterixis	1	1 (1.61)	0	0 (0.00)
Ataxia	1	1 (1.61)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.61)	0	0 (0.00)
Embolic stroke	1	1 (1.61)	1	1 (1.61)
Idiopathic intracranial hypertension	1	1 (1.61)	0	0 (0.00)
Migraine	1	1 (1.61)	0	0 (0.00)
Myoclonus	1	1 (1.61)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.61)	0	0 (0.00)
Pleocytosis	1	1 (1.61)	0	0 (0.00)
Somnolence	1	1 (1.61)	0	0 (0.00)
Product issues				
- Total	1	1 (1.61)	0	0 (0.00)
Device occlusion	1	1 (1.61)	0	0 (0.00)
Psychiatric disorders				
- Total	30	16 (25.81)	1	1 (1.61)
Anxiety	6	6 (9.68)	1	1 (1.61)
Confusional state	6	6 (9.68)	0	0 (0.00)
Delirium	4	4 (6.45)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Agitation	3	2 (3.23)	0	0 (0.00)
Hallucination	3	2 (3.23)	0	0 (0.00)
Irritability	2	2 (3.23)	0	0 (0.00)
Adjustment disorder	1	1 (1.61)	0	0 (0.00)
Insomnia	1	1 (1.61)	0	0 (0.00)
Listless	1	1 (1.61)	0	0 (0.00)
Mental status changes	1	1 (1.61)	0	0 (0.00)
Panic attack	1	1 (1.61)	0	0 (0.00)
Suicidal ideation	1	1 (1.61)	0	0 (0.00)
Renal and urinary disorders				
- Total	18	11 (17.74)	11	7 (11.29)
Acute kidney injury	7	7 (11.29)	5	5 (8.06)
Haematuria	4	4 (6.45)	2	2 (3.23)
Dysuria	2	2 (3.23)	0	0 (0.00)
Oliguria	2	2 (3.23)	2	2 (3.23)
Pollakiuria	1	1 (1.61)	0	0 (0.00)
Renal failure	1	1 (1.61)	1	1 (1.61)
Renal impairment	1	1 (1.61)	1	1 (1.61)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Reproductive system and breast disorders				
- Total	4	3 (4.84)	0	0 (0.00)
Oedema genital	2	1 (1.61)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.23)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	72	27 (43.55)	28	12 (19.35)
Hypoxia	13	10 (16.13)	8	7 (11.29)
Epistaxis	11	7 (11.29)	4	4 (6.45)
Pleural effusion	8	8 (12.90)	2	2 (3.23)
Cough	7	7 (11.29)	0	0 (0.00)
Pulmonary oedema	6	6 (9.68)	5	5 (8.06)
Tachypnoea	6	5 (8.06)	1	1 (1.61)
Dyspnoea	3	2 (3.23)	2	2 (3.23)
Haemoptysis	3	2 (3.23)	1	1 (1.61)
Respiratory failure	3	3 (4.84)	3	3 (4.84)
Oropharyngeal pain	2	2 (3.23)	0	0 (0.00)
Atelectasis	1	1 (1.61)	0	0 (0.00)
Interstitial lung disease	1	1 (1.61)	1	1 (1.61)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Nasal congestion	1	1 (1.61)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.61)	0	0 (0.00)
Pharyngeal ulceration	1	1 (1.61)	0	0 (0.00)
Respiratory depression	1	1 (1.61)	0	0 (0.00)
Respiratory distress	1	1 (1.61)	1	1 (1.61)
Rhinitis allergic	1	1 (1.61)	0	0 (0.00)
Rhinorrhoea	1	1 (1.61)	0	0 (0.00)
Wheezing	1	1 (1.61)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	40	20 (32.26)	2	2 (3.23)
Dry skin	4	4 (6.45)	0	0 (0.00)
Erythema	4	3 (4.84)	0	0 (0.00)
Hyperhidrosis	4	3 (4.84)	0	0 (0.00)
Rash	4	4 (6.45)	0	0 (0.00)
Ingrowing nail	3	2 (3.23)	0	0 (0.00)
Petechiae	3	3 (4.84)	0	0 (0.00)
Rash maculo-papular	3	3 (4.84)	1	1 (1.61)
Pruritus	2	2 (3.23)	0	0 (0.00)
Rash papular	2	2 (3.23)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Dermatitis diaper	1	1 (1.61)	0	0 (0.00)
Ecchymosis	1	1 (1.61)	1	1 (1.61)
Livedo reticularis	1	1 (1.61)	0	0 (0.00)
Macule	1	1 (1.61)	0	0 (0.00)
Night sweats	1	1 (1.61)	0	0 (0.00)
Rash erythematous	1	1 (1.61)	0	0 (0.00)
Rash follicular	1	1 (1.61)	0	0 (0.00)
Rash macular	1	1 (1.61)	0	0 (0.00)
Rash vesicular	1	1 (1.61)	0	0 (0.00)
Skin exfoliation	1	1 (1.61)	0	0 (0.00)
Skin fissures	1	1 (1.61)	0	0 (0.00)
Vascular disorders				
- Total	40	24 (38.71)	19	16 (25.81)
Hypotension	19	16 (25.81)	16	15 (24.19)
Hypertension	12	10 (16.13)	1	1 (1.61)
Flushing	3	2 (3.23)	0	0 (0.00)
Orthostatic hypotension	2	2 (3.23)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.61)	1	1 (1.61)
Embolism	1	1 (1.61)	1	1 (1.61)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Haematoma	1	1 (1.61)	0	0 (0.00)
Secondary hypertension	1	1 (1.61)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Total number of AE per patient	34	2 (100.00)	5	1 (50.00)
Blood and lymphatic system disorders				
- Total	4	2 (100.00)	2	1 (50.00)
Eosinophilia	2	1 (50.00)	1	1 (50.00)
Lymphopenia	1	1 (50.00)	0	0 (0.00)
Neutropenia	1	1 (50.00)	1	1 (50.00)
Cardiac disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Sinus tachycardia	1	1 (50.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Pigmentation lip	1	1 (50.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
General disorders and administration site conditions				
- Total	7	1 (50.00)	0	0 (0.00)
Pyrexia	5	1 (50.00)	0	0 (0.00)
Chills	1	1 (50.00)	0	0 (0.00)
Pain	1	1 (50.00)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Graft versus host disease	1	1 (50.00)	0	0 (0.00)
Infections and infestations				
- Total	7	1 (50.00)	3	1 (50.00)
Cellulitis of male external genital organ	5	1 (50.00)	2	1 (50.00)
Urinary tract infection	2	1 (50.00)	1	1 (50.00)
Investigations				
- Total	2	1 (50.00)	0	0 (0.00)
Blood uric acid increased	1	1 (50.00)	0	0 (0.00)
Neutrophil count decreased	1	1 (50.00)	0	0 (0.00)
Metabolism and nutrition disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
- Total	1	1 (50.00)	0	0 (0.00)
Vitamin D deficiency	1	1 (50.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	4	2 (100.00)	0	0 (0.00)
Joint range of motion decreased	2	2 (100.00)	0	0 (0.00)
Back pain	1	1 (50.00)	0	0 (0.00)
Muscle spasms	1	1 (50.00)	0	0 (0.00)
Nervous system disorders				
- Total	3	1 (50.00)	0	0 (0.00)
Headache	3	1 (50.00)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Scrotal pain	1	1 (50.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	1 (50.00)	0	0 (0.00)
Macule	1	1 (50.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Rash maculo-papular	1	1 (50.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Total number of AE per patient	312	44 (81.48)	66	25 (46.30)
Blood and lymphatic system disorders				
- Total	14	9 (16.67)	11	6 (11.11)
Neutropenia	5	3 (5.56)	5	3 (5.56)
Febrile neutropenia	3	3 (5.56)	3	3 (5.56)
Anaemia	2	2 (3.70)	1	1 (1.85)
Thrombocytopenia	2	2 (3.70)	1	1 (1.85)
Leukopenia	1	1 (1.85)	1	1 (1.85)
Lymphadenopathy	1	1 (1.85)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.85)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.85)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Eye disorders				
- Total	5	5 (9.26)	0	0 (0.00)
Dry eye	2	2 (3.70)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.85)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.85)	0	0 (0.00)
Vision blurred	1	1 (1.85)	0	0 (0.00)
Gastrointestinal disorders				
- Total	37	15 (27.78)	8	4 (7.41)
Vomiting	13	9 (16.67)	2	2 (3.70)
Diarrhoea	8	8 (14.81)	1	1 (1.85)
Nausea	7	6 (11.11)	2	2 (3.70)
Abdominal pain	4	4 (7.41)	1	1 (1.85)
Oral pain	3	2 (3.70)	1	1 (1.85)
Abdominal pain upper	1	1 (1.85)	0	0 (0.00)
Enterocolitis	1	1 (1.85)	1	1 (1.85)
General disorders and administration site conditions				
- Total	19	16 (29.63)	1	1 (1.85)
Pyrexia	9	9 (16.67)	1	1 (1.85)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Fatigue	2	2 (3.70)	0	0 (0.00)
Influenza like illness	2	2 (3.70)	0	0 (0.00)
Acquired gene mutation	1	1 (1.85)	0	0 (0.00)
Catheter site pain	1	1 (1.85)	0	0 (0.00)
Crying	1	1 (1.85)	0	0 (0.00)
Generalised oedema	1	1 (1.85)	0	0 (0.00)
Malaise	1	1 (1.85)	0	0 (0.00)
Oedema peripheral	1	1 (1.85)	0	0 (0.00)
Immune system disorders				
- Total	16	13 (24.07)	1	1 (1.85)
Hypogammaglobulinaemia	9	8 (14.81)	1	1 (1.85)
Graft versus host disease	2	1 (1.85)	0	0 (0.00)
Immunodeficiency common variable	2	2 (3.70)	0	0 (0.00)
Seasonal allergy	2	2 (3.70)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.85)	0	0 (0.00)
Infections and infestations				
- Total	54	32 (59.26)	14	11 (20.37)
Upper respiratory tract infection	7	7 (12.96)	1	1 (1.85)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Rhinovirus infection	4	2 (3.70)	0	0 (0.00)
Gastroenteritis	3	3 (5.56)	0	0 (0.00)
Influenza	3	3 (5.56)	0	0 (0.00)
Urinary tract infection	3	3 (5.56)	1	1 (1.85)
Ear infection	2	2 (3.70)	0	0 (0.00)
Otitis media	2	1 (1.85)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.70)	1	1 (1.85)
Sinusitis	2	2 (3.70)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (3.70)	1	1 (1.85)
Bacterial sepsis	1	1 (1.85)	1	1 (1.85)
Cholecystitis infective	1	1 (1.85)	1	1 (1.85)
Corona virus infection	1	1 (1.85)	1	1 (1.85)
Cytomegalovirus infection	1	1 (1.85)	0	0 (0.00)
Enterovirus infection	1	1 (1.85)	1	1 (1.85)
Escherichia urinary tract infection	1	1 (1.85)	1	1 (1.85)
Gastroenteritis norovirus	1	1 (1.85)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.85)	0	0 (0.00)
Herpes zoster	1	1 (1.85)	1	1 (1.85)
Molluscum contagiosum	1	1 (1.85)	0	0 (0.00)
Oral herpes	1	1 (1.85)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Otitis externa	1	1 (1.85)	0	0 (0.00)
Otitis media acute	1	1 (1.85)	0	0 (0.00)
Paronychia	1	1 (1.85)	0	0 (0.00)
Rash pustular	1	1 (1.85)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (1.85)	1	1 (1.85)
Rhinitis	1	1 (1.85)	0	0 (0.00)
Rotavirus infection	1	1 (1.85)	1	1 (1.85)
Sepsis	1	1 (1.85)	1	1 (1.85)
Subcutaneous abscess	1	1 (1.85)	0	0 (0.00)
Tinea capitis	1	1 (1.85)	0	0 (0.00)
Vascular device infection	1	1 (1.85)	1	1 (1.85)
Viral infection	1	1 (1.85)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (1.85)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	13	8 (14.81)	0	0 (0.00)
Contusion	2	2 (3.70)	0	0 (0.00)
Infusion related reaction	2	2 (3.70)	0	0 (0.00)
Procedural pain	2	2 (3.70)	0	0 (0.00)
Arthropod bite	1	1 (1.85)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Foot fracture	1	1 (1.85)	0	0 (0.00)
Procedural nausea	1	1 (1.85)	0	0 (0.00)
Radius fracture	1	1 (1.85)	0	0 (0.00)
Skin abrasion	1	1 (1.85)	0	0 (0.00)
Skin laceration	1	1 (1.85)	0	0 (0.00)
Sunburn	1	1 (1.85)	0	0 (0.00)
Investigations				
- Total	46	22 (40.74)	16	12 (22.22)
Neutrophil count decreased	11	7 (12.96)	8	6 (11.11)
White blood cell count decreased	7	5 (9.26)	3	2 (3.70)
Platelet count decreased	5	3 (5.56)	0	0 (0.00)
Weight decreased	4	4 (7.41)	0	0 (0.00)
Aspartate aminotransferase increased	3	3 (5.56)	2	2 (3.70)
Alanine aminotransferase increased	2	2 (3.70)	2	2 (3.70)
Blood urea increased	2	1 (1.85)	0	0 (0.00)
Haemoglobin decreased	2	2 (3.70)	0	0 (0.00)
Lymphocyte count decreased	2	2 (3.70)	0	0 (0.00)
Weight increased	2	2 (3.70)	0	0 (0.00)
Blood bilirubin increased	1	1 (1.85)	1	1 (1.85)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Blood creatinine increased	1	1 (1.85)	0	0 (0.00)
Blood magnesium decreased	1	1 (1.85)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.85)	0	0 (0.00)
Serum ferritin increased	1	1 (1.85)	0	0 (0.00)
Transaminases increased	1	1 (1.85)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	14	9 (16.67)	6	4 (7.41)
Decreased appetite	2	2 (3.70)	0	0 (0.00)
Hyperalbuminaemia	2	1 (1.85)	0	0 (0.00)
Hyperphosphataemia	2	2 (3.70)	0	0 (0.00)
Hypokalaemia	2	2 (3.70)	1	1 (1.85)
Dehydration	1	1 (1.85)	1	1 (1.85)
Hypercalcaemia	1	1 (1.85)	0	0 (0.00)
Hyperglycaemia	1	1 (1.85)	1	1 (1.85)
Hypophosphataemia	1	1 (1.85)	1	1 (1.85)
Iron overload	1	1 (1.85)	1	1 (1.85)
Tumour lysis syndrome	1	1 (1.85)	1	1 (1.85)
Musculoskeletal and connective tissue disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
- Total	17	14 (25.93)	0	0 (0.00)
Pain in extremity	8	8 (14.81)	0	0 (0.00)
Arthralgia	2	2 (3.70)	0	0 (0.00)
Muscular weakness	2	2 (3.70)	0	0 (0.00)
Flank pain	1	1 (1.85)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.85)	0	0 (0.00)
Osteonecrosis	1	1 (1.85)	0	0 (0.00)
Pain in jaw	1	1 (1.85)	0	0 (0.00)
Toe walking	1	1 (1.85)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.85)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.85)	0	0 (0.00)
Nervous system disorders				
- Total	9	7 (12.96)	0	0 (0.00)
Headache	4	4 (7.41)	0	0 (0.00)
Dizziness	3	3 (5.56)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.70)	0	0 (0.00)
Psychiatric disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
- Total	4	2 (3.70)	0	0 (0.00)
Depression	2	2 (3.70)	0	0 (0.00)
Anxiety	1	1 (1.85)	0	0 (0.00)
Sleep disorder	1	1 (1.85)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	3 (5.56)	3	2 (3.70)
Acute kidney injury	1	1 (1.85)	1	1 (1.85)
Calculus urinary	1	1 (1.85)	0	0 (0.00)
Haematuria	1	1 (1.85)	1	1 (1.85)
Nephrolithiasis	1	1 (1.85)	1	1 (1.85)
Urinary incontinence	1	1 (1.85)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (1.85)	1	1 (1.85)
Vaginal haemorrhage	1	1 (1.85)	1	1 (1.85)
Respiratory, thoracic and mediastinal disorders				
- Total	30	18 (33.33)	4	3 (5.56)
Cough	9	7 (12.96)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Nasal congestion	4	4 (7.41)	0	0 (0.00)
Rhinorrhoea	4	4 (7.41)	0	0 (0.00)
Oropharyngeal pain	3	3 (5.56)	0	0 (0.00)
Rhinitis allergic	3	3 (5.56)	0	0 (0.00)
Epistaxis	2	2 (3.70)	1	1 (1.85)
Acute respiratory failure	1	1 (1.85)	1	1 (1.85)
Dysphonia	1	1 (1.85)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.85)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.85)	1	1 (1.85)
Pulmonary oedema	1	1 (1.85)	1	1 (1.85)
Skin and subcutaneous tissue disorders				
- Total	23	15 (27.78)	1	1 (1.85)
Rash	5	4 (7.41)	0	0 (0.00)
Erythema	2	2 (3.70)	0	0 (0.00)
Rash erythematous	2	1 (1.85)	0	0 (0.00)
Alopecia	1	1 (1.85)	0	0 (0.00)
Dermatitis	1	1 (1.85)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.85)	1	1 (1.85)
Dermatitis atopic	1	1 (1.85)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Dry skin	1	1 (1.85)	0	0 (0.00)
Eczema	1	1 (1.85)	0	0 (0.00)
Hyperhidrosis	1	1 (1.85)	0	0 (0.00)
Ingrowing nail	1	1 (1.85)	0	0 (0.00)
Keloid scar	1	1 (1.85)	0	0 (0.00)
Papule	1	1 (1.85)	0	0 (0.00)
Petechiae	1	1 (1.85)	0	0 (0.00)
Pruritus	1	1 (1.85)	0	0 (0.00)
Rash maculo-papular	1	1 (1.85)	0	0 (0.00)
Rash pruritic	1	1 (1.85)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (3.70)	0	0 (0.00)
Hypertension	2	2 (3.70)	0	0 (0.00)
Hot flush	1	1 (1.85)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	5	1 (100.00)	2	1 (100.00)
Gastrointestinal disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Diarrhoea	1	1 (100.00)	0	0 (0.00)
Infections and infestations				
- Total	4	1 (100.00)	2	1 (100.00)
Urinary tract infection	2	1 (100.00)	1	1 (100.00)
Cellulitis of male external genital organ	1	1 (100.00)	1	1 (100.00)
Otitis media	1	1 (100.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.

1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Total number of AE per patient	85	21 (63.64)	21	11 (33.33)
Blood and lymphatic system disorders				
- Total	2	2 (6.06)	1	1 (3.03)
Febrile neutropenia	1	1 (3.03)	1	1 (3.03)
Thrombocytopenia	1	1 (3.03)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Tympanic membrane perforation	1	1 (3.03)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	2 (6.06)	0	0 (0.00)
Abdominal pain	1	1 (3.03)	0	0 (0.00)
Diarrhoea	1	1 (3.03)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Nausea	1	1 (3.03)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	2 (6.06)	1	1 (3.03)
Pyrexia	2	1 (3.03)	0	0 (0.00)
Chills	1	1 (3.03)	0	0 (0.00)
Cyst	1	1 (3.03)	1	1 (3.03)
Immune system disorders				
- Total	2	2 (6.06)	0	0 (0.00)
Chronic graft versus host disease	1	1 (3.03)	0	0 (0.00)
Immunodeficiency	1	1 (3.03)	0	0 (0.00)
Infections and infestations				
- Total	28	10 (30.30)	5	3 (9.09)
Otitis media	4	2 (6.06)	1	1 (3.03)
Otitis media acute	4	2 (6.06)	0	0 (0.00)
Upper respiratory tract infection	4	2 (6.06)	0	0 (0.00)
Sinusitis	3	3 (9.09)	0	0 (0.00)
Pneumonia	2	2 (6.06)	0	0 (0.00)
Campylobacter infection	1	1 (3.03)	1	1 (3.03)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Clostridium difficile infection	1	1 (3.03)	1	1 (3.03)
Gingivitis	1	1 (3.03)	0	0 (0.00)
Haemophilus infection	1	1 (3.03)	0	0 (0.00)
Meningitis aseptic	1	1 (3.03)	0	0 (0.00)
Respiratory tract infection	1	1 (3.03)	1	1 (3.03)
Respiratory tract infection viral	1	1 (3.03)	1	1 (3.03)
Skin infection	1	1 (3.03)	0	0 (0.00)
Urinary tract infection	1	1 (3.03)	0	0 (0.00)
Viral infection	1	1 (3.03)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (3.03)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (3.03)	1	1 (3.03)
Procedural pain	1	1 (3.03)	1	1 (3.03)
Investigations				
- Total	22	8 (24.24)	8	5 (15.15)
Lymphocyte count decreased	5	3 (9.09)	1	1 (3.03)
White blood cell count decreased	5	4 (12.12)	3	3 (9.09)
Alanine aminotransferase increased	3	3 (9.09)	2	2 (6.06)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Neutrophil count decreased	3	2 (6.06)	0	0 (0.00)
Aspartate aminotransferase increased	2	2 (6.06)	1	1 (3.03)
Blood alkaline phosphatase increased	1	1 (3.03)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (3.03)	0	0 (0.00)
C-reactive protein increased	1	1 (3.03)	0	0 (0.00)
Platelet count decreased	1	1 (3.03)	1	1 (3.03)
Metabolism and nutrition disorders				
- Total	2	2 (6.06)	1	1 (3.03)
Hypokalaemia	1	1 (3.03)	1	1 (3.03)
Vitamin D deficiency	1	1 (3.03)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Neck pain	1	1 (3.03)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.03)	1	1 (3.03)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Glioblastoma multiforme	1	1 (3.03)	1	1 (3.03)
Nervous system disorders				
- Total	4	3 (9.09)	1	1 (3.03)
Disturbance in attention	1	1 (3.03)	0	0 (0.00)
Dizziness	1	1 (3.03)	0	0 (0.00)
Headache	1	1 (3.03)	0	0 (0.00)
Seizure	1	1 (3.03)	1	1 (3.03)
Renal and urinary disorders				
- Total	3	2 (6.06)	1	1 (3.03)
Acute kidney injury	2	1 (3.03)	1	1 (3.03)
Haematuria	1	1 (3.03)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.03)	1	1 (3.03)
Ovarian failure	1	1 (3.03)	1	1 (3.03)
Respiratory, thoracic and mediastinal disorders				
- Total	7	4 (12.12)	0	0 (0.00)
Cough	3	2 (6.06)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Epistaxis	1	1 (3.03)	0	0 (0.00)
Oropharyngeal pain	1	1 (3.03)	0	0 (0.00)
Rhinitis allergic	1	1 (3.03)	0	0 (0.00)
Rhinorrhoea	1	1 (3.03)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (9.09)	0	0 (0.00)
Acne	1	1 (3.03)	0	0 (0.00)
Papule	1	1 (3.03)	0	0 (0.00)
Pruritus	1	1 (3.03)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Total number of AE per patient	58	2 (100.00)	7	1 (50.00)
Blood and lymphatic system disorders				
- Total	5	2 (100.00)	2	1 (50.00)
Eosinophilia	2	1 (50.00)	1	1 (50.00)
Anaemia	1	1 (50.00)	0	0 (0.00)
Lymphopenia	1	1 (50.00)	0	0 (0.00)
Neutropenia	1	1 (50.00)	1	1 (50.00)
Cardiac disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Sinus tachycardia	1	1 (50.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	2	1 (50.00)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Diarrhoea	1	1 (50.00)	0	0 (0.00)
Pigmentation lip	1	1 (50.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	8	2 (100.00)	0	0 (0.00)
Pyrexia	5	1 (50.00)	0	0 (0.00)
Chills	1	1 (50.00)	0	0 (0.00)
Fatigue	1	1 (50.00)	0	0 (0.00)
Pain	1	1 (50.00)	0	0 (0.00)
Immune system disorders				
- Total	3	2 (100.00)	0	0 (0.00)
Graft versus host disease	1	1 (50.00)	0	0 (0.00)
Graft versus host disease in skin	1	1 (50.00)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (50.00)	0	0 (0.00)
Infections and infestations				
- Total	11	1 (50.00)	5	1 (50.00)
Cellulitis of male external genital organ	6	1 (50.00)	3	1 (50.00)
Urinary tract infection	4	1 (50.00)	2	1 (50.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Otitis media	1	1 (50.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (50.00)	0	0 (0.00)
Skin abrasion	1	1 (50.00)	0	0 (0.00)
Investigations				
- Total	7	1 (50.00)	0	0 (0.00)
Neutrophil count decreased	2	1 (50.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (50.00)	0	0 (0.00)
Blood uric acid increased	1	1 (50.00)	0	0 (0.00)
International normalised ratio increased	1	1 (50.00)	0	0 (0.00)
Lymphocyte count decreased	1	1 (50.00)	0	0 (0.00)
White blood cell count decreased	1	1 (50.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	3	2 (100.00)	0	0 (0.00)
Hyperphosphataemia	1	1 (50.00)	0	0 (0.00)
Hyperuricaemia	1	1 (50.00)	0	0 (0.00)
Vitamin D deficiency	1	1 (50.00)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	7	2 (100.00)	0	0 (0.00)
Joint range of motion decreased	2	2 (100.00)	0	0 (0.00)
Arthralgia	1	1 (50.00)	0	0 (0.00)
Back pain	1	1 (50.00)	0	0 (0.00)
Muscle spasms	1	1 (50.00)	0	0 (0.00)
Myalgia	1	1 (50.00)	0	0 (0.00)
Pain in extremity	1	1 (50.00)	0	0 (0.00)
Nervous system disorders				
- Total	5	2 (100.00)	0	0 (0.00)
Headache	5	2 (100.00)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Scrotal pain	1	1 (50.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	1	1 (50.00)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Cough	1	1 (50.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	1 (50.00)	0	0 (0.00)
Macule	1	1 (50.00)	0	0 (0.00)
Rash maculo-papular	1	1 (50.00)	0	0 (0.00)
Skin irritation	1	1 (50.00)	0	0 (0.00)

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Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Total number of AE per patient	1692	62 (100.00)	545	58 (93.55)
Blood and lymphatic system disorders				
- Total	137	46 (74.19)	105	42 (67.74)
Anaemia	48	26 (41.94)	32	20 (32.26)
Thrombocytopenia	33	10 (16.13)	24	9 (14.52)
Febrile neutropenia	30	24 (38.71)	30	24 (38.71)
Neutropenia	14	10 (16.13)	13	10 (16.13)
Disseminated intravascular coagulation	5	4 (6.45)	2	2 (3.23)
Lymphopenia	3	3 (4.84)	2	2 (3.23)
Coagulopathy	1	1 (1.61)	0	0 (0.00)
Leukopenia	1	1 (1.61)	1	1 (1.61)
Lymphadenopathy	1	1 (1.61)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Pancytopenia	1	1 (1.61)	1	1 (1.61)
Cardiac disorders				
- Total	32	22 (35.48)	3	2 (3.23)
Tachycardia	17	15 (24.19)	2	2 (3.23)
Sinus tachycardia	5	5 (8.06)	0	0 (0.00)
Pericardial effusion	2	2 (3.23)	0	0 (0.00)
Sinus bradycardia	2	1 (1.61)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.61)	0	0 (0.00)
Bradycardia	1	1 (1.61)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.61)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.61)	1	1 (1.61)
Palpitations	1	1 (1.61)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.61)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	4	4 (6.45)	0	0 (0.00)
Ear pain	2	2 (3.23)	0	0 (0.00)
Hypoacusis	1	1 (1.61)	0	0 (0.00)
Tympanic membrane perforation	1	1 (1.61)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Endocrine disorders				
- Total	2	2 (3.23)	0	0 (0.00)
Adrenal insufficiency	2	2 (3.23)	0	0 (0.00)
Eye disorders				
- Total	30	18 (29.03)	0	0 (0.00)
Vision blurred	5	4 (6.45)	0	0 (0.00)
Eye pain	4	3 (4.84)	0	0 (0.00)
Periorbital oedema	4	4 (6.45)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (4.84)	0	0 (0.00)
Photophobia	3	2 (3.23)	0	0 (0.00)
Dry eye	2	2 (3.23)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.23)	0	0 (0.00)
Uveitis	2	2 (3.23)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.61)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.61)	0	0 (0.00)
Ocular hypertension	1	1 (1.61)	0	0 (0.00)
Papilloedema	1	1 (1.61)	0	0 (0.00)
Visual impairment	1	1 (1.61)	0	0 (0.00)
Gastrointestinal disorders				

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
- Total	166	42 (67.74)	23	13 (20.97)
Vomiting	48	27 (43.55)	5	3 (4.84)
Nausea	34	25 (40.32)	5	5 (8.06)
Diarrhoea	27	23 (37.10)	2	2 (3.23)
Abdominal pain	15	11 (17.74)	2	1 (1.61)
Constipation	8	7 (11.29)	0	0 (0.00)
Abdominal pain upper	3	3 (4.84)	0	0 (0.00)
Oral pain	3	2 (3.23)	1	1 (1.61)
Abdominal distension	2	2 (3.23)	0	0 (0.00)
Anal incontinence	2	1 (1.61)	0	0 (0.00)
Dysphagia	2	2 (3.23)	1	1 (1.61)
Haematemesis	2	2 (3.23)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.61)	2	1 (1.61)
Pancreatitis	2	2 (3.23)	1	1 (1.61)
Stomatitis	2	2 (3.23)	0	0 (0.00)
Abdominal discomfort	1	1 (1.61)	0	0 (0.00)
Abdominal pain lower	1	1 (1.61)	0	0 (0.00)
Abdominal tenderness	1	1 (1.61)	0	0 (0.00)
Ascites	1	1 (1.61)	1	1 (1.61)
Dyspepsia	1	1 (1.61)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Enterocolitis	1	1 (1.61)	1	1 (1.61)
Flatulence	1	1 (1.61)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.61)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.61)	0	0 (0.00)
Glossodynia	1	1 (1.61)	0	0 (0.00)
Ileus	1	1 (1.61)	1	1 (1.61)
Intestinal obstruction	1	1 (1.61)	1	1 (1.61)
Lip pain	1	1 (1.61)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.61)	0	0 (0.00)
General disorders and administration site conditions				
- Total	99	40 (64.52)	16	12 (19.35)
Pyrexia	38	24 (38.71)	7	7 (11.29)
Fatigue	15	14 (22.58)	1	1 (1.61)
Chills	10	9 (14.52)	0	0 (0.00)
Catheter site pain	4	4 (6.45)	0	0 (0.00)
Generalised oedema	4	3 (4.84)	0	0 (0.00)
Malaise	4	4 (6.45)	0	0 (0.00)
Oedema peripheral	3	3 (4.84)	1	1 (1.61)
Pain	3	3 (4.84)	2	2 (3.23)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Face oedema	2	2 (3.23)	1	1 (1.61)
Influenza like illness	2	2 (3.23)	0	0 (0.00)
Acquired gene mutation	1	1 (1.61)	0	0 (0.00)
Asthenia	1	1 (1.61)	0	0 (0.00)
Catheter site extravasation	1	1 (1.61)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.61)	0	0 (0.00)
Crying	1	1 (1.61)	0	0 (0.00)
Cyst	1	1 (1.61)	1	1 (1.61)
Facial pain	1	1 (1.61)	0	0 (0.00)
Injection site haematoma	1	1 (1.61)	0	0 (0.00)
Localised oedema	1	1 (1.61)	1	1 (1.61)
Mucosal haemorrhage	1	1 (1.61)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.61)	1	1 (1.61)
Non-cardiac chest pain	1	1 (1.61)	0	0 (0.00)
Peripheral swelling	1	1 (1.61)	0	0 (0.00)
Physical deconditioning	1	1 (1.61)	1	1 (1.61)
Hepatobiliary disorders				
- Total	9	7 (11.29)	2	2 (3.23)
Hyperbilirubinaemia	4	3 (4.84)	2	2 (3.23)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Hepatomegaly	3	3 (4.84)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.61)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.61)	0	0 (0.00)
Immune system disorders				
- Total	132	56 (90.32)	34	22 (35.48)
Cytokine release syndrome	86	50 (80.65)	29	19 (30.65)
Hypogammaglobulinaemia	35	32 (51.61)	5	5 (8.06)
Graft versus host disease	2	1 (1.61)	0	0 (0.00)
Immunodeficiency common variable	2	2 (3.23)	0	0 (0.00)
Seasonal allergy	2	2 (3.23)	0	0 (0.00)
Chronic graft versus host disease	1	1 (1.61)	0	0 (0.00)
Drug hypersensitivity	1	1 (1.61)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.61)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.61)	0	0 (0.00)
Immunodeficiency	1	1 (1.61)	0	0 (0.00)
Infections and infestations				
- Total	123	45 (72.58)	26	17 (27.42)
Upper respiratory tract infection	12	9 (14.52)	1	1 (1.61)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Rhinovirus infection	7	5 (8.06)	0	0 (0.00)
Otitis media	6	3 (4.84)	1	1 (1.61)
Clostridium difficile infection	5	5 (8.06)	1	1 (1.61)
Gastroenteritis	5	5 (8.06)	1	1 (1.61)
Otitis media acute	5	2 (3.23)	0	0 (0.00)
Sinusitis	5	4 (6.45)	0	0 (0.00)
Clostridium difficile colitis	4	4 (6.45)	1	1 (1.61)
Influenza	4	4 (6.45)	0	0 (0.00)
Pneumonia	4	4 (6.45)	1	1 (1.61)
Urinary tract infection	4	4 (6.45)	1	1 (1.61)
Viral infection	3	3 (4.84)	0	0 (0.00)
Viral upper respiratory tract infection	3	3 (4.84)	1	1 (1.61)
Cytomegalovirus infection	2	2 (3.23)	0	0 (0.00)
Ear infection	2	2 (3.23)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (1.61)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.23)	1	1 (1.61)
Skin infection	2	2 (3.23)	0	0 (0.00)
Staphylococcal infection	2	2 (3.23)	1	1 (1.61)
Vulvovaginal candidiasis	2	2 (3.23)	0	0 (0.00)
Acute sinusitis	1	1 (1.61)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Bacterial sepsis	1	1 (1.61)	1	1 (1.61)
Body tinea	1	1 (1.61)	0	0 (0.00)
Campylobacter infection	1	1 (1.61)	1	1 (1.61)
Catheter site cellulitis	1	1 (1.61)	0	0 (0.00)
Catheter site infection	1	1 (1.61)	1	1 (1.61)
Cholecystitis infective	1	1 (1.61)	1	1 (1.61)
Corona virus infection	1	1 (1.61)	1	1 (1.61)
Enterococcal infection	1	1 (1.61)	0	0 (0.00)
Enterovirus infection	1	1 (1.61)	1	1 (1.61)
Escherichia urinary tract infection	1	1 (1.61)	1	1 (1.61)
Folliculitis	1	1 (1.61)	0	0 (0.00)
Fungal skin infection	1	1 (1.61)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.61)	0	0 (0.00)
Gingivitis	1	1 (1.61)	0	0 (0.00)
Haemophilus infection	1	1 (1.61)	0	0 (0.00)
Herpes simplex	1	1 (1.61)	0	0 (0.00)
Herpes zoster	1	1 (1.61)	1	1 (1.61)
Human herpesvirus 6 infection	1	1 (1.61)	0	0 (0.00)
Hypopyon	1	1 (1.61)	0	0 (0.00)
Meningitis aseptic	1	1 (1.61)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Molluscum contagiosum	1	1 (1.61)	0	0 (0.00)
Oral candidiasis	1	1 (1.61)	0	0 (0.00)
Oral herpes	1	1 (1.61)	0	0 (0.00)
Orchitis	1	1 (1.61)	0	0 (0.00)
Otitis externa	1	1 (1.61)	0	0 (0.00)
Paronychia	1	1 (1.61)	0	0 (0.00)
Pharyngitis	1	1 (1.61)	0	0 (0.00)
Rash pustular	1	1 (1.61)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (1.61)	1	1 (1.61)
Respiratory tract infection	1	1 (1.61)	1	1 (1.61)
Respiratory tract infection viral	1	1 (1.61)	1	1 (1.61)
Rhinitis	1	1 (1.61)	0	0 (0.00)
Rotavirus infection	1	1 (1.61)	1	1 (1.61)
Sepsis	1	1 (1.61)	1	1 (1.61)
Septic embolus	1	1 (1.61)	1	1 (1.61)
Streptococcal infection	1	1 (1.61)	0	0 (0.00)
Subcutaneous abscess	1	1 (1.61)	0	0 (0.00)
Tinea capitis	1	1 (1.61)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.61)	1	1 (1.61)
Vascular device infection	1	1 (1.61)	1	1 (1.61)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Vulvovaginal mycotic infection	1	1 (1.61)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	38	21 (33.87)	3	3 (4.84)
Procedural pain	6	5 (8.06)	1	1 (1.61)
Infusion related reaction	4	4 (6.45)	0	0 (0.00)
Transfusion reaction	4	3 (4.84)	0	0 (0.00)
Contusion	3	3 (4.84)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.61)	1	1 (1.61)
Arthropod bite	1	1 (1.61)	0	0 (0.00)
Foot fracture	1	1 (1.61)	0	0 (0.00)
Incision site pain	1	1 (1.61)	0	0 (0.00)
Limb injury	1	1 (1.61)	0	0 (0.00)
Mouth injury	1	1 (1.61)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.61)	0	0 (0.00)
Procedural complication	1	1 (1.61)	0	0 (0.00)
Procedural headache	1	1 (1.61)	0	0 (0.00)
Procedural nausea	1	1 (1.61)	0	0 (0.00)
Procedural site reaction	1	1 (1.61)	0	0 (0.00)
Radius fracture	1	1 (1.61)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Skin abrasion	1	1 (1.61)	0	0 (0.00)
Skin laceration	1	1 (1.61)	0	0 (0.00)
Stoma site irritation	1	1 (1.61)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.61)	0	0 (0.00)
Sunburn	1	1 (1.61)	0	0 (0.00)
Tibia fracture	1	1 (1.61)	0	0 (0.00)
Tongue injury	1	1 (1.61)	0	0 (0.00)
Transfusion related complication	1	1 (1.61)	1	1 (1.61)
Investigations				
- Total	395	55 (88.71)	202	49 (79.03)
White blood cell count decreased	66	34 (54.84)	43	30 (48.39)
Neutrophil count decreased	60	27 (43.55)	52	25 (40.32)
Platelet count decreased	49	20 (32.26)	38	15 (24.19)
Aspartate aminotransferase increased	37	20 (32.26)	19	12 (19.35)
Alanine aminotransferase increased	33	21 (33.87)	18	14 (22.58)
Lymphocyte count decreased	22	15 (24.19)	13	12 (19.35)
Prothrombin time prolonged	17	9 (14.52)	1	1 (1.61)
Blood fibrinogen decreased	15	4 (6.45)	4	3 (4.84)
Blood bilirubin increased	14	8 (12.90)	3	3 (4.84)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Blood creatinine increased	12	9 (14.52)	2	2 (3.23)
International normalised ratio increased	10	8 (12.90)	1	1 (1.61)
Activated partial thromboplastin time prolonged	8	5 (8.06)	0	0 (0.00)
Blood urea increased	5	3 (4.84)	1	1 (1.61)
Blood immunoglobulin M decreased	4	4 (6.45)	0	0 (0.00)
Weight decreased	4	4 (6.45)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.23)	0	0 (0.00)
Haemoglobin decreased	3	3 (4.84)	1	1 (1.61)
Transaminases increased	3	3 (4.84)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (3.23)	0	0 (0.00)
Blood magnesium decreased	2	2 (3.23)	1	1 (1.61)
Blood sodium increased	2	1 (1.61)	0	0 (0.00)
Blood uric acid increased	2	1 (1.61)	0	0 (0.00)
C-reactive protein increased	2	2 (3.23)	1	1 (1.61)
Lipase increased	2	2 (3.23)	2	2 (3.23)
Serum ferritin increased	2	2 (3.23)	0	0 (0.00)
Weight increased	2	2 (3.23)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (1.61)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Blood bicarbonate decreased	1	1 (1.61)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.61)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (1.61)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.61)	1	1 (1.61)
Blood phosphorus decreased	1	1 (1.61)	0	0 (0.00)
Cardiac murmur	1	1 (1.61)	0	0 (0.00)
Culture stool positive	1	1 (1.61)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.61)	0	0 (0.00)
Hepatic enzyme increased	1	1 (1.61)	0	0 (0.00)
Norovirus test positive	1	1 (1.61)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.61)	0	0 (0.00)
Protein total decreased	1	1 (1.61)	1	1 (1.61)
Pulmonary function test decreased	1	1 (1.61)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	130	41 (66.13)	50	27 (43.55)
Decreased appetite	26	22 (35.48)	13	12 (19.35)
Hypokalaemia	23	19 (30.65)	9	9 (14.52)
Hypophosphataemia	14	10 (16.13)	10	8 (12.90)
Hyperphosphataemia	11	7 (11.29)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Hypernatraemia	7	4 (6.45)	1	1 (1.61)
Hypoalbuminaemia	6	5 (8.06)	1	1 (1.61)
Hyperglycaemia	5	3 (4.84)	2	2 (3.23)
Dehydration	4	4 (6.45)	3	3 (4.84)
Hypocalcaemia	4	3 (4.84)	1	1 (1.61)
Fluid overload	3	3 (4.84)	0	0 (0.00)
Hyperalbuminaemia	3	1 (1.61)	0	0 (0.00)
Hypercalcaemia	3	1 (1.61)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.23)	1	1 (1.61)
Hyperuricaemia	3	2 (3.23)	1	1 (1.61)
Hyponatraemia	3	2 (3.23)	3	2 (3.23)
Acidosis	2	2 (3.23)	1	1 (1.61)
Tumour lysis syndrome	2	2 (3.23)	2	2 (3.23)
Hyperchloraemia	1	1 (1.61)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.61)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.61)	0	0 (0.00)
Iron overload	1	1 (1.61)	1	1 (1.61)
Malnutrition	1	1 (1.61)	1	1 (1.61)
Metabolic acidosis	1	1 (1.61)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.61)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Vitamin D deficiency	1	1 (1.61)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	38	23 (37.10)	1	1 (1.61)
Pain in extremity	11	10 (16.13)	0	0 (0.00)
Arthralgia	5	4 (6.45)	1	1 (1.61)
Musculoskeletal pain	4	3 (4.84)	0	0 (0.00)
Myalgia	4	4 (6.45)	0	0 (0.00)
Muscular weakness	3	3 (4.84)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (3.23)	0	0 (0.00)
Coccydynia	1	1 (1.61)	0	0 (0.00)
Flank pain	1	1 (1.61)	0	0 (0.00)
Limb discomfort	1	1 (1.61)	0	0 (0.00)
Muscle spasms	1	1 (1.61)	0	0 (0.00)
Neck pain	1	1 (1.61)	0	0 (0.00)
Osteonecrosis	1	1 (1.61)	0	0 (0.00)
Osteopenia	1	1 (1.61)	0	0 (0.00)
Pain in jaw	1	1 (1.61)	0	0 (0.00)
Toe walking	1	1 (1.61)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (4.84)	1	1 (1.61)
Glioblastoma multiforme	1	1 (1.61)	1	1 (1.61)
Myelodysplastic syndrome	1	1 (1.61)	0	0 (0.00)
Skin papilloma	1	1 (1.61)	0	0 (0.00)
Nervous system disorders				
- Total	69	33 (53.23)	7	6 (9.68)
Headache	34	22 (35.48)	2	2 (3.23)
Dizziness	8	6 (9.68)	0	0 (0.00)
Encephalopathy	6	4 (6.45)	2	2 (3.23)
Seizure	4	4 (6.45)	2	2 (3.23)
Dysarthria	2	2 (3.23)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.23)	0	0 (0.00)
Tremor	2	2 (3.23)	0	0 (0.00)
Asterixis	1	1 (1.61)	0	0 (0.00)
Ataxia	1	1 (1.61)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.61)	0	0 (0.00)
Disturbance in attention	1	1 (1.61)	0	0 (0.00)
Embolic stroke	1	1 (1.61)	1	1 (1.61)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Idiopathic intracranial hypertension	1	1 (1.61)	0	0 (0.00)
Migraine	1	1 (1.61)	0	0 (0.00)
Myoclonus	1	1 (1.61)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.61)	0	0 (0.00)
Pleocytosis	1	1 (1.61)	0	0 (0.00)
Somnolence	1	1 (1.61)	0	0 (0.00)
Product issues				
- Total	1	1 (1.61)	0	0 (0.00)
Device occlusion	1	1 (1.61)	0	0 (0.00)
Psychiatric disorders				
- Total	34	17 (27.42)	1	1 (1.61)
Anxiety	7	7 (11.29)	1	1 (1.61)
Confusional state	6	6 (9.68)	0	0 (0.00)
Delirium	4	4 (6.45)	0	0 (0.00)
Agitation	3	2 (3.23)	0	0 (0.00)
Hallucination	3	2 (3.23)	0	0 (0.00)
Depression	2	2 (3.23)	0	0 (0.00)
Irritability	2	2 (3.23)	0	0 (0.00)
Adjustment disorder	1	1 (1.61)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Insomnia	1	1 (1.61)	0	0 (0.00)
Listless	1	1 (1.61)	0	0 (0.00)
Mental status changes	1	1 (1.61)	0	0 (0.00)
Panic attack	1	1 (1.61)	0	0 (0.00)
Sleep disorder	1	1 (1.61)	0	0 (0.00)
Suicidal ideation	1	1 (1.61)	0	0 (0.00)
Renal and urinary disorders				
- Total	26	15 (24.19)	15	10 (16.13)
Acute kidney injury	10	9 (14.52)	7	7 (11.29)
Haematuria	6	5 (8.06)	3	3 (4.84)
Dysuria	2	2 (3.23)	0	0 (0.00)
Oliguria	2	2 (3.23)	2	2 (3.23)
Calculus urinary	1	1 (1.61)	0	0 (0.00)
Nephrolithiasis	1	1 (1.61)	1	1 (1.61)
Pollakiuria	1	1 (1.61)	0	0 (0.00)
Renal failure	1	1 (1.61)	1	1 (1.61)
Renal impairment	1	1 (1.61)	1	1 (1.61)
Urinary incontinence	1	1 (1.61)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Reproductive system and breast disorders				
- Total	6	5 (8.06)	2	2 (3.23)
Oedema genital	2	1 (1.61)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.23)	0	0 (0.00)
Ovarian failure	1	1 (1.61)	1	1 (1.61)
Vaginal haemorrhage	1	1 (1.61)	1	1 (1.61)
Respiratory, thoracic and mediastinal disorders				
- Total	109	37 (59.68)	32	15 (24.19)
Cough	19	13 (20.97)	0	0 (0.00)
Epistaxis	14	10 (16.13)	5	5 (8.06)
Hypoxia	13	10 (16.13)	8	7 (11.29)
Pleural effusion	8	8 (12.90)	2	2 (3.23)
Pulmonary oedema	7	7 (11.29)	6	6 (9.68)
Oropharyngeal pain	6	6 (9.68)	0	0 (0.00)
Rhinorrhoea	6	6 (9.68)	0	0 (0.00)
Tachypnoea	6	5 (8.06)	1	1 (1.61)
Nasal congestion	5	5 (8.06)	0	0 (0.00)
Rhinitis allergic	5	4 (6.45)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Dyspnoea	3	2 (3.23)	2	2 (3.23)
Haemoptysis	3	2 (3.23)	1	1 (1.61)
Respiratory failure	3	3 (4.84)	3	3 (4.84)
Acute respiratory failure	1	1 (1.61)	1	1 (1.61)
Atelectasis	1	1 (1.61)	0	0 (0.00)
Dysphonia	1	1 (1.61)	0	0 (0.00)
Interstitial lung disease	1	1 (1.61)	1	1 (1.61)
Oropharyngeal plaque	1	1 (1.61)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.61)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.61)	1	1 (1.61)
Pharyngeal ulceration	1	1 (1.61)	0	0 (0.00)
Respiratory depression	1	1 (1.61)	0	0 (0.00)
Respiratory distress	1	1 (1.61)	1	1 (1.61)
Wheezing	1	1 (1.61)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	66	29 (46.77)	3	3 (4.84)
Rash	9	8 (12.90)	0	0 (0.00)
Erythema	6	5 (8.06)	0	0 (0.00)
Dry skin	5	5 (8.06)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Hyperhidrosis	5	4 (6.45)	0	0 (0.00)
Ingrowing nail	4	3 (4.84)	0	0 (0.00)
Petechiae	4	4 (6.45)	0	0 (0.00)
Pruritus	4	4 (6.45)	0	0 (0.00)
Rash maculo-papular	4	4 (6.45)	1	1 (1.61)
Rash erythematous	3	2 (3.23)	0	0 (0.00)
Papule	2	2 (3.23)	0	0 (0.00)
Rash papular	2	2 (3.23)	0	0 (0.00)
Acne	1	1 (1.61)	0	0 (0.00)
Alopecia	1	1 (1.61)	0	0 (0.00)
Dermatitis	1	1 (1.61)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.61)	1	1 (1.61)
Dermatitis atopic	1	1 (1.61)	0	0 (0.00)
Dermatitis diaper	1	1 (1.61)	0	0 (0.00)
Ecchymosis	1	1 (1.61)	1	1 (1.61)
Eczema	1	1 (1.61)	0	0 (0.00)
Keloid scar	1	1 (1.61)	0	0 (0.00)
Livedo reticularis	1	1 (1.61)	0	0 (0.00)
Macule	1	1 (1.61)	0	0 (0.00)
Night sweats	1	1 (1.61)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Rash follicular	1	1 (1.61)	0	0 (0.00)
Rash macular	1	1 (1.61)	0	0 (0.00)
Rash pruritic	1	1 (1.61)	0	0 (0.00)
Rash vesicular	1	1 (1.61)	0	0 (0.00)
Skin exfoliation	1	1 (1.61)	0	0 (0.00)
Skin fissures	1	1 (1.61)	0	0 (0.00)
Vascular disorders				
- Total	43	25 (40.32)	19	16 (25.81)
Hypotension	19	16 (25.81)	16	15 (24.19)
Hypertension	14	12 (19.35)	1	1 (1.61)
Flushing	3	2 (3.23)	0	0 (0.00)
Orthostatic hypotension	2	2 (3.23)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.61)	1	1 (1.61)
Embolism	1	1 (1.61)	1	1 (1.61)
Haematoma	1	1 (1.61)	0	0 (0.00)
Hot flush	1	1 (1.61)	0	0 (0.00)
Secondary hypertension	1	1 (1.61)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Total number of AE per patient	105	3 (100.00)	51	3 (100.00)
Blood and lymphatic system disorders				
- Total	5	2 (66.67)	5	2 (66.67)
Anaemia	3	2 (66.67)	3	2 (66.67)
Neutropenia	1	1 (33.33)	1	1 (33.33)
Thrombocytopenia	1	1 (33.33)	1	1 (33.33)
Cardiac disorders				
- Total	4	2 (66.67)	2	1 (33.33)
Bradycardia	1	1 (33.33)	0	0 (0.00)
Left ventricular dysfunction	1	1 (33.33)	1	1 (33.33)
Pericardial effusion	1	1 (33.33)	0	0 (0.00)
Tachycardia	1	1 (33.33)	1	1 (33.33)
Eye disorders				

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
- Total	2	1 (33.33)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (33.33)	0	0 (0.00)
Periorbital oedema	1	1 (33.33)	0	0 (0.00)
Gastrointestinal disorders				
- Total	5	2 (66.67)	2	2 (66.67)
Nausea	2	1 (33.33)	1	1 (33.33)
Diarrhoea	1	1 (33.33)	0	0 (0.00)
Dysphagia	1	1 (33.33)	1	1 (33.33)
Vomiting	1	1 (33.33)	0	0 (0.00)
General disorders and administration site conditions				
- Total	10	2 (66.67)	5	2 (66.67)
Pyrexia	3	1 (33.33)	1	1 (33.33)
Asthenia	1	1 (33.33)	0	0 (0.00)
Chills	1	1 (33.33)	0	0 (0.00)
Face oedema	1	1 (33.33)	1	1 (33.33)
Localised oedema	1	1 (33.33)	1	1 (33.33)
Mucosal haemorrhage	1	1 (33.33)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (33.33)	1	1 (33.33)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Oedema peripheral	1	1 (33.33)	1	1 (33.33)
Hepatobiliary disorders				
- Total	2	2 (66.67)	1	1 (33.33)
Hepatomegaly	1	1 (33.33)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (33.33)	1	1 (33.33)
Immune system disorders				
- Total	8	2 (66.67)	4	2 (66.67)
Cytokine release syndrome	8	2 (66.67)	4	2 (66.67)
Injury, poisoning and procedural complications				
- Total	3	2 (66.67)	1	1 (33.33)
Tracheal haemorrhage	2	1 (33.33)	1	1 (33.33)
Procedural complication	1	1 (33.33)	0	0 (0.00)
Investigations				
- Total	21	3 (100.00)	13	3 (100.00)
Aspartate aminotransferase increased	6	2 (66.67)	4	2 (66.67)
Blood fibrinogen decreased	2	2 (66.67)	1	1 (33.33)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
International normalised ratio increased	2	1 (33.33)	0	0 (0.00)
Platelet count decreased	2	1 (33.33)	2	1 (33.33)
White blood cell count decreased	2	1 (33.33)	1	1 (33.33)
Alanine aminotransferase increased	1	1 (33.33)	1	1 (33.33)
Blood creatinine increased	1	1 (33.33)	1	1 (33.33)
Blood phosphorus decreased	1	1 (33.33)	0	0 (0.00)
Blood urea increased	1	1 (33.33)	1	1 (33.33)
Neutrophil count decreased	1	1 (33.33)	1	1 (33.33)
Protein total decreased	1	1 (33.33)	1	1 (33.33)
Prothrombin time prolonged	1	1 (33.33)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	16	2 (66.67)	4	2 (66.67)
Hypokalaemia	3	2 (66.67)	1	1 (33.33)
Hypercalcaemia	2	1 (33.33)	0	0 (0.00)
Hypernatraemia	2	1 (33.33)	0	0 (0.00)
Hypophosphataemia	2	2 (66.67)	1	1 (33.33)
Acidosis	1	1 (33.33)	1	1 (33.33)
Decreased appetite	1	1 (33.33)	1	1 (33.33)
Hyperalbuminaemia	1	1 (33.33)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Hyperchloraemia	1	1 (33.33)	0	0 (0.00)
Hypermagnesaemia	1	1 (33.33)	0	0 (0.00)
Hypoalbuminaemia	1	1 (33.33)	0	0 (0.00)
Metabolic alkalosis	1	1 (33.33)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (33.33)	0	0 (0.00)
Dizziness	1	1 (33.33)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (66.67)	0	0 (0.00)
Confusional state	1	1 (33.33)	0	0 (0.00)
Delirium	1	1 (33.33)	0	0 (0.00)
Insomnia	1	1 (33.33)	0	0 (0.00)
Irritability	1	1 (33.33)	0	0 (0.00)
Renal and urinary disorders				
- Total	3	2 (66.67)	3	2 (66.67)
Acute kidney injury	1	1 (33.33)	1	1 (33.33)
Haematuria	1	1 (33.33)	1	1 (33.33)
Renal impairment	1	1 (33.33)	1	1 (33.33)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	11	2 (66.67)	8	2 (66.67)
Hypoxia	2	1 (33.33)	2	1 (33.33)
Pleural effusion	2	2 (66.67)	1	1 (33.33)
Pulmonary oedema	2	2 (66.67)	2	2 (66.67)
Cough	1	1 (33.33)	0	0 (0.00)
Dyspnoea	1	1 (33.33)	1	1 (33.33)
Epistaxis	1	1 (33.33)	0	0 (0.00)
Interstitial lung disease	1	1 (33.33)	1	1 (33.33)
Respiratory distress	1	1 (33.33)	1	1 (33.33)
Skin and subcutaneous tissue disorders				
- Total	3	1 (33.33)	0	0 (0.00)
Hyperhidrosis	2	1 (33.33)	0	0 (0.00)
Rash papular	1	1 (33.33)	0	0 (0.00)
Vascular disorders				
- Total	7	2 (66.67)	3	2 (66.67)
Flushing	2	1 (33.33)	0	0 (0.00)
Hypertension	2	2 (66.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Hypotension	2	2 (66.67)	2	2 (66.67)
Capillary leak syndrome	1	1 (33.33)	1	1 (33.33)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Total number of AE per patient	1209	60 (98.36)	407	51 (83.61)
Blood and lymphatic system disorders				
- Total	117	41 (67.21)	88	36 (59.02)
Anaemia	44	25 (40.98)	28	17 (27.87)
Thrombocytopenia	29	7 (11.48)	22	7 (11.48)
Febrile neutropenia	26	22 (36.07)	26	22 (36.07)
Neutropenia	8	7 (11.48)	7	7 (11.48)
Disseminated intravascular coagulation	5	4 (6.56)	2	2 (3.28)
Lymphopenia	3	3 (4.92)	2	2 (3.28)
Coagulopathy	1	1 (1.64)	0	0 (0.00)
Pancytopenia	1	1 (1.64)	1	1 (1.64)
Cardiac disorders				
- Total	28	20 (32.79)	1	1 (1.64)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Tachycardia	16	14 (22.95)	1	1 (1.64)
Sinus tachycardia	5	5 (8.20)	0	0 (0.00)
Sinus bradycardia	2	1 (1.64)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.64)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.64)	0	0 (0.00)
Palpitations	1	1 (1.64)	0	0 (0.00)
Pericardial effusion	1	1 (1.64)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.64)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (4.92)	0	0 (0.00)
Ear pain	2	2 (3.28)	0	0 (0.00)
Hypoacusis	1	1 (1.64)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.64)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.64)	0	0 (0.00)
Eye disorders				
- Total	23	12 (19.67)	0	0 (0.00)
Eye pain	4	3 (4.92)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Vision blurred	4	3 (4.92)	0	0 (0.00)
Periorbital oedema	3	3 (4.92)	0	0 (0.00)
Photophobia	3	2 (3.28)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (3.28)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.28)	0	0 (0.00)
Uveitis	2	2 (3.28)	0	0 (0.00)
Ocular hypertension	1	1 (1.64)	0	0 (0.00)
Papilloedema	1	1 (1.64)	0	0 (0.00)
Visual impairment	1	1 (1.64)	0	0 (0.00)
Gastrointestinal disorders				
- Total	121	34 (55.74)	13	9 (14.75)
Vomiting	34	21 (34.43)	3	3 (4.92)
Nausea	24	20 (32.79)	2	2 (3.28)
Diarrhoea	17	17 (27.87)	1	1 (1.64)
Abdominal pain	10	9 (14.75)	1	1 (1.64)
Constipation	8	7 (11.48)	0	0 (0.00)
Abdominal distension	2	2 (3.28)	0	0 (0.00)
Abdominal pain upper	2	2 (3.28)	0	0 (0.00)
Anal incontinence	2	1 (1.64)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Haematemesis	2	2 (3.28)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.64)	2	1 (1.64)
Pancreatitis	2	2 (3.28)	1	1 (1.64)
Stomatitis	2	2 (3.28)	0	0 (0.00)
Abdominal discomfort	1	1 (1.64)	0	0 (0.00)
Abdominal pain lower	1	1 (1.64)	0	0 (0.00)
Abdominal tenderness	1	1 (1.64)	0	0 (0.00)
Ascites	1	1 (1.64)	1	1 (1.64)
Dyspepsia	1	1 (1.64)	0	0 (0.00)
Dysphagia	1	1 (1.64)	0	0 (0.00)
Flatulence	1	1 (1.64)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.64)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.64)	0	0 (0.00)
Glossodynia	1	1 (1.64)	0	0 (0.00)
Ileus	1	1 (1.64)	1	1 (1.64)
Intestinal obstruction	1	1 (1.64)	1	1 (1.64)
Lip pain	1	1 (1.64)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.64)	0	0 (0.00)
General disorders and administration site conditions				

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
- Total	67	30 (49.18)	9	8 (13.11)
Pyrexia	24	15 (24.59)	5	5 (8.20)
Fatigue	14	13 (21.31)	1	1 (1.64)
Chills	8	7 (11.48)	0	0 (0.00)
Catheter site pain	3	3 (4.92)	0	0 (0.00)
Generalised oedema	3	2 (3.28)	0	0 (0.00)
Malaise	3	3 (4.92)	0	0 (0.00)
Pain	3	3 (4.92)	2	2 (3.28)
Catheter site extravasation	1	1 (1.64)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.64)	0	0 (0.00)
Face oedema	1	1 (1.64)	0	0 (0.00)
Facial pain	1	1 (1.64)	0	0 (0.00)
Injection site haematoma	1	1 (1.64)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.64)	0	0 (0.00)
Oedema peripheral	1	1 (1.64)	0	0 (0.00)
Peripheral swelling	1	1 (1.64)	0	0 (0.00)
Physical deconditioning	1	1 (1.64)	1	1 (1.64)
Hepatobiliary disorders				
- Total	7	5 (8.20)	1	1 (1.64)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Hyperbilirubinaemia	3	2 (3.28)	1	1 (1.64)
Hepatomegaly	2	2 (3.28)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.64)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.64)	0	0 (0.00)
Immune system disorders				
- Total	108	55 (90.16)	29	20 (32.79)
Cytokine release syndrome	78	48 (78.69)	25	17 (27.87)
Hypogammaglobulinaemia	27	26 (42.62)	4	4 (6.56)
Drug hypersensitivity	1	1 (1.64)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.64)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.64)	0	0 (0.00)
Infections and infestations				
- Total	41	26 (42.62)	7	7 (11.48)
Clostridium difficile colitis	4	4 (6.56)	1	1 (1.64)
Clostridium difficile infection	4	4 (6.56)	0	0 (0.00)
Rhinovirus infection	3	3 (4.92)	0	0 (0.00)
Gastroenteritis	2	2 (3.28)	1	1 (1.64)
Pneumonia	2	2 (3.28)	1	1 (1.64)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Staphylococcal infection	2	2 (3.28)	1	1 (1.64)
Acute sinusitis	1	1 (1.64)	0	0 (0.00)
Body tinea	1	1 (1.64)	0	0 (0.00)
Catheter site cellulitis	1	1 (1.64)	0	0 (0.00)
Catheter site infection	1	1 (1.64)	1	1 (1.64)
Cytomegalovirus infection	1	1 (1.64)	0	0 (0.00)
Enterococcal infection	1	1 (1.64)	0	0 (0.00)
Folliculitis	1	1 (1.64)	0	0 (0.00)
Fungal skin infection	1	1 (1.64)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.64)	0	0 (0.00)
Herpes simplex	1	1 (1.64)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (1.64)	0	0 (0.00)
Hypopyon	1	1 (1.64)	0	0 (0.00)
Influenza	1	1 (1.64)	0	0 (0.00)
Oral candidiasis	1	1 (1.64)	0	0 (0.00)
Orchitis	1	1 (1.64)	0	0 (0.00)
Pharyngitis	1	1 (1.64)	0	0 (0.00)
Septic embolus	1	1 (1.64)	1	1 (1.64)
Skin infection	1	1 (1.64)	0	0 (0.00)
Streptococcal infection	1	1 (1.64)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Upper respiratory tract infection	1	1 (1.64)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.64)	1	1 (1.64)
Viral infection	1	1 (1.64)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.64)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (1.64)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	22	13 (21.31)	1	1 (1.64)
Transfusion reaction	4	3 (4.92)	0	0 (0.00)
Procedural pain	3	3 (4.92)	0	0 (0.00)
Infusion related reaction	2	2 (3.28)	0	0 (0.00)
Contusion	1	1 (1.64)	0	0 (0.00)
Incision site pain	1	1 (1.64)	0	0 (0.00)
Limb injury	1	1 (1.64)	0	0 (0.00)
Mouth injury	1	1 (1.64)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.64)	0	0 (0.00)
Procedural headache	1	1 (1.64)	0	0 (0.00)
Procedural site reaction	1	1 (1.64)	0	0 (0.00)
Skin abrasion	1	1 (1.64)	0	0 (0.00)
Stoma site irritation	1	1 (1.64)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Subdural haemorrhage	1	1 (1.64)	0	0 (0.00)
Tibia fracture	1	1 (1.64)	0	0 (0.00)
Tongue injury	1	1 (1.64)	0	0 (0.00)
Transfusion related complication	1	1 (1.64)	1	1 (1.64)
Investigations				
- Total	311	49 (80.33)	165	41 (67.21)
White blood cell count decreased	53	29 (47.54)	36	25 (40.98)
Neutrophil count decreased	46	24 (39.34)	43	22 (36.07)
Platelet count decreased	41	18 (29.51)	35	13 (21.31)
Alanine aminotransferase increased	27	18 (29.51)	13	10 (16.39)
Aspartate aminotransferase increased	26	16 (26.23)	12	9 (14.75)
Lymphocyte count decreased	16	14 (22.95)	12	11 (18.03)
Prothrombin time prolonged	16	8 (13.11)	1	1 (1.64)
Blood bilirubin increased	13	7 (11.48)	2	2 (3.28)
Blood fibrinogen decreased	13	2 (3.28)	3	2 (3.28)
Blood creatinine increased	10	8 (13.11)	1	1 (1.64)
International normalised ratio increased	9	8 (13.11)	1	1 (1.64)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Activated partial thromboplastin time prolonged	8	5 (8.20)	0	0 (0.00)
Blood immunoglobulin M decreased	4	4 (6.56)	0	0 (0.00)
Blood immunoglobulin A decreased	3	3 (4.92)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.28)	0	0 (0.00)
Blood sodium increased	2	1 (1.64)	0	0 (0.00)
Blood urea increased	2	2 (3.28)	0	0 (0.00)
Blood uric acid increased	2	1 (1.64)	0	0 (0.00)
Lipase increased	2	2 (3.28)	2	2 (3.28)
Transaminases increased	2	2 (3.28)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.64)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.64)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.64)	1	1 (1.64)
Blood magnesium decreased	1	1 (1.64)	1	1 (1.64)
C-reactive protein increased	1	1 (1.64)	1	1 (1.64)
Cardiac murmur	1	1 (1.64)	0	0 (0.00)
Culture stool positive	1	1 (1.64)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.64)	0	0 (0.00)
Haemoglobin decreased	1	1 (1.64)	1	1 (1.64)
Hepatic enzyme increased	1	1 (1.64)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Norovirus test positive	1	1 (1.64)	0	0 (0.00)
Pulmonary function test decreased	1	1 (1.64)	0	0 (0.00)
Serum ferritin increased	1	1 (1.64)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	100	37 (60.66)	39	22 (36.07)
Decreased appetite	23	19 (31.15)	12	11 (18.03)
Hypokalaemia	17	14 (22.95)	6	6 (9.84)
Hypophosphataemia	11	7 (11.48)	8	6 (9.84)
Hyperphosphataemia	10	8 (13.11)	0	0 (0.00)
Hypernatraemia	5	3 (4.92)	1	1 (1.64)
Hypoalbuminaemia	5	4 (6.56)	1	1 (1.64)
Hyperglycaemia	4	3 (4.92)	1	1 (1.64)
Hyperuricaemia	4	3 (4.92)	1	1 (1.64)
Hypocalcaemia	4	3 (4.92)	1	1 (1.64)
Dehydration	3	3 (4.92)	2	2 (3.28)
Fluid overload	3	3 (4.92)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.28)	1	1 (1.64)
Hyponatraemia	3	2 (3.28)	3	2 (3.28)
Acidosis	1	1 (1.64)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Hypomagnesaemia	1	1 (1.64)	0	0 (0.00)
Malnutrition	1	1 (1.64)	1	1 (1.64)
Metabolic acidosis	1	1 (1.64)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.64)	1	1 (1.64)
Musculoskeletal and connective tissue disorders				
- Total	23	15 (24.59)	1	1 (1.64)
Myalgia	5	5 (8.20)	0	0 (0.00)
Arthralgia	4	4 (6.56)	1	1 (1.64)
Musculoskeletal pain	4	3 (4.92)	0	0 (0.00)
Pain in extremity	4	4 (6.56)	0	0 (0.00)
Coccydynia	1	1 (1.64)	0	0 (0.00)
Limb discomfort	1	1 (1.64)	0	0 (0.00)
Muscle spasms	1	1 (1.64)	0	0 (0.00)
Muscular weakness	1	1 (1.64)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.64)	0	0 (0.00)
Osteopenia	1	1 (1.64)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.64)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Skin papilloma	1	1 (1.64)	0	0 (0.00)
Nervous system disorders				
- Total	57	32 (52.46)	6	5 (8.20)
Headache	31	24 (39.34)	2	2 (3.28)
Encephalopathy	6	4 (6.56)	2	2 (3.28)
Dizziness	3	3 (4.92)	0	0 (0.00)
Seizure	3	3 (4.92)	1	1 (1.64)
Dysarthria	2	2 (3.28)	0	0 (0.00)
Tremor	2	2 (3.28)	0	0 (0.00)
Asterixis	1	1 (1.64)	0	0 (0.00)
Ataxia	1	1 (1.64)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.64)	0	0 (0.00)
Embolic stroke	1	1 (1.64)	1	1 (1.64)
Idiopathic intracranial hypertension	1	1 (1.64)	0	0 (0.00)
Migraine	1	1 (1.64)	0	0 (0.00)
Myoclonus	1	1 (1.64)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.64)	0	0 (0.00)
Pleocytosis	1	1 (1.64)	0	0 (0.00)
Somnolence	1	1 (1.64)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Product issues				
- Total	1	1 (1.64)	0	0 (0.00)
Device occlusion	1	1 (1.64)	0	0 (0.00)
Psychiatric disorders				
- Total	26	14 (22.95)	1	1 (1.64)
Anxiety	6	6 (9.84)	1	1 (1.64)
Confusional state	5	5 (8.20)	0	0 (0.00)
Agitation	3	2 (3.28)	0	0 (0.00)
Delirium	3	3 (4.92)	0	0 (0.00)
Hallucination	3	2 (3.28)	0	0 (0.00)
Adjustment disorder	1	1 (1.64)	0	0 (0.00)
Irritability	1	1 (1.64)	0	0 (0.00)
Listless	1	1 (1.64)	0	0 (0.00)
Mental status changes	1	1 (1.64)	0	0 (0.00)
Panic attack	1	1 (1.64)	0	0 (0.00)
Suicidal ideation	1	1 (1.64)	0	0 (0.00)
Renal and urinary disorders				
- Total	15	9 (14.75)	8	5 (8.20)
Acute kidney injury	6	6 (9.84)	4	4 (6.56)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Haematuria	3	3 (4.92)	1	1 (1.64)
Dysuria	2	2 (3.28)	0	0 (0.00)
Oliguria	2	2 (3.28)	2	2 (3.28)
Pollakiuria	1	1 (1.64)	0	0 (0.00)
Renal failure	1	1 (1.64)	1	1 (1.64)
Reproductive system and breast disorders				
- Total	4	3 (4.92)	0	0 (0.00)
Oedema genital	2	1 (1.64)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.28)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	62	26 (42.62)	20	10 (16.39)
Hypoxia	11	9 (14.75)	6	6 (9.84)
Epistaxis	10	6 (9.84)	4	4 (6.56)
Cough	7	7 (11.48)	0	0 (0.00)
Pleural effusion	6	6 (9.84)	1	1 (1.64)
Tachypnoea	6	5 (8.20)	1	1 (1.64)
Pulmonary oedema	4	4 (6.56)	3	3 (4.92)
Haemoptysis	3	2 (3.28)	1	1 (1.64)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Respiratory failure	3	3 (4.92)	3	3 (4.92)
Dyspnoea	2	1 (1.64)	1	1 (1.64)
Oropharyngeal pain	2	2 (3.28)	0	0 (0.00)
Atelectasis	1	1 (1.64)	0	0 (0.00)
Nasal congestion	1	1 (1.64)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.64)	0	0 (0.00)
Pharyngeal ulceration	1	1 (1.64)	0	0 (0.00)
Respiratory depression	1	1 (1.64)	0	0 (0.00)
Rhinitis allergic	1	1 (1.64)	0	0 (0.00)
Rhinorrhoea	1	1 (1.64)	0	0 (0.00)
Wheezing	1	1 (1.64)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	38	20 (32.79)	2	2 (3.28)
Dry skin	4	4 (6.56)	0	0 (0.00)
Erythema	4	3 (4.92)	0	0 (0.00)
Rash	4	4 (6.56)	0	0 (0.00)
Ingrowing nail	3	2 (3.28)	0	0 (0.00)
Petechiae	3	3 (4.92)	0	0 (0.00)
Rash maculo-papular	3	3 (4.92)	1	1 (1.64)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Hyperhidrosis	2	2 (3.28)	0	0 (0.00)
Pruritus	2	2 (3.28)	0	0 (0.00)
Dermatitis diaper	1	1 (1.64)	0	0 (0.00)
Ecchymosis	1	1 (1.64)	1	1 (1.64)
Livedo reticularis	1	1 (1.64)	0	0 (0.00)
Macule	1	1 (1.64)	0	0 (0.00)
Night sweats	1	1 (1.64)	0	0 (0.00)
Rash erythematous	1	1 (1.64)	0	0 (0.00)
Rash follicular	1	1 (1.64)	0	0 (0.00)
Rash macular	1	1 (1.64)	0	0 (0.00)
Rash papular	1	1 (1.64)	0	0 (0.00)
Rash vesicular	1	1 (1.64)	0	0 (0.00)
Skin exfoliation	1	1 (1.64)	0	0 (0.00)
Skin fissures	1	1 (1.64)	0	0 (0.00)
Skin irritation	1	1 (1.64)	0	0 (0.00)
Vascular disorders				
- Total	33	22 (36.07)	16	14 (22.95)
Hypotension	17	14 (22.95)	14	13 (21.31)
Hypertension	10	8 (13.11)	1	1 (1.64)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Orthostatic hypotension	2	2 (3.28)	0	0 (0.00)
Embolism	1	1 (1.64)	1	1 (1.64)
Flushing	1	1 (1.64)	0	0 (0.00)
Haematoma	1	1 (1.64)	0	0 (0.00)
Secondary hypertension	1	1 (1.64)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Total number of AE per patient	9	1 (50.00)	2	1 (50.00)
Blood and lymphatic system disorders				
- Total	1	1 (50.00)	1	1 (50.00)
Leukopenia	1	1 (50.00)	1	1 (50.00)
Immune system disorders				
- Total	1	1 (50.00)	1	1 (50.00)
Hypogammaglobulinaemia	1	1 (50.00)	1	1 (50.00)
Infections and infestations				
- Total	1	1 (50.00)	0	0 (0.00)
Upper respiratory tract infection	1	1 (50.00)	0	0 (0.00)
Investigations				
- Total	2	1 (50.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Blood urea increased	2	1 (50.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	3	1 (50.00)	0	0 (0.00)
Hyperalbuminaemia	2	1 (50.00)	0	0 (0.00)
Hypercalcaemia	1	1 (50.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Papule	1	1 (50.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Total number of AE per patient	337	45 (83.33)	69	25 (46.30)
Blood and lymphatic system disorders				
- Total	17	10 (18.52)	12	6 (11.11)
Neutropenia	6	4 (7.41)	6	4 (7.41)
Febrile neutropenia	3	3 (5.56)	3	3 (5.56)
Anaemia	2	2 (3.70)	1	1 (1.85)
Eosinophilia	2	1 (1.85)	1	1 (1.85)
Thrombocytopenia	2	2 (3.70)	1	1 (1.85)
Lymphadenopathy	1	1 (1.85)	0	0 (0.00)
Lymphopenia	1	1 (1.85)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (1.85)	0	0 (0.00)
Sinus tachycardia	1	1 (1.85)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Endocrine disorders				
- Total	1	1 (1.85)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.85)	0	0 (0.00)
Eye disorders				
- Total	5	5 (9.26)	0	0 (0.00)
Dry eye	2	2 (3.70)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.85)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.85)	0	0 (0.00)
Vision blurred	1	1 (1.85)	0	0 (0.00)
Gastrointestinal disorders				
- Total	38	16 (29.63)	8	4 (7.41)
Vomiting	13	9 (16.67)	2	2 (3.70)
Diarrhoea	8	8 (14.81)	1	1 (1.85)
Nausea	7	6 (11.11)	2	2 (3.70)
Abdominal pain	4	4 (7.41)	1	1 (1.85)
Oral pain	3	2 (3.70)	1	1 (1.85)
Abdominal pain upper	1	1 (1.85)	0	0 (0.00)
Enterocolitis	1	1 (1.85)	1	1 (1.85)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Pigmentation lip	1	1 (1.85)	0	0 (0.00)
General disorders and administration site conditions				
- Total	26	17 (31.48)	1	1 (1.85)
Pyrexia	14	10 (18.52)	1	1 (1.85)
Fatigue	2	2 (3.70)	0	0 (0.00)
Influenza like illness	2	2 (3.70)	0	0 (0.00)
Acquired gene mutation	1	1 (1.85)	0	0 (0.00)
Catheter site pain	1	1 (1.85)	0	0 (0.00)
Chills	1	1 (1.85)	0	0 (0.00)
Crying	1	1 (1.85)	0	0 (0.00)
Generalised oedema	1	1 (1.85)	0	0 (0.00)
Malaise	1	1 (1.85)	0	0 (0.00)
Oedema peripheral	1	1 (1.85)	0	0 (0.00)
Pain	1	1 (1.85)	0	0 (0.00)
Immune system disorders				
- Total	16	13 (24.07)	0	0 (0.00)
Hypogammaglobulinaemia	8	7 (12.96)	0	0 (0.00)
Graft versus host disease	3	2 (3.70)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Immunodeficiency common variable	2	2 (3.70)	0	0 (0.00)
Seasonal allergy	2	2 (3.70)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.85)	0	0 (0.00)
Infections and infestations				
- Total	60	32 (59.26)	17	12 (22.22)
Upper respiratory tract infection	6	6 (11.11)	1	1 (1.85)
Cellulitis of male external genital organ	5	1 (1.85)	2	1 (1.85)
Urinary tract infection	5	4 (7.41)	2	2 (3.70)
Rhinovirus infection	4	2 (3.70)	0	0 (0.00)
Gastroenteritis	3	3 (5.56)	0	0 (0.00)
Influenza	3	3 (5.56)	0	0 (0.00)
Ear infection	2	2 (3.70)	0	0 (0.00)
Otitis media	2	1 (1.85)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.70)	1	1 (1.85)
Sinusitis	2	2 (3.70)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (3.70)	1	1 (1.85)
Bacterial sepsis	1	1 (1.85)	1	1 (1.85)
Cholecystitis infective	1	1 (1.85)	1	1 (1.85)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Corona virus infection	1	1 (1.85)	1	1 (1.85)
Cytomegalovirus infection	1	1 (1.85)	0	0 (0.00)
Enterovirus infection	1	1 (1.85)	1	1 (1.85)
Escherichia urinary tract infection	1	1 (1.85)	1	1 (1.85)
Gastroenteritis norovirus	1	1 (1.85)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.85)	0	0 (0.00)
Herpes zoster	1	1 (1.85)	1	1 (1.85)
Molluscum contagiosum	1	1 (1.85)	0	0 (0.00)
Oral herpes	1	1 (1.85)	0	0 (0.00)
Otitis externa	1	1 (1.85)	0	0 (0.00)
Otitis media acute	1	1 (1.85)	0	0 (0.00)
Paronychia	1	1 (1.85)	0	0 (0.00)
Rash pustular	1	1 (1.85)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (1.85)	1	1 (1.85)
Rhinitis	1	1 (1.85)	0	0 (0.00)
Rotavirus infection	1	1 (1.85)	1	1 (1.85)
Sepsis	1	1 (1.85)	1	1 (1.85)
Subcutaneous abscess	1	1 (1.85)	0	0 (0.00)
Tinea capitis	1	1 (1.85)	0	0 (0.00)
Vascular device infection	1	1 (1.85)	1	1 (1.85)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Viral infection	1	1 (1.85)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (1.85)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	13	8 (14.81)	0	0 (0.00)
Contusion	2	2 (3.70)	0	0 (0.00)
Infusion related reaction	2	2 (3.70)	0	0 (0.00)
Procedural pain	2	2 (3.70)	0	0 (0.00)
Arthropod bite	1	1 (1.85)	0	0 (0.00)
Foot fracture	1	1 (1.85)	0	0 (0.00)
Procedural nausea	1	1 (1.85)	0	0 (0.00)
Radius fracture	1	1 (1.85)	0	0 (0.00)
Skin abrasion	1	1 (1.85)	0	0 (0.00)
Skin laceration	1	1 (1.85)	0	0 (0.00)
Sunburn	1	1 (1.85)	0	0 (0.00)
Investigations				
- Total	46	22 (40.74)	16	12 (22.22)
Neutrophil count decreased	12	8 (14.81)	8	6 (11.11)
White blood cell count decreased	7	5 (9.26)	3	2 (3.70)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Platelet count decreased	5	3 (5.56)	0	0 (0.00)
Weight decreased	4	4 (7.41)	0	0 (0.00)
Aspartate aminotransferase increased	3	3 (5.56)	2	2 (3.70)
Alanine aminotransferase increased	2	2 (3.70)	2	2 (3.70)
Haemoglobin decreased	2	2 (3.70)	0	0 (0.00)
Lymphocyte count decreased	2	2 (3.70)	0	0 (0.00)
Weight increased	2	2 (3.70)	0	0 (0.00)
Blood bilirubin increased	1	1 (1.85)	1	1 (1.85)
Blood creatinine increased	1	1 (1.85)	0	0 (0.00)
Blood magnesium decreased	1	1 (1.85)	0	0 (0.00)
Blood uric acid increased	1	1 (1.85)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.85)	0	0 (0.00)
Serum ferritin increased	1	1 (1.85)	0	0 (0.00)
Transaminases increased	1	1 (1.85)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	12	9 (16.67)	6	4 (7.41)
Decreased appetite	2	2 (3.70)	0	0 (0.00)
Hyperphosphataemia	2	2 (3.70)	0	0 (0.00)
Hypokalaemia	2	2 (3.70)	1	1 (1.85)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Dehydration	1	1 (1.85)	1	1 (1.85)
Hyperglycaemia	1	1 (1.85)	1	1 (1.85)
Hypophosphataemia	1	1 (1.85)	1	1 (1.85)
Iron overload	1	1 (1.85)	1	1 (1.85)
Tumour lysis syndrome	1	1 (1.85)	1	1 (1.85)
Vitamin D deficiency	1	1 (1.85)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	21	16 (29.63)	0	0 (0.00)
Pain in extremity	8	8 (14.81)	0	0 (0.00)
Arthralgia	2	2 (3.70)	0	0 (0.00)
Joint range of motion decreased	2	2 (3.70)	0	0 (0.00)
Muscular weakness	2	2 (3.70)	0	0 (0.00)
Back pain	1	1 (1.85)	0	0 (0.00)
Flank pain	1	1 (1.85)	0	0 (0.00)
Muscle spasms	1	1 (1.85)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.85)	0	0 (0.00)
Osteonecrosis	1	1 (1.85)	0	0 (0.00)
Pain in jaw	1	1 (1.85)	0	0 (0.00)
Toe walking	1	1 (1.85)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.85)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.85)	0	0 (0.00)
Nervous system disorders				
- Total	12	8 (14.81)	0	0 (0.00)
Headache	7	5 (9.26)	0	0 (0.00)
Dizziness	3	3 (5.56)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.70)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (3.70)	0	0 (0.00)
Depression	2	2 (3.70)	0	0 (0.00)
Anxiety	1	1 (1.85)	0	0 (0.00)
Sleep disorder	1	1 (1.85)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	3 (5.56)	3	2 (3.70)
Acute kidney injury	1	1 (1.85)	1	1 (1.85)
Calculus urinary	1	1 (1.85)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Haematuria	1	1 (1.85)	1	1 (1.85)
Nephrolithiasis	1	1 (1.85)	1	1 (1.85)
Urinary incontinence	1	1 (1.85)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	2 (3.70)	1	1 (1.85)
Scrotal pain	1	1 (1.85)	0	0 (0.00)
Vaginal haemorrhage	1	1 (1.85)	1	1 (1.85)
Respiratory, thoracic and mediastinal disorders				
- Total	30	18 (33.33)	4	3 (5.56)
Cough	9	7 (12.96)	0	0 (0.00)
Nasal congestion	4	4 (7.41)	0	0 (0.00)
Rhinorrhoea	4	4 (7.41)	0	0 (0.00)
Oropharyngeal pain	3	3 (5.56)	0	0 (0.00)
Rhinitis allergic	3	3 (5.56)	0	0 (0.00)
Epistaxis	2	2 (3.70)	1	1 (1.85)
Acute respiratory failure	1	1 (1.85)	1	1 (1.85)
Dysphonia	1	1 (1.85)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.85)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Pharyngeal lesion	1	1 (1.85)	1	1 (1.85)
Pulmonary oedema	1	1 (1.85)	1	1 (1.85)
Skin and subcutaneous tissue disorders				
- Total	24	15 (27.78)	1	1 (1.85)
Rash	5	4 (7.41)	0	0 (0.00)
Erythema	2	2 (3.70)	0	0 (0.00)
Rash erythematous	2	1 (1.85)	0	0 (0.00)
Rash maculo-papular	2	2 (3.70)	0	0 (0.00)
Alopecia	1	1 (1.85)	0	0 (0.00)
Dermatitis	1	1 (1.85)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.85)	1	1 (1.85)
Dermatitis atopic	1	1 (1.85)	0	0 (0.00)
Dry skin	1	1 (1.85)	0	0 (0.00)
Eczema	1	1 (1.85)	0	0 (0.00)
Hyperhidrosis	1	1 (1.85)	0	0 (0.00)
Ingrowing nail	1	1 (1.85)	0	0 (0.00)
Keloid scar	1	1 (1.85)	0	0 (0.00)
Macule	1	1 (1.85)	0	0 (0.00)
Petechiae	1	1 (1.85)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Pruritus	1	1 (1.85)	0	0 (0.00)
Rash pruritic	1	1 (1.85)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (3.70)	0	0 (0.00)
Hypertension	2	2 (3.70)	0	0 (0.00)
Hot flush	1	1 (1.85)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	0	0	0	0

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Total number of AE per patient	90	22 (66.67)	23	12 (36.36)
Blood and lymphatic system disorders				
- Total	2	2 (6.06)	1	1 (3.03)
Febrile neutropenia	1	1 (3.03)	1	1 (3.03)
Thrombocytopenia	1	1 (3.03)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Tympanic membrane perforation	1	1 (3.03)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	3 (9.09)	0	0 (0.00)
Diarrhoea	2	2 (6.06)	0	0 (0.00)
Abdominal pain	1	1 (3.03)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Nausea	1	1 (3.03)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	2 (6.06)	1	1 (3.03)
Pyrexia	2	1 (3.03)	0	0 (0.00)
Chills	1	1 (3.03)	0	0 (0.00)
Cyst	1	1 (3.03)	1	1 (3.03)
Immune system disorders				
- Total	2	2 (6.06)	0	0 (0.00)
Chronic graft versus host disease	1	1 (3.03)	0	0 (0.00)
Immunodeficiency	1	1 (3.03)	0	0 (0.00)
Infections and infestations				
- Total	32	11 (33.33)	7	4 (12.12)
Otitis media	5	3 (9.09)	1	1 (3.03)
Otitis media acute	4	2 (6.06)	0	0 (0.00)
Upper respiratory tract infection	4	2 (6.06)	0	0 (0.00)
Sinusitis	3	3 (9.09)	0	0 (0.00)
Urinary tract infection	3	2 (6.06)	1	1 (3.03)
Pneumonia	2	2 (6.06)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Campylobacter infection	1	1 (3.03)	1	1 (3.03)
Cellulitis of male external genital organ	1	1 (3.03)	1	1 (3.03)
Clostridium difficile infection	1	1 (3.03)	1	1 (3.03)
Gingivitis	1	1 (3.03)	0	0 (0.00)
Haemophilus infection	1	1 (3.03)	0	0 (0.00)
Meningitis aseptic	1	1 (3.03)	0	0 (0.00)
Respiratory tract infection	1	1 (3.03)	1	1 (3.03)
Respiratory tract infection viral	1	1 (3.03)	1	1 (3.03)
Skin infection	1	1 (3.03)	0	0 (0.00)
Viral infection	1	1 (3.03)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (3.03)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (3.03)	1	1 (3.03)
Procedural pain	1	1 (3.03)	1	1 (3.03)
Investigations				
- Total	22	8 (24.24)	8	5 (15.15)
Lymphocyte count decreased	5	3 (9.09)	1	1 (3.03)
White blood cell count decreased	5	4 (12.12)	3	3 (9.09)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Alanine aminotransferase increased	3	3 (9.09)	2	2 (6.06)
Neutrophil count decreased	3	2 (6.06)	0	0 (0.00)
Aspartate aminotransferase increased	2	2 (6.06)	1	1 (3.03)
Blood alkaline phosphatase increased	1	1 (3.03)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (3.03)	0	0 (0.00)
C-reactive protein increased	1	1 (3.03)	0	0 (0.00)
Platelet count decreased	1	1 (3.03)	1	1 (3.03)
Metabolism and nutrition disorders				
- Total	2	2 (6.06)	1	1 (3.03)
Hypokalaemia	1	1 (3.03)	1	1 (3.03)
Vitamin D deficiency	1	1 (3.03)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Neck pain	1	1 (3.03)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
- Total	1	1 (3.03)	1	1 (3.03)
Glioblastoma multiforme	1	1 (3.03)	1	1 (3.03)
Nervous system disorders				
- Total	4	3 (9.09)	1	1 (3.03)
Disturbance in attention	1	1 (3.03)	0	0 (0.00)
Dizziness	1	1 (3.03)	0	0 (0.00)
Headache	1	1 (3.03)	0	0 (0.00)
Seizure	1	1 (3.03)	1	1 (3.03)
Renal and urinary disorders				
- Total	3	2 (6.06)	1	1 (3.03)
Acute kidney injury	2	1 (3.03)	1	1 (3.03)
Haematuria	1	1 (3.03)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.03)	1	1 (3.03)
Ovarian failure	1	1 (3.03)	1	1 (3.03)
Respiratory, thoracic and mediastinal disorders				
- Total	7	4 (12.12)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Cough	3	2 (6.06)	0	0 (0.00)
Epistaxis	1	1 (3.03)	0	0 (0.00)
Oropharyngeal pain	1	1 (3.03)	0	0 (0.00)
Rhinitis allergic	1	1 (3.03)	0	0 (0.00)
Rhinorrhoea	1	1 (3.03)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (9.09)	0	0 (0.00)
Acne	1	1 (3.03)	0	0 (0.00)
Papule	1	1 (3.03)	0	0 (0.00)
Pruritus	1	1 (3.03)	0	0 (0.00)

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Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: At anytime, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Total number of AE per patient	114	3 (100.00)	53	3 (100.00)
Blood and lymphatic system disorders				
- Total	6	3 (100.00)	6	3 (100.00)
Anaemia	3	2 (66.67)	3	2 (66.67)
Leukopenia	1	1 (33.33)	1	1 (33.33)
Neutropenia	1	1 (33.33)	1	1 (33.33)
Thrombocytopenia	1	1 (33.33)	1	1 (33.33)
Cardiac disorders				
- Total	4	2 (66.67)	2	1 (33.33)
Bradycardia	1	1 (33.33)	0	0 (0.00)
Left ventricular dysfunction	1	1 (33.33)	1	1 (33.33)
Pericardial effusion	1	1 (33.33)	0	0 (0.00)
Tachycardia	1	1 (33.33)	1	1 (33.33)

Timing: At anytime, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Eye disorders				
- Total	2	1 (33.33)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (33.33)	0	0 (0.00)
Periorbital oedema	1	1 (33.33)	0	0 (0.00)
Gastrointestinal disorders				
- Total	5	2 (66.67)	2	2 (66.67)
Nausea	2	1 (33.33)	1	1 (33.33)
Diarrhoea	1	1 (33.33)	0	0 (0.00)
Dysphagia	1	1 (33.33)	1	1 (33.33)
Vomiting	1	1 (33.33)	0	0 (0.00)
General disorders and administration site conditions				
- Total	10	2 (66.67)	5	2 (66.67)
Pyrexia	3	1 (33.33)	1	1 (33.33)
Asthenia	1	1 (33.33)	0	0 (0.00)
Chills	1	1 (33.33)	0	0 (0.00)
Face oedema	1	1 (33.33)	1	1 (33.33)
Localised oedema	1	1 (33.33)	1	1 (33.33)
Mucosal haemorrhage	1	1 (33.33)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Multiple organ dysfunction syndrome	1	1 (33.33)	1	1 (33.33)
Oedema peripheral	1	1 (33.33)	1	1 (33.33)
Hepatobiliary disorders				
- Total	2	2 (66.67)	1	1 (33.33)
Hepatomegaly	1	1 (33.33)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (33.33)	1	1 (33.33)
Immune system disorders				
- Total	9	2 (66.67)	5	2 (66.67)
Cytokine release syndrome	8	2 (66.67)	4	2 (66.67)
Hypogammaglobulinaemia	1	1 (33.33)	1	1 (33.33)
Infections and infestations				
- Total	1	1 (33.33)	0	0 (0.00)
Upper respiratory tract infection	1	1 (33.33)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	3	2 (66.67)	1	1 (33.33)
Tracheal haemorrhage	2	1 (33.33)	1	1 (33.33)
Procedural complication	1	1 (33.33)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Investigations				
- Total	23	3 (100.00)	13	3 (100.00)
Aspartate aminotransferase increased	6	2 (66.67)	4	2 (66.67)
Blood urea increased	3	1 (33.33)	1	1 (33.33)
Blood fibrinogen decreased	2	2 (66.67)	1	1 (33.33)
International normalised ratio increased	2	1 (33.33)	0	0 (0.00)
Platelet count decreased	2	1 (33.33)	2	1 (33.33)
White blood cell count decreased	2	1 (33.33)	1	1 (33.33)
Alanine aminotransferase increased	1	1 (33.33)	1	1 (33.33)
Blood creatinine increased	1	1 (33.33)	1	1 (33.33)
Blood phosphorus decreased	1	1 (33.33)	0	0 (0.00)
Neutrophil count decreased	1	1 (33.33)	1	1 (33.33)
Protein total decreased	1	1 (33.33)	1	1 (33.33)
Prothrombin time prolonged	1	1 (33.33)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	19	2 (66.67)	4	2 (66.67)
Hyperalbuminaemia	3	1 (33.33)	0	0 (0.00)
Hypercalcaemia	3	1 (33.33)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Hypokalaemia	3	2 (66.67)	1	1 (33.33)
Hypernatraemia	2	1 (33.33)	0	0 (0.00)
Hypophosphataemia	2	2 (66.67)	1	1 (33.33)
Acidosis	1	1 (33.33)	1	1 (33.33)
Decreased appetite	1	1 (33.33)	1	1 (33.33)
Hyperchloraemia	1	1 (33.33)	0	0 (0.00)
Hypermagnesaemia	1	1 (33.33)	0	0 (0.00)
Hypoalbuminaemia	1	1 (33.33)	0	0 (0.00)
Metabolic alkalosis	1	1 (33.33)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (33.33)	0	0 (0.00)
Dizziness	1	1 (33.33)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (66.67)	0	0 (0.00)
Confusional state	1	1 (33.33)	0	0 (0.00)
Delirium	1	1 (33.33)	0	0 (0.00)
Insomnia	1	1 (33.33)	0	0 (0.00)
Irritability	1	1 (33.33)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Renal and urinary disorders				
- Total	3	2 (66.67)	3	2 (66.67)
Acute kidney injury	1	1 (33.33)	1	1 (33.33)
Haematuria	1	1 (33.33)	1	1 (33.33)
Renal impairment	1	1 (33.33)	1	1 (33.33)
Respiratory, thoracic and mediastinal disorders				
- Total	11	2 (66.67)	8	2 (66.67)
Hypoxia	2	1 (33.33)	2	1 (33.33)
Pleural effusion	2	2 (66.67)	1	1 (33.33)
Pulmonary oedema	2	2 (66.67)	2	2 (66.67)
Cough	1	1 (33.33)	0	0 (0.00)
Dyspnoea	1	1 (33.33)	1	1 (33.33)
Epistaxis	1	1 (33.33)	0	0 (0.00)
Interstitial lung disease	1	1 (33.33)	1	1 (33.33)
Respiratory distress	1	1 (33.33)	1	1 (33.33)
Skin and subcutaneous tissue disorders				
- Total	4	1 (33.33)	0	0 (0.00)
Hyperhidrosis	2	1 (33.33)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Papule	1	1 (33.33)	0	0 (0.00)
Rash papular	1	1 (33.33)	0	0 (0.00)
Vascular disorders				
- Total	7	2 (66.67)	3	2 (66.67)
Flushing	2	1 (33.33)	0	0 (0.00)
Hypertension	2	2 (66.67)	0	0 (0.00)
Hypotension	2	2 (66.67)	2	2 (66.67)
Capillary leak syndrome	1	1 (33.33)	1	1 (33.33)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Total number of AE per patient	1636	61 (100.00)	499	56 (91.80)
Blood and lymphatic system disorders				
- Total	136	45 (73.77)	101	40 (65.57)
Anaemia	46	25 (40.98)	29	18 (29.51)
Thrombocytopenia	32	9 (14.75)	23	8 (13.11)
Febrile neutropenia	30	24 (39.34)	30	24 (39.34)
Neutropenia	14	10 (16.39)	13	10 (16.39)
Disseminated intravascular coagulation	5	4 (6.56)	2	2 (3.28)
Lymphopenia	4	4 (6.56)	2	2 (3.28)
Eosinophilia	2	1 (1.64)	1	1 (1.64)
Coagulopathy	1	1 (1.64)	0	0 (0.00)
Lymphadenopathy	1	1 (1.64)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Pancytopenia	1	1 (1.64)	1	1 (1.64)
Cardiac disorders				
- Total	29	21 (34.43)	1	1 (1.64)
Tachycardia	16	14 (22.95)	1	1 (1.64)
Sinus tachycardia	6	6 (9.84)	0	0 (0.00)
Sinus bradycardia	2	1 (1.64)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.64)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.64)	0	0 (0.00)
Palpitations	1	1 (1.64)	0	0 (0.00)
Pericardial effusion	1	1 (1.64)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.64)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	4	4 (6.56)	0	0 (0.00)
Ear pain	2	2 (3.28)	0	0 (0.00)
Hypoacusis	1	1 (1.64)	0	0 (0.00)
Tympanic membrane perforation	1	1 (1.64)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (3.28)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Adrenal insufficiency	2	2 (3.28)	0	0 (0.00)
Eye disorders				
- Total	28	17 (27.87)	0	0 (0.00)
Vision blurred	5	4 (6.56)	0	0 (0.00)
Eye pain	4	3 (4.92)	0	0 (0.00)
Periorbital oedema	3	3 (4.92)	0	0 (0.00)
Photophobia	3	2 (3.28)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (3.28)	0	0 (0.00)
Dry eye	2	2 (3.28)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.28)	0	0 (0.00)
Uveitis	2	2 (3.28)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.64)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.64)	0	0 (0.00)
Ocular hypertension	1	1 (1.64)	0	0 (0.00)
Papilloedema	1	1 (1.64)	0	0 (0.00)
Visual impairment	1	1 (1.64)	0	0 (0.00)
Gastrointestinal disorders				
- Total	163	41 (67.21)	21	11 (18.03)
Vomiting	47	26 (42.62)	5	3 (4.92)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Nausea	32	24 (39.34)	4	4 (6.56)
Diarrhoea	27	23 (37.70)	2	2 (3.28)
Abdominal pain	15	11 (18.03)	2	1 (1.64)
Constipation	8	7 (11.48)	0	0 (0.00)
Abdominal pain upper	3	3 (4.92)	0	0 (0.00)
Oral pain	3	2 (3.28)	1	1 (1.64)
Abdominal distension	2	2 (3.28)	0	0 (0.00)
Anal incontinence	2	1 (1.64)	0	0 (0.00)
Haematemesis	2	2 (3.28)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.64)	2	1 (1.64)
Pancreatitis	2	2 (3.28)	1	1 (1.64)
Stomatitis	2	2 (3.28)	0	0 (0.00)
Abdominal discomfort	1	1 (1.64)	0	0 (0.00)
Abdominal pain lower	1	1 (1.64)	0	0 (0.00)
Abdominal tenderness	1	1 (1.64)	0	0 (0.00)
Ascites	1	1 (1.64)	1	1 (1.64)
Dyspepsia	1	1 (1.64)	0	0 (0.00)
Dysphagia	1	1 (1.64)	0	0 (0.00)
Enterocolitis	1	1 (1.64)	1	1 (1.64)
Flatulence	1	1 (1.64)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Gastrointestinal haemorrhage	1	1 (1.64)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.64)	0	0 (0.00)
Glossodynia	1	1 (1.64)	0	0 (0.00)
Ileus	1	1 (1.64)	1	1 (1.64)
Intestinal obstruction	1	1 (1.64)	1	1 (1.64)
Lip pain	1	1 (1.64)	0	0 (0.00)
Pigmentation lip	1	1 (1.64)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.64)	0	0 (0.00)
General disorders and administration site conditions				
- Total	97	40 (65.57)	11	10 (16.39)
Pyrexia	40	24 (39.34)	6	6 (9.84)
Fatigue	16	15 (24.59)	1	1 (1.64)
Chills	10	9 (14.75)	0	0 (0.00)
Catheter site pain	4	4 (6.56)	0	0 (0.00)
Generalised oedema	4	3 (4.92)	0	0 (0.00)
Malaise	4	4 (6.56)	0	0 (0.00)
Pain	4	4 (6.56)	2	2 (3.28)
Influenza like illness	2	2 (3.28)	0	0 (0.00)
Oedema peripheral	2	2 (3.28)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Acquired gene mutation	1	1 (1.64)	0	0 (0.00)
Catheter site extravasation	1	1 (1.64)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.64)	0	0 (0.00)
Crying	1	1 (1.64)	0	0 (0.00)
Cyst	1	1 (1.64)	1	1 (1.64)
Face oedema	1	1 (1.64)	0	0 (0.00)
Facial pain	1	1 (1.64)	0	0 (0.00)
Injection site haematoma	1	1 (1.64)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.64)	0	0 (0.00)
Peripheral swelling	1	1 (1.64)	0	0 (0.00)
Physical deconditioning	1	1 (1.64)	1	1 (1.64)
Hepatobiliary disorders				
- Total	7	5 (8.20)	1	1 (1.64)
Hyperbilirubinaemia	3	2 (3.28)	1	1 (1.64)
Hepatomegaly	2	2 (3.28)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.64)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.64)	0	0 (0.00)
Immune system disorders				
- Total	126	56 (91.80)	29	20 (32.79)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=61** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=61** **n (%)[2]**
Cytokine release syndrome	78	48 (78.69)	25	17 (27.87)
Hypogammaglobulinaemia	35	32 (52.46)	4	4 (6.56)
Graft versus host disease	3	2 (3.28)	0	0 (0.00)
Immunodeficiency common variable	2	2 (3.28)	0	0 (0.00)
Seasonal allergy	2	2 (3.28)	0	0 (0.00)
Chronic graft versus host disease	1	1 (1.64)	0	0 (0.00)
Drug hypersensitivity	1	1 (1.64)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.64)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.64)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.64)	0	0 (0.00)
Immunodeficiency	1	1 (1.64)	0	0 (0.00)
Infections and infestations				
- Total	133	45 (73.77)	31	18 (29.51)
Upper respiratory tract infection	11	8 (13.11)	1	1 (1.64)
Urinary tract infection	8	5 (8.20)	3	2 (3.28)
Otitis media	7	4 (6.56)	1	1 (1.64)
Rhinovirus infection	7	5 (8.20)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Cellulitis of male external genital organ	6	1 (1.64)	3	1 (1.64)
Clostridium difficile infection	5	5 (8.20)	1	1 (1.64)
Gastroenteritis	5	5 (8.20)	1	1 (1.64)
Otitis media acute	5	2 (3.28)	0	0 (0.00)
Sinusitis	5	4 (6.56)	0	0 (0.00)
Clostridium difficile colitis	4	4 (6.56)	1	1 (1.64)
Influenza	4	4 (6.56)	0	0 (0.00)
Pneumonia	4	4 (6.56)	1	1 (1.64)
Viral infection	3	3 (4.92)	0	0 (0.00)
Viral upper respiratory tract infection	3	3 (4.92)	1	1 (1.64)
Cytomegalovirus infection	2	2 (3.28)	0	0 (0.00)
Ear infection	2	2 (3.28)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (1.64)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.28)	1	1 (1.64)
Skin infection	2	2 (3.28)	0	0 (0.00)
Staphylococcal infection	2	2 (3.28)	1	1 (1.64)
Vulvovaginal candidiasis	2	2 (3.28)	0	0 (0.00)
Acute sinusitis	1	1 (1.64)	0	0 (0.00)
Bacterial sepsis	1	1 (1.64)	1	1 (1.64)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Body tinea	1	1 (1.64)	0	0 (0.00)
Campylobacter infection	1	1 (1.64)	1	1 (1.64)
Catheter site cellulitis	1	1 (1.64)	0	0 (0.00)
Catheter site infection	1	1 (1.64)	1	1 (1.64)
Cholecystitis infective	1	1 (1.64)	1	1 (1.64)
Corona virus infection	1	1 (1.64)	1	1 (1.64)
Enterococcal infection	1	1 (1.64)	0	0 (0.00)
Enterovirus infection	1	1 (1.64)	1	1 (1.64)
Escherichia urinary tract infection	1	1 (1.64)	1	1 (1.64)
Folliculitis	1	1 (1.64)	0	0 (0.00)
Fungal skin infection	1	1 (1.64)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.64)	0	0 (0.00)
Gingivitis	1	1 (1.64)	0	0 (0.00)
Haemophilus infection	1	1 (1.64)	0	0 (0.00)
Herpes simplex	1	1 (1.64)	0	0 (0.00)
Herpes zoster	1	1 (1.64)	1	1 (1.64)
Human herpesvirus 6 infection	1	1 (1.64)	0	0 (0.00)
Hypopyon	1	1 (1.64)	0	0 (0.00)
Meningitis aseptic	1	1 (1.64)	0	0 (0.00)
Molluscum contagiosum	1	1 (1.64)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Oral candidiasis	1	1 (1.64)	0	0 (0.00)
Oral herpes	1	1 (1.64)	0	0 (0.00)
Orchitis	1	1 (1.64)	0	0 (0.00)
Otitis externa	1	1 (1.64)	0	0 (0.00)
Paronychia	1	1 (1.64)	0	0 (0.00)
Pharyngitis	1	1 (1.64)	0	0 (0.00)
Rash pustular	1	1 (1.64)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (1.64)	1	1 (1.64)
Respiratory tract infection	1	1 (1.64)	1	1 (1.64)
Respiratory tract infection viral	1	1 (1.64)	1	1 (1.64)
Rhinitis	1	1 (1.64)	0	0 (0.00)
Rotavirus infection	1	1 (1.64)	1	1 (1.64)
Sepsis	1	1 (1.64)	1	1 (1.64)
Septic embolus	1	1 (1.64)	1	1 (1.64)
Streptococcal infection	1	1 (1.64)	0	0 (0.00)
Subcutaneous abscess	1	1 (1.64)	0	0 (0.00)
Tinea capitis	1	1 (1.64)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.64)	1	1 (1.64)
Vascular device infection	1	1 (1.64)	1	1 (1.64)
Vulvovaginal mycotic infection	1	1 (1.64)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Injury, poisoning and procedural complications				
- Total	36	20 (32.79)	2	2 (3.28)
Procedural pain	6	5 (8.20)	1	1 (1.64)
Infusion related reaction	4	4 (6.56)	0	0 (0.00)
Transfusion reaction	4	3 (4.92)	0	0 (0.00)
Contusion	3	3 (4.92)	0	0 (0.00)
Skin abrasion	2	2 (3.28)	0	0 (0.00)
Arthropod bite	1	1 (1.64)	0	0 (0.00)
Foot fracture	1	1 (1.64)	0	0 (0.00)
Incision site pain	1	1 (1.64)	0	0 (0.00)
Limb injury	1	1 (1.64)	0	0 (0.00)
Mouth injury	1	1 (1.64)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.64)	0	0 (0.00)
Procedural headache	1	1 (1.64)	0	0 (0.00)
Procedural nausea	1	1 (1.64)	0	0 (0.00)
Procedural site reaction	1	1 (1.64)	0	0 (0.00)
Radius fracture	1	1 (1.64)	0	0 (0.00)
Skin laceration	1	1 (1.64)	0	0 (0.00)
Stoma site irritation	1	1 (1.64)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Subdural haemorrhage	1	1 (1.64)	0	0 (0.00)
Sunburn	1	1 (1.64)	0	0 (0.00)
Tibia fracture	1	1 (1.64)	0	0 (0.00)
Tongue injury	1	1 (1.64)	0	0 (0.00)
Transfusion related complication	1	1 (1.64)	1	1 (1.64)
Investigations				
- Total	379	53 (86.89)	189	46 (75.41)
White blood cell count decreased	65	34 (55.74)	42	29 (47.54)
Neutrophil count decreased	61	27 (44.26)	51	24 (39.34)
Platelet count decreased	47	19 (31.15)	36	14 (22.95)
Alanine aminotransferase increased	32	20 (32.79)	17	13 (21.31)
Aspartate aminotransferase increased	31	18 (29.51)	15	10 (16.39)
Lymphocyte count decreased	23	16 (26.23)	13	12 (19.67)
Prothrombin time prolonged	16	8 (13.11)	1	1 (1.64)
Blood bilirubin increased	14	8 (13.11)	3	3 (4.92)
Blood fibrinogen decreased	13	2 (3.28)	3	2 (3.28)
Blood creatinine increased	11	8 (13.11)	1	1 (1.64)
International normalised ratio increased	9	8 (13.11)	1	1 (1.64)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Activated partial thromboplastin time prolonged	8	5 (8.20)	0	0 (0.00)
Blood immunoglobulin M decreased	4	4 (6.56)	0	0 (0.00)
Weight decreased	4	4 (6.56)	0	0 (0.00)
Blood immunoglobulin A decreased	3	3 (4.92)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.28)	0	0 (0.00)
Blood uric acid increased	3	2 (3.28)	0	0 (0.00)
Haemoglobin decreased	3	3 (4.92)	1	1 (1.64)
Transaminases increased	3	3 (4.92)	0	0 (0.00)
Blood magnesium decreased	2	2 (3.28)	1	1 (1.64)
Blood sodium increased	2	1 (1.64)	0	0 (0.00)
Blood urea increased	2	2 (3.28)	0	0 (0.00)
C-reactive protein increased	2	2 (3.28)	1	1 (1.64)
Lipase increased	2	2 (3.28)	2	2 (3.28)
Serum ferritin increased	2	2 (3.28)	0	0 (0.00)
Weight increased	2	2 (3.28)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (1.64)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.64)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.64)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Blood lactate dehydrogenase increased	1	1 (1.64)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.64)	1	1 (1.64)
Cardiac murmur	1	1 (1.64)	0	0 (0.00)
Culture stool positive	1	1 (1.64)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.64)	0	0 (0.00)
Hepatic enzyme increased	1	1 (1.64)	0	0 (0.00)
Norovirus test positive	1	1 (1.64)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.64)	0	0 (0.00)
Pulmonary function test decreased	1	1 (1.64)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	114	41 (67.21)	46	25 (40.98)
Decreased appetite	25	21 (34.43)	12	11 (18.03)
Hypokalaemia	20	17 (27.87)	8	8 (13.11)
Hyperphosphataemia	12	8 (13.11)	0	0 (0.00)
Hypophosphataemia	12	8 (13.11)	9	7 (11.48)
Hyperglycaemia	5	3 (4.92)	2	2 (3.28)
Hypernatraemia	5	3 (4.92)	1	1 (1.64)
Hypoalbuminaemia	5	4 (6.56)	1	1 (1.64)
Dehydration	4	4 (6.56)	3	3 (4.92)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Hyperuricaemia	4	3 (4.92)	1	1 (1.64)
Hypocalcaemia	4	3 (4.92)	1	1 (1.64)
Fluid overload	3	3 (4.92)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.28)	1	1 (1.64)
Hyponatraemia	3	2 (3.28)	3	2 (3.28)
Tumour lysis syndrome	2	2 (3.28)	2	2 (3.28)
Vitamin D deficiency	2	2 (3.28)	0	0 (0.00)
Acidosis	1	1 (1.64)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.64)	0	0 (0.00)
Iron overload	1	1 (1.64)	1	1 (1.64)
Malnutrition	1	1 (1.64)	1	1 (1.64)
Metabolic acidosis	1	1 (1.64)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	45	25 (40.98)	1	1 (1.64)
Pain in extremity	12	11 (18.03)	0	0 (0.00)
Arthralgia	6	5 (8.20)	1	1 (1.64)
Myalgia	5	5 (8.20)	0	0 (0.00)
Musculoskeletal pain	4	3 (4.92)	0	0 (0.00)
Muscular weakness	3	3 (4.92)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Joint range of motion decreased	2	2 (3.28)	0	0 (0.00)
Muscle spasms	2	2 (3.28)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (3.28)	0	0 (0.00)
Back pain	1	1 (1.64)	0	0 (0.00)
Coccydynia	1	1 (1.64)	0	0 (0.00)
Flank pain	1	1 (1.64)	0	0 (0.00)
Limb discomfort	1	1 (1.64)	0	0 (0.00)
Neck pain	1	1 (1.64)	0	0 (0.00)
Osteonecrosis	1	1 (1.64)	0	0 (0.00)
Osteopenia	1	1 (1.64)	0	0 (0.00)
Pain in jaw	1	1 (1.64)	0	0 (0.00)
Toe walking	1	1 (1.64)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (4.92)	1	1 (1.64)
Glioblastoma multiforme	1	1 (1.64)	1	1 (1.64)
Myelodysplastic syndrome	1	1 (1.64)	0	0 (0.00)
Skin papilloma	1	1 (1.64)	0	0 (0.00)
Nervous system disorders				

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
- Total	73	34 (55.74)	7	6 (9.84)
Headache	39	24 (39.34)	2	2 (3.28)
Dizziness	7	5 (8.20)	0	0 (0.00)
Encephalopathy	6	4 (6.56)	2	2 (3.28)
Seizure	4	4 (6.56)	2	2 (3.28)
Dysarthria	2	2 (3.28)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.28)	0	0 (0.00)
Tremor	2	2 (3.28)	0	0 (0.00)
Asterixis	1	1 (1.64)	0	0 (0.00)
Ataxia	1	1 (1.64)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.64)	0	0 (0.00)
Disturbance in attention	1	1 (1.64)	0	0 (0.00)
Embolic stroke	1	1 (1.64)	1	1 (1.64)
Idiopathic intracranial hypertension	1	1 (1.64)	0	0 (0.00)
Migraine	1	1 (1.64)	0	0 (0.00)
Myoclonus	1	1 (1.64)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.64)	0	0 (0.00)
Pleocytosis	1	1 (1.64)	0	0 (0.00)
Somnolence	1	1 (1.64)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Product issues				
- Total	1	1 (1.64)	0	0 (0.00)
Device occlusion	1	1 (1.64)	0	0 (0.00)
Psychiatric disorders				
- Total	30	15 (24.59)	1	1 (1.64)
Anxiety	7	7 (11.48)	1	1 (1.64)
Confusional state	5	5 (8.20)	0	0 (0.00)
Agitation	3	2 (3.28)	0	0 (0.00)
Delirium	3	3 (4.92)	0	0 (0.00)
Hallucination	3	2 (3.28)	0	0 (0.00)
Depression	2	2 (3.28)	0	0 (0.00)
Adjustment disorder	1	1 (1.64)	0	0 (0.00)
Irritability	1	1 (1.64)	0	0 (0.00)
Listless	1	1 (1.64)	0	0 (0.00)
Mental status changes	1	1 (1.64)	0	0 (0.00)
Panic attack	1	1 (1.64)	0	0 (0.00)
Sleep disorder	1	1 (1.64)	0	0 (0.00)
Suicidal ideation	1	1 (1.64)	0	0 (0.00)
Renal and urinary disorders				

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
- Total	23	13 (21.31)	12	8 (13.11)
Acute kidney injury	9	8 (13.11)	6	6 (9.84)
Haematuria	5	4 (6.56)	2	2 (3.28)
Dysuria	2	2 (3.28)	0	0 (0.00)
Oliguria	2	2 (3.28)	2	2 (3.28)
Calculus urinary	1	1 (1.64)	0	0 (0.00)
Nephrolithiasis	1	1 (1.64)	1	1 (1.64)
Pollakiuria	1	1 (1.64)	0	0 (0.00)
Renal failure	1	1 (1.64)	1	1 (1.64)
Urinary incontinence	1	1 (1.64)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	7	6 (9.84)	2	2 (3.28)
Oedema genital	2	1 (1.64)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.28)	0	0 (0.00)
Ovarian failure	1	1 (1.64)	1	1 (1.64)
Scrotal pain	1	1 (1.64)	0	0 (0.00)
Vaginal haemorrhage	1	1 (1.64)	1	1 (1.64)
Respiratory, thoracic and mediastinal disorders				

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
- Total	99	36 (59.02)	24	13 (21.31)
Cough	19	13 (21.31)	0	0 (0.00)
Epistaxis	13	9 (14.75)	5	5 (8.20)
Hypoxia	11	9 (14.75)	6	6 (9.84)
Oropharyngeal pain	6	6 (9.84)	0	0 (0.00)
Pleural effusion	6	6 (9.84)	1	1 (1.64)
Rhinorrhoea	6	6 (9.84)	0	0 (0.00)
Tachypnoea	6	5 (8.20)	1	1 (1.64)
Nasal congestion	5	5 (8.20)	0	0 (0.00)
Pulmonary oedema	5	5 (8.20)	4	4 (6.56)
Rhinitis allergic	5	4 (6.56)	0	0 (0.00)
Haemoptysis	3	2 (3.28)	1	1 (1.64)
Respiratory failure	3	3 (4.92)	3	3 (4.92)
Dyspnoea	2	1 (1.64)	1	1 (1.64)
Acute respiratory failure	1	1 (1.64)	1	1 (1.64)
Atelectasis	1	1 (1.64)	0	0 (0.00)
Dysphonia	1	1 (1.64)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.64)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.64)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.64)	1	1 (1.64)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Pharyngeal ulceration	1	1 (1.64)	0	0 (0.00)
Respiratory depression	1	1 (1.64)	0	0 (0.00)
Wheezing	1	1 (1.64)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	65	29 (47.54)	3	3 (4.92)
Rash	9	8 (13.11)	0	0 (0.00)
Erythema	6	5 (8.20)	0	0 (0.00)
Dry skin	5	5 (8.20)	0	0 (0.00)
Rash maculo-papular	5	5 (8.20)	1	1 (1.64)
Ingrowing nail	4	3 (4.92)	0	0 (0.00)
Petechiae	4	4 (6.56)	0	0 (0.00)
Pruritus	4	4 (6.56)	0	0 (0.00)
Hyperhidrosis	3	3 (4.92)	0	0 (0.00)
Rash erythematous	3	2 (3.28)	0	0 (0.00)
Macule	2	2 (3.28)	0	0 (0.00)
Acne	1	1 (1.64)	0	0 (0.00)
Alopecia	1	1 (1.64)	0	0 (0.00)
Dermatitis	1	1 (1.64)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.64)	1	1 (1.64)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Dermatitis atopic	1	1 (1.64)	0	0 (0.00)
Dermatitis diaper	1	1 (1.64)	0	0 (0.00)
Ecchymosis	1	1 (1.64)	1	1 (1.64)
Eczema	1	1 (1.64)	0	0 (0.00)
Keloid scar	1	1 (1.64)	0	0 (0.00)
Livedo reticularis	1	1 (1.64)	0	0 (0.00)
Night sweats	1	1 (1.64)	0	0 (0.00)
Papule	1	1 (1.64)	0	0 (0.00)
Rash follicular	1	1 (1.64)	0	0 (0.00)
Rash macular	1	1 (1.64)	0	0 (0.00)
Rash papular	1	1 (1.64)	0	0 (0.00)
Rash pruritic	1	1 (1.64)	0	0 (0.00)
Rash vesicular	1	1 (1.64)	0	0 (0.00)
Skin exfoliation	1	1 (1.64)	0	0 (0.00)
Skin fissures	1	1 (1.64)	0	0 (0.00)
Skin irritation	1	1 (1.64)	0	0 (0.00)
Vascular disorders				
- Total	36	23 (37.70)	16	14 (22.95)
Hypotension	17	14 (22.95)	14	13 (21.31)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Hypertension	12	10 (16.39)	1	1 (1.64)
Orthostatic hypotension	2	2 (3.28)	0	0 (0.00)
Embolism	1	1 (1.64)	1	1 (1.64)
Flushing	1	1 (1.64)	0	0 (0.00)
Haematoma	1	1 (1.64)	0	0 (0.00)
Hot flush	1	1 (1.64)	0	0 (0.00)
Secondary hypertension	1	1 (1.64)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	18	1 (100.00)	4	1 (100.00)
Blood and lymphatic system disorders				
- Total	2	1 (100.00)	2	1 (100.00)
Anaemia	1	1 (100.00)	1	1 (100.00)
Febrile neutropenia	1	1 (100.00)	1	1 (100.00)
Gastrointestinal disorders				
- Total	3	1 (100.00)	0	0 (0.00)
Haematemesis	1	1 (100.00)	0	0 (0.00)
Nausea	1	1 (100.00)	0	0 (0.00)
Vomiting	1	1 (100.00)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (100.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Cytokine release syndrome	1	1 (100.00)	0	0 (0.00)
Investigations				
- Total	11	1 (100.00)	2	1 (100.00)
Activated partial thromboplastin time prolonged	3	1 (100.00)	0	0 (0.00)
Blood phosphorus increased	2	1 (100.00)	0	0 (0.00)
International normalised ratio increased	2	1 (100.00)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (100.00)	0	0 (0.00)
Neutrophil count decreased	1	1 (100.00)	1	1 (100.00)
Platelet count decreased	1	1 (100.00)	1	1 (100.00)
White blood cell count decreased	1	1 (100.00)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Encephalopathy	1	1 (100.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.

1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Total number of AE per patient	1296	62 (98.41)	454	53 (84.13)
Blood and lymphatic system disorders				
- Total	120	42 (66.67)	91	37 (58.73)
Anaemia	46	26 (41.27)	30	18 (28.57)
Thrombocytopenia	30	8 (12.70)	23	8 (12.70)
Febrile neutropenia	25	21 (33.33)	25	21 (33.33)
Neutropenia	9	8 (12.70)	8	8 (12.70)
Disseminated intravascular coagulation	5	4 (6.35)	2	2 (3.17)
Lymphopenia	3	3 (4.76)	2	2 (3.17)
Coagulopathy	1	1 (1.59)	0	0 (0.00)
Pancytopenia	1	1 (1.59)	1	1 (1.59)
Cardiac disorders				

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
- Total	32	22 (34.92)	3	2 (3.17)
Tachycardia	17	15 (23.81)	2	2 (3.17)
Sinus tachycardia	5	5 (7.94)	0	0 (0.00)
Pericardial effusion	2	2 (3.17)	0	0 (0.00)
Sinus bradycardia	2	1 (1.59)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.59)	0	0 (0.00)
Bradycardia	1	1 (1.59)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.59)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.59)	1	1 (1.59)
Palpitations	1	1 (1.59)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.59)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (4.76)	0	0 (0.00)
Ear pain	2	2 (3.17)	0	0 (0.00)
Hypoacusis	1	1 (1.59)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.59)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Eye disorders				
- Total	25	13 (20.63)	0	0 (0.00)
Eye pain	4	3 (4.76)	0	0 (0.00)
Periorbital oedema	4	4 (6.35)	0	0 (0.00)
Vision blurred	4	3 (4.76)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (4.76)	0	0 (0.00)
Photophobia	3	2 (3.17)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.17)	0	0 (0.00)
Uveitis	2	2 (3.17)	0	0 (0.00)
Ocular hypertension	1	1 (1.59)	0	0 (0.00)
Papilloedema	1	1 (1.59)	0	0 (0.00)
Visual impairment	1	1 (1.59)	0	0 (0.00)
Gastrointestinal disorders				
- Total	123	35 (55.56)	15	11 (17.46)
Vomiting	34	21 (33.33)	3	3 (4.76)
Nausea	25	20 (31.75)	3	3 (4.76)
Diarrhoea	18	18 (28.57)	1	1 (1.59)
Abdominal pain	10	9 (14.29)	1	1 (1.59)
Constipation	8	7 (11.11)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Abdominal distension	2	2 (3.17)	0	0 (0.00)
Abdominal pain upper	2	2 (3.17)	0	0 (0.00)
Anal incontinence	2	1 (1.59)	0	0 (0.00)
Dysphagia	2	2 (3.17)	1	1 (1.59)
Mouth haemorrhage	2	1 (1.59)	2	1 (1.59)
Pancreatitis	2	2 (3.17)	1	1 (1.59)
Stomatitis	2	2 (3.17)	0	0 (0.00)
Abdominal discomfort	1	1 (1.59)	0	0 (0.00)
Abdominal pain lower	1	1 (1.59)	0	0 (0.00)
Abdominal tenderness	1	1 (1.59)	0	0 (0.00)
Ascites	1	1 (1.59)	1	1 (1.59)
Dyspepsia	1	1 (1.59)	0	0 (0.00)
Flatulence	1	1 (1.59)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.59)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.59)	0	0 (0.00)
Glossodynia	1	1 (1.59)	0	0 (0.00)
Haematemesis	1	1 (1.59)	0	0 (0.00)
Ileus	1	1 (1.59)	1	1 (1.59)
Intestinal obstruction	1	1 (1.59)	1	1 (1.59)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Lip pain	1	1 (1.59)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.59)	0	0 (0.00)
General disorders and administration site conditions				
- Total	77	32 (50.79)	14	10 (15.87)
Pyrexia	27	16 (25.40)	6	6 (9.52)
Fatigue	14	13 (20.63)	1	1 (1.59)
Chills	9	8 (12.70)	0	0 (0.00)
Catheter site pain	3	3 (4.76)	0	0 (0.00)
Generalised oedema	3	2 (3.17)	0	0 (0.00)
Malaise	3	3 (4.76)	0	0 (0.00)
Pain	3	3 (4.76)	2	2 (3.17)
Face oedema	2	2 (3.17)	1	1 (1.59)
Oedema peripheral	2	2 (3.17)	1	1 (1.59)
Asthenia	1	1 (1.59)	0	0 (0.00)
Catheter site extravasation	1	1 (1.59)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.59)	0	0 (0.00)
Facial pain	1	1 (1.59)	0	0 (0.00)
Injection site haematoma	1	1 (1.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Localised oedema	1	1 (1.59)	1	1 (1.59)
Mucosal haemorrhage	1	1 (1.59)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.59)	1	1 (1.59)
Non-cardiac chest pain	1	1 (1.59)	0	0 (0.00)
Peripheral swelling	1	1 (1.59)	0	0 (0.00)
Physical deconditioning	1	1 (1.59)	1	1 (1.59)
Hepatobiliary disorders				
- Total	9	7 (11.11)	2	2 (3.17)
Hyperbilirubinaemia	4	3 (4.76)	2	2 (3.17)
Hepatomegaly	3	3 (4.76)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.59)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.59)	0	0 (0.00)
Immune system disorders				
- Total	115	56 (88.89)	33	22 (34.92)
Cytokine release syndrome	85	49 (77.78)	29	19 (30.16)
Hypogammaglobulinaemia	27	26 (41.27)	4	4 (6.35)
Drug hypersensitivity	1	1 (1.59)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Haemophagocytic lymphohistiocytosis	1	1 (1.59)	0	0 (0.00)
Infections and infestations				
- Total	41	26 (41.27)	7	7 (11.11)
Clostridium difficile colitis	4	4 (6.35)	1	1 (1.59)
Clostridium difficile infection	4	4 (6.35)	0	0 (0.00)
Rhinovirus infection	3	3 (4.76)	0	0 (0.00)
Gastroenteritis	2	2 (3.17)	1	1 (1.59)
Pneumonia	2	2 (3.17)	1	1 (1.59)
Staphylococcal infection	2	2 (3.17)	1	1 (1.59)
Acute sinusitis	1	1 (1.59)	0	0 (0.00)
Body tinea	1	1 (1.59)	0	0 (0.00)
Catheter site cellulitis	1	1 (1.59)	0	0 (0.00)
Catheter site infection	1	1 (1.59)	1	1 (1.59)
Cytomegalovirus infection	1	1 (1.59)	0	0 (0.00)
Enterococcal infection	1	1 (1.59)	0	0 (0.00)
Folliculitis	1	1 (1.59)	0	0 (0.00)
Fungal skin infection	1	1 (1.59)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Herpes simplex	1	1 (1.59)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (1.59)	0	0 (0.00)
Hypopyon	1	1 (1.59)	0	0 (0.00)
Influenza	1	1 (1.59)	0	0 (0.00)
Oral candidiasis	1	1 (1.59)	0	0 (0.00)
Orchitis	1	1 (1.59)	0	0 (0.00)
Pharyngitis	1	1 (1.59)	0	0 (0.00)
Septic embolus	1	1 (1.59)	1	1 (1.59)
Skin infection	1	1 (1.59)	0	0 (0.00)
Streptococcal infection	1	1 (1.59)	0	0 (0.00)
Upper respiratory tract infection	1	1 (1.59)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.59)	1	1 (1.59)
Viral infection	1	1 (1.59)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.59)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (1.59)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	25	15 (23.81)	2	2 (3.17)
Transfusion reaction	4	3 (4.76)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Procedural pain	3	3 (4.76)	0	0 (0.00)
Infusion related reaction	2	2 (3.17)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.59)	1	1 (1.59)
Contusion	1	1 (1.59)	0	0 (0.00)
Incision site pain	1	1 (1.59)	0	0 (0.00)
Limb injury	1	1 (1.59)	0	0 (0.00)
Mouth injury	1	1 (1.59)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.59)	0	0 (0.00)
Procedural complication	1	1 (1.59)	0	0 (0.00)
Procedural headache	1	1 (1.59)	0	0 (0.00)
Procedural site reaction	1	1 (1.59)	0	0 (0.00)
Skin abrasion	1	1 (1.59)	0	0 (0.00)
Stoma site irritation	1	1 (1.59)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.59)	0	0 (0.00)
Tibia fracture	1	1 (1.59)	0	0 (0.00)
Tongue injury	1	1 (1.59)	0	0 (0.00)
Transfusion related complication	1	1 (1.59)	1	1 (1.59)
Investigations				
- Total	321	51 (80.95)	176	43 (68.25)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
White blood cell count decreased	54	29 (46.03)	37	26 (41.27)
Neutrophil count decreased	46	24 (38.10)	43	22 (34.92)
Platelet count decreased	42	18 (28.57)	36	13 (20.63)
Aspartate aminotransferase increased	31	17 (26.98)	16	11 (17.46)
Alanine aminotransferase increased	28	19 (30.16)	14	11 (17.46)
Prothrombin time prolonged	17	9 (14.29)	1	1 (1.59)
Lymphocyte count decreased	16	14 (22.22)	12	11 (17.46)
Blood fibrinogen decreased	15	4 (6.35)	4	3 (4.76)
Blood bilirubin increased	13	7 (11.11)	2	2 (3.17)
Blood creatinine increased	11	9 (14.29)	2	2 (3.17)
International normalised ratio increased	9	8 (12.70)	1	1 (1.59)
Activated partial thromboplastin time prolonged	5	4 (6.35)	0	0 (0.00)
Blood immunoglobulin M decreased	4	4 (6.35)	0	0 (0.00)
Blood immunoglobulin A decreased	3	3 (4.76)	0	0 (0.00)
Blood urea increased	3	3 (4.76)	1	1 (1.59)
Blood sodium increased	2	1 (1.59)	0	0 (0.00)
Blood uric acid increased	2	1 (1.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Lipase increased	2	2 (3.17)	2	2 (3.17)
Transaminases increased	2	2 (3.17)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.59)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.59)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.59)	1	1 (1.59)
Blood magnesium decreased	1	1 (1.59)	1	1 (1.59)
Blood phosphorus decreased	1	1 (1.59)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.59)	0	0 (0.00)
C-reactive protein increased	1	1 (1.59)	1	1 (1.59)
Cardiac murmur	1	1 (1.59)	0	0 (0.00)
Culture stool positive	1	1 (1.59)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.59)	0	0 (0.00)
Haemoglobin decreased	1	1 (1.59)	1	1 (1.59)
Hepatic enzyme increased	1	1 (1.59)	0	0 (0.00)
Norovirus test positive	1	1 (1.59)	0	0 (0.00)
Protein total decreased	1	1 (1.59)	1	1 (1.59)
Pulmonary function test decreased	1	1 (1.59)	0	0 (0.00)
Serum ferritin increased	1	1 (1.59)	0	0 (0.00)
Metabolism and nutrition disorders				

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
- Total	116	39 (61.90)	43	24 (38.10)
Decreased appetite	24	20 (31.75)	13	12 (19.05)
Hypokalaemia	20	16 (25.40)	7	7 (11.11)
Hypophosphataemia	13	9 (14.29)	9	7 (11.11)
Hyperphosphataemia	10	8 (12.70)	0	0 (0.00)
Hypernatraemia	7	4 (6.35)	1	1 (1.59)
Hypoalbuminaemia	6	5 (7.94)	1	1 (1.59)
Hyperglycaemia	4	3 (4.76)	1	1 (1.59)
Hyperuricaemia	4	3 (4.76)	1	1 (1.59)
Hypocalcaemia	4	3 (4.76)	1	1 (1.59)
Dehydration	3	3 (4.76)	2	2 (3.17)
Fluid overload	3	3 (4.76)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.17)	1	1 (1.59)
Hyponatraemia	3	2 (3.17)	3	2 (3.17)
Acidosis	2	2 (3.17)	1	1 (1.59)
Hypercalcaemia	2	1 (1.59)	0	0 (0.00)
Hyperalbuminaemia	1	1 (1.59)	0	0 (0.00)
Hyperchloraemia	1	1 (1.59)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Hypomagnesaemia	1	1 (1.59)	0	0 (0.00)
Malnutrition	1	1 (1.59)	1	1 (1.59)
Metabolic acidosis	1	1 (1.59)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.59)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.59)	1	1 (1.59)
Musculoskeletal and connective tissue disorders				
- Total	23	15 (23.81)	1	1 (1.59)
Myalgia	5	5 (7.94)	0	0 (0.00)
Arthralgia	4	4 (6.35)	1	1 (1.59)
Musculoskeletal pain	4	3 (4.76)	0	0 (0.00)
Pain in extremity	4	4 (6.35)	0	0 (0.00)
Coccydynia	1	1 (1.59)	0	0 (0.00)
Limb discomfort	1	1 (1.59)	0	0 (0.00)
Muscle spasms	1	1 (1.59)	0	0 (0.00)
Muscular weakness	1	1 (1.59)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.59)	0	0 (0.00)
Osteopenia	1	1 (1.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.59)	0	0 (0.00)
Skin papilloma	1	1 (1.59)	0	0 (0.00)
Nervous system disorders				
- Total	57	32 (50.79)	6	5 (7.94)
Headache	31	24 (38.10)	2	2 (3.17)
Encephalopathy	5	3 (4.76)	2	2 (3.17)
Dizziness	4	4 (6.35)	0	0 (0.00)
Seizure	3	3 (4.76)	1	1 (1.59)
Dysarthria	2	2 (3.17)	0	0 (0.00)
Tremor	2	2 (3.17)	0	0 (0.00)
Asterixis	1	1 (1.59)	0	0 (0.00)
Ataxia	1	1 (1.59)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.59)	0	0 (0.00)
Embolic stroke	1	1 (1.59)	1	1 (1.59)
Idiopathic intracranial hypertension	1	1 (1.59)	0	0 (0.00)
Migraine	1	1 (1.59)	0	0 (0.00)
Myoclonus	1	1 (1.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Neuropathy peripheral	1	1 (1.59)	0	0 (0.00)
Pleocytosis	1	1 (1.59)	0	0 (0.00)
Somnolence	1	1 (1.59)	0	0 (0.00)
Product issues				
- Total	1	1 (1.59)	0	0 (0.00)
Device occlusion	1	1 (1.59)	0	0 (0.00)
Psychiatric disorders				
- Total	30	16 (25.40)	1	1 (1.59)
Anxiety	6	6 (9.52)	1	1 (1.59)
Confusional state	6	6 (9.52)	0	0 (0.00)
Delirium	4	4 (6.35)	0	0 (0.00)
Agitation	3	2 (3.17)	0	0 (0.00)
Hallucination	3	2 (3.17)	0	0 (0.00)
Irritability	2	2 (3.17)	0	0 (0.00)
Adjustment disorder	1	1 (1.59)	0	0 (0.00)
Insomnia	1	1 (1.59)	0	0 (0.00)
Listless	1	1 (1.59)	0	0 (0.00)
Mental status changes	1	1 (1.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Panic attack	1	1 (1.59)	0	0 (0.00)
Suicidal ideation	1	1 (1.59)	0	0 (0.00)
Renal and urinary disorders				
- Total	18	11 (17.46)	11	7 (11.11)
Acute kidney injury	7	7 (11.11)	5	5 (7.94)
Haematuria	4	4 (6.35)	2	2 (3.17)
Dysuria	2	2 (3.17)	0	0 (0.00)
Oliguria	2	2 (3.17)	2	2 (3.17)
Pollakiuria	1	1 (1.59)	0	0 (0.00)
Renal failure	1	1 (1.59)	1	1 (1.59)
Renal impairment	1	1 (1.59)	1	1 (1.59)
Reproductive system and breast disorders				
- Total	4	3 (4.76)	0	0 (0.00)
Oedema genital	2	1 (1.59)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.17)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
- Total	73	28 (44.44)	28	12 (19.05)
Hypoxia	13	10 (15.87)	8	7 (11.11)
Epistaxis	11	7 (11.11)	4	4 (6.35)
Cough	8	8 (12.70)	0	0 (0.00)
Pleural effusion	8	8 (12.70)	2	2 (3.17)
Pulmonary oedema	6	6 (9.52)	5	5 (7.94)
Tachypnoea	6	5 (7.94)	1	1 (1.59)
Dyspnoea	3	2 (3.17)	2	2 (3.17)
Haemoptysis	3	2 (3.17)	1	1 (1.59)
Respiratory failure	3	3 (4.76)	3	3 (4.76)
Oropharyngeal pain	2	2 (3.17)	0	0 (0.00)
Atelectasis	1	1 (1.59)	0	0 (0.00)
Interstitial lung disease	1	1 (1.59)	1	1 (1.59)
Nasal congestion	1	1 (1.59)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.59)	0	0 (0.00)
Pharyngeal ulceration	1	1 (1.59)	0	0 (0.00)
Respiratory depression	1	1 (1.59)	0	0 (0.00)
Respiratory distress	1	1 (1.59)	1	1 (1.59)
Rhinitis allergic	1	1 (1.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Rhinorrhoea	1	1 (1.59)	0	0 (0.00)
Wheezing	1	1 (1.59)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	41	21 (33.33)	2	2 (3.17)
Dry skin	4	4 (6.35)	0	0 (0.00)
Erythema	4	3 (4.76)	0	0 (0.00)
Hyperhidrosis	4	3 (4.76)	0	0 (0.00)
Rash	4	4 (6.35)	0	0 (0.00)
Ingrowing nail	3	2 (3.17)	0	0 (0.00)
Petechiae	3	3 (4.76)	0	0 (0.00)
Rash maculo-papular	3	3 (4.76)	1	1 (1.59)
Pruritus	2	2 (3.17)	0	0 (0.00)
Rash papular	2	2 (3.17)	0	0 (0.00)
Dermatitis diaper	1	1 (1.59)	0	0 (0.00)
Ecchymosis	1	1 (1.59)	1	1 (1.59)
Livedo reticularis	1	1 (1.59)	0	0 (0.00)
Macule	1	1 (1.59)	0	0 (0.00)
Night sweats	1	1 (1.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Rash erythematous	1	1 (1.59)	0	0 (0.00)
Rash follicular	1	1 (1.59)	0	0 (0.00)
Rash macular	1	1 (1.59)	0	0 (0.00)
Rash vesicular	1	1 (1.59)	0	0 (0.00)
Skin exfoliation	1	1 (1.59)	0	0 (0.00)
Skin fissures	1	1 (1.59)	0	0 (0.00)
Skin irritation	1	1 (1.59)	0	0 (0.00)
Vascular disorders				
- Total	40	24 (38.10)	19	16 (25.40)
Hypotension	19	16 (25.40)	16	15 (23.81)
Hypertension	12	10 (15.87)	1	1 (1.59)
Flushing	3	2 (3.17)	0	0 (0.00)
Orthostatic hypotension	2	2 (3.17)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.59)	1	1 (1.59)
Embolism	1	1 (1.59)	1	1 (1.59)
Haematoma	1	1 (1.59)	0	0 (0.00)
Secondary hypertension	1	1 (1.59)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	0	0	0	0

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Total number of AE per patient	346	46 (83.64)	71	26 (47.27)
Blood and lymphatic system disorders				
- Total	18	11 (20.00)	13	7 (12.73)
Neutropenia	6	4 (7.27)	6	4 (7.27)
Febrile neutropenia	3	3 (5.45)	3	3 (5.45)
Anaemia	2	2 (3.64)	1	1 (1.82)
Eosinophilia	2	1 (1.82)	1	1 (1.82)
Thrombocytopenia	2	2 (3.64)	1	1 (1.82)
Leukopenia	1	1 (1.82)	1	1 (1.82)
Lymphadenopathy	1	1 (1.82)	0	0 (0.00)
Lymphopenia	1	1 (1.82)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (1.82)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Sinus tachycardia	1	1 (1.82)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.82)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.82)	0	0 (0.00)
Eye disorders				
- Total	5	5 (9.09)	0	0 (0.00)
Dry eye	2	2 (3.64)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.82)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.82)	0	0 (0.00)
Vision blurred	1	1 (1.82)	0	0 (0.00)
Gastrointestinal disorders				
- Total	38	16 (29.09)	8	4 (7.27)
Vomiting	13	9 (16.36)	2	2 (3.64)
Diarrhoea	8	8 (14.55)	1	1 (1.82)
Nausea	7	6 (10.91)	2	2 (3.64)
Abdominal pain	4	4 (7.27)	1	1 (1.82)
Oral pain	3	2 (3.64)	1	1 (1.82)
Abdominal pain upper	1	1 (1.82)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Enterocolitis	1	1 (1.82)	1	1 (1.82)
Pigmentation lip	1	1 (1.82)	0	0 (0.00)
General disorders and administration site conditions				
- Total	26	17 (30.91)	1	1 (1.82)
Pyrexia	14	10 (18.18)	1	1 (1.82)
Fatigue	2	2 (3.64)	0	0 (0.00)
Influenza like illness	2	2 (3.64)	0	0 (0.00)
Acquired gene mutation	1	1 (1.82)	0	0 (0.00)
Catheter site pain	1	1 (1.82)	0	0 (0.00)
Chills	1	1 (1.82)	0	0 (0.00)
Crying	1	1 (1.82)	0	0 (0.00)
Generalised oedema	1	1 (1.82)	0	0 (0.00)
Malaise	1	1 (1.82)	0	0 (0.00)
Oedema peripheral	1	1 (1.82)	0	0 (0.00)
Pain	1	1 (1.82)	0	0 (0.00)
Immune system disorders				
- Total	17	14 (25.45)	1	1 (1.82)
Hypogammaglobulinaemia	9	8 (14.55)	1	1 (1.82)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Graft versus host disease	3	2 (3.64)	0	0 (0.00)
Immunodeficiency common variable	2	2 (3.64)	0	0 (0.00)
Seasonal allergy	2	2 (3.64)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.82)	0	0 (0.00)
Infections and infestations				
- Total	61	33 (60.00)	17	12 (21.82)
Upper respiratory tract infection	7	7 (12.73)	1	1 (1.82)
Cellulitis of male external genital organ	5	1 (1.82)	2	1 (1.82)
Urinary tract infection	5	4 (7.27)	2	2 (3.64)
Rhinovirus infection	4	2 (3.64)	0	0 (0.00)
Gastroenteritis	3	3 (5.45)	0	0 (0.00)
Influenza	3	3 (5.45)	0	0 (0.00)
Ear infection	2	2 (3.64)	0	0 (0.00)
Otitis media	2	1 (1.82)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.64)	1	1 (1.82)
Sinusitis	2	2 (3.64)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (3.64)	1	1 (1.82)
Bacterial sepsis	1	1 (1.82)	1	1 (1.82)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Cholecystitis infective	1	1 (1.82)	1	1 (1.82)
Corona virus infection	1	1 (1.82)	1	1 (1.82)
Cytomegalovirus infection	1	1 (1.82)	0	0 (0.00)
Enterovirus infection	1	1 (1.82)	1	1 (1.82)
Escherichia urinary tract infection	1	1 (1.82)	1	1 (1.82)
Gastroenteritis norovirus	1	1 (1.82)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.82)	0	0 (0.00)
Herpes zoster	1	1 (1.82)	1	1 (1.82)
Molluscum contagiosum	1	1 (1.82)	0	0 (0.00)
Oral herpes	1	1 (1.82)	0	0 (0.00)
Otitis externa	1	1 (1.82)	0	0 (0.00)
Otitis media acute	1	1 (1.82)	0	0 (0.00)
Paronychia	1	1 (1.82)	0	0 (0.00)
Rash pustular	1	1 (1.82)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (1.82)	1	1 (1.82)
Rhinitis	1	1 (1.82)	0	0 (0.00)
Rotavirus infection	1	1 (1.82)	1	1 (1.82)
Sepsis	1	1 (1.82)	1	1 (1.82)
Subcutaneous abscess	1	1 (1.82)	0	0 (0.00)
Tinea capitis	1	1 (1.82)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Vascular device infection	1	1 (1.82)	1	1 (1.82)
Viral infection	1	1 (1.82)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (1.82)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	13	8 (14.55)	0	0 (0.00)
Contusion	2	2 (3.64)	0	0 (0.00)
Infusion related reaction	2	2 (3.64)	0	0 (0.00)
Procedural pain	2	2 (3.64)	0	0 (0.00)
Arthropod bite	1	1 (1.82)	0	0 (0.00)
Foot fracture	1	1 (1.82)	0	0 (0.00)
Procedural nausea	1	1 (1.82)	0	0 (0.00)
Radius fracture	1	1 (1.82)	0	0 (0.00)
Skin abrasion	1	1 (1.82)	0	0 (0.00)
Skin laceration	1	1 (1.82)	0	0 (0.00)
Sunburn	1	1 (1.82)	0	0 (0.00)
Investigations				
- Total	48	23 (41.82)	16	12 (21.82)
Neutrophil count decreased	12	8 (14.55)	8	6 (10.91)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
White blood cell count decreased	7	5 (9.09)	3	2 (3.64)
Platelet count decreased	5	3 (5.45)	0	0 (0.00)
Weight decreased	4	4 (7.27)	0	0 (0.00)
Aspartate aminotransferase increased	3	3 (5.45)	2	2 (3.64)
Alanine aminotransferase increased	2	2 (3.64)	2	2 (3.64)
Blood urea increased	2	1 (1.82)	0	0 (0.00)
Haemoglobin decreased	2	2 (3.64)	0	0 (0.00)
Lymphocyte count decreased	2	2 (3.64)	0	0 (0.00)
Weight increased	2	2 (3.64)	0	0 (0.00)
Blood bilirubin increased	1	1 (1.82)	1	1 (1.82)
Blood creatinine increased	1	1 (1.82)	0	0 (0.00)
Blood magnesium decreased	1	1 (1.82)	0	0 (0.00)
Blood uric acid increased	1	1 (1.82)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.82)	0	0 (0.00)
Serum ferritin increased	1	1 (1.82)	0	0 (0.00)
Transaminases increased	1	1 (1.82)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	15	10 (18.18)	6	4 (7.27)
Decreased appetite	2	2 (3.64)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Hyperalbuminaemia	2	1 (1.82)	0	0 (0.00)
Hyperphosphataemia	2	2 (3.64)	0	0 (0.00)
Hypokalaemia	2	2 (3.64)	1	1 (1.82)
Dehydration	1	1 (1.82)	1	1 (1.82)
Hypercalcaemia	1	1 (1.82)	0	0 (0.00)
Hyperglycaemia	1	1 (1.82)	1	1 (1.82)
Hypophosphataemia	1	1 (1.82)	1	1 (1.82)
Iron overload	1	1 (1.82)	1	1 (1.82)
Tumour lysis syndrome	1	1 (1.82)	1	1 (1.82)
Vitamin D deficiency	1	1 (1.82)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	21	16 (29.09)	0	0 (0.00)
Pain in extremity	8	8 (14.55)	0	0 (0.00)
Arthralgia	2	2 (3.64)	0	0 (0.00)
Joint range of motion decreased	2	2 (3.64)	0	0 (0.00)
Muscular weakness	2	2 (3.64)	0	0 (0.00)
Back pain	1	1 (1.82)	0	0 (0.00)
Flank pain	1	1 (1.82)	0	0 (0.00)
Muscle spasms	1	1 (1.82)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Musculoskeletal chest pain	1	1 (1.82)	0	0 (0.00)
Osteonecrosis	1	1 (1.82)	0	0 (0.00)
Pain in jaw	1	1 (1.82)	0	0 (0.00)
Toe walking	1	1 (1.82)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.82)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.82)	0	0 (0.00)
Nervous system disorders				
- Total	12	8 (14.55)	0	0 (0.00)
Headache	7	5 (9.09)	0	0 (0.00)
Dizziness	3	3 (5.45)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.64)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (3.64)	0	0 (0.00)
Depression	2	2 (3.64)	0	0 (0.00)
Anxiety	1	1 (1.82)	0	0 (0.00)
Sleep disorder	1	1 (1.82)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Renal and urinary disorders				
- Total	5	3 (5.45)	3	2 (3.64)
Acute kidney injury	1	1 (1.82)	1	1 (1.82)
Calculus urinary	1	1 (1.82)	0	0 (0.00)
Haematuria	1	1 (1.82)	1	1 (1.82)
Nephrolithiasis	1	1 (1.82)	1	1 (1.82)
Urinary incontinence	1	1 (1.82)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	2 (3.64)	1	1 (1.82)
Scrotal pain	1	1 (1.82)	0	0 (0.00)
Vaginal haemorrhage	1	1 (1.82)	1	1 (1.82)
Respiratory, thoracic and mediastinal disorders				
- Total	30	18 (32.73)	4	3 (5.45)
Cough	9	7 (12.73)	0	0 (0.00)
Nasal congestion	4	4 (7.27)	0	0 (0.00)
Rhinorrhoea	4	4 (7.27)	0	0 (0.00)
Oropharyngeal pain	3	3 (5.45)	0	0 (0.00)
Rhinitis allergic	3	3 (5.45)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Epistaxis	2	2 (3.64)	1	1 (1.82)
Acute respiratory failure	1	1 (1.82)	1	1 (1.82)
Dysphonia	1	1 (1.82)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.82)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.82)	1	1 (1.82)
Pulmonary oedema	1	1 (1.82)	1	1 (1.82)
Skin and subcutaneous tissue disorders				
- Total	25	16 (29.09)	1	1 (1.82)
Rash	5	4 (7.27)	0	0 (0.00)
Erythema	2	2 (3.64)	0	0 (0.00)
Rash erythematous	2	1 (1.82)	0	0 (0.00)
Rash maculo-papular	2	2 (3.64)	0	0 (0.00)
Alopecia	1	1 (1.82)	0	0 (0.00)
Dermatitis	1	1 (1.82)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.82)	1	1 (1.82)
Dermatitis atopic	1	1 (1.82)	0	0 (0.00)
Dry skin	1	1 (1.82)	0	0 (0.00)
Eczema	1	1 (1.82)	0	0 (0.00)
Hyperhidrosis	1	1 (1.82)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Ingrowing nail	1	1 (1.82)	0	0 (0.00)
Keloid scar	1	1 (1.82)	0	0 (0.00)
Macule	1	1 (1.82)	0	0 (0.00)
Papule	1	1 (1.82)	0	0 (0.00)
Petechiae	1	1 (1.82)	0	0 (0.00)
Pruritus	1	1 (1.82)	0	0 (0.00)
Rash pruritic	1	1 (1.82)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (3.64)	0	0 (0.00)
Hypertension	2	2 (3.64)	0	0 (0.00)
Hot flush	1	1 (1.82)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	0	0	0	0

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Total number of AE per patient	90	22 (66.67)	23	12 (36.36)
Blood and lymphatic system disorders				
- Total	2	2 (6.06)	1	1 (3.03)
Febrile neutropenia	1	1 (3.03)	1	1 (3.03)
Thrombocytopenia	1	1 (3.03)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Tympanic membrane perforation	1	1 (3.03)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	3 (9.09)	0	0 (0.00)
Diarrhoea	2	2 (6.06)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Abdominal pain	1	1 (3.03)	0	0 (0.00)
Nausea	1	1 (3.03)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	2 (6.06)	1	1 (3.03)
Pyrexia	2	1 (3.03)	0	0 (0.00)
Chills	1	1 (3.03)	0	0 (0.00)
Cyst	1	1 (3.03)	1	1 (3.03)
Immune system disorders				
- Total	2	2 (6.06)	0	0 (0.00)
Chronic graft versus host disease	1	1 (3.03)	0	0 (0.00)
Immunodeficiency	1	1 (3.03)	0	0 (0.00)
Infections and infestations				
- Total	32	11 (33.33)	7	4 (12.12)
Otitis media	5	3 (9.09)	1	1 (3.03)
Otitis media acute	4	2 (6.06)	0	0 (0.00)
Upper respiratory tract infection	4	2 (6.06)	0	0 (0.00)
Sinusitis	3	3 (9.09)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Urinary tract infection	3	2 (6.06)	1	1 (3.03)
Pneumonia	2	2 (6.06)	0	0 (0.00)
Campylobacter infection	1	1 (3.03)	1	1 (3.03)
Cellulitis of male external genital organ	1	1 (3.03)	1	1 (3.03)
Clostridium difficile infection	1	1 (3.03)	1	1 (3.03)
Gingivitis	1	1 (3.03)	0	0 (0.00)
Haemophilus infection	1	1 (3.03)	0	0 (0.00)
Meningitis aseptic	1	1 (3.03)	0	0 (0.00)
Respiratory tract infection	1	1 (3.03)	1	1 (3.03)
Respiratory tract infection viral	1	1 (3.03)	1	1 (3.03)
Skin infection	1	1 (3.03)	0	0 (0.00)
Viral infection	1	1 (3.03)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (3.03)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (3.03)	1	1 (3.03)
Procedural pain	1	1 (3.03)	1	1 (3.03)
Investigations				

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
- Total	22	8 (24.24)	8	5 (15.15)
Lymphocyte count decreased	5	3 (9.09)	1	1 (3.03)
White blood cell count decreased	5	4 (12.12)	3	3 (9.09)
Alanine aminotransferase increased	3	3 (9.09)	2	2 (6.06)
Neutrophil count decreased	3	2 (6.06)	0	0 (0.00)
Aspartate aminotransferase increased	2	2 (6.06)	1	1 (3.03)
Blood alkaline phosphatase increased	1	1 (3.03)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (3.03)	0	0 (0.00)
C-reactive protein increased	1	1 (3.03)	0	0 (0.00)
Platelet count decreased	1	1 (3.03)	1	1 (3.03)
Metabolism and nutrition disorders				
- Total	2	2 (6.06)	1	1 (3.03)
Hypokalaemia	1	1 (3.03)	1	1 (3.03)
Vitamin D deficiency	1	1 (3.03)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (3.03)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Neck pain	1	1 (3.03)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.03)	1	1 (3.03)
Glioblastoma multiforme	1	1 (3.03)	1	1 (3.03)
Nervous system disorders				
- Total	4	3 (9.09)	1	1 (3.03)
Disturbance in attention	1	1 (3.03)	0	0 (0.00)
Dizziness	1	1 (3.03)	0	0 (0.00)
Headache	1	1 (3.03)	0	0 (0.00)
Seizure	1	1 (3.03)	1	1 (3.03)
Renal and urinary disorders				
- Total	3	2 (6.06)	1	1 (3.03)
Acute kidney injury	2	1 (3.03)	1	1 (3.03)
Haematuria	1	1 (3.03)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.03)	1	1 (3.03)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Ovarian failure	1	1 (3.03)	1	1 (3.03)
Respiratory, thoracic and mediastinal disorders				
- Total	7	4 (12.12)	0	0 (0.00)
Cough	3	2 (6.06)	0	0 (0.00)
Epistaxis	1	1 (3.03)	0	0 (0.00)
Oropharyngeal pain	1	1 (3.03)	0	0 (0.00)
Rhinitis allergic	1	1 (3.03)	0	0 (0.00)
Rhinorrhoea	1	1 (3.03)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (9.09)	0	0 (0.00)
Acne	1	1 (3.03)	0	0 (0.00)
Papule	1	1 (3.03)	0	0 (0.00)
Pruritus	1	1 (3.03)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)

2 number of patients with Grade 3 or more AE

Table 220h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: At anytime, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	18	1 (100.00)	4	1 (100.00)
Blood and lymphatic system disorders				
- Total	2	1 (100.00)	2	1 (100.00)
Anaemia	1	1 (100.00)	1	1 (100.00)
Febrile neutropenia	1	1 (100.00)	1	1 (100.00)
Gastrointestinal disorders				
- Total	3	1 (100.00)	0	0 (0.00)
Haematemesis	1	1 (100.00)	0	0 (0.00)
Nausea	1	1 (100.00)	0	0 (0.00)
Vomiting	1	1 (100.00)	0	0 (0.00)
Immune system disorders				

Timing: At anytime, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
- Total	1	1 (100.00)	0	0 (0.00)
Cytokine release syndrome	1	1 (100.00)	0	0 (0.00)
Investigations				
- Total	11	1 (100.00)	2	1 (100.00)
Activated partial thromboplastin time prolonged	3	1 (100.00)	0	0 (0.00)
Blood phosphorus increased	2	1 (100.00)	0	0 (0.00)
International normalised ratio increased	2	1 (100.00)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (100.00)	0	0 (0.00)
Neutrophil count decreased	1	1 (100.00)	1	1 (100.00)
Platelet count decreased	1	1 (100.00)	1	1 (100.00)
White blood cell count decreased	1	1 (100.00)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Encephalopathy	1	1 (100.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Total number of AE per patient	1732	63 (100.00)	548	58 (92.06)
Blood and lymphatic system disorders				
- Total	140	47 (74.60)	105	42 (66.67)
Anaemia	48	26 (41.27)	31	19 (30.16)
Thrombocytopenia	33	10 (15.87)	24	9 (14.29)
Febrile neutropenia	29	23 (36.51)	29	23 (36.51)
Neutropenia	15	11 (17.46)	14	11 (17.46)
Disseminated intravascular coagulation	5	4 (6.35)	2	2 (3.17)
Lymphopenia	4	4 (6.35)	2	2 (3.17)
Eosinophilia	2	1 (1.59)	1	1 (1.59)
Coagulopathy	1	1 (1.59)	0	0 (0.00)
Leukopenia	1	1 (1.59)	1	1 (1.59)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Lymphadenopathy	1	1 (1.59)	0	0 (0.00)
Pancytopenia	1	1 (1.59)	1	1 (1.59)
Cardiac disorders				
- Total	33	23 (36.51)	3	2 (3.17)
Tachycardia	17	15 (23.81)	2	2 (3.17)
Sinus tachycardia	6	6 (9.52)	0	0 (0.00)
Pericardial effusion	2	2 (3.17)	0	0 (0.00)
Sinus bradycardia	2	1 (1.59)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.59)	0	0 (0.00)
Bradycardia	1	1 (1.59)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.59)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.59)	1	1 (1.59)
Palpitations	1	1 (1.59)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.59)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	4	4 (6.35)	0	0 (0.00)
Ear pain	2	2 (3.17)	0	0 (0.00)
Hypoacusis	1	1 (1.59)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Tympanic membrane perforation	1	1 (1.59)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (3.17)	0	0 (0.00)
Adrenal insufficiency	2	2 (3.17)	0	0 (0.00)
Eye disorders				
- Total	30	18 (28.57)	0	0 (0.00)
Vision blurred	5	4 (6.35)	0	0 (0.00)
Eye pain	4	3 (4.76)	0	0 (0.00)
Periorbital oedema	4	4 (6.35)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (4.76)	0	0 (0.00)
Photophobia	3	2 (3.17)	0	0 (0.00)
Dry eye	2	2 (3.17)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.17)	0	0 (0.00)
Uveitis	2	2 (3.17)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.59)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.59)	0	0 (0.00)
Ocular hypertension	1	1 (1.59)	0	0 (0.00)
Papilloedema	1	1 (1.59)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Visual impairment	1	1 (1.59)	0	0 (0.00)
Gastrointestinal disorders				
- Total	165	42 (66.67)	23	13 (20.63)
Vomiting	47	26 (41.27)	5	3 (4.76)
Nausea	33	24 (38.10)	5	5 (7.94)
Diarrhoea	28	24 (38.10)	2	2 (3.17)
Abdominal pain	15	11 (17.46)	2	1 (1.59)
Constipation	8	7 (11.11)	0	0 (0.00)
Abdominal pain upper	3	3 (4.76)	0	0 (0.00)
Oral pain	3	2 (3.17)	1	1 (1.59)
Abdominal distension	2	2 (3.17)	0	0 (0.00)
Anal incontinence	2	1 (1.59)	0	0 (0.00)
Dysphagia	2	2 (3.17)	1	1 (1.59)
Mouth haemorrhage	2	1 (1.59)	2	1 (1.59)
Pancreatitis	2	2 (3.17)	1	1 (1.59)
Stomatitis	2	2 (3.17)	0	0 (0.00)
Abdominal discomfort	1	1 (1.59)	0	0 (0.00)
Abdominal pain lower	1	1 (1.59)	0	0 (0.00)
Abdominal tenderness	1	1 (1.59)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Ascites	1	1 (1.59)	1	1 (1.59)
Dyspepsia	1	1 (1.59)	0	0 (0.00)
Enterocolitis	1	1 (1.59)	1	1 (1.59)
Flatulence	1	1 (1.59)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.59)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.59)	0	0 (0.00)
Glossodynia	1	1 (1.59)	0	0 (0.00)
Haematemesis	1	1 (1.59)	0	0 (0.00)
Ileus	1	1 (1.59)	1	1 (1.59)
Intestinal obstruction	1	1 (1.59)	1	1 (1.59)
Lip pain	1	1 (1.59)	0	0 (0.00)
Pigmentation lip	1	1 (1.59)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.59)	0	0 (0.00)
General disorders and administration site conditions				
- Total	107	42 (66.67)	16	12 (19.05)
Pyrexia	43	25 (39.68)	7	7 (11.11)
Fatigue	16	15 (23.81)	1	1 (1.59)
Chills	11	10 (15.87)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Catheter site pain	4	4 (6.35)	0	0 (0.00)
Generalised oedema	4	3 (4.76)	0	0 (0.00)
Malaise	4	4 (6.35)	0	0 (0.00)
Pain	4	4 (6.35)	2	2 (3.17)
Oedema peripheral	3	3 (4.76)	1	1 (1.59)
Face oedema	2	2 (3.17)	1	1 (1.59)
Influenza like illness	2	2 (3.17)	0	0 (0.00)
Acquired gene mutation	1	1 (1.59)	0	0 (0.00)
Asthenia	1	1 (1.59)	0	0 (0.00)
Catheter site extravasation	1	1 (1.59)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.59)	0	0 (0.00)
Crying	1	1 (1.59)	0	0 (0.00)
Cyst	1	1 (1.59)	1	1 (1.59)
Facial pain	1	1 (1.59)	0	0 (0.00)
Injection site haematoma	1	1 (1.59)	0	0 (0.00)
Localised oedema	1	1 (1.59)	1	1 (1.59)
Mucosal haemorrhage	1	1 (1.59)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.59)	1	1 (1.59)
Non-cardiac chest pain	1	1 (1.59)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Peripheral swelling	1	1 (1.59)	0	0 (0.00)
Physical deconditioning	1	1 (1.59)	1	1 (1.59)
Hepatobiliary disorders				
- Total	9	7 (11.11)	2	2 (3.17)
Hyperbilirubinaemia	4	3 (4.76)	2	2 (3.17)
Hepatomegaly	3	3 (4.76)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.59)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.59)	0	0 (0.00)
Immune system disorders				
- Total	134	57 (90.48)	34	22 (34.92)
Cytokine release syndrome	85	49 (77.78)	29	19 (30.16)
Hypogammaglobulinaemia	36	33 (52.38)	5	5 (7.94)
Graft versus host disease	3	2 (3.17)	0	0 (0.00)
Immunodeficiency common variable	2	2 (3.17)	0	0 (0.00)
Seasonal allergy	2	2 (3.17)	0	0 (0.00)
Chronic graft versus host disease	1	1 (1.59)	0	0 (0.00)
Drug hypersensitivity	1	1 (1.59)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.59)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Graft versus host disease in skin	1	1 (1.59)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.59)	0	0 (0.00)
Immunodeficiency	1	1 (1.59)	0	0 (0.00)
Infections and infestations				
- Total	134	46 (73.02)	31	18 (28.57)
Upper respiratory tract infection	12	9 (14.29)	1	1 (1.59)
Urinary tract infection	8	5 (7.94)	3	2 (3.17)
Otitis media	7	4 (6.35)	1	1 (1.59)
Rhinovirus infection	7	5 (7.94)	0	0 (0.00)
Cellulitis of male external genital organ	6	1 (1.59)	3	1 (1.59)
Clostridium difficile infection	5	5 (7.94)	1	1 (1.59)
Gastroenteritis	5	5 (7.94)	1	1 (1.59)
Otitis media acute	5	2 (3.17)	0	0 (0.00)
Sinusitis	5	4 (6.35)	0	0 (0.00)
Clostridium difficile colitis	4	4 (6.35)	1	1 (1.59)
Influenza	4	4 (6.35)	0	0 (0.00)
Pneumonia	4	4 (6.35)	1	1 (1.59)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Viral infection	3	3 (4.76)	0	0 (0.00)
Viral upper respiratory tract infection	3	3 (4.76)	1	1 (1.59)
Cytomegalovirus infection	2	2 (3.17)	0	0 (0.00)
Ear infection	2	2 (3.17)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (1.59)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.17)	1	1 (1.59)
Skin infection	2	2 (3.17)	0	0 (0.00)
Staphylococcal infection	2	2 (3.17)	1	1 (1.59)
Vulvovaginal candidiasis	2	2 (3.17)	0	0 (0.00)
Acute sinusitis	1	1 (1.59)	0	0 (0.00)
Bacterial sepsis	1	1 (1.59)	1	1 (1.59)
Body tinea	1	1 (1.59)	0	0 (0.00)
Campylobacter infection	1	1 (1.59)	1	1 (1.59)
Catheter site cellulitis	1	1 (1.59)	0	0 (0.00)
Catheter site infection	1	1 (1.59)	1	1 (1.59)
Cholecystitis infective	1	1 (1.59)	1	1 (1.59)
Corona virus infection	1	1 (1.59)	1	1 (1.59)
Enterococcal infection	1	1 (1.59)	0	0 (0.00)
Enterovirus infection	1	1 (1.59)	1	1 (1.59)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Escherichia urinary tract infection	1	1 (1.59)	1	1 (1.59)
Folliculitis	1	1 (1.59)	0	0 (0.00)
Fungal skin infection	1	1 (1.59)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.59)	0	0 (0.00)
Gingivitis	1	1 (1.59)	0	0 (0.00)
Haemophilus infection	1	1 (1.59)	0	0 (0.00)
Herpes simplex	1	1 (1.59)	0	0 (0.00)
Herpes zoster	1	1 (1.59)	1	1 (1.59)
Human herpesvirus 6 infection	1	1 (1.59)	0	0 (0.00)
Hypopyon	1	1 (1.59)	0	0 (0.00)
Meningitis aseptic	1	1 (1.59)	0	0 (0.00)
Molluscum contagiosum	1	1 (1.59)	0	0 (0.00)
Oral candidiasis	1	1 (1.59)	0	0 (0.00)
Oral herpes	1	1 (1.59)	0	0 (0.00)
Orchitis	1	1 (1.59)	0	0 (0.00)
Otitis externa	1	1 (1.59)	0	0 (0.00)
Paronychia	1	1 (1.59)	0	0 (0.00)
Pharyngitis	1	1 (1.59)	0	0 (0.00)
Rash pustular	1	1 (1.59)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Respiratory syncytial virus infection	1	1 (1.59)	1	1 (1.59)
Respiratory tract infection	1	1 (1.59)	1	1 (1.59)
Respiratory tract infection viral	1	1 (1.59)	1	1 (1.59)
Rhinitis	1	1 (1.59)	0	0 (0.00)
Rotavirus infection	1	1 (1.59)	1	1 (1.59)
Sepsis	1	1 (1.59)	1	1 (1.59)
Septic embolus	1	1 (1.59)	1	1 (1.59)
Streptococcal infection	1	1 (1.59)	0	0 (0.00)
Subcutaneous abscess	1	1 (1.59)	0	0 (0.00)
Tinea capitis	1	1 (1.59)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.59)	1	1 (1.59)
Vascular device infection	1	1 (1.59)	1	1 (1.59)
Vulvovaginal mycotic infection	1	1 (1.59)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	39	22 (34.92)	3	3 (4.76)
Procedural pain	6	5 (7.94)	1	1 (1.59)
Infusion related reaction	4	4 (6.35)	0	0 (0.00)
Transfusion reaction	4	3 (4.76)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Contusion	3	3 (4.76)	0	0 (0.00)
Skin abrasion	2	2 (3.17)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.59)	1	1 (1.59)
Arthropod bite	1	1 (1.59)	0	0 (0.00)
Foot fracture	1	1 (1.59)	0	0 (0.00)
Incision site pain	1	1 (1.59)	0	0 (0.00)
Limb injury	1	1 (1.59)	0	0 (0.00)
Mouth injury	1	1 (1.59)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.59)	0	0 (0.00)
Procedural complication	1	1 (1.59)	0	0 (0.00)
Procedural headache	1	1 (1.59)	0	0 (0.00)
Procedural nausea	1	1 (1.59)	0	0 (0.00)
Procedural site reaction	1	1 (1.59)	0	0 (0.00)
Radius fracture	1	1 (1.59)	0	0 (0.00)
Skin laceration	1	1 (1.59)	0	0 (0.00)
Stoma site irritation	1	1 (1.59)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.59)	0	0 (0.00)
Sunburn	1	1 (1.59)	0	0 (0.00)
Tibia fracture	1	1 (1.59)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Tongue injury	1	1 (1.59)	0	0 (0.00)
Transfusion related complication	1	1 (1.59)	1	1 (1.59)
Investigations				
- Total	391	55 (87.30)	200	48 (76.19)
White blood cell count decreased	66	34 (53.97)	43	30 (47.62)
Neutrophil count decreased	61	27 (42.86)	51	24 (38.10)
Platelet count decreased	48	19 (30.16)	37	14 (22.22)
Aspartate aminotransferase increased	36	19 (30.16)	19	12 (19.05)
Alanine aminotransferase increased	33	21 (33.33)	18	14 (22.22)
Lymphocyte count decreased	23	16 (25.40)	13	12 (19.05)
Prothrombin time prolonged	17	9 (14.29)	1	1 (1.59)
Blood fibrinogen decreased	15	4 (6.35)	4	3 (4.76)
Blood bilirubin increased	14	8 (12.70)	3	3 (4.76)
Blood creatinine increased	12	9 (14.29)	2	2 (3.17)
International normalised ratio increased	9	8 (12.70)	1	1 (1.59)
Activated partial thromboplastin time prolonged	5	4 (6.35)	0	0 (0.00)
Blood urea increased	5	3 (4.76)	1	1 (1.59)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Blood immunoglobulin M decreased	4	4 (6.35)	0	0 (0.00)
Weight decreased	4	4 (6.35)	0	0 (0.00)
Blood immunoglobulin A decreased	3	3 (4.76)	0	0 (0.00)
Blood uric acid increased	3	2 (3.17)	0	0 (0.00)
Haemoglobin decreased	3	3 (4.76)	1	1 (1.59)
Transaminases increased	3	3 (4.76)	0	0 (0.00)
Blood magnesium decreased	2	2 (3.17)	1	1 (1.59)
Blood sodium increased	2	1 (1.59)	0	0 (0.00)
C-reactive protein increased	2	2 (3.17)	1	1 (1.59)
Lipase increased	2	2 (3.17)	2	2 (3.17)
Serum ferritin increased	2	2 (3.17)	0	0 (0.00)
Weight increased	2	2 (3.17)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (1.59)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.59)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.59)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (1.59)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.59)	1	1 (1.59)
Blood phosphorus decreased	1	1 (1.59)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Blood phosphorus increased	1	1 (1.59)	0	0 (0.00)
Cardiac murmur	1	1 (1.59)	0	0 (0.00)
Culture stool positive	1	1 (1.59)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.59)	0	0 (0.00)
Hepatic enzyme increased	1	1 (1.59)	0	0 (0.00)
Norovirus test positive	1	1 (1.59)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.59)	0	0 (0.00)
Protein total decreased	1	1 (1.59)	1	1 (1.59)
Pulmonary function test decreased	1	1 (1.59)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	133	43 (68.25)	50	27 (42.86)
Decreased appetite	26	22 (34.92)	13	12 (19.05)
Hypokalaemia	23	19 (30.16)	9	9 (14.29)
Hypophosphataemia	14	10 (15.87)	10	8 (12.70)
Hyperphosphataemia	12	8 (12.70)	0	0 (0.00)
Hypernatraemia	7	4 (6.35)	1	1 (1.59)
Hypoalbuminaemia	6	5 (7.94)	1	1 (1.59)
Hyperglycaemia	5	3 (4.76)	2	2 (3.17)
Dehydration	4	4 (6.35)	3	3 (4.76)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Hyperuricaemia	4	3 (4.76)	1	1 (1.59)
Hypocalcaemia	4	3 (4.76)	1	1 (1.59)
Fluid overload	3	3 (4.76)	0	0 (0.00)
Hyperalbuminaemia	3	1 (1.59)	0	0 (0.00)
Hypercalcaemia	3	1 (1.59)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.17)	1	1 (1.59)
Hyponatraemia	3	2 (3.17)	3	2 (3.17)
Acidosis	2	2 (3.17)	1	1 (1.59)
Tumour lysis syndrome	2	2 (3.17)	2	2 (3.17)
Vitamin D deficiency	2	2 (3.17)	0	0 (0.00)
Hyperchloraemia	1	1 (1.59)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.59)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.59)	0	0 (0.00)
Iron overload	1	1 (1.59)	1	1 (1.59)
Malnutrition	1	1 (1.59)	1	1 (1.59)
Metabolic acidosis	1	1 (1.59)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.59)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
- Total	45	25 (39.68)	1	1 (1.59)
Pain in extremity	12	11 (17.46)	0	0 (0.00)
Arthralgia	6	5 (7.94)	1	1 (1.59)
Myalgia	5	5 (7.94)	0	0 (0.00)
Musculoskeletal pain	4	3 (4.76)	0	0 (0.00)
Muscular weakness	3	3 (4.76)	0	0 (0.00)
Joint range of motion decreased	2	2 (3.17)	0	0 (0.00)
Muscle spasms	2	2 (3.17)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (3.17)	0	0 (0.00)
Back pain	1	1 (1.59)	0	0 (0.00)
Coccydynia	1	1 (1.59)	0	0 (0.00)
Flank pain	1	1 (1.59)	0	0 (0.00)
Limb discomfort	1	1 (1.59)	0	0 (0.00)
Neck pain	1	1 (1.59)	0	0 (0.00)
Osteonecrosis	1	1 (1.59)	0	0 (0.00)
Osteopenia	1	1 (1.59)	0	0 (0.00)
Pain in jaw	1	1 (1.59)	0	0 (0.00)
Toe walking	1	1 (1.59)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (4.76)	1	1 (1.59)
Glioblastoma multiforme	1	1 (1.59)	1	1 (1.59)
Myelodysplastic syndrome	1	1 (1.59)	0	0 (0.00)
Skin papilloma	1	1 (1.59)	0	0 (0.00)
Nervous system disorders				
- Total	73	34 (53.97)	7	6 (9.52)
Headache	39	24 (38.10)	2	2 (3.17)
Dizziness	8	6 (9.52)	0	0 (0.00)
Encephalopathy	5	3 (4.76)	2	2 (3.17)
Seizure	4	4 (6.35)	2	2 (3.17)
Dysarthria	2	2 (3.17)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.17)	0	0 (0.00)
Tremor	2	2 (3.17)	0	0 (0.00)
Asterixis	1	1 (1.59)	0	0 (0.00)
Ataxia	1	1 (1.59)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.59)	0	0 (0.00)
Disturbance in attention	1	1 (1.59)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Embolic stroke	1	1 (1.59)	1	1 (1.59)
Idiopathic intracranial hypertension	1	1 (1.59)	0	0 (0.00)
Migraine	1	1 (1.59)	0	0 (0.00)
Myoclonus	1	1 (1.59)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.59)	0	0 (0.00)
Pleocytosis	1	1 (1.59)	0	0 (0.00)
Somnolence	1	1 (1.59)	0	0 (0.00)
Product issues				
- Total	1	1 (1.59)	0	0 (0.00)
Device occlusion	1	1 (1.59)	0	0 (0.00)
Psychiatric disorders				
- Total	34	17 (26.98)	1	1 (1.59)
Anxiety	7	7 (11.11)	1	1 (1.59)
Confusional state	6	6 (9.52)	0	0 (0.00)
Delirium	4	4 (6.35)	0	0 (0.00)
Agitation	3	2 (3.17)	0	0 (0.00)
Hallucination	3	2 (3.17)	0	0 (0.00)
Depression	2	2 (3.17)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Irritability	2	2 (3.17)	0	0 (0.00)
Adjustment disorder	1	1 (1.59)	0	0 (0.00)
Insomnia	1	1 (1.59)	0	0 (0.00)
Listless	1	1 (1.59)	0	0 (0.00)
Mental status changes	1	1 (1.59)	0	0 (0.00)
Panic attack	1	1 (1.59)	0	0 (0.00)
Sleep disorder	1	1 (1.59)	0	0 (0.00)
Suicidal ideation	1	1 (1.59)	0	0 (0.00)
Renal and urinary disorders				
- Total	26	15 (23.81)	15	10 (15.87)
Acute kidney injury	10	9 (14.29)	7	7 (11.11)
Haematuria	6	5 (7.94)	3	3 (4.76)
Dysuria	2	2 (3.17)	0	0 (0.00)
Oliguria	2	2 (3.17)	2	2 (3.17)
Calculus urinary	1	1 (1.59)	0	0 (0.00)
Nephrolithiasis	1	1 (1.59)	1	1 (1.59)
Pollakiuria	1	1 (1.59)	0	0 (0.00)
Renal failure	1	1 (1.59)	1	1 (1.59)
Renal impairment	1	1 (1.59)	1	1 (1.59)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Urinary incontinence	1	1 (1.59)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	7	6 (9.52)	2	2 (3.17)
Oedema genital	2	1 (1.59)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.17)	0	0 (0.00)
Ovarian failure	1	1 (1.59)	1	1 (1.59)
Scrotal pain	1	1 (1.59)	0	0 (0.00)
Vaginal haemorrhage	1	1 (1.59)	1	1 (1.59)
Respiratory, thoracic and mediastinal disorders				
- Total	110	38 (60.32)	32	15 (23.81)
Cough	20	14 (22.22)	0	0 (0.00)
Epistaxis	14	10 (15.87)	5	5 (7.94)
Hypoxia	13	10 (15.87)	8	7 (11.11)
Pleural effusion	8	8 (12.70)	2	2 (3.17)
Pulmonary oedema	7	7 (11.11)	6	6 (9.52)
Oropharyngeal pain	6	6 (9.52)	0	0 (0.00)
Rhinorrhoea	6	6 (9.52)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Tachypnoea	6	5 (7.94)	1	1 (1.59)
Nasal congestion	5	5 (7.94)	0	0 (0.00)
Rhinitis allergic	5	4 (6.35)	0	0 (0.00)
Dyspnoea	3	2 (3.17)	2	2 (3.17)
Haemoptysis	3	2 (3.17)	1	1 (1.59)
Respiratory failure	3	3 (4.76)	3	3 (4.76)
Acute respiratory failure	1	1 (1.59)	1	1 (1.59)
Atelectasis	1	1 (1.59)	0	0 (0.00)
Dysphonia	1	1 (1.59)	0	0 (0.00)
Interstitial lung disease	1	1 (1.59)	1	1 (1.59)
Oropharyngeal plaque	1	1 (1.59)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.59)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.59)	1	1 (1.59)
Pharyngeal ulceration	1	1 (1.59)	0	0 (0.00)
Respiratory depression	1	1 (1.59)	0	0 (0.00)
Respiratory distress	1	1 (1.59)	1	1 (1.59)
Wheezing	1	1 (1.59)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
- Total	69	30 (47.62)	3	3 (4.76)
Rash	9	8 (12.70)	0	0 (0.00)
Erythema	6	5 (7.94)	0	0 (0.00)
Dry skin	5	5 (7.94)	0	0 (0.00)
Hyperhidrosis	5	4 (6.35)	0	0 (0.00)
Rash maculo-papular	5	5 (7.94)	1	1 (1.59)
Ingrowing nail	4	3 (4.76)	0	0 (0.00)
Petechiae	4	4 (6.35)	0	0 (0.00)
Pruritus	4	4 (6.35)	0	0 (0.00)
Rash erythematous	3	2 (3.17)	0	0 (0.00)
Macule	2	2 (3.17)	0	0 (0.00)
Papule	2	2 (3.17)	0	0 (0.00)
Rash papular	2	2 (3.17)	0	0 (0.00)
Acne	1	1 (1.59)	0	0 (0.00)
Alopecia	1	1 (1.59)	0	0 (0.00)
Dermatitis	1	1 (1.59)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.59)	1	1 (1.59)
Dermatitis atopic	1	1 (1.59)	0	0 (0.00)
Dermatitis diaper	1	1 (1.59)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Ecchymosis	1	1 (1.59)	1	1 (1.59)
Eczema	1	1 (1.59)	0	0 (0.00)
Keloid scar	1	1 (1.59)	0	0 (0.00)
Livedo reticularis	1	1 (1.59)	0	0 (0.00)
Night sweats	1	1 (1.59)	0	0 (0.00)
Rash follicular	1	1 (1.59)	0	0 (0.00)
Rash macular	1	1 (1.59)	0	0 (0.00)
Rash pruritic	1	1 (1.59)	0	0 (0.00)
Rash vesicular	1	1 (1.59)	0	0 (0.00)
Skin exfoliation	1	1 (1.59)	0	0 (0.00)
Skin fissures	1	1 (1.59)	0	0 (0.00)
Skin irritation	1	1 (1.59)	0	0 (0.00)
Vascular disorders				
- Total	43	25 (39.68)	19	16 (25.40)
Hypotension	19	16 (25.40)	16	15 (23.81)
Hypertension	14	12 (19.05)	1	1 (1.59)
Flushing	3	2 (3.17)	0	0 (0.00)
Orthostatic hypotension	2	2 (3.17)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.59)	1	1 (1.59)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=63 n (%)[1]	Grade >= 3 Total events	All patients N=63 n (%)[2]
Embolism	1	1 (1.59)	1	1 (1.59)
Haematoma	1	1 (1.59)	0	0 (0.00)
Hot flush	1	1 (1.59)	0	0 (0.00)
Secondary hypertension	1	1 (1.59)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Total number of AE per patient	85	4 (100.00)	14	2 (50.00)
Blood and lymphatic system disorders				
- Total	5	3 (75.00)	3	2 (50.00)
Anaemia	3	3 (75.00)	1	1 (25.00)
Febrile neutropenia	2	2 (50.00)	2	2 (50.00)
Cardiac disorders				
- Total	3	2 (50.00)	0	0 (0.00)
Cardiac dysfunction	1	1 (25.00)	0	0 (0.00)
Sinus tachycardia	1	1 (25.00)	0	0 (0.00)
Tachycardia	1	1 (25.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	13	3 (75.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Diarrhoea	3	3 (75.00)	0	0 (0.00)
Abdominal pain	2	2 (50.00)	0	0 (0.00)
Constipation	2	1 (25.00)	0	0 (0.00)
Nausea	2	2 (50.00)	0	0 (0.00)
Abdominal distension	1	1 (25.00)	0	0 (0.00)
Abdominal tenderness	1	1 (25.00)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (25.00)	0	0 (0.00)
Vomiting	1	1 (25.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	3 (75.00)	0	0 (0.00)
Fatigue	3	3 (75.00)	0	0 (0.00)
Pain	1	1 (25.00)	0	0 (0.00)
Immune system disorders				
- Total	6	4 (100.00)	1	1 (25.00)
Hypogammaglobulinaemia	4	4 (100.00)	0	0 (0.00)
Cytokine release syndrome	2	2 (50.00)	1	1 (25.00)
Infections and infestations				

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
- Total	4	2 (50.00)	1	1 (25.00)
Clostridium difficile infection	1	1 (25.00)	0	0 (0.00)
Gastroenteritis	1	1 (25.00)	1	1 (25.00)
Pharyngitis	1	1 (25.00)	0	0 (0.00)
Streptococcal infection	1	1 (25.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	4	2 (50.00)	0	0 (0.00)
Contusion	1	1 (25.00)	0	0 (0.00)
Infusion related reaction	1	1 (25.00)	0	0 (0.00)
Procedural pain	1	1 (25.00)	0	0 (0.00)
Procedural site reaction	1	1 (25.00)	0	0 (0.00)
Investigations				
- Total	19	3 (75.00)	6	1 (25.00)
Alanine aminotransferase increased	2	1 (25.00)	2	1 (25.00)
Blood bilirubin increased	2	1 (25.00)	0	0 (0.00)
Blood creatinine increased	2	1 (25.00)	0	0 (0.00)
International normalised ratio increased	2	2 (50.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Lymphocyte count decreased	2	2 (50.00)	1	1 (25.00)
Neutrophil count decreased	2	2 (50.00)	1	1 (25.00)
White blood cell count decreased	2	2 (50.00)	1	1 (25.00)
Activated partial thromboplastin time prolonged	1	1 (25.00)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (25.00)	1	1 (25.00)
Blood immunoglobulin A decreased	1	1 (25.00)	0	0 (0.00)
Platelet count decreased	1	1 (25.00)	0	0 (0.00)
Pulmonary function test decreased	1	1 (25.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	7	4 (100.00)	2	2 (50.00)
Decreased appetite	2	1 (25.00)	1	1 (25.00)
Hyperphosphataemia	2	2 (50.00)	0	0 (0.00)
Dehydration	1	1 (25.00)	1	1 (25.00)
Hyperuricaemia	1	1 (25.00)	0	0 (0.00)
Hypokalaemia	1	1 (25.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
- Total	6	2 (50.00)	0	0 (0.00)
Arthralgia	2	2 (50.00)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (25.00)	0	0 (0.00)
Musculoskeletal pain	1	1 (25.00)	0	0 (0.00)
Myalgia	1	1 (25.00)	0	0 (0.00)
Pain in extremity	1	1 (25.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (25.00)	0	0 (0.00)
Skin papilloma	1	1 (25.00)	0	0 (0.00)
Nervous system disorders				
- Total	6	3 (75.00)	0	0 (0.00)
Headache	5	3 (75.00)	0	0 (0.00)
Dizziness	1	1 (25.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	3	2 (50.00)	0	0 (0.00)
Rhinorrhoea	1	1 (25.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Tachypnoea	1	1 (25.00)	0	0 (0.00)
Wheezing	1	1 (25.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	2 (50.00)	0	0 (0.00)
Petechiae	1	1 (25.00)	0	0 (0.00)
Rash follicular	1	1 (25.00)	0	0 (0.00)
Rash papular	1	1 (25.00)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (25.00)	1	1 (25.00)
Hypotension	1	1 (25.00)	1	1 (25.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Total number of AE per patient	1229	59 (98.33)	444	52 (86.67)
Blood and lymphatic system disorders				
- Total	117	40 (66.67)	90	36 (60.00)
Anaemia	44	24 (40.00)	30	18 (30.00)
Thrombocytopenia	30	8 (13.33)	23	8 (13.33)
Febrile neutropenia	24	20 (33.33)	24	20 (33.33)
Neutropenia	9	8 (13.33)	8	8 (13.33)
Disseminated intravascular coagulation	5	4 (6.67)	2	2 (3.33)
Lymphopenia	3	3 (5.00)	2	2 (3.33)
Coagulopathy	1	1 (1.67)	0	0 (0.00)
Pancytopenia	1	1 (1.67)	1	1 (1.67)
Cardiac disorders				

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
- Total	29	20 (33.33)	3	2 (3.33)
Tachycardia	16	14 (23.33)	2	2 (3.33)
Sinus tachycardia	4	4 (6.67)	0	0 (0.00)
Pericardial effusion	2	2 (3.33)	0	0 (0.00)
Sinus bradycardia	2	1 (1.67)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.67)	0	0 (0.00)
Bradycardia	1	1 (1.67)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.67)	1	1 (1.67)
Palpitations	1	1 (1.67)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.67)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (5.00)	0	0 (0.00)
Ear pain	2	2 (3.33)	0	0 (0.00)
Hypoacusis	1	1 (1.67)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.67)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.67)	0	0 (0.00)
Eye disorders				

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
- Total	25	13 (21.67)	0	0 (0.00)
Eye pain	4	3 (5.00)	0	0 (0.00)
Periorbital oedema	4	4 (6.67)	0	0 (0.00)
Vision blurred	4	3 (5.00)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (5.00)	0	0 (0.00)
Photophobia	3	2 (3.33)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.33)	0	0 (0.00)
Uveitis	2	2 (3.33)	0	0 (0.00)
Ocular hypertension	1	1 (1.67)	0	0 (0.00)
Papilloedema	1	1 (1.67)	0	0 (0.00)
Visual impairment	1	1 (1.67)	0	0 (0.00)
Gastrointestinal disorders				
- Total	113	33 (55.00)	15	11 (18.33)
Vomiting	34	21 (35.00)	3	3 (5.00)
Nausea	24	19 (31.67)	3	3 (5.00)
Diarrhoea	15	15 (25.00)	1	1 (1.67)
Abdominal pain	8	7 (11.67)	1	1 (1.67)
Constipation	6	6 (10.00)	0	0 (0.00)
Abdominal pain upper	2	2 (3.33)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Anal incontinence	2	1 (1.67)	0	0 (0.00)
Dysphagia	2	2 (3.33)	1	1 (1.67)
Haematemesis	2	2 (3.33)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.67)	2	1 (1.67)
Pancreatitis	2	2 (3.33)	1	1 (1.67)
Stomatitis	2	2 (3.33)	0	0 (0.00)
Abdominal discomfort	1	1 (1.67)	0	0 (0.00)
Abdominal distension	1	1 (1.67)	0	0 (0.00)
Abdominal pain lower	1	1 (1.67)	0	0 (0.00)
Ascites	1	1 (1.67)	1	1 (1.67)
Dyspepsia	1	1 (1.67)	0	0 (0.00)
Flatulence	1	1 (1.67)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.67)	0	0 (0.00)
Glossodynia	1	1 (1.67)	0	0 (0.00)
Ileus	1	1 (1.67)	1	1 (1.67)
Intestinal obstruction	1	1 (1.67)	1	1 (1.67)
Lip pain	1	1 (1.67)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
General disorders and administration site conditions				
- Total	73	29 (48.33)	14	10 (16.67)
Pyrexia	27	16 (26.67)	6	6 (10.00)
Fatigue	11	10 (16.67)	1	1 (1.67)
Chills	9	8 (13.33)	0	0 (0.00)
Catheter site pain	3	3 (5.00)	0	0 (0.00)
Generalised oedema	3	2 (3.33)	0	0 (0.00)
Malaise	3	3 (5.00)	0	0 (0.00)
Face oedema	2	2 (3.33)	1	1 (1.67)
Oedema peripheral	2	2 (3.33)	1	1 (1.67)
Pain	2	2 (3.33)	2	2 (3.33)
Asthenia	1	1 (1.67)	0	0 (0.00)
Catheter site extravasation	1	1 (1.67)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.67)	0	0 (0.00)
Facial pain	1	1 (1.67)	0	0 (0.00)
Injection site haematoma	1	1 (1.67)	0	0 (0.00)
Localised oedema	1	1 (1.67)	1	1 (1.67)
Mucosal haemorrhage	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Multiple organ dysfunction syndrome	1	1 (1.67)	1	1 (1.67)
Non-cardiac chest pain	1	1 (1.67)	0	0 (0.00)
Peripheral swelling	1	1 (1.67)	0	0 (0.00)
Physical deconditioning	1	1 (1.67)	1	1 (1.67)
Hepatobiliary disorders				
- Total	9	7 (11.67)	2	2 (3.33)
Hyperbilirubinaemia	4	3 (5.00)	2	2 (3.33)
Hepatomegaly	3	3 (5.00)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.67)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.67)	0	0 (0.00)
Immune system disorders				
- Total	110	53 (88.33)	32	21 (35.00)
Cytokine release syndrome	84	48 (80.00)	28	18 (30.00)
Hypogammaglobulinaemia	23	22 (36.67)	4	4 (6.67)
Drug hypersensitivity	1	1 (1.67)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.67)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Infections and infestations				
- Total	37	24 (40.00)	6	6 (10.00)
Clostridium difficile colitis	4	4 (6.67)	1	1 (1.67)
Clostridium difficile infection	3	3 (5.00)	0	0 (0.00)
Rhinovirus infection	3	3 (5.00)	0	0 (0.00)
Pneumonia	2	2 (3.33)	1	1 (1.67)
Staphylococcal infection	2	2 (3.33)	1	1 (1.67)
Acute sinusitis	1	1 (1.67)	0	0 (0.00)
Body tinea	1	1 (1.67)	0	0 (0.00)
Catheter site cellulitis	1	1 (1.67)	0	0 (0.00)
Catheter site infection	1	1 (1.67)	1	1 (1.67)
Cytomegalovirus infection	1	1 (1.67)	0	0 (0.00)
Enterococcal infection	1	1 (1.67)	0	0 (0.00)
Folliculitis	1	1 (1.67)	0	0 (0.00)
Fungal skin infection	1	1 (1.67)	0	0 (0.00)
Gastroenteritis	1	1 (1.67)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.67)	0	0 (0.00)
Herpes simplex	1	1 (1.67)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Hypopyon	1	1 (1.67)	0	0 (0.00)
Influenza	1	1 (1.67)	0	0 (0.00)
Oral candidiasis	1	1 (1.67)	0	0 (0.00)
Orchitis	1	1 (1.67)	0	0 (0.00)
Septic embolus	1	1 (1.67)	1	1 (1.67)
Skin infection	1	1 (1.67)	0	0 (0.00)
Upper respiratory tract infection	1	1 (1.67)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.67)	1	1 (1.67)
Viral infection	1	1 (1.67)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.67)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (1.67)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	21	13 (21.67)	2	2 (3.33)
Transfusion reaction	4	3 (5.00)	0	0 (0.00)
Procedural pain	2	2 (3.33)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.67)	1	1 (1.67)
Incision site pain	1	1 (1.67)	0	0 (0.00)
Infusion related reaction	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Limb injury	1	1 (1.67)	0	0 (0.00)
Mouth injury	1	1 (1.67)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.67)	0	0 (0.00)
Procedural complication	1	1 (1.67)	0	0 (0.00)
Procedural headache	1	1 (1.67)	0	0 (0.00)
Skin abrasion	1	1 (1.67)	0	0 (0.00)
Stoma site irritation	1	1 (1.67)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.67)	0	0 (0.00)
Tibia fracture	1	1 (1.67)	0	0 (0.00)
Tongue injury	1	1 (1.67)	0	0 (0.00)
Transfusion related complication	1	1 (1.67)	1	1 (1.67)
Investigations				
- Total	313	49 (81.67)	172	43 (71.67)
White blood cell count decreased	53	28 (46.67)	36	25 (41.67)
Neutrophil count decreased	45	23 (38.33)	43	22 (36.67)
Platelet count decreased	42	18 (30.00)	37	14 (23.33)
Aspartate aminotransferase increased	31	17 (28.33)	15	10 (16.67)
Alanine aminotransferase increased	26	18 (30.00)	12	10 (16.67)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Prothrombin time prolonged	17	9 (15.00)	1	1 (1.67)
Blood fibrinogen decreased	15	4 (6.67)	4	3 (5.00)
Lymphocyte count decreased	14	12 (20.00)	11	10 (16.67)
Blood bilirubin increased	11	6 (10.00)	2	2 (3.33)
Blood creatinine increased	9	8 (13.33)	2	2 (3.33)
International normalised ratio increased	9	7 (11.67)	1	1 (1.67)
Activated partial thromboplastin time prolonged	7	4 (6.67)	0	0 (0.00)
Blood immunoglobulin M decreased	4	4 (6.67)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.33)	0	0 (0.00)
Blood urea increased	3	3 (5.00)	1	1 (1.67)
Blood immunoglobulin A decreased	2	2 (3.33)	0	0 (0.00)
Blood sodium increased	2	1 (1.67)	0	0 (0.00)
Blood uric acid increased	2	1 (1.67)	0	0 (0.00)
Lipase increased	2	2 (3.33)	2	2 (3.33)
Transaminases increased	2	2 (3.33)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.67)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.67)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.67)	1	1 (1.67)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Blood magnesium decreased	1	1 (1.67)	1	1 (1.67)
Blood phosphorus decreased	1	1 (1.67)	0	0 (0.00)
C-reactive protein increased	1	1 (1.67)	1	1 (1.67)
Cardiac murmur	1	1 (1.67)	0	0 (0.00)
Culture stool positive	1	1 (1.67)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.67)	0	0 (0.00)
Haemoglobin decreased	1	1 (1.67)	1	1 (1.67)
Hepatic enzyme increased	1	1 (1.67)	0	0 (0.00)
Norovirus test positive	1	1 (1.67)	0	0 (0.00)
Protein total decreased	1	1 (1.67)	1	1 (1.67)
Serum ferritin increased	1	1 (1.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	109	35 (58.33)	41	22 (36.67)
Decreased appetite	22	19 (31.67)	12	11 (18.33)
Hypokalaemia	19	15 (25.00)	7	7 (11.67)
Hypophosphataemia	13	9 (15.00)	9	7 (11.67)
Hyperphosphataemia	8	6 (10.00)	0	0 (0.00)
Hypernatraemia	7	4 (6.67)	1	1 (1.67)
Hypoalbuminaemia	6	5 (8.33)	1	1 (1.67)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Hyperglycaemia	4	3 (5.00)	1	1 (1.67)
Hypocalcaemia	4	3 (5.00)	1	1 (1.67)
Fluid overload	3	3 (5.00)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.33)	1	1 (1.67)
Hyperuricaemia	3	2 (3.33)	1	1 (1.67)
Hyponatraemia	3	2 (3.33)	3	2 (3.33)
Acidosis	2	2 (3.33)	1	1 (1.67)
Dehydration	2	2 (3.33)	1	1 (1.67)
Hypercalcaemia	2	1 (1.67)	0	0 (0.00)
Hyperalbuminaemia	1	1 (1.67)	0	0 (0.00)
Hyperchloraemia	1	1 (1.67)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.67)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.67)	0	0 (0.00)
Malnutrition	1	1 (1.67)	1	1 (1.67)
Metabolic acidosis	1	1 (1.67)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.67)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.67)	1	1 (1.67)
Musculoskeletal and connective tissue disorders				

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
- Total	17	13 (21.67)	1	1 (1.67)
Myalgia	4	4 (6.67)	0	0 (0.00)
Musculoskeletal pain	3	2 (3.33)	0	0 (0.00)
Pain in extremity	3	3 (5.00)	0	0 (0.00)
Arthralgia	2	2 (3.33)	1	1 (1.67)
Coccydynia	1	1 (1.67)	0	0 (0.00)
Limb discomfort	1	1 (1.67)	0	0 (0.00)
Muscle spasms	1	1 (1.67)	0	0 (0.00)
Muscular weakness	1	1 (1.67)	0	0 (0.00)
Osteopenia	1	1 (1.67)	0	0 (0.00)
Nervous system disorders				
- Total	52	30 (50.00)	6	5 (8.33)
Headache	26	21 (35.00)	2	2 (3.33)
Encephalopathy	6	4 (6.67)	2	2 (3.33)
Dizziness	3	3 (5.00)	0	0 (0.00)
Seizure	3	3 (5.00)	1	1 (1.67)
Dysarthria	2	2 (3.33)	0	0 (0.00)
Tremor	2	2 (3.33)	0	0 (0.00)
Asterixis	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Ataxia	1	1 (1.67)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.67)	0	0 (0.00)
Embolic stroke	1	1 (1.67)	1	1 (1.67)
Idiopathic intracranial hypertension	1	1 (1.67)	0	0 (0.00)
Migraine	1	1 (1.67)	0	0 (0.00)
Myoclonus	1	1 (1.67)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.67)	0	0 (0.00)
Pleocytosis	1	1 (1.67)	0	0 (0.00)
Somnolence	1	1 (1.67)	0	0 (0.00)
Product issues				
- Total	1	1 (1.67)	0	0 (0.00)
Device occlusion	1	1 (1.67)	0	0 (0.00)
Psychiatric disorders				
- Total	30	16 (26.67)	1	1 (1.67)
Anxiety	6	6 (10.00)	1	1 (1.67)
Confusional state	6	6 (10.00)	0	0 (0.00)
Delirium	4	4 (6.67)	0	0 (0.00)
Agitation	3	2 (3.33)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Hallucination	3	2 (3.33)	0	0 (0.00)
Irritability	2	2 (3.33)	0	0 (0.00)
Adjustment disorder	1	1 (1.67)	0	0 (0.00)
Insomnia	1	1 (1.67)	0	0 (0.00)
Listless	1	1 (1.67)	0	0 (0.00)
Mental status changes	1	1 (1.67)	0	0 (0.00)
Panic attack	1	1 (1.67)	0	0 (0.00)
Suicidal ideation	1	1 (1.67)	0	0 (0.00)
Renal and urinary disorders				
- Total	18	11 (18.33)	11	7 (11.67)
Acute kidney injury	7	7 (11.67)	5	5 (8.33)
Haematuria	4	4 (6.67)	2	2 (3.33)
Dysuria	2	2 (3.33)	0	0 (0.00)
Oliguria	2	2 (3.33)	2	2 (3.33)
Pollakiuria	1	1 (1.67)	0	0 (0.00)
Renal failure	1	1 (1.67)	1	1 (1.67)
Renal impairment	1	1 (1.67)	1	1 (1.67)
Reproductive system and breast disorders				

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
- Total	4	3 (5.00)	0	0 (0.00)
Oedema genital	2	1 (1.67)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.33)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	70	26 (43.33)	28	12 (20.00)
Hypoxia	13	10 (16.67)	8	7 (11.67)
Epistaxis	11	7 (11.67)	4	4 (6.67)
Cough	8	8 (13.33)	0	0 (0.00)
Pleural effusion	8	8 (13.33)	2	2 (3.33)
Pulmonary oedema	6	6 (10.00)	5	5 (8.33)
Tachypnoea	5	4 (6.67)	1	1 (1.67)
Dyspnoea	3	2 (3.33)	2	2 (3.33)
Haemoptysis	3	2 (3.33)	1	1 (1.67)
Respiratory failure	3	3 (5.00)	3	3 (5.00)
Oropharyngeal pain	2	2 (3.33)	0	0 (0.00)
Atelectasis	1	1 (1.67)	0	0 (0.00)
Interstitial lung disease	1	1 (1.67)	1	1 (1.67)
Nasal congestion	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Oropharyngeal plaque	1	1 (1.67)	0	0 (0.00)
Pharyngeal ulceration	1	1 (1.67)	0	0 (0.00)
Respiratory depression	1	1 (1.67)	0	0 (0.00)
Respiratory distress	1	1 (1.67)	1	1 (1.67)
Rhinitis allergic	1	1 (1.67)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	38	19 (31.67)	2	2 (3.33)
Dry skin	4	4 (6.67)	0	0 (0.00)
Erythema	4	3 (5.00)	0	0 (0.00)
Hyperhidrosis	4	3 (5.00)	0	0 (0.00)
Rash	4	4 (6.67)	0	0 (0.00)
Ingrowing nail	3	2 (3.33)	0	0 (0.00)
Rash maculo-papular	3	3 (5.00)	1	1 (1.67)
Petechiae	2	2 (3.33)	0	0 (0.00)
Pruritus	2	2 (3.33)	0	0 (0.00)
Dermatitis diaper	1	1 (1.67)	0	0 (0.00)
Ecchymosis	1	1 (1.67)	1	1 (1.67)
Livedo reticularis	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Macule	1	1 (1.67)	0	0 (0.00)
Night sweats	1	1 (1.67)	0	0 (0.00)
Rash erythematous	1	1 (1.67)	0	0 (0.00)
Rash macular	1	1 (1.67)	0	0 (0.00)
Rash papular	1	1 (1.67)	0	0 (0.00)
Rash vesicular	1	1 (1.67)	0	0 (0.00)
Skin exfoliation	1	1 (1.67)	0	0 (0.00)
Skin fissures	1	1 (1.67)	0	0 (0.00)
Skin irritation	1	1 (1.67)	0	0 (0.00)
Vascular disorders				
- Total	39	23 (38.33)	18	15 (25.00)
Hypotension	18	15 (25.00)	15	14 (23.33)
Hypertension	12	10 (16.67)	1	1 (1.67)
Flushing	3	2 (3.33)	0	0 (0.00)
Orthostatic hypotension	2	2 (3.33)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.67)	1	1 (1.67)
Embolism	1	1 (1.67)	1	1 (1.67)
Haematoma	1	1 (1.67)	0	0 (0.00)
Secondary hypertension	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Total number of AE per patient	28	4 (100.00)	10	2 (50.00)
Blood and lymphatic system disorders				
- Total	5	2 (50.00)	4	1 (25.00)
Neutropenia	3	1 (25.00)	3	1 (25.00)
Febrile neutropenia	1	1 (25.00)	1	1 (25.00)
Lymphopenia	1	1 (25.00)	0	0 (0.00)
Eye disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Dry eye	1	1 (25.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Vomiting	1	1 (25.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
General disorders and administration site conditions				
- Total	2	1 (25.00)	0	0 (0.00)
Fatigue	1	1 (25.00)	0	0 (0.00)
Pyrexia	1	1 (25.00)	0	0 (0.00)
Infections and infestations				
- Total	6	3 (75.00)	1	1 (25.00)
Cytomegalovirus infection	1	1 (25.00)	0	0 (0.00)
Herpes zoster	1	1 (25.00)	1	1 (25.00)
Otitis media acute	1	1 (25.00)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (25.00)	0	0 (0.00)
Sinusitis	1	1 (25.00)	0	0 (0.00)
Upper respiratory tract infection	1	1 (25.00)	0	0 (0.00)
Investigations				
- Total	8	3 (75.00)	4	2 (50.00)
Neutrophil count decreased	4	3 (75.00)	3	2 (50.00)
Aspartate aminotransferase increased	1	1 (25.00)	1	1 (25.00)
Blood uric acid increased	1	1 (25.00)	0	0 (0.00)
Platelet count decreased	1	1 (25.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
White blood cell count decreased	1	1 (25.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Decreased appetite	1	1 (25.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	2	2 (50.00)	0	0 (0.00)
Joint range of motion decreased	1	1 (25.00)	0	0 (0.00)
Osteonecrosis	1	1 (25.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	1	1 (25.00)	1	1 (25.00)
Pulmonary oedema	1	1 (25.00)	1	1 (25.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Rash	1	1 (25.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Total number of AE per patient	318	42 (80.77)	61	24 (46.15)
Blood and lymphatic system disorders				
- Total	13	9 (17.31)	9	6 (11.54)
Neutropenia	3	3 (5.77)	3	3 (5.77)
Anaemia	2	2 (3.85)	1	1 (1.92)
Eosinophilia	2	1 (1.92)	1	1 (1.92)
Febrile neutropenia	2	2 (3.85)	2	2 (3.85)
Thrombocytopenia	2	2 (3.85)	1	1 (1.92)
Leukopenia	1	1 (1.92)	1	1 (1.92)
Lymphadenopathy	1	1 (1.92)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (1.92)	0	0 (0.00)
Sinus tachycardia	1	1 (1.92)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Endocrine disorders				
- Total	1	1 (1.92)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.92)	0	0 (0.00)
Eye disorders				
- Total	4	4 (7.69)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.92)	0	0 (0.00)
Dry eye	1	1 (1.92)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.92)	0	0 (0.00)
Vision blurred	1	1 (1.92)	0	0 (0.00)
Gastrointestinal disorders				
- Total	37	15 (28.85)	8	4 (7.69)
Vomiting	12	8 (15.38)	2	2 (3.85)
Diarrhoea	8	8 (15.38)	1	1 (1.92)
Nausea	7	6 (11.54)	2	2 (3.85)
Abdominal pain	4	4 (7.69)	1	1 (1.92)
Oral pain	3	2 (3.85)	1	1 (1.92)
Abdominal pain upper	1	1 (1.92)	0	0 (0.00)
Enterocolitis	1	1 (1.92)	1	1 (1.92)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Pigmentation lip	1	1 (1.92)	0	0 (0.00)
General disorders and administration site conditions				
- Total	24	16 (30.77)	1	1 (1.92)
Pyrexia	13	9 (17.31)	1	1 (1.92)
Influenza like illness	2	2 (3.85)	0	0 (0.00)
Acquired gene mutation	1	1 (1.92)	0	0 (0.00)
Catheter site pain	1	1 (1.92)	0	0 (0.00)
Chills	1	1 (1.92)	0	0 (0.00)
Crying	1	1 (1.92)	0	0 (0.00)
Fatigue	1	1 (1.92)	0	0 (0.00)
Generalised oedema	1	1 (1.92)	0	0 (0.00)
Malaise	1	1 (1.92)	0	0 (0.00)
Oedema peripheral	1	1 (1.92)	0	0 (0.00)
Pain	1	1 (1.92)	0	0 (0.00)
Immune system disorders				
- Total	17	14 (26.92)	1	1 (1.92)
Hypogammaglobulinaemia	9	8 (15.38)	1	1 (1.92)
Graft versus host disease	3	2 (3.85)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Immunodeficiency common variable	2	2 (3.85)	0	0 (0.00)
Seasonal allergy	2	2 (3.85)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.92)	0	0 (0.00)
Infections and infestations				
- Total	55	30 (57.69)	16	11 (21.15)
Upper respiratory tract infection	6	6 (11.54)	1	1 (1.92)
Cellulitis of male external genital organ	5	1 (1.92)	2	1 (1.92)
Urinary tract infection	5	4 (7.69)	2	2 (3.85)
Rhinovirus infection	4	2 (3.85)	0	0 (0.00)
Gastroenteritis	3	3 (5.77)	0	0 (0.00)
Influenza	3	3 (5.77)	0	0 (0.00)
Ear infection	2	2 (3.85)	0	0 (0.00)
Otitis media	2	1 (1.92)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (3.85)	1	1 (1.92)
Bacterial sepsis	1	1 (1.92)	1	1 (1.92)
Cholecystitis infective	1	1 (1.92)	1	1 (1.92)
Corona virus infection	1	1 (1.92)	1	1 (1.92)
Enterovirus infection	1	1 (1.92)	1	1 (1.92)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Escherichia urinary tract infection	1	1 (1.92)	1	1 (1.92)
Gastroenteritis norovirus	1	1 (1.92)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.92)	0	0 (0.00)
Molluscum contagiosum	1	1 (1.92)	0	0 (0.00)
Oral herpes	1	1 (1.92)	0	0 (0.00)
Otitis externa	1	1 (1.92)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (1.92)	1	1 (1.92)
Paronychia	1	1 (1.92)	0	0 (0.00)
Rash pustular	1	1 (1.92)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (1.92)	1	1 (1.92)
Rhinitis	1	1 (1.92)	0	0 (0.00)
Rotavirus infection	1	1 (1.92)	1	1 (1.92)
Sepsis	1	1 (1.92)	1	1 (1.92)
Sinusitis	1	1 (1.92)	0	0 (0.00)
Subcutaneous abscess	1	1 (1.92)	0	0 (0.00)
Tinea capitis	1	1 (1.92)	0	0 (0.00)
Vascular device infection	1	1 (1.92)	1	1 (1.92)
Viral infection	1	1 (1.92)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (1.92)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Injury, poisoning and procedural complications				
- Total	13	8 (15.38)	0	0 (0.00)
Contusion	2	2 (3.85)	0	0 (0.00)
Infusion related reaction	2	2 (3.85)	0	0 (0.00)
Procedural pain	2	2 (3.85)	0	0 (0.00)
Arthropod bite	1	1 (1.92)	0	0 (0.00)
Foot fracture	1	1 (1.92)	0	0 (0.00)
Procedural nausea	1	1 (1.92)	0	0 (0.00)
Radius fracture	1	1 (1.92)	0	0 (0.00)
Skin abrasion	1	1 (1.92)	0	0 (0.00)
Skin laceration	1	1 (1.92)	0	0 (0.00)
Sunburn	1	1 (1.92)	0	0 (0.00)
Investigations				
- Total	40	20 (38.46)	12	10 (19.23)
Neutrophil count decreased	8	5 (9.62)	5	4 (7.69)
White blood cell count decreased	6	4 (7.69)	3	2 (3.85)
Platelet count decreased	4	2 (3.85)	0	0 (0.00)
Weight decreased	4	4 (7.69)	0	0 (0.00)
Alanine aminotransferase increased	2	2 (3.85)	2	2 (3.85)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Aspartate aminotransferase increased	2	2 (3.85)	1	1 (1.92)
Blood urea increased	2	1 (1.92)	0	0 (0.00)
Haemoglobin decreased	2	2 (3.85)	0	0 (0.00)
Lymphocyte count decreased	2	2 (3.85)	0	0 (0.00)
Weight increased	2	2 (3.85)	0	0 (0.00)
Blood bilirubin increased	1	1 (1.92)	1	1 (1.92)
Blood creatinine increased	1	1 (1.92)	0	0 (0.00)
Blood magnesium decreased	1	1 (1.92)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.92)	0	0 (0.00)
Serum ferritin increased	1	1 (1.92)	0	0 (0.00)
Transaminases increased	1	1 (1.92)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	14	9 (17.31)	6	4 (7.69)
Hyperalbuminaemia	2	1 (1.92)	0	0 (0.00)
Hyperphosphataemia	2	2 (3.85)	0	0 (0.00)
Hypokalaemia	2	2 (3.85)	1	1 (1.92)
Decreased appetite	1	1 (1.92)	0	0 (0.00)
Dehydration	1	1 (1.92)	1	1 (1.92)
Hypercalcaemia	1	1 (1.92)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Hyperglycaemia	1	1 (1.92)	1	1 (1.92)
Hypophosphataemia	1	1 (1.92)	1	1 (1.92)
Iron overload	1	1 (1.92)	1	1 (1.92)
Tumour lysis syndrome	1	1 (1.92)	1	1 (1.92)
Vitamin D deficiency	1	1 (1.92)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	19	14 (26.92)	0	0 (0.00)
Pain in extremity	8	8 (15.38)	0	0 (0.00)
Arthralgia	2	2 (3.85)	0	0 (0.00)
Muscular weakness	2	2 (3.85)	0	0 (0.00)
Back pain	1	1 (1.92)	0	0 (0.00)
Flank pain	1	1 (1.92)	0	0 (0.00)
Joint range of motion decreased	1	1 (1.92)	0	0 (0.00)
Muscle spasms	1	1 (1.92)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.92)	0	0 (0.00)
Pain in jaw	1	1 (1.92)	0	0 (0.00)
Toe walking	1	1 (1.92)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
- Total	1	1 (1.92)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.92)	0	0 (0.00)
Nervous system disorders				
- Total	12	8 (15.38)	0	0 (0.00)
Headache	7	5 (9.62)	0	0 (0.00)
Dizziness	3	3 (5.77)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.85)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (3.85)	0	0 (0.00)
Depression	2	2 (3.85)	0	0 (0.00)
Anxiety	1	1 (1.92)	0	0 (0.00)
Sleep disorder	1	1 (1.92)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	3 (5.77)	3	2 (3.85)
Acute kidney injury	1	1 (1.92)	1	1 (1.92)
Calculus urinary	1	1 (1.92)	0	0 (0.00)
Haematuria	1	1 (1.92)	1	1 (1.92)
Nephrolithiasis	1	1 (1.92)	1	1 (1.92)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Urinary incontinence	1	1 (1.92)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	2 (3.85)	1	1 (1.92)
Scrotal pain	1	1 (1.92)	0	0 (0.00)
Vaginal haemorrhage	1	1 (1.92)	1	1 (1.92)
Respiratory, thoracic and mediastinal disorders				
- Total	29	17 (32.69)	3	2 (3.85)
Cough	9	7 (13.46)	0	0 (0.00)
Nasal congestion	4	4 (7.69)	0	0 (0.00)
Rhinorrhoea	4	4 (7.69)	0	0 (0.00)
Oropharyngeal pain	3	3 (5.77)	0	0 (0.00)
Rhinitis allergic	3	3 (5.77)	0	0 (0.00)
Epistaxis	2	2 (3.85)	1	1 (1.92)
Acute respiratory failure	1	1 (1.92)	1	1 (1.92)
Dysphonia	1	1 (1.92)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.92)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.92)	1	1 (1.92)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	24	15 (28.85)	1	1 (1.92)
Rash	4	3 (5.77)	0	0 (0.00)
Erythema	2	2 (3.85)	0	0 (0.00)
Rash erythematous	2	1 (1.92)	0	0 (0.00)
Rash maculo-papular	2	2 (3.85)	0	0 (0.00)
Alopecia	1	1 (1.92)	0	0 (0.00)
Dermatitis	1	1 (1.92)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.92)	1	1 (1.92)
Dermatitis atopic	1	1 (1.92)	0	0 (0.00)
Dry skin	1	1 (1.92)	0	0 (0.00)
Eczema	1	1 (1.92)	0	0 (0.00)
Hyperhidrosis	1	1 (1.92)	0	0 (0.00)
Ingrowing nail	1	1 (1.92)	0	0 (0.00)
Keloid scar	1	1 (1.92)	0	0 (0.00)
Macule	1	1 (1.92)	0	0 (0.00)
Papule	1	1 (1.92)	0	0 (0.00)
Petechiae	1	1 (1.92)	0	0 (0.00)
Pruritus	1	1 (1.92)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Rash pruritic	1	1 (1.92)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (3.85)	0	0 (0.00)
Hypertension	2	2 (3.85)	0	0 (0.00)
Hot flush	1	1 (1.92)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Total number of AE per patient	5	2 (66.67)	2	2 (66.67)
General disorders and administration site conditions				
- Total	1	1 (33.33)	1	1 (33.33)
Cyst	1	1 (33.33)	1	1 (33.33)
Infections and infestations				
- Total	3	2 (66.67)	0	0 (0.00)
Gingivitis	1	1 (33.33)	0	0 (0.00)
Otitis media acute	1	1 (33.33)	0	0 (0.00)
Viral infection	1	1 (33.33)	0	0 (0.00)
Investigations				
- Total	1	1 (33.33)	1	1 (33.33)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
White blood cell count decreased	1	1 (33.33)	1	1 (33.33)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Total number of AE per patient	85	20 (64.52)	21	10 (32.26)
Blood and lymphatic system disorders				
- Total	2	2 (6.45)	1	1 (3.23)
Febrile neutropenia	1	1 (3.23)	1	1 (3.23)
Thrombocytopenia	1	1 (3.23)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Tympanic membrane perforation	1	1 (3.23)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	3 (9.68)	0	0 (0.00)
Diarrhoea	2	2 (6.45)	0	0 (0.00)
Abdominal pain	1	1 (3.23)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Nausea	1	1 (3.23)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	1 (3.23)	0	0 (0.00)
Pyrexia	2	1 (3.23)	0	0 (0.00)
Chills	1	1 (3.23)	0	0 (0.00)
Immune system disorders				
- Total	2	2 (6.45)	0	0 (0.00)
Chronic graft versus host disease	1	1 (3.23)	0	0 (0.00)
Immunodeficiency	1	1 (3.23)	0	0 (0.00)
Infections and infestations				
- Total	29	9 (29.03)	7	4 (12.90)
Otitis media	5	3 (9.68)	1	1 (3.23)
Upper respiratory tract infection	4	2 (6.45)	0	0 (0.00)
Otitis media acute	3	1 (3.23)	0	0 (0.00)
Sinusitis	3	3 (9.68)	0	0 (0.00)
Urinary tract infection	3	2 (6.45)	1	1 (3.23)
Pneumonia	2	2 (6.45)	0	0 (0.00)
Campylobacter infection	1	1 (3.23)	1	1 (3.23)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Cellulitis of male external genital organ	1	1 (3.23)	1	1 (3.23)
Clostridium difficile infection	1	1 (3.23)	1	1 (3.23)
Haemophilus infection	1	1 (3.23)	0	0 (0.00)
Meningitis aseptic	1	1 (3.23)	0	0 (0.00)
Respiratory tract infection	1	1 (3.23)	1	1 (3.23)
Respiratory tract infection viral	1	1 (3.23)	1	1 (3.23)
Skin infection	1	1 (3.23)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (3.23)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (3.23)	1	1 (3.23)
Procedural pain	1	1 (3.23)	1	1 (3.23)
Investigations				
- Total	21	7 (22.58)	7	4 (12.90)
Lymphocyte count decreased	5	3 (9.68)	1	1 (3.23)
White blood cell count decreased	4	3 (9.68)	2	2 (6.45)
Alanine aminotransferase increased	3	3 (9.68)	2	2 (6.45)
Neutrophil count decreased	3	2 (6.45)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Aspartate aminotransferase increased	2	2 (6.45)	1	1 (3.23)
Blood alkaline phosphatase increased	1	1 (3.23)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (3.23)	0	0 (0.00)
C-reactive protein increased	1	1 (3.23)	0	0 (0.00)
Platelet count decreased	1	1 (3.23)	1	1 (3.23)
Metabolism and nutrition disorders				
- Total	2	2 (6.45)	1	1 (3.23)
Hypokalaemia	1	1 (3.23)	1	1 (3.23)
Vitamin D deficiency	1	1 (3.23)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Neck pain	1	1 (3.23)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.23)	1	1 (3.23)
Glioblastoma multiforme	1	1 (3.23)	1	1 (3.23)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Nervous system disorders				
- Total	4	3 (9.68)	1	1 (3.23)
Disturbance in attention	1	1 (3.23)	0	0 (0.00)
Dizziness	1	1 (3.23)	0	0 (0.00)
Headache	1	1 (3.23)	0	0 (0.00)
Seizure	1	1 (3.23)	1	1 (3.23)
Renal and urinary disorders				
- Total	3	2 (6.45)	1	1 (3.23)
Acute kidney injury	2	1 (3.23)	1	1 (3.23)
Haematuria	1	1 (3.23)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.23)	1	1 (3.23)
Ovarian failure	1	1 (3.23)	1	1 (3.23)
Respiratory, thoracic and mediastinal disorders				
- Total	7	4 (12.90)	0	0 (0.00)
Cough	3	2 (6.45)	0	0 (0.00)
Epistaxis	1	1 (3.23)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Oropharyngeal pain	1	1 (3.23)	0	0 (0.00)
Rhinitis allergic	1	1 (3.23)	0	0 (0.00)
Rhinorrhoea	1	1 (3.23)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (9.68)	0	0 (0.00)
Acne	1	1 (3.23)	0	0 (0.00)
Papule	1	1 (3.23)	0	0 (0.00)
Pruritus	1	1 (3.23)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: At anytime, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Total number of AE per patient	118	4 (100.00)	26	3 (75.00)
Blood and lymphatic system disorders				
- Total	10	3 (75.00)	7	2 (50.00)
Anaemia	3	3 (75.00)	1	1 (25.00)
Febrile neutropenia	3	2 (50.00)	3	2 (50.00)
Neutropenia	3	1 (25.00)	3	1 (25.00)
Lymphopenia	1	1 (25.00)	0	0 (0.00)
Cardiac disorders				
- Total	3	2 (50.00)	0	0 (0.00)
Cardiac dysfunction	1	1 (25.00)	0	0 (0.00)
Sinus tachycardia	1	1 (25.00)	0	0 (0.00)
Tachycardia	1	1 (25.00)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Eye disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Dry eye	1	1 (25.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	14	3 (75.00)	0	0 (0.00)
Diarrhoea	3	3 (75.00)	0	0 (0.00)
Abdominal pain	2	2 (50.00)	0	0 (0.00)
Constipation	2	1 (25.00)	0	0 (0.00)
Nausea	2	2 (50.00)	0	0 (0.00)
Vomiting	2	2 (50.00)	0	0 (0.00)
Abdominal distension	1	1 (25.00)	0	0 (0.00)
Abdominal tenderness	1	1 (25.00)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (25.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	7	4 (100.00)	1	1 (25.00)
Fatigue	4	4 (100.00)	0	0 (0.00)
Cyst	1	1 (25.00)	1	1 (25.00)

Timing: At anytime, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Pain	1	1 (25.00)	0	0 (0.00)
Pyrexia	1	1 (25.00)	0	0 (0.00)
Immune system disorders				
- Total	6	4 (100.00)	1	1 (25.00)
Hypogammaglobulinaemia	4	4 (100.00)	0	0 (0.00)
Cytokine release syndrome	2	2 (50.00)	1	1 (25.00)
Infections and infestations				
- Total	13	3 (75.00)	2	1 (25.00)
Otitis media acute	2	1 (25.00)	0	0 (0.00)
Clostridium difficile infection	1	1 (25.00)	0	0 (0.00)
Cytomegalovirus infection	1	1 (25.00)	0	0 (0.00)
Gastroenteritis	1	1 (25.00)	1	1 (25.00)
Gingivitis	1	1 (25.00)	0	0 (0.00)
Herpes zoster	1	1 (25.00)	1	1 (25.00)
Parainfluenzae virus infection	1	1 (25.00)	0	0 (0.00)
Pharyngitis	1	1 (25.00)	0	0 (0.00)
Sinusitis	1	1 (25.00)	0	0 (0.00)
Streptococcal infection	1	1 (25.00)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Upper respiratory tract infection	1	1 (25.00)	0	0 (0.00)
Viral infection	1	1 (25.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	4	2 (50.00)	0	0 (0.00)
Contusion	1	1 (25.00)	0	0 (0.00)
Infusion related reaction	1	1 (25.00)	0	0 (0.00)
Procedural pain	1	1 (25.00)	0	0 (0.00)
Procedural site reaction	1	1 (25.00)	0	0 (0.00)
Investigations				
- Total	28	4 (100.00)	11	2 (50.00)
Neutrophil count decreased	6	3 (75.00)	4	2 (50.00)
White blood cell count decreased	4	3 (75.00)	2	2 (50.00)
Alanine aminotransferase increased	2	1 (25.00)	2	1 (25.00)
Aspartate aminotransferase increased	2	1 (25.00)	2	1 (25.00)
Blood bilirubin increased	2	1 (25.00)	0	0 (0.00)
Blood creatinine increased	2	1 (25.00)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: Yes

Primary system organ class **Preferred term**	**All grades Total events**	**All patients N=4 n (%)[1]**	**Grade >= 3 Total events**	**All patients N=4 n (%)[2]**
International normalised ratio increased	2	2 (50.00)	0	0 (0.00)
Lymphocyte count decreased	2	2 (50.00)	1	1 (25.00)
Platelet count decreased	2	1 (25.00)	0	0 (0.00)
Activated partial thromboplastin time prolonged	1	1 (25.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (25.00)	0	0 (0.00)
Blood uric acid increased	1	1 (25.00)	0	0 (0.00)
Pulmonary function test decreased	1	1 (25.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	8	4 (100.00)	2	2 (50.00)
Decreased appetite	3	2 (50.00)	1	1 (25.00)
Hyperphosphataemia	2	2 (50.00)	0	0 (0.00)
Dehydration	1	1 (25.00)	1	1 (25.00)
Hyperuricaemia	1	1 (25.00)	0	0 (0.00)
Hypokalaemia	1	1 (25.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	8	3 (75.00)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Arthralgia	2	2 (50.00)	0	0 (0.00)
Joint range of motion decreased	1	1 (25.00)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (25.00)	0	0 (0.00)
Musculoskeletal pain	1	1 (25.00)	0	0 (0.00)
Myalgia	1	1 (25.00)	0	0 (0.00)
Osteonecrosis	1	1 (25.00)	0	0 (0.00)
Pain in extremity	1	1 (25.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (25.00)	0	0 (0.00)
Skin papilloma	1	1 (25.00)	0	0 (0.00)
Nervous system disorders				
- Total	6	3 (75.00)	0	0 (0.00)
Headache	5	3 (75.00)	0	0 (0.00)
Dizziness	1	1 (25.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	4	3 (75.00)	1	1 (25.00)

Timing: At anytime, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Pulmonary oedema	1	1 (25.00)	1	1 (25.00)
Rhinorrhoea	1	1 (25.00)	0	0 (0.00)
Tachypnoea	1	1 (25.00)	0	0 (0.00)
Wheezing	1	1 (25.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	4	3 (75.00)	0	0 (0.00)
Petechiae	1	1 (25.00)	0	0 (0.00)
Rash	1	1 (25.00)	0	0 (0.00)
Rash follicular	1	1 (25.00)	0	0 (0.00)
Rash papular	1	1 (25.00)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (25.00)	1	1 (25.00)
Hypotension	1	1 (25.00)	1	1 (25.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Total number of AE per patient	1632	60 (100.00)	526	56 (93.33)
Blood and lymphatic system disorders				
- Total	132	45 (75.00)	100	41 (68.33)
Anaemia	46	24 (40.00)	31	19 (31.67)
Thrombocytopenia	33	10 (16.67)	24	9 (15.00)
Febrile neutropenia	27	22 (36.67)	27	22 (36.67)
Neutropenia	12	10 (16.67)	11	10 (16.67)
Disseminated intravascular coagulation	5	4 (6.67)	2	2 (3.33)
Lymphopenia	3	3 (5.00)	2	2 (3.33)
Eosinophilia	2	1 (1.67)	1	1 (1.67)
Coagulopathy	1	1 (1.67)	0	0 (0.00)
Leukopenia	1	1 (1.67)	1	1 (1.67)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Lymphadenopathy	1	1 (1.67)	0	0 (0.00)
Pancytopenia	1	1 (1.67)	1	1 (1.67)
Cardiac disorders				
- Total	30	21 (35.00)	3	2 (3.33)
Tachycardia	16	14 (23.33)	2	2 (3.33)
Sinus tachycardia	5	5 (8.33)	0	0 (0.00)
Pericardial effusion	2	2 (3.33)	0	0 (0.00)
Sinus bradycardia	2	1 (1.67)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.67)	0	0 (0.00)
Bradycardia	1	1 (1.67)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.67)	1	1 (1.67)
Palpitations	1	1 (1.67)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.67)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	4	4 (6.67)	0	0 (0.00)
Ear pain	2	2 (3.33)	0	0 (0.00)
Hypoacusis	1	1 (1.67)	0	0 (0.00)
Tympanic membrane perforation	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Endocrine disorders				
- Total	2	2 (3.33)	0	0 (0.00)
Adrenal insufficiency	2	2 (3.33)	0	0 (0.00)
Eye disorders				
- Total	29	17 (28.33)	0	0 (0.00)
Vision blurred	5	4 (6.67)	0	0 (0.00)
Eye pain	4	3 (5.00)	0	0 (0.00)
Periorbital oedema	4	4 (6.67)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (5.00)	0	0 (0.00)
Photophobia	3	2 (3.33)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.33)	0	0 (0.00)
Uveitis	2	2 (3.33)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.67)	0	0 (0.00)
Dry eye	1	1 (1.67)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.67)	0	0 (0.00)
Ocular hypertension	1	1 (1.67)	0	0 (0.00)
Papilloedema	1	1 (1.67)	0	0 (0.00)
Visual impairment	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Gastrointestinal disorders				
- Total	154	40 (66.67)	23	13 (21.67)
Vomiting	46	25 (41.67)	5	3 (5.00)
Nausea	32	23 (38.33)	5	5 (8.33)
Diarrhoea	25	21 (35.00)	2	2 (3.33)
Abdominal pain	13	9 (15.00)	2	1 (1.67)
Constipation	6	6 (10.00)	0	0 (0.00)
Abdominal pain upper	3	3 (5.00)	0	0 (0.00)
Oral pain	3	2 (3.33)	1	1 (1.67)
Anal incontinence	2	1 (1.67)	0	0 (0.00)
Dysphagia	2	2 (3.33)	1	1 (1.67)
Haematemesis	2	2 (3.33)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.67)	2	1 (1.67)
Pancreatitis	2	2 (3.33)	1	1 (1.67)
Stomatitis	2	2 (3.33)	0	0 (0.00)
Abdominal discomfort	1	1 (1.67)	0	0 (0.00)
Abdominal distension	1	1 (1.67)	0	0 (0.00)
Abdominal pain lower	1	1 (1.67)	0	0 (0.00)
Ascites	1	1 (1.67)	1	1 (1.67)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Dyspepsia	1	1 (1.67)	0	0 (0.00)
Enterocolitis	1	1 (1.67)	1	1 (1.67)
Flatulence	1	1 (1.67)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.67)	0	0 (0.00)
Glossodynia	1	1 (1.67)	0	0 (0.00)
Ileus	1	1 (1.67)	1	1 (1.67)
Intestinal obstruction	1	1 (1.67)	1	1 (1.67)
Lip pain	1	1 (1.67)	0	0 (0.00)
Pigmentation lip	1	1 (1.67)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.67)	0	0 (0.00)
General disorders and administration site conditions				
- Total	100	38 (63.33)	15	11 (18.33)
Pyrexia	42	24 (40.00)	7	7 (11.67)
Fatigue	12	11 (18.33)	1	1 (1.67)
Chills	11	10 (16.67)	0	0 (0.00)
Catheter site pain	4	4 (6.67)	0	0 (0.00)
Generalised oedema	4	3 (5.00)	0	0 (0.00)
Malaise	4	4 (6.67)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Oedema peripheral	3	3 (5.00)	1	1 (1.67)
Pain	3	3 (5.00)	2	2 (3.33)
Face oedema	2	2 (3.33)	1	1 (1.67)
Influenza like illness	2	2 (3.33)	0	0 (0.00)
Acquired gene mutation	1	1 (1.67)	0	0 (0.00)
Asthenia	1	1 (1.67)	0	0 (0.00)
Catheter site extravasation	1	1 (1.67)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.67)	0	0 (0.00)
Crying	1	1 (1.67)	0	0 (0.00)
Facial pain	1	1 (1.67)	0	0 (0.00)
Injection site haematoma	1	1 (1.67)	0	0 (0.00)
Localised oedema	1	1 (1.67)	1	1 (1.67)
Mucosal haemorrhage	1	1 (1.67)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.67)	1	1 (1.67)
Non-cardiac chest pain	1	1 (1.67)	0	0 (0.00)
Peripheral swelling	1	1 (1.67)	0	0 (0.00)
Physical deconditioning	1	1 (1.67)	1	1 (1.67)
Hepatobiliary disorders				
- Total	9	7 (11.67)	2	2 (3.33)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Hyperbilirubinaemia	4	3 (5.00)	2	2 (3.33)
Hepatomegaly	3	3 (5.00)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.67)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.67)	0	0 (0.00)
Immune system disorders				
- Total	129	54 (90.00)	33	21 (35.00)
Cytokine release syndrome	84	48 (80.00)	28	18 (30.00)
Hypogammaglobulinaemia	32	29 (48.33)	5	5 (8.33)
Graft versus host disease	3	2 (3.33)	0	0 (0.00)
Immunodeficiency common variable	2	2 (3.33)	0	0 (0.00)
Seasonal allergy	2	2 (3.33)	0	0 (0.00)
Chronic graft versus host disease	1	1 (1.67)	0	0 (0.00)
Drug hypersensitivity	1	1 (1.67)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.67)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.67)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.67)	0	0 (0.00)
Immunodeficiency	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Infections and infestations				
- Total	121	43 (71.67)	29	17 (28.33)
Upper respiratory tract infection	11	8 (13.33)	1	1 (1.67)
Urinary tract infection	8	5 (8.33)	3	2 (3.33)
Otitis media	7	4 (6.67)	1	1 (1.67)
Rhinovirus infection	7	5 (8.33)	0	0 (0.00)
Cellulitis of male external genital organ	6	1 (1.67)	3	1 (1.67)
Clostridium difficile colitis	4	4 (6.67)	1	1 (1.67)
Clostridium difficile infection	4	4 (6.67)	1	1 (1.67)
Gastroenteritis	4	4 (6.67)	0	0 (0.00)
Influenza	4	4 (6.67)	0	0 (0.00)
Pneumonia	4	4 (6.67)	1	1 (1.67)
Sinusitis	4	3 (5.00)	0	0 (0.00)
Otitis media acute	3	1 (1.67)	0	0 (0.00)
Viral upper respiratory tract infection	3	3 (5.00)	1	1 (1.67)
Ear infection	2	2 (3.33)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (1.67)	0	0 (0.00)
Skin infection	2	2 (3.33)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Staphylococcal infection	2	2 (3.33)	1	1 (1.67)
Viral infection	2	2 (3.33)	0	0 (0.00)
Vulvovaginal candidiasis	2	2 (3.33)	0	0 (0.00)
Acute sinusitis	1	1 (1.67)	0	0 (0.00)
Bacterial sepsis	1	1 (1.67)	1	1 (1.67)
Body tinea	1	1 (1.67)	0	0 (0.00)
Campylobacter infection	1	1 (1.67)	1	1 (1.67)
Catheter site cellulitis	1	1 (1.67)	0	0 (0.00)
Catheter site infection	1	1 (1.67)	1	1 (1.67)
Cholecystitis infective	1	1 (1.67)	1	1 (1.67)
Corona virus infection	1	1 (1.67)	1	1 (1.67)
Cytomegalovirus infection	1	1 (1.67)	0	0 (0.00)
Enterococcal infection	1	1 (1.67)	0	0 (0.00)
Enterovirus infection	1	1 (1.67)	1	1 (1.67)
Escherichia urinary tract infection	1	1 (1.67)	1	1 (1.67)
Folliculitis	1	1 (1.67)	0	0 (0.00)
Fungal skin infection	1	1 (1.67)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.67)	0	0 (0.00)
Haemophilus infection	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Herpes simplex	1	1 (1.67)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (1.67)	0	0 (0.00)
Hypopyon	1	1 (1.67)	0	0 (0.00)
Meningitis aseptic	1	1 (1.67)	0	0 (0.00)
Molluscum contagiosum	1	1 (1.67)	0	0 (0.00)
Oral candidiasis	1	1 (1.67)	0	0 (0.00)
Oral herpes	1	1 (1.67)	0	0 (0.00)
Orchitis	1	1 (1.67)	0	0 (0.00)
Otitis externa	1	1 (1.67)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (1.67)	1	1 (1.67)
Paronychia	1	1 (1.67)	0	0 (0.00)
Rash pustular	1	1 (1.67)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (1.67)	1	1 (1.67)
Respiratory tract infection	1	1 (1.67)	1	1 (1.67)
Respiratory tract infection viral	1	1 (1.67)	1	1 (1.67)
Rhinitis	1	1 (1.67)	0	0 (0.00)
Rotavirus infection	1	1 (1.67)	1	1 (1.67)
Sepsis	1	1 (1.67)	1	1 (1.67)
Septic embolus	1	1 (1.67)	1	1 (1.67)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Subcutaneous abscess	1	1 (1.67)	0	0 (0.00)
Tinea capitis	1	1 (1.67)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.67)	1	1 (1.67)
Vascular device infection	1	1 (1.67)	1	1 (1.67)
Vulvovaginal mycotic infection	1	1 (1.67)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	35	20 (33.33)	3	3 (5.00)
Procedural pain	5	4 (6.67)	1	1 (1.67)
Transfusion reaction	4	3 (5.00)	0	0 (0.00)
Infusion related reaction	3	3 (5.00)	0	0 (0.00)
Contusion	2	2 (3.33)	0	0 (0.00)
Skin abrasion	2	2 (3.33)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.67)	1	1 (1.67)
Arthropod bite	1	1 (1.67)	0	0 (0.00)
Foot fracture	1	1 (1.67)	0	0 (0.00)
Incision site pain	1	1 (1.67)	0	0 (0.00)
Limb injury	1	1 (1.67)	0	0 (0.00)
Mouth injury	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Post procedural haemorrhage	1	1 (1.67)	0	0 (0.00)
Procedural complication	1	1 (1.67)	0	0 (0.00)
Procedural headache	1	1 (1.67)	0	0 (0.00)
Procedural nausea	1	1 (1.67)	0	0 (0.00)
Radius fracture	1	1 (1.67)	0	0 (0.00)
Skin laceration	1	1 (1.67)	0	0 (0.00)
Stoma site irritation	1	1 (1.67)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.67)	0	0 (0.00)
Sunburn	1	1 (1.67)	0	0 (0.00)
Tibia fracture	1	1 (1.67)	0	0 (0.00)
Tongue injury	1	1 (1.67)	0	0 (0.00)
Transfusion related complication	1	1 (1.67)	1	1 (1.67)
Investigations				
- Total	374	52 (86.67)	191	47 (78.33)
White blood cell count decreased	63	32 (53.33)	41	28 (46.67)
Neutrophil count decreased	56	25 (41.67)	48	23 (38.33)
Platelet count decreased	47	19 (31.67)	38	15 (25.00)
Aspartate aminotransferase increased	35	19 (31.67)	17	11 (18.33)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Alanine aminotransferase increased	31	20 (33.33)	16	13 (21.67)
Lymphocyte count decreased	21	14 (23.33)	12	11 (18.33)
Prothrombin time prolonged	17	9 (15.00)	1	1 (1.67)
Blood fibrinogen decreased	15	4 (6.67)	4	3 (5.00)
Blood bilirubin increased	12	7 (11.67)	3	3 (5.00)
Blood creatinine increased	10	8 (13.33)	2	2 (3.33)
International normalised ratio increased	9	7 (11.67)	1	1 (1.67)
Activated partial thromboplastin time prolonged	7	4 (6.67)	0	0 (0.00)
Blood urea increased	5	3 (5.00)	1	1 (1.67)
Blood immunoglobulin M decreased	4	4 (6.67)	0	0 (0.00)
Weight decreased	4	4 (6.67)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.33)	0	0 (0.00)
Haemoglobin decreased	3	3 (5.00)	1	1 (1.67)
Transaminases increased	3	3 (5.00)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (3.33)	0	0 (0.00)
Blood magnesium decreased	2	2 (3.33)	1	1 (1.67)
Blood sodium increased	2	1 (1.67)	0	0 (0.00)
Blood uric acid increased	2	1 (1.67)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
C-reactive protein increased	2	2 (3.33)	1	1 (1.67)
Lipase increased	2	2 (3.33)	2	2 (3.33)
Serum ferritin increased	2	2 (3.33)	0	0 (0.00)
Weight increased	2	2 (3.33)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (1.67)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.67)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.67)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (1.67)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.67)	1	1 (1.67)
Blood phosphorus decreased	1	1 (1.67)	0	0 (0.00)
Cardiac murmur	1	1 (1.67)	0	0 (0.00)
Culture stool positive	1	1 (1.67)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.67)	0	0 (0.00)
Hepatic enzyme increased	1	1 (1.67)	0	0 (0.00)
Norovirus test positive	1	1 (1.67)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.67)	0	0 (0.00)
Protein total decreased	1	1 (1.67)	1	1 (1.67)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Metabolism and nutrition disorders				
- Total	125	39 (65.00)	48	25 (41.67)
Decreased appetite	23	20 (33.33)	12	11 (18.33)
Hypokalaemia	22	18 (30.00)	9	9 (15.00)
Hypophosphataemia	14	10 (16.67)	10	8 (13.33)
Hyperphosphataemia	10	6 (10.00)	0	0 (0.00)
Hypernatraemia	7	4 (6.67)	1	1 (1.67)
Hypoalbuminaemia	6	5 (8.33)	1	1 (1.67)
Hyperglycaemia	5	3 (5.00)	2	2 (3.33)
Hypocalcaemia	4	3 (5.00)	1	1 (1.67)
Dehydration	3	3 (5.00)	2	2 (3.33)
Fluid overload	3	3 (5.00)	0	0 (0.00)
Hyperalbuminaemia	3	1 (1.67)	0	0 (0.00)
Hypercalcaemia	3	1 (1.67)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.33)	1	1 (1.67)
Hyperuricaemia	3	2 (3.33)	1	1 (1.67)
Hyponatraemia	3	2 (3.33)	3	2 (3.33)
Acidosis	2	2 (3.33)	1	1 (1.67)
Tumour lysis syndrome	2	2 (3.33)	2	2 (3.33)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Vitamin D deficiency	2	2 (3.33)	0	0 (0.00)
Hyperchloraemia	1	1 (1.67)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.67)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.67)	0	0 (0.00)
Iron overload	1	1 (1.67)	1	1 (1.67)
Malnutrition	1	1 (1.67)	1	1 (1.67)
Metabolic acidosis	1	1 (1.67)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.67)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	37	22 (36.67)	1	1 (1.67)
Pain in extremity	11	10 (16.67)	0	0 (0.00)
Arthralgia	4	3 (5.00)	1	1 (1.67)
Myalgia	4	4 (6.67)	0	0 (0.00)
Muscular weakness	3	3 (5.00)	0	0 (0.00)
Musculoskeletal pain	3	2 (3.33)	0	0 (0.00)
Muscle spasms	2	2 (3.33)	0	0 (0.00)
Back pain	1	1 (1.67)	0	0 (0.00)
Coccydynia	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Flank pain	1	1 (1.67)	0	0 (0.00)
Joint range of motion decreased	1	1 (1.67)	0	0 (0.00)
Limb discomfort	1	1 (1.67)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.67)	0	0 (0.00)
Neck pain	1	1 (1.67)	0	0 (0.00)
Osteopenia	1	1 (1.67)	0	0 (0.00)
Pain in jaw	1	1 (1.67)	0	0 (0.00)
Toe walking	1	1 (1.67)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	2 (3.33)	1	1 (1.67)
Glioblastoma multiforme	1	1 (1.67)	1	1 (1.67)
Myelodysplastic syndrome	1	1 (1.67)	0	0 (0.00)
Nervous system disorders				
- Total	68	32 (53.33)	7	6 (10.00)
Headache	34	21 (35.00)	2	2 (3.33)
Dizziness	7	5 (8.33)	0	0 (0.00)
Encephalopathy	6	4 (6.67)	2	2 (3.33)
Seizure	4	4 (6.67)	2	2 (3.33)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Dysarthria	2	2 (3.33)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.33)	0	0 (0.00)
Tremor	2	2 (3.33)	0	0 (0.00)
Asterixis	1	1 (1.67)	0	0 (0.00)
Ataxia	1	1 (1.67)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.67)	0	0 (0.00)
Disturbance in attention	1	1 (1.67)	0	0 (0.00)
Embolic stroke	1	1 (1.67)	1	1 (1.67)
Idiopathic intracranial hypertension	1	1 (1.67)	0	0 (0.00)
Migraine	1	1 (1.67)	0	0 (0.00)
Myoclonus	1	1 (1.67)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.67)	0	0 (0.00)
Pleocytosis	1	1 (1.67)	0	0 (0.00)
Somnolence	1	1 (1.67)	0	0 (0.00)
Product issues				
- Total	1	1 (1.67)	0	0 (0.00)
Device occlusion	1	1 (1.67)	0	0 (0.00)
Psychiatric disorders				

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
- Total	34	17 (28.33)	1	1 (1.67)
Anxiety	7	7 (11.67)	1	1 (1.67)
Confusional state	6	6 (10.00)	0	0 (0.00)
Delirium	4	4 (6.67)	0	0 (0.00)
Agitation	3	2 (3.33)	0	0 (0.00)
Hallucination	3	2 (3.33)	0	0 (0.00)
Depression	2	2 (3.33)	0	0 (0.00)
Irritability	2	2 (3.33)	0	0 (0.00)
Adjustment disorder	1	1 (1.67)	0	0 (0.00)
Insomnia	1	1 (1.67)	0	0 (0.00)
Listless	1	1 (1.67)	0	0 (0.00)
Mental status changes	1	1 (1.67)	0	0 (0.00)
Panic attack	1	1 (1.67)	0	0 (0.00)
Sleep disorder	1	1 (1.67)	0	0 (0.00)
Suicidal ideation	1	1 (1.67)	0	0 (0.00)
Renal and urinary disorders				
- Total	26	15 (25.00)	15	10 (16.67)
Acute kidney injury	10	9 (15.00)	7	7 (11.67)
Haematuria	6	5 (8.33)	3	3 (5.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Dysuria	2	2 (3.33)	0	0 (0.00)
Oliguria	2	2 (3.33)	2	2 (3.33)
Calculus urinary	1	1 (1.67)	0	0 (0.00)
Nephrolithiasis	1	1 (1.67)	1	1 (1.67)
Pollakiuria	1	1 (1.67)	0	0 (0.00)
Renal failure	1	1 (1.67)	1	1 (1.67)
Renal impairment	1	1 (1.67)	1	1 (1.67)
Urinary incontinence	1	1 (1.67)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	7	6 (10.00)	2	2 (3.33)
Oedema genital	2	1 (1.67)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.33)	0	0 (0.00)
Ovarian failure	1	1 (1.67)	1	1 (1.67)
Scrotal pain	1	1 (1.67)	0	0 (0.00)
Vaginal haemorrhage	1	1 (1.67)	1	1 (1.67)
Respiratory, thoracic and mediastinal disorders				
- Total	106	35 (58.33)	31	14 (23.33)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Cough	20	14 (23.33)	0	0 (0.00)
Epistaxis	14	10 (16.67)	5	5 (8.33)
Hypoxia	13	10 (16.67)	8	7 (11.67)
Pleural effusion	8	8 (13.33)	2	2 (3.33)
Oropharyngeal pain	6	6 (10.00)	0	0 (0.00)
Pulmonary oedema	6	6 (10.00)	5	5 (8.33)
Nasal congestion	5	5 (8.33)	0	0 (0.00)
Rhinitis allergic	5	4 (6.67)	0	0 (0.00)
Rhinorrhoea	5	5 (8.33)	0	0 (0.00)
Tachypnoea	5	4 (6.67)	1	1 (1.67)
Dyspnoea	3	2 (3.33)	2	2 (3.33)
Haemoptysis	3	2 (3.33)	1	1 (1.67)
Respiratory failure	3	3 (5.00)	3	3 (5.00)
Acute respiratory failure	1	1 (1.67)	1	1 (1.67)
Atelectasis	1	1 (1.67)	0	0 (0.00)
Dysphonia	1	1 (1.67)	0	0 (0.00)
Interstitial lung disease	1	1 (1.67)	1	1 (1.67)
Oropharyngeal plaque	1	1 (1.67)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Pharyngeal lesion	1	1 (1.67)	1	1 (1.67)
Pharyngeal ulceration	1	1 (1.67)	0	0 (0.00)
Respiratory depression	1	1 (1.67)	0	0 (0.00)
Respiratory distress	1	1 (1.67)	1	1 (1.67)
Skin and subcutaneous tissue disorders				
- Total	65	27 (45.00)	3	3 (5.00)
Rash	8	7 (11.67)	0	0 (0.00)
Erythema	6	5 (8.33)	0	0 (0.00)
Dry skin	5	5 (8.33)	0	0 (0.00)
Hyperhidrosis	5	4 (6.67)	0	0 (0.00)
Rash maculo-papular	5	5 (8.33)	1	1 (1.67)
Ingrowing nail	4	3 (5.00)	0	0 (0.00)
Pruritus	4	4 (6.67)	0	0 (0.00)
Petechiae	3	3 (5.00)	0	0 (0.00)
Rash erythematous	3	2 (3.33)	0	0 (0.00)
Macule	2	2 (3.33)	0	0 (0.00)
Papule	2	2 (3.33)	0	0 (0.00)
Acne	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Alopecia	1	1 (1.67)	0	0 (0.00)
Dermatitis	1	1 (1.67)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.67)	1	1 (1.67)
Dermatitis atopic	1	1 (1.67)	0	0 (0.00)
Dermatitis diaper	1	1 (1.67)	0	0 (0.00)
Ecchymosis	1	1 (1.67)	1	1 (1.67)
Eczema	1	1 (1.67)	0	0 (0.00)
Keloid scar	1	1 (1.67)	0	0 (0.00)
Livedo reticularis	1	1 (1.67)	0	0 (0.00)
Night sweats	1	1 (1.67)	0	0 (0.00)
Rash macular	1	1 (1.67)	0	0 (0.00)
Rash papular	1	1 (1.67)	0	0 (0.00)
Rash pruritic	1	1 (1.67)	0	0 (0.00)
Rash vesicular	1	1 (1.67)	0	0 (0.00)
Skin exfoliation	1	1 (1.67)	0	0 (0.00)
Skin fissures	1	1 (1.67)	0	0 (0.00)
Skin irritation	1	1 (1.67)	0	0 (0.00)
Vascular disorders				
- Total	42	24 (40.00)	18	15 (25.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Hypotension	18	15 (25.00)	15	14 (23.33)
Hypertension	14	12 (20.00)	1	1 (1.67)
Flushing	3	2 (3.33)	0	0 (0.00)
Orthostatic hypotension	2	2 (3.33)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.67)	1	1 (1.67)
Embolism	1	1 (1.67)	1	1 (1.67)
Haematoma	1	1 (1.67)	0	0 (0.00)
Hot flush	1	1 (1.67)	0	0 (0.00)
Secondary hypertension	1	1 (1.67)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Total number of AE per patient	512	19 (100.00)	174	16 (84.21)
Blood and lymphatic system disorders				
- Total	49	13 (68.42)	33	12 (63.16)
Anaemia	19	7 (36.84)	11	6 (31.58)
Thrombocytopenia	14	2 (10.53)	8	2 (10.53)
Febrile neutropenia	10	8 (42.11)	10	8 (42.11)
Neutropenia	2	1 (5.26)	1	1 (5.26)
Coagulopathy	1	1 (5.26)	0	0 (0.00)
Disseminated intravascular coagulation	1	1 (5.26)	1	1 (5.26)
Lymphopenia	1	1 (5.26)	1	1 (5.26)
Pancytopenia	1	1 (5.26)	1	1 (5.26)
Cardiac disorders				

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
- Total	10	8 (42.11)	1	1 (5.26)
Tachycardia	5	4 (21.05)	1	1 (5.26)
Sinus tachycardia	2	2 (10.53)	0	0 (0.00)
Atrioventricular block second degree	1	1 (5.26)	0	0 (0.00)
Bradycardia	1	1 (5.26)	0	0 (0.00)
Pericardial effusion	1	1 (5.26)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (5.26)	0	0 (0.00)
Ear pain	1	1 (5.26)	0	0 (0.00)
Eye disorders				
- Total	12	6 (31.58)	0	0 (0.00)
Periorbital oedema	3	3 (15.79)	0	0 (0.00)
Photophobia	3	2 (10.53)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (10.53)	0	0 (0.00)
Vision blurred	2	2 (10.53)	0	0 (0.00)
Eye pain	1	1 (5.26)	0	0 (0.00)
Retinal haemorrhage	1	1 (5.26)	0	0 (0.00)
Gastrointestinal disorders				

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
- Total	47	13 (68.42)	9	6 (31.58)
Vomiting	13	10 (52.63)	2	2 (10.53)
Diarrhoea	8	8 (42.11)	1	1 (5.26)
Nausea	7	7 (36.84)	1	1 (5.26)
Abdominal pain	6	5 (26.32)	1	1 (5.26)
Constipation	3	3 (15.79)	0	0 (0.00)
Mouth haemorrhage	2	1 (5.26)	2	1 (5.26)
Abdominal discomfort	1	1 (5.26)	0	0 (0.00)
Abdominal distension	1	1 (5.26)	0	0 (0.00)
Abdominal pain upper	1	1 (5.26)	0	0 (0.00)
Dyspepsia	1	1 (5.26)	0	0 (0.00)
Dysphagia	1	1 (5.26)	1	1 (5.26)
Haematemesis	1	1 (5.26)	0	0 (0.00)
Intestinal obstruction	1	1 (5.26)	1	1 (5.26)
Lip pain	1	1 (5.26)	0	0 (0.00)
General disorders and administration site conditions				
- Total	38	11 (57.89)	8	4 (21.05)
Pyrexia	12	7 (36.84)	2	2 (10.53)
Fatigue	6	5 (26.32)	1	1 (5.26)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Chills	2	2 (10.53)	0	0 (0.00)
Face oedema	2	2 (10.53)	1	1 (5.26)
Generalised oedema	2	1 (5.26)	0	0 (0.00)
Malaise	2	2 (10.53)	0	0 (0.00)
Oedema peripheral	2	2 (10.53)	1	1 (5.26)
Pain	2	2 (10.53)	1	1 (5.26)
Catheter site extravasation	1	1 (5.26)	0	0 (0.00)
Catheter site haemorrhage	1	1 (5.26)	0	0 (0.00)
Catheter site pain	1	1 (5.26)	0	0 (0.00)
Injection site haematoma	1	1 (5.26)	0	0 (0.00)
Localised oedema	1	1 (5.26)	1	1 (5.26)
Mucosal haemorrhage	1	1 (5.26)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (5.26)	1	1 (5.26)
Peripheral swelling	1	1 (5.26)	0	0 (0.00)
Hepatobiliary disorders				
- Total	5	3 (15.79)	2	2 (10.53)
Hyperbilirubinaemia	4	3 (15.79)	2	2 (10.53)
Hepatomegaly	1	1 (5.26)	0	0 (0.00)
Immune system disorders				

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
- Total	47	19 (100.00)	14	9 (47.37)
Cytokine release syndrome	35	18 (94.74)	12	8 (42.11)
Hypogammaglobulinaemia	10	10 (52.63)	2	2 (10.53)
Graft versus host disease in skin	1	1 (5.26)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (5.26)	0	0 (0.00)
Infections and infestations				
- Total	19	11 (57.89)	4	4 (21.05)
Clostridium difficile colitis	2	2 (10.53)	0	0 (0.00)
Gastroenteritis	2	2 (10.53)	1	1 (5.26)
Rhinovirus infection	2	2 (10.53)	0	0 (0.00)
Catheter site cellulitis	1	1 (5.26)	0	0 (0.00)
Clostridium difficile infection	1	1 (5.26)	0	0 (0.00)
Folliculitis	1	1 (5.26)	0	0 (0.00)
Fungal skin infection	1	1 (5.26)	0	0 (0.00)
Herpes simplex	1	1 (5.26)	0	0 (0.00)
Orchitis	1	1 (5.26)	0	0 (0.00)
Pharyngitis	1	1 (5.26)	0	0 (0.00)
Pneumonia	1	1 (5.26)	0	0 (0.00)
Septic embolus	1	1 (5.26)	1	1 (5.26)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Staphylococcal infection	1	1 (5.26)	1	1 (5.26)
Streptococcal infection	1	1 (5.26)	0	0 (0.00)
Upper respiratory tract infection	1	1 (5.26)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (5.26)	1	1 (5.26)
Injury, poisoning and procedural complications				
- Total	15	9 (47.37)	1	1 (5.26)
Transfusion reaction	3	2 (10.53)	0	0 (0.00)
Incision site pain	1	1 (5.26)	0	0 (0.00)
Infusion related reaction	1	1 (5.26)	0	0 (0.00)
Mouth injury	1	1 (5.26)	0	0 (0.00)
Procedural complication	1	1 (5.26)	0	0 (0.00)
Procedural headache	1	1 (5.26)	0	0 (0.00)
Procedural pain	1	1 (5.26)	0	0 (0.00)
Skin abrasion	1	1 (5.26)	0	0 (0.00)
Stoma site irritation	1	1 (5.26)	0	0 (0.00)
Subdural haemorrhage	1	1 (5.26)	0	0 (0.00)
Tibia fracture	1	1 (5.26)	0	0 (0.00)
Tongue injury	1	1 (5.26)	0	0 (0.00)
Transfusion related complication	1	1 (5.26)	1	1 (5.26)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Investigations				
- Total	114	14 (73.68)	58	13 (68.42)
Aspartate aminotransferase increased	16	6 (31.58)	8	3 (15.79)
White blood cell count decreased	15	7 (36.84)	11	7 (36.84)
Alanine aminotransferase increased	13	8 (42.11)	6	5 (26.32)
Platelet count decreased	13	6 (31.58)	12	5 (26.32)
Blood fibrinogen decreased	9	2 (10.53)	3	2 (10.53)
Prothrombin time prolonged	9	4 (21.05)	1	1 (5.26)
Neutrophil count decreased	8	6 (31.58)	8	6 (31.58)
Blood bilirubin increased	6	3 (15.79)	1	1 (5.26)
Blood creatinine increased	6	5 (26.32)	2	2 (10.53)
International normalised ratio increased	3	3 (15.79)	1	1 (5.26)
Activated partial thromboplastin time prolonged	2	1 (5.26)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (10.53)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (10.53)	0	0 (0.00)
Blood urea increased	2	2 (10.53)	1	1 (5.26)
Lymphocyte count decreased	2	2 (10.53)	2	2 (10.53)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Blood bicarbonate decreased	1	1 (5.26)	0	0 (0.00)
Blood phosphorus decreased	1	1 (5.26)	0	0 (0.00)
Culture stool positive	1	1 (5.26)	0	0 (0.00)
Haemoglobin decreased	1	1 (5.26)	1	1 (5.26)
Protein total decreased	1	1 (5.26)	1	1 (5.26)
Transaminases increased	1	1 (5.26)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	47	16 (84.21)	18	10 (52.63)
Decreased appetite	9	7 (36.84)	5	4 (21.05)
Hypernatraemia	5	2 (10.53)	1	1 (5.26)
Hypokalaemia	5	4 (21.05)	2	2 (10.53)
Hypophosphataemia	5	4 (21.05)	2	2 (10.53)
Hypocalcaemia	3	2 (10.53)	1	1 (5.26)
Dehydration	2	2 (10.53)	2	2 (10.53)
Fluid overload	2	2 (10.53)	0	0 (0.00)
Hypercalcaemia	2	1 (5.26)	0	0 (0.00)
Hyperphosphataemia	2	2 (10.53)	0	0 (0.00)
Hypoalbuminaemia	2	2 (10.53)	0	0 (0.00)
Hyponatraemia	2	1 (5.26)	2	1 (5.26)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Acidosis	1	1 (5.26)	1	1 (5.26)
Hyperalbuminaemia	1	1 (5.26)	0	0 (0.00)
Hyperchloraemia	1	1 (5.26)	0	0 (0.00)
Hyperglycaemia	1	1 (5.26)	1	1 (5.26)
Hypermagnesaemia	1	1 (5.26)	0	0 (0.00)
Malnutrition	1	1 (5.26)	1	1 (5.26)
Metabolic acidosis	1	1 (5.26)	0	0 (0.00)
Metabolic alkalosis	1	1 (5.26)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	10	7 (36.84)	0	0 (0.00)
Musculoskeletal pain	2	1 (5.26)	0	0 (0.00)
Myalgia	2	2 (10.53)	0	0 (0.00)
Pain in extremity	2	2 (10.53)	0	0 (0.00)
Coccydynia	1	1 (5.26)	0	0 (0.00)
Limb discomfort	1	1 (5.26)	0	0 (0.00)
Muscle spasms	1	1 (5.26)	0	0 (0.00)
Osteopenia	1	1 (5.26)	0	0 (0.00)
Nervous system disorders				

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
- Total	17	10 (52.63)	4	4 (21.05)
Headache	9	7 (36.84)	1	1 (5.26)
Encephalopathy	4	2 (10.53)	1	1 (5.26)
Dizziness	1	1 (5.26)	0	0 (0.00)
Embolic stroke	1	1 (5.26)	1	1 (5.26)
Myoclonus	1	1 (5.26)	0	0 (0.00)
Seizure	1	1 (5.26)	1	1 (5.26)
Psychiatric disorders				
- Total	18	8 (42.11)	0	0 (0.00)
Anxiety	3	3 (15.79)	0	0 (0.00)
Hallucination	3	2 (10.53)	0	0 (0.00)
Agitation	2	1 (5.26)	0	0 (0.00)
Confusional state	2	2 (10.53)	0	0 (0.00)
Delirium	2	2 (10.53)	0	0 (0.00)
Irritability	2	2 (10.53)	0	0 (0.00)
Insomnia	1	1 (5.26)	0	0 (0.00)
Listless	1	1 (5.26)	0	0 (0.00)
Mental status changes	1	1 (5.26)	0	0 (0.00)
Panic attack	1	1 (5.26)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Renal and urinary disorders				
- Total	7	4 (21.05)	4	3 (15.79)
Acute kidney injury	3	3 (15.79)	2	2 (10.53)
Haematuria	2	2 (10.53)	0	0 (0.00)
Oliguria	1	1 (5.26)	1	1 (5.26)
Renal impairment	1	1 (5.26)	1	1 (5.26)
Respiratory, thoracic and mediastinal disorders				
- Total	28	11 (57.89)	10	5 (26.32)
Epistaxis	8	4 (21.05)	2	2 (10.53)
Hypoxia	5	4 (21.05)	3	3 (15.79)
Cough	4	4 (21.05)	0	0 (0.00)
Pulmonary oedema	3	3 (15.79)	2	2 (10.53)
Dyspnoea	2	1 (5.26)	1	1 (5.26)
Pleural effusion	2	2 (10.53)	1	1 (5.26)
Pharyngeal ulceration	1	1 (5.26)	0	0 (0.00)
Respiratory depression	1	1 (5.26)	0	0 (0.00)
Respiratory distress	1	1 (5.26)	1	1 (5.26)
Tachypnoea	1	1 (5.26)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	14	6 (31.58)	0	0 (0.00)
Erythema	3	2 (10.53)	0	0 (0.00)
Hyperhidrosis	3	2 (10.53)	0	0 (0.00)
Dry skin	1	1 (5.26)	0	0 (0.00)
Night sweats	1	1 (5.26)	0	0 (0.00)
Pruritus	1	1 (5.26)	0	0 (0.00)
Rash	1	1 (5.26)	0	0 (0.00)
Rash maculo-papular	1	1 (5.26)	0	0 (0.00)
Rash papular	1	1 (5.26)	0	0 (0.00)
Rash vesicular	1	1 (5.26)	0	0 (0.00)
Skin irritation	1	1 (5.26)	0	0 (0.00)
Vascular disorders				
- Total	14	8 (42.11)	8	6 (31.58)
Hypotension	7	7 (36.84)	6	6 (31.58)
Flushing	3	2 (10.53)	0	0 (0.00)
Hypertension	3	3 (15.79)	1	1 (5.26)
Capillary leak syndrome	1	1 (5.26)	1	1 (5.26)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Total number of AE per patient	802	44 (97.78)	284	38 (84.44)
Blood and lymphatic system disorders				
- Total	73	30 (66.67)	60	26 (57.78)
Anaemia	28	20 (44.44)	20	13 (28.89)
Febrile neutropenia	16	14 (31.11)	16	14 (31.11)
Thrombocytopenia	16	6 (13.33)	15	6 (13.33)
Neutropenia	7	7 (15.56)	7	7 (15.56)
Disseminated intravascular coagulation	4	3 (6.67)	1	1 (2.22)
Lymphopenia	2	2 (4.44)	1	1 (2.22)
Cardiac disorders				
- Total	22	14 (31.11)	2	1 (2.22)
Tachycardia	12	11 (24.44)	1	1 (2.22)
Sinus tachycardia	3	3 (6.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Sinus bradycardia	2	1 (2.22)	0	0 (0.00)
Cardiac dysfunction	1	1 (2.22)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.22)	1	1 (2.22)
Palpitations	1	1 (2.22)	0	0 (0.00)
Pericardial effusion	1	1 (2.22)	0	0 (0.00)
Ventricular tachycardia	1	1 (2.22)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (4.44)	0	0 (0.00)
Ear pain	1	1 (2.22)	0	0 (0.00)
Hypoacusis	1	1 (2.22)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.22)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.22)	0	0 (0.00)
Eye disorders				
- Total	13	7 (15.56)	0	0 (0.00)
Eye pain	3	2 (4.44)	0	0 (0.00)
Uveitis	2	2 (4.44)	0	0 (0.00)
Vision blurred	2	1 (2.22)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Conjunctival haemorrhage	1	1 (2.22)	0	0 (0.00)
Ocular hypertension	1	1 (2.22)	0	0 (0.00)
Papilloedema	1	1 (2.22)	0	0 (0.00)
Periorbital oedema	1	1 (2.22)	0	0 (0.00)
Retinal haemorrhage	1	1 (2.22)	0	0 (0.00)
Visual impairment	1	1 (2.22)	0	0 (0.00)
Gastrointestinal disorders				
- Total	79	23 (51.11)	6	5 (11.11)
Vomiting	22	12 (26.67)	1	1 (2.22)
Nausea	19	14 (31.11)	2	2 (4.44)
Diarrhoea	10	10 (22.22)	0	0 (0.00)
Constipation	5	4 (8.89)	0	0 (0.00)
Abdominal pain	4	4 (8.89)	0	0 (0.00)
Anal incontinence	2	1 (2.22)	0	0 (0.00)
Pancreatitis	2	2 (4.44)	1	1 (2.22)
Stomatitis	2	2 (4.44)	0	0 (0.00)
Abdominal distension	1	1 (2.22)	0	0 (0.00)
Abdominal pain lower	1	1 (2.22)	0	0 (0.00)
Abdominal pain upper	1	1 (2.22)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Abdominal tenderness	1	1 (2.22)	0	0 (0.00)
Ascites	1	1 (2.22)	1	1 (2.22)
Dysphagia	1	1 (2.22)	0	0 (0.00)
Flatulence	1	1 (2.22)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (2.22)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.22)	0	0 (0.00)
Glossodynia	1	1 (2.22)	0	0 (0.00)
Haematemesis	1	1 (2.22)	0	0 (0.00)
Ileus	1	1 (2.22)	1	1 (2.22)
Tooth socket haemorrhage	1	1 (2.22)	0	0 (0.00)
General disorders and administration site conditions				
- Total	39	21 (46.67)	6	6 (13.33)
Pyrexia	15	9 (20.00)	4	4 (8.89)
Fatigue	8	8 (17.78)	0	0 (0.00)
Chills	7	6 (13.33)	0	0 (0.00)
Catheter site pain	2	2 (4.44)	0	0 (0.00)
Asthenia	1	1 (2.22)	0	0 (0.00)
Facial pain	1	1 (2.22)	0	0 (0.00)
Generalised oedema	1	1 (2.22)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Malaise	1	1 (2.22)	0	0 (0.00)
Non-cardiac chest pain	1	1 (2.22)	0	0 (0.00)
Pain	1	1 (2.22)	1	1 (2.22)
Physical deconditioning	1	1 (2.22)	1	1 (2.22)
Hepatobiliary disorders				
- Total	4	4 (8.89)	0	0 (0.00)
Hepatomegaly	2	2 (4.44)	0	0 (0.00)
Gallbladder enlargement	1	1 (2.22)	0	0 (0.00)
Hepatosplenomegaly	1	1 (2.22)	0	0 (0.00)
Immune system disorders				
- Total	69	38 (84.44)	19	13 (28.89)
Cytokine release syndrome	51	32 (71.11)	17	11 (24.44)
Hypogammaglobulinaemia	17	16 (35.56)	2	2 (4.44)
Drug hypersensitivity	1	1 (2.22)	0	0 (0.00)
Infections and infestations				
- Total	22	15 (33.33)	3	3 (6.67)
Clostridium difficile infection	3	3 (6.67)	0	0 (0.00)
Clostridium difficile colitis	2	2 (4.44)	1	1 (2.22)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Acute sinusitis	1	1 (2.22)	0	0 (0.00)
Body tinea	1	1 (2.22)	0	0 (0.00)
Catheter site infection	1	1 (2.22)	1	1 (2.22)
Cytomegalovirus infection	1	1 (2.22)	0	0 (0.00)
Enterococcal infection	1	1 (2.22)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (2.22)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (2.22)	0	0 (0.00)
Hypopyon	1	1 (2.22)	0	0 (0.00)
Influenza	1	1 (2.22)	0	0 (0.00)
Oral candidiasis	1	1 (2.22)	0	0 (0.00)
Pneumonia	1	1 (2.22)	1	1 (2.22)
Rhinovirus infection	1	1 (2.22)	0	0 (0.00)
Skin infection	1	1 (2.22)	0	0 (0.00)
Staphylococcal infection	1	1 (2.22)	0	0 (0.00)
Viral infection	1	1 (2.22)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (2.22)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (2.22)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	10	6 (13.33)	1	1 (2.22)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Procedural pain	2	2 (4.44)	0	0 (0.00)
Tracheal haemorrhage	2	1 (2.22)	1	1 (2.22)
Contusion	1	1 (2.22)	0	0 (0.00)
Infusion related reaction	1	1 (2.22)	0	0 (0.00)
Limb injury	1	1 (2.22)	0	0 (0.00)
Post procedural haemorrhage	1	1 (2.22)	0	0 (0.00)
Procedural site reaction	1	1 (2.22)	0	0 (0.00)
Transfusion reaction	1	1 (2.22)	0	0 (0.00)
Investigations				
- Total	218	38 (84.44)	120	31 (68.89)
White blood cell count decreased	40	23 (51.11)	26	19 (42.22)
Neutrophil count decreased	39	19 (42.22)	36	17 (37.78)
Platelet count decreased	30	13 (28.89)	25	9 (20.00)
Aspartate aminotransferase increased	16	12 (26.67)	8	8 (17.78)
Alanine aminotransferase increased	15	11 (24.44)	8	6 (13.33)
Lymphocyte count decreased	14	12 (26.67)	10	9 (20.00)
International normalised ratio increased	8	6 (13.33)	0	0 (0.00)
Prothrombin time prolonged	8	5 (11.11)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Blood bilirubin increased	7	4 (8.89)	1	1 (2.22)
Activated partial thromboplastin time prolonged	6	4 (8.89)	0	0 (0.00)
Blood fibrinogen decreased	6	2 (4.44)	1	1 (2.22)
Blood creatinine increased	5	4 (8.89)	0	0 (0.00)
Blood phosphorus increased	3	2 (4.44)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (4.44)	0	0 (0.00)
Blood sodium increased	2	1 (2.22)	0	0 (0.00)
Blood uric acid increased	2	1 (2.22)	0	0 (0.00)
Lipase increased	2	2 (4.44)	2	2 (4.44)
Blood immunoglobulin A decreased	1	1 (2.22)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.22)	0	0 (0.00)
Blood lactic acid increased	1	1 (2.22)	1	1 (2.22)
Blood magnesium decreased	1	1 (2.22)	1	1 (2.22)
Blood urea increased	1	1 (2.22)	0	0 (0.00)
C-reactive protein increased	1	1 (2.22)	1	1 (2.22)
Cardiac murmur	1	1 (2.22)	0	0 (0.00)
Fibrin D dimer increased	1	1 (2.22)	0	0 (0.00)
Hepatic enzyme increased	1	1 (2.22)	0	0 (0.00)
Norovirus test positive	1	1 (2.22)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Pulmonary function test decreased	1	1 (2.22)	0	0 (0.00)
Serum ferritin increased	1	1 (2.22)	0	0 (0.00)
Transaminases increased	1	1 (2.22)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	69	23 (51.11)	25	14 (31.11)
Decreased appetite	15	13 (28.89)	8	8 (17.78)
Hypokalaemia	15	12 (26.67)	5	5 (11.11)
Hyperphosphataemia	8	6 (13.33)	0	0 (0.00)
Hypophosphataemia	8	5 (11.11)	7	5 (11.11)
Hyperuricaemia	4	3 (6.67)	1	1 (2.22)
Hypoalbuminaemia	4	3 (6.67)	1	1 (2.22)
Hyperglycaemia	3	2 (4.44)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (4.44)	1	1 (2.22)
Hypernatraemia	2	2 (4.44)	0	0 (0.00)
Acidosis	1	1 (2.22)	0	0 (0.00)
Dehydration	1	1 (2.22)	0	0 (0.00)
Fluid overload	1	1 (2.22)	0	0 (0.00)
Hypocalcaemia	1	1 (2.22)	0	0 (0.00)
Hypomagnesaemia	1	1 (2.22)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Hyponatraemia	1	1 (2.22)	1	1 (2.22)
Tumour lysis syndrome	1	1 (2.22)	1	1 (2.22)
Musculoskeletal and connective tissue disorders				
- Total	13	8 (17.78)	1	1 (2.22)
Arthralgia	4	4 (8.89)	1	1 (2.22)
Myalgia	3	3 (6.67)	0	0 (0.00)
Musculoskeletal pain	2	2 (4.44)	0	0 (0.00)
Pain in extremity	2	2 (4.44)	0	0 (0.00)
Muscular weakness	1	1 (2.22)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.22)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (2.22)	0	0 (0.00)
Skin papilloma	1	1 (2.22)	0	0 (0.00)
Nervous system disorders				
- Total	41	23 (51.11)	2	1 (2.22)
Headache	22	17 (37.78)	1	1 (2.22)
Dizziness	3	3 (6.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Dysarthria	2	2 (4.44)	0	0 (0.00)
Encephalopathy	2	2 (4.44)	1	1 (2.22)
Seizure	2	2 (4.44)	0	0 (0.00)
Tremor	2	2 (4.44)	0	0 (0.00)
Asterixis	1	1 (2.22)	0	0 (0.00)
Ataxia	1	1 (2.22)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.22)	0	0 (0.00)
Idiopathic intracranial hypertension	1	1 (2.22)	0	0 (0.00)
Migraine	1	1 (2.22)	0	0 (0.00)
Neuropathy peripheral	1	1 (2.22)	0	0 (0.00)
Pleocytosis	1	1 (2.22)	0	0 (0.00)
Somnolence	1	1 (2.22)	0	0 (0.00)
Product issues				
- Total	1	1 (2.22)	0	0 (0.00)
Device occlusion	1	1 (2.22)	0	0 (0.00)
Psychiatric disorders				
- Total	12	8 (17.78)	1	1 (2.22)
Confusional state	4	4 (8.89)	0	0 (0.00)
Anxiety	3	3 (6.67)	1	1 (2.22)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Delirium	2	2 (4.44)	0	0 (0.00)
Adjustment disorder	1	1 (2.22)	0	0 (0.00)
Agitation	1	1 (2.22)	0	0 (0.00)
Suicidal ideation	1	1 (2.22)	0	0 (0.00)
Renal and urinary disorders				
- Total	11	7 (15.56)	7	4 (8.89)
Acute kidney injury	4	4 (8.89)	3	3 (6.67)
Dysuria	2	2 (4.44)	0	0 (0.00)
Haematuria	2	2 (4.44)	2	2 (4.44)
Oliguria	1	1 (2.22)	1	1 (2.22)
Pollakiuria	1	1 (2.22)	0	0 (0.00)
Renal failure	1	1 (2.22)	1	1 (2.22)
Reproductive system and breast disorders				
- Total	4	3 (6.67)	0	0 (0.00)
Oedema genital	2	1 (2.22)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (4.44)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
- Total	45	17 (37.78)	18	7 (15.56)
Hypoxia	8	6 (13.33)	5	4 (8.89)
Pleural effusion	6	6 (13.33)	1	1 (2.22)
Tachypnoea	5	4 (8.89)	1	1 (2.22)
Cough	4	4 (8.89)	0	0 (0.00)
Epistaxis	3	3 (6.67)	2	2 (4.44)
Haemoptysis	3	2 (4.44)	1	1 (2.22)
Pulmonary oedema	3	3 (6.67)	3	3 (6.67)
Respiratory failure	3	3 (6.67)	3	3 (6.67)
Oropharyngeal pain	2	2 (4.44)	0	0 (0.00)
Atelectasis	1	1 (2.22)	0	0 (0.00)
Dyspnoea	1	1 (2.22)	1	1 (2.22)
Interstitial lung disease	1	1 (2.22)	1	1 (2.22)
Nasal congestion	1	1 (2.22)	0	0 (0.00)
Oropharyngeal plaque	1	1 (2.22)	0	0 (0.00)
Rhinitis allergic	1	1 (2.22)	0	0 (0.00)
Rhinorrhoea	1	1 (2.22)	0	0 (0.00)
Wheezing	1	1 (2.22)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
- Total	27	15 (33.33)	2	2 (4.44)
Dry skin	3	3 (6.67)	0	0 (0.00)
Ingrowing nail	3	2 (4.44)	0	0 (0.00)
Petechiae	3	3 (6.67)	0	0 (0.00)
Rash	3	3 (6.67)	0	0 (0.00)
Rash maculo-papular	2	2 (4.44)	1	1 (2.22)
Dermatitis diaper	1	1 (2.22)	0	0 (0.00)
Ecchymosis	1	1 (2.22)	1	1 (2.22)
Erythema	1	1 (2.22)	0	0 (0.00)
Hyperhidrosis	1	1 (2.22)	0	0 (0.00)
Livedo reticularis	1	1 (2.22)	0	0 (0.00)
Macule	1	1 (2.22)	0	0 (0.00)
Pruritus	1	1 (2.22)	0	0 (0.00)
Rash erythematous	1	1 (2.22)	0	0 (0.00)
Rash follicular	1	1 (2.22)	0	0 (0.00)
Rash macular	1	1 (2.22)	0	0 (0.00)
Rash papular	1	1 (2.22)	0	0 (0.00)
Skin exfoliation	1	1 (2.22)	0	0 (0.00)
Skin fissures	1	1 (2.22)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Vascular disorders				
- Total	26	16 (35.56)	11	10 (22.22)
Hypotension	12	9 (20.00)	10	9 (20.00)
Hypertension	9	7 (15.56)	0	0 (0.00)
Orthostatic hypotension	2	2 (4.44)	0	0 (0.00)
Embolism	1	1 (2.22)	1	1 (2.22)
Haematoma	1	1 (2.22)	0	0 (0.00)
Secondary hypertension	1	1 (2.22)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Total number of AE per patient	150	16 (88.89)	33	9 (50.00)
Blood and lymphatic system disorders				
- Total	10	5 (27.78)	8	4 (22.22)
Neutropenia	5	3 (16.67)	5	3 (16.67)
Eosinophilia	2	1 (5.56)	1	1 (5.56)
Anaemia	1	1 (5.56)	0	0 (0.00)
Febrile neutropenia	1	1 (5.56)	1	1 (5.56)
Leukopenia	1	1 (5.56)	1	1 (5.56)
Cardiac disorders				
- Total	1	1 (5.56)	0	0 (0.00)
Sinus tachycardia	1	1 (5.56)	0	0 (0.00)
Eye disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
- Total	3	3 (16.67)	0	0 (0.00)
Conjunctivitis allergic	1	1 (5.56)	0	0 (0.00)
Ocular hyperaemia	1	1 (5.56)	0	0 (0.00)
Vision blurred	1	1 (5.56)	0	0 (0.00)
Gastrointestinal disorders				
- Total	16	7 (38.89)	4	1 (5.56)
Vomiting	5	4 (22.22)	1	1 (5.56)
Diarrhoea	4	4 (22.22)	1	1 (5.56)
Nausea	4	3 (16.67)	1	1 (5.56)
Abdominal pain	2	2 (11.11)	1	1 (5.56)
Pigmentation lip	1	1 (5.56)	0	0 (0.00)
General disorders and administration site conditions				
- Total	14	7 (38.89)	0	0 (0.00)
Pyrexia	10	6 (33.33)	0	0 (0.00)
Chills	1	1 (5.56)	0	0 (0.00)
Crying	1	1 (5.56)	0	0 (0.00)
Influenza like illness	1	1 (5.56)	0	0 (0.00)
Pain	1	1 (5.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Immune system disorders				
- Total	5	5 (27.78)	1	1 (5.56)
Hypogammaglobulinaemia	3	3 (16.67)	1	1 (5.56)
Graft versus host disease	1	1 (5.56)	0	0 (0.00)
Seasonal allergy	1	1 (5.56)	0	0 (0.00)
Infections and infestations				
- Total	24	13 (72.22)	8	5 (27.78)
Cellulitis of male external genital organ	5	1 (5.56)	2	1 (5.56)
Upper respiratory tract infection	3	3 (16.67)	0	0 (0.00)
Ear infection	2	2 (11.11)	0	0 (0.00)
Gastroenteritis	2	2 (11.11)	0	0 (0.00)
Urinary tract infection	2	1 (5.56)	1	1 (5.56)
Bacterial sepsis	1	1 (5.56)	1	1 (5.56)
Enterovirus infection	1	1 (5.56)	1	1 (5.56)
Herpes zoster	1	1 (5.56)	1	1 (5.56)
Molluscum contagiosum	1	1 (5.56)	0	0 (0.00)
Oral herpes	1	1 (5.56)	0	0 (0.00)
Rhinitis	1	1 (5.56)	0	0 (0.00)
Rhinovirus infection	1	1 (5.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Rotavirus infection	1	1 (5.56)	1	1 (5.56)
Tinea capitis	1	1 (5.56)	0	0 (0.00)
Vascular device infection	1	1 (5.56)	1	1 (5.56)
Injury, poisoning and procedural complications				
- Total	4	4 (22.22)	0	0 (0.00)
Contusion	1	1 (5.56)	0	0 (0.00)
Radius fracture	1	1 (5.56)	0	0 (0.00)
Skin abrasion	1	1 (5.56)	0	0 (0.00)
Skin laceration	1	1 (5.56)	0	0 (0.00)
Investigations				
- Total	21	10 (55.56)	7	4 (22.22)
Neutrophil count decreased	6	4 (22.22)	5	3 (16.67)
White blood cell count decreased	4	2 (11.11)	2	1 (5.56)
Blood urea increased	2	1 (5.56)	0	0 (0.00)
Lymphocyte count decreased	2	2 (11.11)	0	0 (0.00)
Platelet count decreased	2	1 (5.56)	0	0 (0.00)
Weight decreased	2	2 (11.11)	0	0 (0.00)
Blood creatinine increased	1	1 (5.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Haemoglobin decreased	1	1 (5.56)	0	0 (0.00)
Weight increased	1	1 (5.56)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	7	5 (27.78)	1	1 (5.56)
Hyperalbuminaemia	2	1 (5.56)	0	0 (0.00)
Decreased appetite	1	1 (5.56)	0	0 (0.00)
Dehydration	1	1 (5.56)	1	1 (5.56)
Hypercalcaemia	1	1 (5.56)	0	0 (0.00)
Hyperphosphataemia	1	1 (5.56)	0	0 (0.00)
Vitamin D deficiency	1	1 (5.56)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	13	10 (55.56)	0	0 (0.00)
Pain in extremity	6	6 (33.33)	0	0 (0.00)
Arthralgia	1	1 (5.56)	0	0 (0.00)
Back pain	1	1 (5.56)	0	0 (0.00)
Joint range of motion decreased	1	1 (5.56)	0	0 (0.00)
Muscle spasms	1	1 (5.56)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (5.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Osteonecrosis	1	1 (5.56)	0	0 (0.00)
Toe walking	1	1 (5.56)	0	0 (0.00)
Nervous system disorders				
- Total	6	3 (16.67)	0	0 (0.00)
Headache	5	3 (16.67)	0	0 (0.00)
Dizziness	1	1 (5.56)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (5.56)	1	1 (5.56)
Acute kidney injury	1	1 (5.56)	1	1 (5.56)
Reproductive system and breast disorders				
- Total	2	2 (11.11)	1	1 (5.56)
Scrotal pain	1	1 (5.56)	0	0 (0.00)
Vaginal haemorrhage	1	1 (5.56)	1	1 (5.56)
Respiratory, thoracic and mediastinal disorders				
- Total	13	9 (50.00)	2	2 (11.11)
Cough	6	5 (27.78)	0	0 (0.00)
Rhinitis allergic	2	2 (11.11)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Acute respiratory failure	1	1 (5.56)	1	1 (5.56)
Dysphonia	1	1 (5.56)	0	0 (0.00)
Nasal congestion	1	1 (5.56)	0	0 (0.00)
Pulmonary oedema	1	1 (5.56)	1	1 (5.56)
Rhinorrhoea	1	1 (5.56)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	10	7 (38.89)	0	0 (0.00)
Rash	4	3 (16.67)	0	0 (0.00)
Rash maculo-papular	2	2 (11.11)	0	0 (0.00)
Dermatitis atopic	1	1 (5.56)	0	0 (0.00)
Macule	1	1 (5.56)	0	0 (0.00)
Papule	1	1 (5.56)	0	0 (0.00)
Pruritus	1	1 (5.56)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=38 n (%)[1]	Grade >= 3 Total events	All patients N=38 n (%)[2]
Total number of AE per patient	196	30 (78.95)	38	17 (44.74)
Blood and lymphatic system disorders				
- Total	8	6 (15.79)	5	3 (7.89)
Febrile neutropenia	2	2 (5.26)	2	2 (5.26)
Thrombocytopenia	2	2 (5.26)	1	1 (2.63)
Anaemia	1	1 (2.63)	1	1 (2.63)
Lymphadenopathy	1	1 (2.63)	0	0 (0.00)
Lymphopenia	1	1 (2.63)	0	0 (0.00)
Neutropenia	1	1 (2.63)	1	1 (2.63)
Endocrine disorders				
- Total	1	1 (2.63)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.63)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=38 n (%)[1]	Grade >= 3 Total events	All patients N=38 n (%)[2]
Eye disorders				
- Total	2	2 (5.26)	0	0 (0.00)
Dry eye	2	2 (5.26)	0	0 (0.00)
Gastrointestinal disorders				
- Total	22	9 (23.68)	4	3 (7.89)
Vomiting	8	5 (13.16)	1	1 (2.63)
Diarrhoea	4	4 (10.53)	0	0 (0.00)
Nausea	3	3 (7.89)	1	1 (2.63)
Oral pain	3	2 (5.26)	1	1 (2.63)
Abdominal pain	2	2 (5.26)	0	0 (0.00)
Abdominal pain upper	1	1 (2.63)	0	0 (0.00)
Enterocolitis	1	1 (2.63)	1	1 (2.63)
General disorders and administration site conditions				
- Total	12	10 (26.32)	1	1 (2.63)
Pyrexia	4	4 (10.53)	1	1 (2.63)
Fatigue	2	2 (5.26)	0	0 (0.00)
Acquired gene mutation	1	1 (2.63)	0	0 (0.00)
Catheter site pain	1	1 (2.63)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=38 n (%)[1]	Grade >= 3 Total events	All patients N=38 n (%)[2]
Generalised oedema	1	1 (2.63)	0	0 (0.00)
Influenza like illness	1	1 (2.63)	0	0 (0.00)
Malaise	1	1 (2.63)	0	0 (0.00)
Oedema peripheral	1	1 (2.63)	0	0 (0.00)
Immune system disorders				
- Total	12	9 (23.68)	0	0 (0.00)
Hypogammaglobulinaemia	6	5 (13.16)	0	0 (0.00)
Graft versus host disease	2	1 (2.63)	0	0 (0.00)
Immunodeficiency common variable	2	2 (5.26)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (2.63)	0	0 (0.00)
Seasonal allergy	1	1 (2.63)	0	0 (0.00)
Infections and infestations				
- Total	37	20 (52.63)	9	7 (18.42)
Upper respiratory tract infection	4	4 (10.53)	1	1 (2.63)
Influenza	3	3 (7.89)	0	0 (0.00)
Rhinovirus infection	3	1 (2.63)	0	0 (0.00)
Urinary tract infection	3	3 (7.89)	1	1 (2.63)
Otitis media	2	1 (2.63)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=38 n (%)[1]	Grade >= 3 Total events	All patients N=38 n (%)[2]
Parainfluenzae virus infection	2	2 (5.26)	1	1 (2.63)
Sinusitis	2	2 (5.26)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (5.26)	1	1 (2.63)
Cholecystitis infective	1	1 (2.63)	1	1 (2.63)
Corona virus infection	1	1 (2.63)	1	1 (2.63)
Cytomegalovirus infection	1	1 (2.63)	0	0 (0.00)
Escherichia urinary tract infection	1	1 (2.63)	1	1 (2.63)
Gastroenteritis	1	1 (2.63)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (2.63)	0	0 (0.00)
Gastroenteritis viral	1	1 (2.63)	0	0 (0.00)
Otitis externa	1	1 (2.63)	0	0 (0.00)
Otitis media acute	1	1 (2.63)	0	0 (0.00)
Paronychia	1	1 (2.63)	0	0 (0.00)
Rash pustular	1	1 (2.63)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (2.63)	1	1 (2.63)
Sepsis	1	1 (2.63)	1	1 (2.63)
Subcutaneous abscess	1	1 (2.63)	0	0 (0.00)
Viral infection	1	1 (2.63)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (2.63)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=38 n (%)[1]	Grade >= 3 Total events	All patients N=38 n (%)[2]
Injury, poisoning and procedural complications				
- Total	9	4 (10.53)	0	0 (0.00)
Infusion related reaction	2	2 (5.26)	0	0 (0.00)
Procedural pain	2	2 (5.26)	0	0 (0.00)
Arthropod bite	1	1 (2.63)	0	0 (0.00)
Contusion	1	1 (2.63)	0	0 (0.00)
Foot fracture	1	1 (2.63)	0	0 (0.00)
Procedural nausea	1	1 (2.63)	0	0 (0.00)
Sunburn	1	1 (2.63)	0	0 (0.00)
Investigations				
- Total	27	13 (34.21)	9	8 (21.05)
Neutrophil count decreased	6	4 (10.53)	3	3 (7.89)
Aspartate aminotransferase increased	3	3 (7.89)	2	2 (5.26)
Platelet count decreased	3	2 (5.26)	0	0 (0.00)
White blood cell count decreased	3	3 (7.89)	1	1 (2.63)
Alanine aminotransferase increased	2	2 (5.26)	2	2 (5.26)
Weight decreased	2	2 (5.26)	0	0 (0.00)
Blood bilirubin increased	1	1 (2.63)	1	1 (2.63)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=38 n (%)[1]	Grade >= 3 Total events	All patients N=38 n (%)[2]
Blood magnesium decreased	1	1 (2.63)	0	0 (0.00)
Blood uric acid increased	1	1 (2.63)	0	0 (0.00)
Haemoglobin decreased	1	1 (2.63)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.63)	0	0 (0.00)
Serum ferritin increased	1	1 (2.63)	0	0 (0.00)
Transaminases increased	1	1 (2.63)	0	0 (0.00)
Weight increased	1	1 (2.63)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	8	5 (13.16)	5	3 (7.89)
Hypokalaemia	2	2 (5.26)	1	1 (2.63)
Decreased appetite	1	1 (2.63)	0	0 (0.00)
Hyperglycaemia	1	1 (2.63)	1	1 (2.63)
Hyperphosphataemia	1	1 (2.63)	0	0 (0.00)
Hypophosphataemia	1	1 (2.63)	1	1 (2.63)
Iron overload	1	1 (2.63)	1	1 (2.63)
Tumour lysis syndrome	1	1 (2.63)	1	1 (2.63)
Musculoskeletal and connective tissue disorders				
- Total	8	6 (15.79)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=38 n (%)[1]	Grade >= 3 Total events	All patients N=38 n (%)[2]
Muscular weakness	2	2 (5.26)	0	0 (0.00)
Pain in extremity	2	2 (5.26)	0	0 (0.00)
Arthralgia	1	1 (2.63)	0	0 (0.00)
Flank pain	1	1 (2.63)	0	0 (0.00)
Joint range of motion decreased	1	1 (2.63)	0	0 (0.00)
Pain in jaw	1	1 (2.63)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (2.63)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (2.63)	0	0 (0.00)
Nervous system disorders				
- Total	6	5 (13.16)	0	0 (0.00)
Dizziness	2	2 (5.26)	0	0 (0.00)
Headache	2	2 (5.26)	0	0 (0.00)
Peroneal nerve palsy	2	2 (5.26)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (5.26)	0	0 (0.00)
Depression	2	2 (5.26)	0	0 (0.00)
Anxiety	1	1 (2.63)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=38 n (%)[1]	Grade >= 3 Total events	All patients N=38 n (%)[2]
Sleep disorder	1	1 (2.63)	0	0 (0.00)
Renal and urinary disorders				
- Total	4	2 (5.26)	2	1 (2.63)
Calculus urinary	1	1 (2.63)	0	0 (0.00)
Haematuria	1	1 (2.63)	1	1 (2.63)
Nephrolithiasis	1	1 (2.63)	1	1 (2.63)
Urinary incontinence	1	1 (2.63)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	17	9 (23.68)	2	1 (2.63)
Cough	3	2 (5.26)	0	0 (0.00)
Nasal congestion	3	3 (7.89)	0	0 (0.00)
Oropharyngeal pain	3	3 (7.89)	0	0 (0.00)
Rhinorrhoea	3	3 (7.89)	0	0 (0.00)
Epistaxis	2	2 (5.26)	1	1 (2.63)
Pharyngeal erythema	1	1 (2.63)	0	0 (0.00)
Pharyngeal lesion	1	1 (2.63)	1	1 (2.63)
Rhinitis allergic	1	1 (2.63)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=38 n (%)[1]	Grade >= 3 Total events	All patients N=38 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	15	9 (23.68)	1	1 (2.63)
Erythema	2	2 (5.26)	0	0 (0.00)
Rash erythematous	2	1 (2.63)	0	0 (0.00)
Alopecia	1	1 (2.63)	0	0 (0.00)
Dermatitis	1	1 (2.63)	0	0 (0.00)
Dermatitis acneiform	1	1 (2.63)	1	1 (2.63)
Dry skin	1	1 (2.63)	0	0 (0.00)
Eczema	1	1 (2.63)	0	0 (0.00)
Hyperhidrosis	1	1 (2.63)	0	0 (0.00)
Ingrowing nail	1	1 (2.63)	0	0 (0.00)
Keloid scar	1	1 (2.63)	0	0 (0.00)
Petechiae	1	1 (2.63)	0	0 (0.00)
Rash	1	1 (2.63)	0	0 (0.00)
Rash pruritic	1	1 (2.63)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (5.26)	0	0 (0.00)
Hypertension	2	2 (5.26)	0	0 (0.00)
Hot flush	1	1 (2.63)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=38 n (%)[1]	Grade >= 3 Total events	All patients N=38 n (%)[2]

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Total number of AE per patient	40	10 (90.91)	8	5 (45.45)
Gastrointestinal disorders				
- Total	3	2 (18.18)	0	0 (0.00)
Diarrhoea	2	2 (18.18)	0	0 (0.00)
Abdominal pain	1	1 (9.09)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Chronic graft versus host disease	1	1 (9.09)	0	0 (0.00)
Infections and infestations				
- Total	14	6 (54.55)	6	3 (27.27)
Urinary tract infection	3	2 (18.18)	1	1 (9.09)
Campylobacter infection	1	1 (9.09)	1	1 (9.09)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Cellulitis of male external genital organ	1	1 (9.09)	1	1 (9.09)
Clostridium difficile infection	1	1 (9.09)	1	1 (9.09)
Gingivitis	1	1 (9.09)	0	0 (0.00)
Otitis media	1	1 (9.09)	0	0 (0.00)
Respiratory tract infection	1	1 (9.09)	1	1 (9.09)
Respiratory tract infection viral	1	1 (9.09)	1	1 (9.09)
Skin infection	1	1 (9.09)	0	0 (0.00)
Upper respiratory tract infection	1	1 (9.09)	0	0 (0.00)
Viral infection	1	1 (9.09)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (9.09)	0	0 (0.00)
Investigations				
- Total	11	4 (36.36)	2	2 (18.18)
Lymphocyte count decreased	5	3 (27.27)	1	1 (9.09)
Neutrophil count decreased	3	2 (18.18)	0	0 (0.00)
White blood cell count decreased	3	2 (18.18)	1	1 (9.09)
Metabolism and nutrition disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Vitamin D deficiency	1	1 (9.09)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Neck pain	1	1 (9.09)	0	0 (0.00)
Nervous system disorders				
- Total	3	2 (18.18)	0	0 (0.00)
Disturbance in attention	1	1 (9.09)	0	0 (0.00)
Dizziness	1	1 (9.09)	0	0 (0.00)
Headache	1	1 (9.09)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	5	2 (18.18)	0	0 (0.00)
Cough	2	1 (9.09)	0	0 (0.00)
Oropharyngeal pain	1	1 (9.09)	0	0 (0.00)
Rhinitis allergic	1	1 (9.09)	0	0 (0.00)
Rhinorrhoea	1	1 (9.09)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (9.09)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Acne	1	1 (9.09)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Total number of AE per patient	50	12 (52.17)	15	7 (30.43)
Blood and lymphatic system disorders				
- Total	2	2 (8.70)	1	1 (4.35)
Febrile neutropenia	1	1 (4.35)	1	1 (4.35)
Thrombocytopenia	1	1 (4.35)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (4.35)	0	0 (0.00)
Tympanic membrane perforation	1	1 (4.35)	0	0 (0.00)
Gastrointestinal disorders				
- Total	1	1 (4.35)	0	0 (0.00)
Nausea	1	1 (4.35)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
General disorders and administration site conditions				
- Total	4	2 (8.70)	1	1 (4.35)
Pyrexia	2	1 (4.35)	0	0 (0.00)
Chills	1	1 (4.35)	0	0 (0.00)
Cyst	1	1 (4.35)	1	1 (4.35)
Immune system disorders				
- Total	1	1 (4.35)	0	0 (0.00)
Immunodeficiency	1	1 (4.35)	0	0 (0.00)
Infections and infestations				
- Total	18	5 (21.74)	1	1 (4.35)
Otitis media	4	2 (8.70)	1	1 (4.35)
Otitis media acute	4	2 (8.70)	0	0 (0.00)
Sinusitis	3	3 (13.04)	0	0 (0.00)
Upper respiratory tract infection	3	1 (4.35)	0	0 (0.00)
Pneumonia	2	2 (8.70)	0	0 (0.00)
Haemophilus infection	1	1 (4.35)	0	0 (0.00)
Meningitis aseptic	1	1 (4.35)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Injury, poisoning and procedural complications				
- Total	1	1 (4.35)	1	1 (4.35)
Procedural pain	1	1 (4.35)	1	1 (4.35)
Investigations				
- Total	11	4 (17.39)	6	3 (13.04)
Alanine aminotransferase increased	3	3 (13.04)	2	2 (8.70)
Aspartate aminotransferase increased	2	2 (8.70)	1	1 (4.35)
White blood cell count decreased	2	2 (8.70)	2	2 (8.70)
Blood alkaline phosphatase increased	1	1 (4.35)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (4.35)	0	0 (0.00)
C-reactive protein increased	1	1 (4.35)	0	0 (0.00)
Platelet count decreased	1	1 (4.35)	1	1 (4.35)
Metabolism and nutrition disorders				
- Total	1	1 (4.35)	1	1 (4.35)
Hypokalaemia	1	1 (4.35)	1	1 (4.35)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (4.35)	1	1 (4.35)
Glioblastoma multiforme	1	1 (4.35)	1	1 (4.35)
Nervous system disorders				
- Total	1	1 (4.35)	1	1 (4.35)
Seizure	1	1 (4.35)	1	1 (4.35)
Renal and urinary disorders				
- Total	3	2 (8.70)	1	1 (4.35)
Acute kidney injury	2	1 (4.35)	1	1 (4.35)
Haematuria	1	1 (4.35)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (4.35)	1	1 (4.35)
Ovarian failure	1	1 (4.35)	1	1 (4.35)
Respiratory, thoracic and mediastinal disorders				
- Total	2	2 (8.70)	0	0 (0.00)
Cough	1	1 (4.35)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Epistaxis	1	1 (4.35)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	2 (8.70)	0	0 (0.00)
Papule	1	1 (4.35)	0	0 (0.00)
Pruritus	1	1 (4.35)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Total number of AE per patient	702	19 (100.00)	215	18 (94.74)
Blood and lymphatic system disorders				
- Total	59	16 (84.21)	41	15 (78.95)
Anaemia	20	7 (36.84)	11	6 (31.58)
Thrombocytopenia	14	2 (10.53)	8	2 (10.53)
Febrile neutropenia	11	8 (42.11)	11	8 (42.11)
Neutropenia	7	4 (21.05)	6	4 (21.05)
Eosinophilia	2	1 (5.26)	1	1 (5.26)
Coagulopathy	1	1 (5.26)	0	0 (0.00)
Disseminated intravascular coagulation	1	1 (5.26)	1	1 (5.26)
Leukopenia	1	1 (5.26)	1	1 (5.26)
Lymphopenia	1	1 (5.26)	1	1 (5.26)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Pancytopenia	1	1 (5.26)	1	1 (5.26)
Cardiac disorders				
- Total	11	9 (47.37)	1	1 (5.26)
Tachycardia	5	4 (21.05)	1	1 (5.26)
Sinus tachycardia	3	3 (15.79)	0	0 (0.00)
Atrioventricular block second degree	1	1 (5.26)	0	0 (0.00)
Bradycardia	1	1 (5.26)	0	0 (0.00)
Pericardial effusion	1	1 (5.26)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (5.26)	0	0 (0.00)
Ear pain	1	1 (5.26)	0	0 (0.00)
Eye disorders				
- Total	15	9 (47.37)	0	0 (0.00)
Periorbital oedema	3	3 (15.79)	0	0 (0.00)
Photophobia	3	2 (10.53)	0	0 (0.00)
Vision blurred	3	3 (15.79)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (10.53)	0	0 (0.00)
Conjunctivitis allergic	1	1 (5.26)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Eye pain	1	1 (5.26)	0	0 (0.00)
Ocular hyperaemia	1	1 (5.26)	0	0 (0.00)
Retinal haemorrhage	1	1 (5.26)	0	0 (0.00)
Gastrointestinal disorders				
- Total	66	15 (78.95)	13	6 (31.58)
Vomiting	18	11 (57.89)	3	2 (10.53)
Diarrhoea	14	12 (63.16)	2	2 (10.53)
Nausea	11	8 (42.11)	2	2 (10.53)
Abdominal pain	9	5 (26.32)	2	1 (5.26)
Constipation	3	3 (15.79)	0	0 (0.00)
Mouth haemorrhage	2	1 (5.26)	2	1 (5.26)
Abdominal discomfort	1	1 (5.26)	0	0 (0.00)
Abdominal distension	1	1 (5.26)	0	0 (0.00)
Abdominal pain upper	1	1 (5.26)	0	0 (0.00)
Dyspepsia	1	1 (5.26)	0	0 (0.00)
Dysphagia	1	1 (5.26)	1	1 (5.26)
Haematemesis	1	1 (5.26)	0	0 (0.00)
Intestinal obstruction	1	1 (5.26)	1	1 (5.26)
Lip pain	1	1 (5.26)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Pigmentation lip	1	1 (5.26)	0	0 (0.00)
General disorders and administration site conditions				
- Total	52	15 (78.95)	8	4 (21.05)
Pyrexia	22	11 (57.89)	2	2 (10.53)
Fatigue	6	5 (26.32)	1	1 (5.26)
Chills	3	3 (15.79)	0	0 (0.00)
Pain	3	3 (15.79)	1	1 (5.26)
Face oedema	2	2 (10.53)	1	1 (5.26)
Generalised oedema	2	1 (5.26)	0	0 (0.00)
Malaise	2	2 (10.53)	0	0 (0.00)
Oedema peripheral	2	2 (10.53)	1	1 (5.26)
Catheter site extravasation	1	1 (5.26)	0	0 (0.00)
Catheter site haemorrhage	1	1 (5.26)	0	0 (0.00)
Catheter site pain	1	1 (5.26)	0	0 (0.00)
Crying	1	1 (5.26)	0	0 (0.00)
Influenza like illness	1	1 (5.26)	0	0 (0.00)
Injection site haematoma	1	1 (5.26)	0	0 (0.00)
Localised oedema	1	1 (5.26)	1	1 (5.26)
Mucosal haemorrhage	1	1 (5.26)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Multiple organ dysfunction syndrome	1	1 (5.26)	1	1 (5.26)
Peripheral swelling	1	1 (5.26)	0	0 (0.00)
Hepatobiliary disorders				
- Total	5	3 (15.79)	2	2 (10.53)
Hyperbilirubinaemia	4	3 (15.79)	2	2 (10.53)
Hepatomegaly	1	1 (5.26)	0	0 (0.00)
Immune system disorders				
- Total	53	19 (100.00)	15	9 (47.37)
Cytokine release syndrome	35	18 (94.74)	12	8 (42.11)
Hypogammaglobulinaemia	13	13 (68.42)	3	3 (15.79)
Chronic graft versus host disease	1	1 (5.26)	0	0 (0.00)
Graft versus host disease	1	1 (5.26)	0	0 (0.00)
Graft versus host disease in skin	1	1 (5.26)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (5.26)	0	0 (0.00)
Seasonal allergy	1	1 (5.26)	0	0 (0.00)
Infections and infestations				
- Total	57	16 (84.21)	18	8 (42.11)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Cellulitis of male external genital organ	6	1 (5.26)	3	1 (5.26)
Upper respiratory tract infection	5	4 (21.05)	0	0 (0.00)
Urinary tract infection	5	2 (10.53)	2	1 (5.26)
Gastroenteritis	4	4 (21.05)	1	1 (5.26)
Rhinovirus infection	3	3 (15.79)	0	0 (0.00)
Clostridium difficile colitis	2	2 (10.53)	0	0 (0.00)
Clostridium difficile infection	2	2 (10.53)	1	1 (5.26)
Ear infection	2	2 (10.53)	0	0 (0.00)
Bacterial sepsis	1	1 (5.26)	1	1 (5.26)
Campylobacter infection	1	1 (5.26)	1	1 (5.26)
Catheter site cellulitis	1	1 (5.26)	0	0 (0.00)
Enterovirus infection	1	1 (5.26)	1	1 (5.26)
Folliculitis	1	1 (5.26)	0	0 (0.00)
Fungal skin infection	1	1 (5.26)	0	0 (0.00)
Gingivitis	1	1 (5.26)	0	0 (0.00)
Herpes simplex	1	1 (5.26)	0	0 (0.00)
Herpes zoster	1	1 (5.26)	1	1 (5.26)
Molluscum contagiosum	1	1 (5.26)	0	0 (0.00)
Oral herpes	1	1 (5.26)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Orchitis	1	1 (5.26)	0	0 (0.00)
Otitis media	1	1 (5.26)	0	0 (0.00)
Pharyngitis	1	1 (5.26)	0	0 (0.00)
Pneumonia	1	1 (5.26)	0	0 (0.00)
Respiratory tract infection	1	1 (5.26)	1	1 (5.26)
Respiratory tract infection viral	1	1 (5.26)	1	1 (5.26)
Rhinitis	1	1 (5.26)	0	0 (0.00)
Rotavirus infection	1	1 (5.26)	1	1 (5.26)
Septic embolus	1	1 (5.26)	1	1 (5.26)
Skin infection	1	1 (5.26)	0	0 (0.00)
Staphylococcal infection	1	1 (5.26)	1	1 (5.26)
Streptococcal infection	1	1 (5.26)	0	0 (0.00)
Tinea capitis	1	1 (5.26)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (5.26)	1	1 (5.26)
Vascular device infection	1	1 (5.26)	1	1 (5.26)
Viral infection	1	1 (5.26)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (5.26)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	19	12 (63.16)	1	1 (5.26)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Transfusion reaction	3	2 (10.53)	0	0 (0.00)
Skin abrasion	2	2 (10.53)	0	0 (0.00)
Contusion	1	1 (5.26)	0	0 (0.00)
Incision site pain	1	1 (5.26)	0	0 (0.00)
Infusion related reaction	1	1 (5.26)	0	0 (0.00)
Mouth injury	1	1 (5.26)	0	0 (0.00)
Procedural complication	1	1 (5.26)	0	0 (0.00)
Procedural headache	1	1 (5.26)	0	0 (0.00)
Procedural pain	1	1 (5.26)	0	0 (0.00)
Radius fracture	1	1 (5.26)	0	0 (0.00)
Skin laceration	1	1 (5.26)	0	0 (0.00)
Stoma site irritation	1	1 (5.26)	0	0 (0.00)
Subdural haemorrhage	1	1 (5.26)	0	0 (0.00)
Tibia fracture	1	1 (5.26)	0	0 (0.00)
Tongue injury	1	1 (5.26)	0	0 (0.00)
Transfusion related complication	1	1 (5.26)	1	1 (5.26)
Investigations				
- Total	146	16 (84.21)	67	15 (78.95)
White blood cell count decreased	22	10 (52.63)	14	9 (47.37)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Neutrophil count decreased	17	8 (42.11)	13	7 (36.84)
Aspartate aminotransferase increased	16	6 (31.58)	8	3 (15.79)
Platelet count decreased	15	6 (31.58)	12	5 (26.32)
Alanine aminotransferase increased	13	8 (42.11)	6	5 (26.32)
Blood fibrinogen decreased	9	2 (10.53)	3	2 (10.53)
Lymphocyte count decreased	9	4 (21.05)	3	3 (15.79)
Prothrombin time prolonged	9	4 (21.05)	1	1 (5.26)
Blood creatinine increased	7	5 (26.32)	2	2 (10.53)
Blood bilirubin increased	6	3 (15.79)	1	1 (5.26)
Blood urea increased	4	2 (10.53)	1	1 (5.26)
International normalised ratio increased	3	3 (15.79)	1	1 (5.26)
Activated partial thromboplastin time prolonged	2	1 (5.26)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (10.53)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (10.53)	0	0 (0.00)
Haemoglobin decreased	2	2 (10.53)	1	1 (5.26)
Weight decreased	2	2 (10.53)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (5.26)	0	0 (0.00)
Blood phosphorus decreased	1	1 (5.26)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Culture stool positive	1	1 (5.26)	0	0 (0.00)
Protein total decreased	1	1 (5.26)	1	1 (5.26)
Transaminases increased	1	1 (5.26)	0	0 (0.00)
Weight increased	1	1 (5.26)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	55	18 (94.74)	19	11 (57.89)
Decreased appetite	10	8 (42.11)	5	4 (21.05)
Hypernatraemia	5	2 (10.53)	1	1 (5.26)
Hypokalaemia	5	4 (21.05)	2	2 (10.53)
Hypophosphataemia	5	4 (21.05)	2	2 (10.53)
Dehydration	3	3 (15.79)	3	3 (15.79)
Hyperalbuminaemia	3	1 (5.26)	0	0 (0.00)
Hypercalcaemia	3	1 (5.26)	0	0 (0.00)
Hyperphosphataemia	3	2 (10.53)	0	0 (0.00)
Hypocalcaemia	3	2 (10.53)	1	1 (5.26)
Fluid overload	2	2 (10.53)	0	0 (0.00)
Hypoalbuminaemia	2	2 (10.53)	0	0 (0.00)
Hyponatraemia	2	1 (5.26)	2	1 (5.26)
Vitamin D deficiency	2	2 (10.53)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Acidosis	1	1 (5.26)	1	1 (5.26)
Hyperchloraemia	1	1 (5.26)	0	0 (0.00)
Hyperglycaemia	1	1 (5.26)	1	1 (5.26)
Hypermagnesaemia	1	1 (5.26)	0	0 (0.00)
Malnutrition	1	1 (5.26)	1	1 (5.26)
Metabolic acidosis	1	1 (5.26)	0	0 (0.00)
Metabolic alkalosis	1	1 (5.26)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	24	13 (68.42)	0	0 (0.00)
Pain in extremity	8	7 (36.84)	0	0 (0.00)
Muscle spasms	2	2 (10.53)	0	0 (0.00)
Musculoskeletal pain	2	1 (5.26)	0	0 (0.00)
Myalgia	2	2 (10.53)	0	0 (0.00)
Arthralgia	1	1 (5.26)	0	0 (0.00)
Back pain	1	1 (5.26)	0	0 (0.00)
Coccydynia	1	1 (5.26)	0	0 (0.00)
Joint range of motion decreased	1	1 (5.26)	0	0 (0.00)
Limb discomfort	1	1 (5.26)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (5.26)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Neck pain	1	1 (5.26)	0	0 (0.00)
Osteonecrosis	1	1 (5.26)	0	0 (0.00)
Osteopenia	1	1 (5.26)	0	0 (0.00)
Toe walking	1	1 (5.26)	0	0 (0.00)
Nervous system disorders				
- Total	26	10 (52.63)	4	4 (21.05)
Headache	15	7 (36.84)	1	1 (5.26)
Encephalopathy	4	2 (10.53)	1	1 (5.26)
Dizziness	3	1 (5.26)	0	0 (0.00)
Disturbance in attention	1	1 (5.26)	0	0 (0.00)
Embolic stroke	1	1 (5.26)	1	1 (5.26)
Myoclonus	1	1 (5.26)	0	0 (0.00)
Seizure	1	1 (5.26)	1	1 (5.26)
Psychiatric disorders				
- Total	18	8 (42.11)	0	0 (0.00)
Anxiety	3	3 (15.79)	0	0 (0.00)
Hallucination	3	2 (10.53)	0	0 (0.00)
Agitation	2	1 (5.26)	0	0 (0.00)
Confusional state	2	2 (10.53)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Delirium	2	2 (10.53)	0	0 (0.00)
Irritability	2	2 (10.53)	0	0 (0.00)
Insomnia	1	1 (5.26)	0	0 (0.00)
Listless	1	1 (5.26)	0	0 (0.00)
Mental status changes	1	1 (5.26)	0	0 (0.00)
Panic attack	1	1 (5.26)	0	0 (0.00)
Renal and urinary disorders				
- Total	8	5 (26.32)	5	4 (21.05)
Acute kidney injury	4	4 (21.05)	3	3 (15.79)
Haematuria	2	2 (10.53)	0	0 (0.00)
Oliguria	1	1 (5.26)	1	1 (5.26)
Renal impairment	1	1 (5.26)	1	1 (5.26)
Reproductive system and breast disorders				
- Total	2	2 (10.53)	1	1 (5.26)
Scrotal pain	1	1 (5.26)	0	0 (0.00)
Vaginal haemorrhage	1	1 (5.26)	1	1 (5.26)
Respiratory, thoracic and mediastinal disorders				

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
- Total	46	15 (78.95)	12	7 (36.84)
Cough	12	8 (42.11)	0	0 (0.00)
Epistaxis	8	4 (21.05)	2	2 (10.53)
Hypoxia	5	4 (21.05)	3	3 (15.79)
Pulmonary oedema	4	4 (21.05)	3	3 (15.79)
Rhinitis allergic	3	2 (10.53)	0	0 (0.00)
Dyspnoea	2	1 (5.26)	1	1 (5.26)
Pleural effusion	2	2 (10.53)	1	1 (5.26)
Rhinorrhoea	2	2 (10.53)	0	0 (0.00)
Acute respiratory failure	1	1 (5.26)	1	1 (5.26)
Dysphonia	1	1 (5.26)	0	0 (0.00)
Nasal congestion	1	1 (5.26)	0	0 (0.00)
Oropharyngeal pain	1	1 (5.26)	0	0 (0.00)
Pharyngeal ulceration	1	1 (5.26)	0	0 (0.00)
Respiratory depression	1	1 (5.26)	0	0 (0.00)
Respiratory distress	1	1 (5.26)	1	1 (5.26)
Tachypnoea	1	1 (5.26)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	25	10 (52.63)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Rash	5	4 (21.05)	0	0 (0.00)
Erythema	3	2 (10.53)	0	0 (0.00)
Hyperhidrosis	3	2 (10.53)	0	0 (0.00)
Rash maculo-papular	3	3 (15.79)	0	0 (0.00)
Pruritus	2	2 (10.53)	0	0 (0.00)
Acne	1	1 (5.26)	0	0 (0.00)
Dermatitis atopic	1	1 (5.26)	0	0 (0.00)
Dry skin	1	1 (5.26)	0	0 (0.00)
Macule	1	1 (5.26)	0	0 (0.00)
Night sweats	1	1 (5.26)	0	0 (0.00)
Papule	1	1 (5.26)	0	0 (0.00)
Rash papular	1	1 (5.26)	0	0 (0.00)
Rash vesicular	1	1 (5.26)	0	0 (0.00)
Skin irritation	1	1 (5.26)	0	0 (0.00)
Vascular disorders				
- Total	14	8 (42.11)	8	6 (31.58)
Hypotension	7	7 (36.84)	6	6 (31.58)
Flushing	3	2 (10.53)	0	0 (0.00)
Hypertension	3	3 (15.79)	1	1 (5.26)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Capillary leak syndrome	1	1 (5.26)	1	1 (5.26)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Total number of AE per patient	1048	45 (100.00)	337	41 (91.11)
Blood and lymphatic system disorders				
- Total	83	32 (71.11)	66	28 (62.22)
Anaemia	29	20 (44.44)	21	14 (31.11)
Febrile neutropenia	19	16 (35.56)	19	16 (35.56)
Thrombocytopenia	19	8 (17.78)	16	7 (15.56)
Neutropenia	8	7 (15.56)	8	7 (15.56)
Disseminated intravascular coagulation	4	3 (6.67)	1	1 (2.22)
Lymphopenia	3	3 (6.67)	1	1 (2.22)
Lymphadenopathy	1	1 (2.22)	0	0 (0.00)
Cardiac disorders				
- Total	22	14 (31.11)	2	1 (2.22)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Tachycardia	12	11 (24.44)	1	1 (2.22)
Sinus tachycardia	3	3 (6.67)	0	0 (0.00)
Sinus bradycardia	2	1 (2.22)	0	0 (0.00)
Cardiac dysfunction	1	1 (2.22)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.22)	1	1 (2.22)
Palpitations	1	1 (2.22)	0	0 (0.00)
Pericardial effusion	1	1 (2.22)	0	0 (0.00)
Ventricular tachycardia	1	1 (2.22)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (6.67)	0	0 (0.00)
Ear pain	1	1 (2.22)	0	0 (0.00)
Hypoacusis	1	1 (2.22)	0	0 (0.00)
Tympanic membrane perforation	1	1 (2.22)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (4.44)	0	0 (0.00)
Adrenal insufficiency	2	2 (4.44)	0	0 (0.00)
Eye disorders				
- Total	15	9 (20.00)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Eye pain	3	2 (4.44)	0	0 (0.00)
Dry eye	2	2 (4.44)	0	0 (0.00)
Uveitis	2	2 (4.44)	0	0 (0.00)
Vision blurred	2	1 (2.22)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (2.22)	0	0 (0.00)
Ocular hypertension	1	1 (2.22)	0	0 (0.00)
Papilloedema	1	1 (2.22)	0	0 (0.00)
Periorbital oedema	1	1 (2.22)	0	0 (0.00)
Retinal haemorrhage	1	1 (2.22)	0	0 (0.00)
Visual impairment	1	1 (2.22)	0	0 (0.00)
Gastrointestinal disorders				
- Total	102	28 (62.22)	10	7 (15.56)
Vomiting	30	16 (35.56)	2	1 (2.22)
Nausea	23	17 (37.78)	3	3 (6.67)
Diarrhoea	14	12 (26.67)	0	0 (0.00)
Abdominal pain	6	6 (13.33)	0	0 (0.00)
Constipation	5	4 (8.89)	0	0 (0.00)
Oral pain	3	2 (4.44)	1	1 (2.22)
Abdominal pain upper	2	2 (4.44)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Anal incontinence	2	1 (2.22)	0	0 (0.00)
Pancreatitis	2	2 (4.44)	1	1 (2.22)
Stomatitis	2	2 (4.44)	0	0 (0.00)
Abdominal distension	1	1 (2.22)	0	0 (0.00)
Abdominal pain lower	1	1 (2.22)	0	0 (0.00)
Abdominal tenderness	1	1 (2.22)	0	0 (0.00)
Ascites	1	1 (2.22)	1	1 (2.22)
Dysphagia	1	1 (2.22)	0	0 (0.00)
Enterocolitis	1	1 (2.22)	1	1 (2.22)
Flatulence	1	1 (2.22)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (2.22)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.22)	0	0 (0.00)
Glossodynia	1	1 (2.22)	0	0 (0.00)
Haematemesis	1	1 (2.22)	0	0 (0.00)
Ileus	1	1 (2.22)	1	1 (2.22)
Tooth socket haemorrhage	1	1 (2.22)	0	0 (0.00)
General disorders and administration site conditions				
- Total	55	27 (60.00)	8	8 (17.78)
Pyrexia	21	14 (31.11)	5	5 (11.11)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Fatigue	10	10 (22.22)	0	0 (0.00)
Chills	8	7 (15.56)	0	0 (0.00)
Catheter site pain	3	3 (6.67)	0	0 (0.00)
Generalised oedema	2	2 (4.44)	0	0 (0.00)
Malaise	2	2 (4.44)	0	0 (0.00)
Acquired gene mutation	1	1 (2.22)	0	0 (0.00)
Asthenia	1	1 (2.22)	0	0 (0.00)
Cyst	1	1 (2.22)	1	1 (2.22)
Facial pain	1	1 (2.22)	0	0 (0.00)
Influenza like illness	1	1 (2.22)	0	0 (0.00)
Non-cardiac chest pain	1	1 (2.22)	0	0 (0.00)
Oedema peripheral	1	1 (2.22)	0	0 (0.00)
Pain	1	1 (2.22)	1	1 (2.22)
Physical deconditioning	1	1 (2.22)	1	1 (2.22)
Hepatobiliary disorders				
- Total	4	4 (8.89)	0	0 (0.00)
Hepatomegaly	2	2 (4.44)	0	0 (0.00)
Gallbladder enlargement	1	1 (2.22)	0	0 (0.00)
Hepatosplenomegaly	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Immune system disorders				
- Total	82	39 (86.67)	19	13 (28.89)
Cytokine release syndrome	51	32 (71.11)	17	11 (24.44)
Hypogammaglobulinaemia	23	20 (44.44)	2	2 (4.44)
Graft versus host disease	2	1 (2.22)	0	0 (0.00)
Immunodeficiency common variable	2	2 (4.44)	0	0 (0.00)
Drug hypersensitivity	1	1 (2.22)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (2.22)	0	0 (0.00)
Immunodeficiency	1	1 (2.22)	0	0 (0.00)
Seasonal allergy	1	1 (2.22)	0	0 (0.00)
Infections and infestations				
- Total	77	30 (66.67)	13	10 (22.22)
Upper respiratory tract infection	7	5 (11.11)	1	1 (2.22)
Otitis media	6	3 (6.67)	1	1 (2.22)
Otitis media acute	5	2 (4.44)	0	0 (0.00)
Sinusitis	5	4 (8.89)	0	0 (0.00)
Influenza	4	4 (8.89)	0	0 (0.00)
Rhinovirus infection	4	2 (4.44)	0	0 (0.00)
Clostridium difficile infection	3	3 (6.67)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Pneumonia	3	3 (6.67)	1	1 (2.22)
Urinary tract infection	3	3 (6.67)	1	1 (2.22)
Viral upper respiratory tract infection	3	3 (6.67)	1	1 (2.22)
Clostridium difficile colitis	2	2 (4.44)	1	1 (2.22)
Cytomegalovirus infection	2	2 (4.44)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (2.22)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (4.44)	1	1 (2.22)
Viral infection	2	2 (4.44)	0	0 (0.00)
Acute sinusitis	1	1 (2.22)	0	0 (0.00)
Body tinea	1	1 (2.22)	0	0 (0.00)
Catheter site infection	1	1 (2.22)	1	1 (2.22)
Cholecystitis infective	1	1 (2.22)	1	1 (2.22)
Corona virus infection	1	1 (2.22)	1	1 (2.22)
Enterococcal infection	1	1 (2.22)	0	0 (0.00)
Escherichia urinary tract infection	1	1 (2.22)	1	1 (2.22)
Gastroenteritis	1	1 (2.22)	0	0 (0.00)
Gastroenteritis viral	1	1 (2.22)	0	0 (0.00)
Haemophilus infection	1	1 (2.22)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (2.22)	0	0 (0.00)
Hypopyon	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Meningitis aseptic	1	1 (2.22)	0	0 (0.00)
Oral candidiasis	1	1 (2.22)	0	0 (0.00)
Otitis externa	1	1 (2.22)	0	0 (0.00)
Paronychia	1	1 (2.22)	0	0 (0.00)
Rash pustular	1	1 (2.22)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (2.22)	1	1 (2.22)
Sepsis	1	1 (2.22)	1	1 (2.22)
Skin infection	1	1 (2.22)	0	0 (0.00)
Staphylococcal infection	1	1 (2.22)	0	0 (0.00)
Subcutaneous abscess	1	1 (2.22)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (2.22)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (2.22)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	20	10 (22.22)	2	2 (4.44)
Procedural pain	5	4 (8.89)	1	1 (2.22)
Infusion related reaction	3	3 (6.67)	0	0 (0.00)
Contusion	2	2 (4.44)	0	0 (0.00)
Tracheal haemorrhage	2	1 (2.22)	1	1 (2.22)
Arthropod bite	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Foot fracture	1	1 (2.22)	0	0 (0.00)
Limb injury	1	1 (2.22)	0	0 (0.00)
Post procedural haemorrhage	1	1 (2.22)	0	0 (0.00)
Procedural nausea	1	1 (2.22)	0	0 (0.00)
Procedural site reaction	1	1 (2.22)	0	0 (0.00)
Sunburn	1	1 (2.22)	0	0 (0.00)
Transfusion reaction	1	1 (2.22)	0	0 (0.00)
Investigations				
- Total	256	40 (88.89)	135	34 (75.56)
Neutrophil count decreased	45	20 (44.44)	39	18 (40.00)
White blood cell count decreased	45	25 (55.56)	29	21 (46.67)
Platelet count decreased	34	14 (31.11)	26	10 (22.22)
Aspartate aminotransferase increased	21	14 (31.11)	11	9 (20.00)
Alanine aminotransferase increased	20	13 (28.89)	12	9 (20.00)
Lymphocyte count decreased	14	12 (26.67)	10	9 (20.00)
Blood bilirubin increased	8	5 (11.11)	2	2 (4.44)
International normalised ratio increased	8	6 (13.33)	0	0 (0.00)
Prothrombin time prolonged	8	5 (11.11)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Activated partial thromboplastin time prolonged	6	4 (8.89)	0	0 (0.00)
Blood fibrinogen decreased	6	2 (4.44)	1	1 (2.22)
Blood creatinine increased	5	4 (8.89)	0	0 (0.00)
Blood phosphorus increased	3	2 (4.44)	0	0 (0.00)
Blood uric acid increased	3	2 (4.44)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (4.44)	0	0 (0.00)
Blood magnesium decreased	2	2 (4.44)	1	1 (2.22)
Blood sodium increased	2	1 (2.22)	0	0 (0.00)
C-reactive protein increased	2	2 (4.44)	1	1 (2.22)
Lipase increased	2	2 (4.44)	2	2 (4.44)
Serum ferritin increased	2	2 (4.44)	0	0 (0.00)
Transaminases increased	2	2 (4.44)	0	0 (0.00)
Weight decreased	2	2 (4.44)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (2.22)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (2.22)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.22)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (2.22)	0	0 (0.00)
Blood lactic acid increased	1	1 (2.22)	1	1 (2.22)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Blood urea increased	1	1 (2.22)	0	0 (0.00)
Cardiac murmur	1	1 (2.22)	0	0 (0.00)
Fibrin D dimer increased	1	1 (2.22)	0	0 (0.00)
Haemoglobin decreased	1	1 (2.22)	0	0 (0.00)
Hepatic enzyme increased	1	1 (2.22)	0	0 (0.00)
Norovirus test positive	1	1 (2.22)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.22)	0	0 (0.00)
Pulmonary function test decreased	1	1 (2.22)	0	0 (0.00)
Weight increased	1	1 (2.22)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	78	25 (55.56)	31	16 (35.56)
Hypokalaemia	18	15 (33.33)	7	7 (15.56)
Decreased appetite	16	14 (31.11)	8	8 (17.78)
Hyperphosphataemia	9	6 (13.33)	0	0 (0.00)
Hypophosphataemia	9	6 (13.33)	8	6 (13.33)
Hyperglycaemia	4	2 (4.44)	1	1 (2.22)
Hyperuricaemia	4	3 (6.67)	1	1 (2.22)
Hypoalbuminaemia	4	3 (6.67)	1	1 (2.22)
Hypertriglyceridaemia	3	2 (4.44)	1	1 (2.22)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Hypernatraemia	2	2 (4.44)	0	0 (0.00)
Tumour lysis syndrome	2	2 (4.44)	2	2 (4.44)
Acidosis	1	1 (2.22)	0	0 (0.00)
Dehydration	1	1 (2.22)	0	0 (0.00)
Fluid overload	1	1 (2.22)	0	0 (0.00)
Hypocalcaemia	1	1 (2.22)	0	0 (0.00)
Hypomagnesaemia	1	1 (2.22)	0	0 (0.00)
Hyponatraemia	1	1 (2.22)	1	1 (2.22)
Iron overload	1	1 (2.22)	1	1 (2.22)
Musculoskeletal and connective tissue disorders				
- Total	21	12 (26.67)	1	1 (2.22)
Arthralgia	5	4 (8.89)	1	1 (2.22)
Pain in extremity	4	4 (8.89)	0	0 (0.00)
Muscular weakness	3	3 (6.67)	0	0 (0.00)
Myalgia	3	3 (6.67)	0	0 (0.00)
Musculoskeletal pain	2	2 (4.44)	0	0 (0.00)
Flank pain	1	1 (2.22)	0	0 (0.00)
Joint range of motion decreased	1	1 (2.22)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Pain in jaw	1	1 (2.22)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (6.67)	1	1 (2.22)
Glioblastoma multiforme	1	1 (2.22)	1	1 (2.22)
Myelodysplastic syndrome	1	1 (2.22)	0	0 (0.00)
Skin papilloma	1	1 (2.22)	0	0 (0.00)
Nervous system disorders				
- Total	48	25 (55.56)	3	2 (4.44)
Headache	24	17 (37.78)	1	1 (2.22)
Dizziness	5	5 (11.11)	0	0 (0.00)
Seizure	3	3 (6.67)	1	1 (2.22)
Dysarthria	2	2 (4.44)	0	0 (0.00)
Encephalopathy	2	2 (4.44)	1	1 (2.22)
Peroneal nerve palsy	2	2 (4.44)	0	0 (0.00)
Tremor	2	2 (4.44)	0	0 (0.00)
Asterixis	1	1 (2.22)	0	0 (0.00)
Ataxia	1	1 (2.22)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Idiopathic intracranial hypertension	1	1 (2.22)	0	0 (0.00)
Migraine	1	1 (2.22)	0	0 (0.00)
Neuropathy peripheral	1	1 (2.22)	0	0 (0.00)
Pleocytosis	1	1 (2.22)	0	0 (0.00)
Somnolence	1	1 (2.22)	0	0 (0.00)
Product issues				
- Total	1	1 (2.22)	0	0 (0.00)
Device occlusion	1	1 (2.22)	0	0 (0.00)
Psychiatric disorders				
- Total	16	9 (20.00)	1	1 (2.22)
Anxiety	4	4 (8.89)	1	1 (2.22)
Confusional state	4	4 (8.89)	0	0 (0.00)
Delirium	2	2 (4.44)	0	0 (0.00)
Depression	2	2 (4.44)	0	0 (0.00)
Adjustment disorder	1	1 (2.22)	0	0 (0.00)
Agitation	1	1 (2.22)	0	0 (0.00)
Sleep disorder	1	1 (2.22)	0	0 (0.00)
Suicidal ideation	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Renal and urinary disorders				
- Total	18	10 (22.22)	10	6 (13.33)
Acute kidney injury	6	5 (11.11)	4	4 (8.89)
Haematuria	4	3 (6.67)	3	3 (6.67)
Dysuria	2	2 (4.44)	0	0 (0.00)
Calculus urinary	1	1 (2.22)	0	0 (0.00)
Nephrolithiasis	1	1 (2.22)	1	1 (2.22)
Oliguria	1	1 (2.22)	1	1 (2.22)
Pollakiuria	1	1 (2.22)	0	0 (0.00)
Renal failure	1	1 (2.22)	1	1 (2.22)
Urinary incontinence	1	1 (2.22)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	5	4 (8.89)	1	1 (2.22)
Oedema genital	2	1 (2.22)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (4.44)	0	0 (0.00)
Ovarian failure	1	1 (2.22)	1	1 (2.22)
Respiratory, thoracic and mediastinal disorders				
- Total	64	23 (51.11)	20	8 (17.78)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Cough	8	6 (13.33)	0	0 (0.00)
Hypoxia	8	6 (13.33)	5	4 (8.89)
Epistaxis	6	6 (13.33)	3	3 (6.67)
Pleural effusion	6	6 (13.33)	1	1 (2.22)
Oropharyngeal pain	5	5 (11.11)	0	0 (0.00)
Tachypnoea	5	4 (8.89)	1	1 (2.22)
Nasal congestion	4	4 (8.89)	0	0 (0.00)
Rhinorrhoea	4	4 (8.89)	0	0 (0.00)
Haemoptysis	3	2 (4.44)	1	1 (2.22)
Pulmonary oedema	3	3 (6.67)	3	3 (6.67)
Respiratory failure	3	3 (6.67)	3	3 (6.67)
Rhinitis allergic	2	2 (4.44)	0	0 (0.00)
Atelectasis	1	1 (2.22)	0	0 (0.00)
Dyspnoea	1	1 (2.22)	1	1 (2.22)
Interstitial lung disease	1	1 (2.22)	1	1 (2.22)
Oropharyngeal plaque	1	1 (2.22)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.22)	0	0 (0.00)
Pharyngeal lesion	1	1 (2.22)	1	1 (2.22)
Wheezing	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	44	20 (44.44)	3	3 (6.67)
Dry skin	4	4 (8.89)	0	0 (0.00)
Ingrowing nail	4	3 (6.67)	0	0 (0.00)
Petechiae	4	4 (8.89)	0	0 (0.00)
Rash	4	4 (8.89)	0	0 (0.00)
Erythema	3	3 (6.67)	0	0 (0.00)
Rash erythematous	3	2 (4.44)	0	0 (0.00)
Hyperhidrosis	2	2 (4.44)	0	0 (0.00)
Pruritus	2	2 (4.44)	0	0 (0.00)
Rash maculo-papular	2	2 (4.44)	1	1 (2.22)
Alopecia	1	1 (2.22)	0	0 (0.00)
Dermatitis	1	1 (2.22)	0	0 (0.00)
Dermatitis acneiform	1	1 (2.22)	1	1 (2.22)
Dermatitis diaper	1	1 (2.22)	0	0 (0.00)
Ecchymosis	1	1 (2.22)	1	1 (2.22)
Eczema	1	1 (2.22)	0	0 (0.00)
Keloid scar	1	1 (2.22)	0	0 (0.00)
Livedo reticularis	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Macule	1	1 (2.22)	0	0 (0.00)
Papule	1	1 (2.22)	0	0 (0.00)
Rash follicular	1	1 (2.22)	0	0 (0.00)
Rash macular	1	1 (2.22)	0	0 (0.00)
Rash papular	1	1 (2.22)	0	0 (0.00)
Rash pruritic	1	1 (2.22)	0	0 (0.00)
Skin exfoliation	1	1 (2.22)	0	0 (0.00)
Skin fissures	1	1 (2.22)	0	0 (0.00)
Vascular disorders				
- Total	29	17 (37.78)	11	10 (22.22)
Hypotension	12	9 (20.00)	10	9 (20.00)
Hypertension	11	9 (20.00)	0	0 (0.00)
Orthostatic hypotension	2	2 (4.44)	0	0 (0.00)
Embolism	1	1 (2.22)	1	1 (2.22)
Haematoma	1	1 (2.22)	0	0 (0.00)
Hot flush	1	1 (2.22)	0	0 (0.00)
Secondary hypertension	1	1 (2.22)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Total number of AE per patient	1314	63 (98.44)	458	54 (84.38)
Blood and lymphatic system disorders				
- Total	122	43 (67.19)	93	38 (59.38)
Anaemia	47	27 (42.19)	31	19 (29.69)
Thrombocytopenia	30	8 (12.50)	23	8 (12.50)
Febrile neutropenia	26	22 (34.38)	26	22 (34.38)
Neutropenia	9	8 (12.50)	8	8 (12.50)
Disseminated intravascular coagulation	5	4 (6.25)	2	2 (3.13)
Lymphopenia	3	3 (4.69)	2	2 (3.13)
Coagulopathy	1	1 (1.56)	0	0 (0.00)
Pancytopenia	1	1 (1.56)	1	1 (1.56)
Cardiac disorders				

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
- Total	32	22 (34.38)	3	2 (3.13)
Tachycardia	17	15 (23.44)	2	2 (3.13)
Sinus tachycardia	5	5 (7.81)	0	0 (0.00)
Pericardial effusion	2	2 (3.13)	0	0 (0.00)
Sinus bradycardia	2	1 (1.56)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.56)	0	0 (0.00)
Bradycardia	1	1 (1.56)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.56)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.56)	1	1 (1.56)
Palpitations	1	1 (1.56)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.56)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (4.69)	0	0 (0.00)
Ear pain	2	2 (3.13)	0	0 (0.00)
Hypoacusis	1	1 (1.56)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.56)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Eye disorders				
- Total	25	13 (20.31)	0	0 (0.00)
Eye pain	4	3 (4.69)	0	0 (0.00)
Periorbital oedema	4	4 (6.25)	0	0 (0.00)
Vision blurred	4	3 (4.69)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (4.69)	0	0 (0.00)
Photophobia	3	2 (3.13)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.13)	0	0 (0.00)
Uveitis	2	2 (3.13)	0	0 (0.00)
Ocular hypertension	1	1 (1.56)	0	0 (0.00)
Papilloedema	1	1 (1.56)	0	0 (0.00)
Visual impairment	1	1 (1.56)	0	0 (0.00)
Gastrointestinal disorders				
- Total	126	36 (56.25)	15	11 (17.19)
Vomiting	35	22 (34.38)	3	3 (4.69)
Nausea	26	21 (32.81)	3	3 (4.69)
Diarrhoea	18	18 (28.13)	1	1 (1.56)
Abdominal pain	10	9 (14.06)	1	1 (1.56)
Constipation	8	7 (10.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Abdominal distension	2	2 (3.13)	0	0 (0.00)
Abdominal pain upper	2	2 (3.13)	0	0 (0.00)
Anal incontinence	2	1 (1.56)	0	0 (0.00)
Dysphagia	2	2 (3.13)	1	1 (1.56)
Haematemesis	2	2 (3.13)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.56)	2	1 (1.56)
Pancreatitis	2	2 (3.13)	1	1 (1.56)
Stomatitis	2	2 (3.13)	0	0 (0.00)
Abdominal discomfort	1	1 (1.56)	0	0 (0.00)
Abdominal pain lower	1	1 (1.56)	0	0 (0.00)
Abdominal tenderness	1	1 (1.56)	0	0 (0.00)
Ascites	1	1 (1.56)	1	1 (1.56)
Dyspepsia	1	1 (1.56)	0	0 (0.00)
Flatulence	1	1 (1.56)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.56)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.56)	0	0 (0.00)
Glossodynia	1	1 (1.56)	0	0 (0.00)
Ileus	1	1 (1.56)	1	1 (1.56)
Intestinal obstruction	1	1 (1.56)	1	1 (1.56)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Lip pain	1	1 (1.56)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.56)	0	0 (0.00)
General disorders and administration site conditions				
- Total	77	32 (50.00)	14	10 (15.63)
Pyrexia	27	16 (25.00)	6	6 (9.38)
Fatigue	14	13 (20.31)	1	1 (1.56)
Chills	9	8 (12.50)	0	0 (0.00)
Catheter site pain	3	3 (4.69)	0	0 (0.00)
Generalised oedema	3	2 (3.13)	0	0 (0.00)
Malaise	3	3 (4.69)	0	0 (0.00)
Pain	3	3 (4.69)	2	2 (3.13)
Face oedema	2	2 (3.13)	1	1 (1.56)
Oedema peripheral	2	2 (3.13)	1	1 (1.56)
Asthenia	1	1 (1.56)	0	0 (0.00)
Catheter site extravasation	1	1 (1.56)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.56)	0	0 (0.00)
Facial pain	1	1 (1.56)	0	0 (0.00)
Injection site haematoma	1	1 (1.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Localised oedema	1	1 (1.56)	1	1 (1.56)
Mucosal haemorrhage	1	1 (1.56)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.56)	1	1 (1.56)
Non-cardiac chest pain	1	1 (1.56)	0	0 (0.00)
Peripheral swelling	1	1 (1.56)	0	0 (0.00)
Physical deconditioning	1	1 (1.56)	1	1 (1.56)
Hepatobiliary disorders				
- Total	9	7 (10.94)	2	2 (3.13)
Hyperbilirubinaemia	4	3 (4.69)	2	2 (3.13)
Hepatomegaly	3	3 (4.69)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.56)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.56)	0	0 (0.00)
Immune system disorders				
- Total	116	57 (89.06)	33	22 (34.38)
Cytokine release syndrome	86	50 (78.13)	29	19 (29.69)
Hypogammaglobulinaemia	27	26 (40.63)	4	4 (6.25)
Drug hypersensitivity	1	1 (1.56)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Haemophagocytic lymphohistiocytosis	1	1 (1.56)	0	0 (0.00)
Infections and infestations				
- Total	41	26 (40.63)	7	7 (10.94)
Clostridium difficile colitis	4	4 (6.25)	1	1 (1.56)
Clostridium difficile infection	4	4 (6.25)	0	0 (0.00)
Rhinovirus infection	3	3 (4.69)	0	0 (0.00)
Gastroenteritis	2	2 (3.13)	1	1 (1.56)
Pneumonia	2	2 (3.13)	1	1 (1.56)
Staphylococcal infection	2	2 (3.13)	1	1 (1.56)
Acute sinusitis	1	1 (1.56)	0	0 (0.00)
Body tinea	1	1 (1.56)	0	0 (0.00)
Catheter site cellulitis	1	1 (1.56)	0	0 (0.00)
Catheter site infection	1	1 (1.56)	1	1 (1.56)
Cytomegalovirus infection	1	1 (1.56)	0	0 (0.00)
Enterococcal infection	1	1 (1.56)	0	0 (0.00)
Folliculitis	1	1 (1.56)	0	0 (0.00)
Fungal skin infection	1	1 (1.56)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Herpes simplex	1	1 (1.56)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (1.56)	0	0 (0.00)
Hypopyon	1	1 (1.56)	0	0 (0.00)
Influenza	1	1 (1.56)	0	0 (0.00)
Oral candidiasis	1	1 (1.56)	0	0 (0.00)
Orchitis	1	1 (1.56)	0	0 (0.00)
Pharyngitis	1	1 (1.56)	0	0 (0.00)
Septic embolus	1	1 (1.56)	1	1 (1.56)
Skin infection	1	1 (1.56)	0	0 (0.00)
Streptococcal infection	1	1 (1.56)	0	0 (0.00)
Upper respiratory tract infection	1	1 (1.56)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.56)	1	1 (1.56)
Viral infection	1	1 (1.56)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.56)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (1.56)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	25	15 (23.44)	2	2 (3.13)
Transfusion reaction	4	3 (4.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Procedural pain	3	3 (4.69)	0	0 (0.00)
Infusion related reaction	2	2 (3.13)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.56)	1	1 (1.56)
Contusion	1	1 (1.56)	0	0 (0.00)
Incision site pain	1	1 (1.56)	0	0 (0.00)
Limb injury	1	1 (1.56)	0	0 (0.00)
Mouth injury	1	1 (1.56)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.56)	0	0 (0.00)
Procedural complication	1	1 (1.56)	0	0 (0.00)
Procedural headache	1	1 (1.56)	0	0 (0.00)
Procedural site reaction	1	1 (1.56)	0	0 (0.00)
Skin abrasion	1	1 (1.56)	0	0 (0.00)
Stoma site irritation	1	1 (1.56)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.56)	0	0 (0.00)
Tibia fracture	1	1 (1.56)	0	0 (0.00)
Tongue injury	1	1 (1.56)	0	0 (0.00)
Transfusion related complication	1	1 (1.56)	1	1 (1.56)
Investigations				
- Total	332	52 (81.25)	178	44 (68.75)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
White blood cell count decreased	55	30 (46.88)	37	26 (40.63)
Neutrophil count decreased	47	25 (39.06)	44	23 (35.94)
Platelet count decreased	43	19 (29.69)	37	14 (21.88)
Aspartate aminotransferase increased	32	18 (28.13)	16	11 (17.19)
Alanine aminotransferase increased	28	19 (29.69)	14	11 (17.19)
Prothrombin time prolonged	17	9 (14.06)	1	1 (1.56)
Lymphocyte count decreased	16	14 (21.88)	12	11 (17.19)
Blood fibrinogen decreased	15	4 (6.25)	4	3 (4.69)
Blood bilirubin increased	13	7 (10.94)	2	2 (3.13)
Blood creatinine increased	11	9 (14.06)	2	2 (3.13)
International normalised ratio increased	11	9 (14.06)	1	1 (1.56)
Activated partial thromboplastin time prolonged	8	5 (7.81)	0	0 (0.00)
Blood immunoglobulin M decreased	4	4 (6.25)	0	0 (0.00)
Blood immunoglobulin A decreased	3	3 (4.69)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.13)	0	0 (0.00)
Blood urea increased	3	3 (4.69)	1	1 (1.56)
Blood sodium increased	2	1 (1.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Blood uric acid increased	2	1 (1.56)	0	0 (0.00)
Lipase increased	2	2 (3.13)	2	2 (3.13)
Transaminases increased	2	2 (3.13)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.56)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.56)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.56)	1	1 (1.56)
Blood magnesium decreased	1	1 (1.56)	1	1 (1.56)
Blood phosphorus decreased	1	1 (1.56)	0	0 (0.00)
C-reactive protein increased	1	1 (1.56)	1	1 (1.56)
Cardiac murmur	1	1 (1.56)	0	0 (0.00)
Culture stool positive	1	1 (1.56)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.56)	0	0 (0.00)
Haemoglobin decreased	1	1 (1.56)	1	1 (1.56)
Hepatic enzyme increased	1	1 (1.56)	0	0 (0.00)
Norovirus test positive	1	1 (1.56)	0	0 (0.00)
Protein total decreased	1	1 (1.56)	1	1 (1.56)
Pulmonary function test decreased	1	1 (1.56)	0	0 (0.00)
Serum ferritin increased	1	1 (1.56)	0	0 (0.00)
Metabolism and nutrition disorders				

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
- Total	116	39 (60.94)	43	24 (37.50)
Decreased appetite	24	20 (31.25)	13	12 (18.75)
Hypokalaemia	20	16 (25.00)	7	7 (10.94)
Hypophosphataemia	13	9 (14.06)	9	7 (10.94)
Hyperphosphataemia	10	8 (12.50)	0	0 (0.00)
Hypernatraemia	7	4 (6.25)	1	1 (1.56)
Hypoalbuminaemia	6	5 (7.81)	1	1 (1.56)
Hyperglycaemia	4	3 (4.69)	1	1 (1.56)
Hyperuricaemia	4	3 (4.69)	1	1 (1.56)
Hypocalcaemia	4	3 (4.69)	1	1 (1.56)
Dehydration	3	3 (4.69)	2	2 (3.13)
Fluid overload	3	3 (4.69)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.13)	1	1 (1.56)
Hyponatraemia	3	2 (3.13)	3	2 (3.13)
Acidosis	2	2 (3.13)	1	1 (1.56)
Hypercalcaemia	2	1 (1.56)	0	0 (0.00)
Hyperalbuminaemia	1	1 (1.56)	0	0 (0.00)
Hyperchloraemia	1	1 (1.56)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Hypomagnesaemia	1	1 (1.56)	0	0 (0.00)
Malnutrition	1	1 (1.56)	1	1 (1.56)
Metabolic acidosis	1	1 (1.56)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.56)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.56)	1	1 (1.56)
Musculoskeletal and connective tissue disorders				
- Total	23	15 (23.44)	1	1 (1.56)
Myalgia	5	5 (7.81)	0	0 (0.00)
Arthralgia	4	4 (6.25)	1	1 (1.56)
Musculoskeletal pain	4	3 (4.69)	0	0 (0.00)
Pain in extremity	4	4 (6.25)	0	0 (0.00)
Coccydynia	1	1 (1.56)	0	0 (0.00)
Limb discomfort	1	1 (1.56)	0	0 (0.00)
Muscle spasms	1	1 (1.56)	0	0 (0.00)
Muscular weakness	1	1 (1.56)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.56)	0	0 (0.00)
Osteopenia	1	1 (1.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.56)	0	0 (0.00)
Skin papilloma	1	1 (1.56)	0	0 (0.00)
Nervous system disorders				
- Total	58	33 (51.56)	6	5 (7.81)
Headache	31	24 (37.50)	2	2 (3.13)
Encephalopathy	6	4 (6.25)	2	2 (3.13)
Dizziness	4	4 (6.25)	0	0 (0.00)
Seizure	3	3 (4.69)	1	1 (1.56)
Dysarthria	2	2 (3.13)	0	0 (0.00)
Tremor	2	2 (3.13)	0	0 (0.00)
Asterixis	1	1 (1.56)	0	0 (0.00)
Ataxia	1	1 (1.56)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.56)	0	0 (0.00)
Embolic stroke	1	1 (1.56)	1	1 (1.56)
Idiopathic intracranial hypertension	1	1 (1.56)	0	0 (0.00)
Migraine	1	1 (1.56)	0	0 (0.00)
Myoclonus	1	1 (1.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Neuropathy peripheral	1	1 (1.56)	0	0 (0.00)
Pleocytosis	1	1 (1.56)	0	0 (0.00)
Somnolence	1	1 (1.56)	0	0 (0.00)
Product issues				
- Total	1	1 (1.56)	0	0 (0.00)
Device occlusion	1	1 (1.56)	0	0 (0.00)
Psychiatric disorders				
- Total	30	16 (25.00)	1	1 (1.56)
Anxiety	6	6 (9.38)	1	1 (1.56)
Confusional state	6	6 (9.38)	0	0 (0.00)
Delirium	4	4 (6.25)	0	0 (0.00)
Agitation	3	2 (3.13)	0	0 (0.00)
Hallucination	3	2 (3.13)	0	0 (0.00)
Irritability	2	2 (3.13)	0	0 (0.00)
Adjustment disorder	1	1 (1.56)	0	0 (0.00)
Insomnia	1	1 (1.56)	0	0 (0.00)
Listless	1	1 (1.56)	0	0 (0.00)
Mental status changes	1	1 (1.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Panic attack	1	1 (1.56)	0	0 (0.00)
Suicidal ideation	1	1 (1.56)	0	0 (0.00)
Renal and urinary disorders				
- Total	18	11 (17.19)	11	7 (10.94)
Acute kidney injury	7	7 (10.94)	5	5 (7.81)
Haematuria	4	4 (6.25)	2	2 (3.13)
Dysuria	2	2 (3.13)	0	0 (0.00)
Oliguria	2	2 (3.13)	2	2 (3.13)
Pollakiuria	1	1 (1.56)	0	0 (0.00)
Renal failure	1	1 (1.56)	1	1 (1.56)
Renal impairment	1	1 (1.56)	1	1 (1.56)
Reproductive system and breast disorders				
- Total	4	3 (4.69)	0	0 (0.00)
Oedema genital	2	1 (1.56)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.13)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
- Total	73	28 (43.75)	28	12 (18.75)
Hypoxia	13	10 (15.63)	8	7 (10.94)
Epistaxis	11	7 (10.94)	4	4 (6.25)
Cough	8	8 (12.50)	0	0 (0.00)
Pleural effusion	8	8 (12.50)	2	2 (3.13)
Pulmonary oedema	6	6 (9.38)	5	5 (7.81)
Tachypnoea	6	5 (7.81)	1	1 (1.56)
Dyspnoea	3	2 (3.13)	2	2 (3.13)
Haemoptysis	3	2 (3.13)	1	1 (1.56)
Respiratory failure	3	3 (4.69)	3	3 (4.69)
Oropharyngeal pain	2	2 (3.13)	0	0 (0.00)
Atelectasis	1	1 (1.56)	0	0 (0.00)
Interstitial lung disease	1	1 (1.56)	1	1 (1.56)
Nasal congestion	1	1 (1.56)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.56)	0	0 (0.00)
Pharyngeal ulceration	1	1 (1.56)	0	0 (0.00)
Respiratory depression	1	1 (1.56)	0	0 (0.00)
Respiratory distress	1	1 (1.56)	1	1 (1.56)
Rhinitis allergic	1	1 (1.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Rhinorrhoea	1	1 (1.56)	0	0 (0.00)
Wheezing	1	1 (1.56)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	41	21 (32.81)	2	2 (3.13)
Dry skin	4	4 (6.25)	0	0 (0.00)
Erythema	4	3 (4.69)	0	0 (0.00)
Hyperhidrosis	4	3 (4.69)	0	0 (0.00)
Rash	4	4 (6.25)	0	0 (0.00)
Ingrowing nail	3	2 (3.13)	0	0 (0.00)
Petechiae	3	3 (4.69)	0	0 (0.00)
Rash maculo-papular	3	3 (4.69)	1	1 (1.56)
Pruritus	2	2 (3.13)	0	0 (0.00)
Rash papular	2	2 (3.13)	0	0 (0.00)
Dermatitis diaper	1	1 (1.56)	0	0 (0.00)
Ecchymosis	1	1 (1.56)	1	1 (1.56)
Livedo reticularis	1	1 (1.56)	0	0 (0.00)
Macule	1	1 (1.56)	0	0 (0.00)
Night sweats	1	1 (1.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Rash erythematous	1	1 (1.56)	0	0 (0.00)
Rash follicular	1	1 (1.56)	0	0 (0.00)
Rash macular	1	1 (1.56)	0	0 (0.00)
Rash vesicular	1	1 (1.56)	0	0 (0.00)
Skin exfoliation	1	1 (1.56)	0	0 (0.00)
Skin fissures	1	1 (1.56)	0	0 (0.00)
Skin irritation	1	1 (1.56)	0	0 (0.00)
Vascular disorders				
- Total	40	24 (37.50)	19	16 (25.00)
Hypotension	19	16 (25.00)	16	15 (23.44)
Hypertension	12	10 (15.63)	1	1 (1.56)
Flushing	3	2 (3.13)	0	0 (0.00)
Orthostatic hypotension	2	2 (3.13)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.56)	1	1 (1.56)
Embolism	1	1 (1.56)	1	1 (1.56)
Haematoma	1	1 (1.56)	0	0 (0.00)
Secondary hypertension	1	1 (1.56)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=56 n (%)[1]	Grade >= 3 Total events	All patients N=56 n (%)[2]
Total number of AE per patient	346	46 (82.14)	71	26 (46.43)
Blood and lymphatic system disorders				
- Total	18	11 (19.64)	13	7 (12.50)
Neutropenia	6	4 (7.14)	6	4 (7.14)
Febrile neutropenia	3	3 (5.36)	3	3 (5.36)
Anaemia	2	2 (3.57)	1	1 (1.79)
Eosinophilia	2	1 (1.79)	1	1 (1.79)
Thrombocytopenia	2	2 (3.57)	1	1 (1.79)
Leukopenia	1	1 (1.79)	1	1 (1.79)
Lymphadenopathy	1	1 (1.79)	0	0 (0.00)
Lymphopenia	1	1 (1.79)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (1.79)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=56 n (%)[1]	Grade >= 3 Total events	All patients N=56 n (%)[2]
Sinus tachycardia	1	1 (1.79)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.79)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.79)	0	0 (0.00)
Eye disorders				
- Total	5	5 (8.93)	0	0 (0.00)
Dry eye	2	2 (3.57)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.79)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.79)	0	0 (0.00)
Vision blurred	1	1 (1.79)	0	0 (0.00)
Gastrointestinal disorders				
- Total	38	16 (28.57)	8	4 (7.14)
Vomiting	13	9 (16.07)	2	2 (3.57)
Diarrhoea	8	8 (14.29)	1	1 (1.79)
Nausea	7	6 (10.71)	2	2 (3.57)
Abdominal pain	4	4 (7.14)	1	1 (1.79)
Oral pain	3	2 (3.57)	1	1 (1.79)
Abdominal pain upper	1	1 (1.79)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=56 n (%)[1]	Grade >= 3 Total events	All patients N=56 n (%)[2]
Enterocolitis	1	1 (1.79)	1	1 (1.79)
Pigmentation lip	1	1 (1.79)	0	0 (0.00)
General disorders and administration site conditions				
- Total	26	17 (30.36)	1	1 (1.79)
Pyrexia	14	10 (17.86)	1	1 (1.79)
Fatigue	2	2 (3.57)	0	0 (0.00)
Influenza like illness	2	2 (3.57)	0	0 (0.00)
Acquired gene mutation	1	1 (1.79)	0	0 (0.00)
Catheter site pain	1	1 (1.79)	0	0 (0.00)
Chills	1	1 (1.79)	0	0 (0.00)
Crying	1	1 (1.79)	0	0 (0.00)
Generalised oedema	1	1 (1.79)	0	0 (0.00)
Malaise	1	1 (1.79)	0	0 (0.00)
Oedema peripheral	1	1 (1.79)	0	0 (0.00)
Pain	1	1 (1.79)	0	0 (0.00)
Immune system disorders				
- Total	17	14 (25.00)	1	1 (1.79)
Hypogammaglobulinaemia	9	8 (14.29)	1	1 (1.79)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=56 n (%)[1]	Grade >= 3 Total events	All patients N=56 n (%)[2]
Graft versus host disease	3	2 (3.57)	0	0 (0.00)
Immunodeficiency common variable	2	2 (3.57)	0	0 (0.00)
Seasonal allergy	2	2 (3.57)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.79)	0	0 (0.00)
Infections and infestations				
- Total	61	33 (58.93)	17	12 (21.43)
Upper respiratory tract infection	7	7 (12.50)	1	1 (1.79)
Cellulitis of male external genital organ	5	1 (1.79)	2	1 (1.79)
Urinary tract infection	5	4 (7.14)	2	2 (3.57)
Rhinovirus infection	4	2 (3.57)	0	0 (0.00)
Gastroenteritis	3	3 (5.36)	0	0 (0.00)
Influenza	3	3 (5.36)	0	0 (0.00)
Ear infection	2	2 (3.57)	0	0 (0.00)
Otitis media	2	1 (1.79)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.57)	1	1 (1.79)
Sinusitis	2	2 (3.57)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (3.57)	1	1 (1.79)
Bacterial sepsis	1	1 (1.79)	1	1 (1.79)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=56 n (%)[1]	Grade >= 3 Total events	All patients N=56 n (%)[2]
Cholecystitis infective	1	1 (1.79)	1	1 (1.79)
Corona virus infection	1	1 (1.79)	1	1 (1.79)
Cytomegalovirus infection	1	1 (1.79)	0	0 (0.00)
Enterovirus infection	1	1 (1.79)	1	1 (1.79)
Escherichia urinary tract infection	1	1 (1.79)	1	1 (1.79)
Gastroenteritis norovirus	1	1 (1.79)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.79)	0	0 (0.00)
Herpes zoster	1	1 (1.79)	1	1 (1.79)
Molluscum contagiosum	1	1 (1.79)	0	0 (0.00)
Oral herpes	1	1 (1.79)	0	0 (0.00)
Otitis externa	1	1 (1.79)	0	0 (0.00)
Otitis media acute	1	1 (1.79)	0	0 (0.00)
Paronychia	1	1 (1.79)	0	0 (0.00)
Rash pustular	1	1 (1.79)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (1.79)	1	1 (1.79)
Rhinitis	1	1 (1.79)	0	0 (0.00)
Rotavirus infection	1	1 (1.79)	1	1 (1.79)
Sepsis	1	1 (1.79)	1	1 (1.79)
Subcutaneous abscess	1	1 (1.79)	0	0 (0.00)
Tinea capitis	1	1 (1.79)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=56 n (%)[1]	Grade >= 3 Total events	All patients N=56 n (%)[2]
Vascular device infection	1	1 (1.79)	1	1 (1.79)
Viral infection	1	1 (1.79)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (1.79)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	13	8 (14.29)	0	0 (0.00)
Contusion	2	2 (3.57)	0	0 (0.00)
Infusion related reaction	2	2 (3.57)	0	0 (0.00)
Procedural pain	2	2 (3.57)	0	0 (0.00)
Arthropod bite	1	1 (1.79)	0	0 (0.00)
Foot fracture	1	1 (1.79)	0	0 (0.00)
Procedural nausea	1	1 (1.79)	0	0 (0.00)
Radius fracture	1	1 (1.79)	0	0 (0.00)
Skin abrasion	1	1 (1.79)	0	0 (0.00)
Skin laceration	1	1 (1.79)	0	0 (0.00)
Sunburn	1	1 (1.79)	0	0 (0.00)
Investigations				
- Total	48	23 (41.07)	16	12 (21.43)
Neutrophil count decreased	12	8 (14.29)	8	6 (10.71)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=56 n (%)[1]	Grade >= 3 Total events	All patients N=56 n (%)[2]
White blood cell count decreased	7	5 (8.93)	3	2 (3.57)
Platelet count decreased	5	3 (5.36)	0	0 (0.00)
Weight decreased	4	4 (7.14)	0	0 (0.00)
Aspartate aminotransferase increased	3	3 (5.36)	2	2 (3.57)
Alanine aminotransferase increased	2	2 (3.57)	2	2 (3.57)
Blood urea increased	2	1 (1.79)	0	0 (0.00)
Haemoglobin decreased	2	2 (3.57)	0	0 (0.00)
Lymphocyte count decreased	2	2 (3.57)	0	0 (0.00)
Weight increased	2	2 (3.57)	0	0 (0.00)
Blood bilirubin increased	1	1 (1.79)	1	1 (1.79)
Blood creatinine increased	1	1 (1.79)	0	0 (0.00)
Blood magnesium decreased	1	1 (1.79)	0	0 (0.00)
Blood uric acid increased	1	1 (1.79)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.79)	0	0 (0.00)
Serum ferritin increased	1	1 (1.79)	0	0 (0.00)
Transaminases increased	1	1 (1.79)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	15	10 (17.86)	6	4 (7.14)
Decreased appetite	2	2 (3.57)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=56 n (%)[1]	Grade >= 3 Total events	All patients N=56 n (%)[2]
Hyperalbuminaemia	2	1 (1.79)	0	0 (0.00)
Hyperphosphataemia	2	2 (3.57)	0	0 (0.00)
Hypokalaemia	2	2 (3.57)	1	1 (1.79)
Dehydration	1	1 (1.79)	1	1 (1.79)
Hypercalcaemia	1	1 (1.79)	0	0 (0.00)
Hyperglycaemia	1	1 (1.79)	1	1 (1.79)
Hypophosphataemia	1	1 (1.79)	1	1 (1.79)
Iron overload	1	1 (1.79)	1	1 (1.79)
Tumour lysis syndrome	1	1 (1.79)	1	1 (1.79)
Vitamin D deficiency	1	1 (1.79)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	21	16 (28.57)	0	0 (0.00)
Pain in extremity	8	8 (14.29)	0	0 (0.00)
Arthralgia	2	2 (3.57)	0	0 (0.00)
Joint range of motion decreased	2	2 (3.57)	0	0 (0.00)
Muscular weakness	2	2 (3.57)	0	0 (0.00)
Back pain	1	1 (1.79)	0	0 (0.00)
Flank pain	1	1 (1.79)	0	0 (0.00)
Muscle spasms	1	1 (1.79)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=56 n (%)[1]	Grade >= 3 Total events	All patients N=56 n (%)[2]
Musculoskeletal chest pain	1	1 (1.79)	0	0 (0.00)
Osteonecrosis	1	1 (1.79)	0	0 (0.00)
Pain in jaw	1	1 (1.79)	0	0 (0.00)
Toe walking	1	1 (1.79)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.79)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.79)	0	0 (0.00)
Nervous system disorders				
- Total	12	8 (14.29)	0	0 (0.00)
Headache	7	5 (8.93)	0	0 (0.00)
Dizziness	3	3 (5.36)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.57)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (3.57)	0	0 (0.00)
Depression	2	2 (3.57)	0	0 (0.00)
Anxiety	1	1 (1.79)	0	0 (0.00)
Sleep disorder	1	1 (1.79)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=56 n (%)[1]	Grade >= 3 Total events	All patients N=56 n (%)[2]
Renal and urinary disorders				
- Total	5	3 (5.36)	3	2 (3.57)
Acute kidney injury	1	1 (1.79)	1	1 (1.79)
Calculus urinary	1	1 (1.79)	0	0 (0.00)
Haematuria	1	1 (1.79)	1	1 (1.79)
Nephrolithiasis	1	1 (1.79)	1	1 (1.79)
Urinary incontinence	1	1 (1.79)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	2 (3.57)	1	1 (1.79)
Scrotal pain	1	1 (1.79)	0	0 (0.00)
Vaginal haemorrhage	1	1 (1.79)	1	1 (1.79)
Respiratory, thoracic and mediastinal disorders				
- Total	30	18 (32.14)	4	3 (5.36)
Cough	9	7 (12.50)	0	0 (0.00)
Nasal congestion	4	4 (7.14)	0	0 (0.00)
Rhinorrhoea	4	4 (7.14)	0	0 (0.00)
Oropharyngeal pain	3	3 (5.36)	0	0 (0.00)
Rhinitis allergic	3	3 (5.36)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=56 n (%)[1]	Grade >= 3 Total events	All patients N=56 n (%)[2]
Epistaxis	2	2 (3.57)	1	1 (1.79)
Acute respiratory failure	1	1 (1.79)	1	1 (1.79)
Dysphonia	1	1 (1.79)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.79)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.79)	1	1 (1.79)
Pulmonary oedema	1	1 (1.79)	1	1 (1.79)
Skin and subcutaneous tissue disorders				
- Total	25	16 (28.57)	1	1 (1.79)
Rash	5	4 (7.14)	0	0 (0.00)
Erythema	2	2 (3.57)	0	0 (0.00)
Rash erythematous	2	1 (1.79)	0	0 (0.00)
Rash maculo-papular	2	2 (3.57)	0	0 (0.00)
Alopecia	1	1 (1.79)	0	0 (0.00)
Dermatitis	1	1 (1.79)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.79)	1	1 (1.79)
Dermatitis atopic	1	1 (1.79)	0	0 (0.00)
Dry skin	1	1 (1.79)	0	0 (0.00)
Eczema	1	1 (1.79)	0	0 (0.00)
Hyperhidrosis	1	1 (1.79)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=56 n (%)[1]	Grade >= 3 Total events	All patients N=56 n (%)[2]
Ingrowing nail	1	1 (1.79)	0	0 (0.00)
Keloid scar	1	1 (1.79)	0	0 (0.00)
Macule	1	1 (1.79)	0	0 (0.00)
Papule	1	1 (1.79)	0	0 (0.00)
Petechiae	1	1 (1.79)	0	0 (0.00)
Pruritus	1	1 (1.79)	0	0 (0.00)
Rash pruritic	1	1 (1.79)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (3.57)	0	0 (0.00)
Hypertension	2	2 (3.57)	0	0 (0.00)
Hot flush	1	1 (1.79)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Total number of AE per patient	90	22 (64.71)	23	12 (35.29)
Blood and lymphatic system disorders				
- Total	2	2 (5.88)	1	1 (2.94)
Febrile neutropenia	1	1 (2.94)	1	1 (2.94)
Thrombocytopenia	1	1 (2.94)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (2.94)	0	0 (0.00)
Tympanic membrane perforation	1	1 (2.94)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	3 (8.82)	0	0 (0.00)
Diarrhoea	2	2 (5.88)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Abdominal pain	1	1 (2.94)	0	0 (0.00)
Nausea	1	1 (2.94)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	2 (5.88)	1	1 (2.94)
Pyrexia	2	1 (2.94)	0	0 (0.00)
Chills	1	1 (2.94)	0	0 (0.00)
Cyst	1	1 (2.94)	1	1 (2.94)
Immune system disorders				
- Total	2	2 (5.88)	0	0 (0.00)
Chronic graft versus host disease	1	1 (2.94)	0	0 (0.00)
Immunodeficiency	1	1 (2.94)	0	0 (0.00)
Infections and infestations				
- Total	32	11 (32.35)	7	4 (11.76)
Otitis media	5	3 (8.82)	1	1 (2.94)
Otitis media acute	4	2 (5.88)	0	0 (0.00)
Upper respiratory tract infection	4	2 (5.88)	0	0 (0.00)
Sinusitis	3	3 (8.82)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Urinary tract infection	3	2 (5.88)	1	1 (2.94)
Pneumonia	2	2 (5.88)	0	0 (0.00)
Campylobacter infection	1	1 (2.94)	1	1 (2.94)
Cellulitis of male external genital organ	1	1 (2.94)	1	1 (2.94)
Clostridium difficile infection	1	1 (2.94)	1	1 (2.94)
Gingivitis	1	1 (2.94)	0	0 (0.00)
Haemophilus infection	1	1 (2.94)	0	0 (0.00)
Meningitis aseptic	1	1 (2.94)	0	0 (0.00)
Respiratory tract infection	1	1 (2.94)	1	1 (2.94)
Respiratory tract infection viral	1	1 (2.94)	1	1 (2.94)
Skin infection	1	1 (2.94)	0	0 (0.00)
Viral infection	1	1 (2.94)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (2.94)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (2.94)	1	1 (2.94)
Procedural pain	1	1 (2.94)	1	1 (2.94)
Investigations				

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
- Total	22	8 (23.53)	8	5 (14.71)
Lymphocyte count decreased	5	3 (8.82)	1	1 (2.94)
White blood cell count decreased	5	4 (11.76)	3	3 (8.82)
Alanine aminotransferase increased	3	3 (8.82)	2	2 (5.88)
Neutrophil count decreased	3	2 (5.88)	0	0 (0.00)
Aspartate aminotransferase increased	2	2 (5.88)	1	1 (2.94)
Blood alkaline phosphatase increased	1	1 (2.94)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (2.94)	0	0 (0.00)
C-reactive protein increased	1	1 (2.94)	0	0 (0.00)
Platelet count decreased	1	1 (2.94)	1	1 (2.94)
Metabolism and nutrition disorders				
- Total	2	2 (5.88)	1	1 (2.94)
Hypokalaemia	1	1 (2.94)	1	1 (2.94)
Vitamin D deficiency	1	1 (2.94)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (2.94)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Neck pain	1	1 (2.94)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (2.94)	1	1 (2.94)
Glioblastoma multiforme	1	1 (2.94)	1	1 (2.94)
Nervous system disorders				
- Total	4	3 (8.82)	1	1 (2.94)
Disturbance in attention	1	1 (2.94)	0	0 (0.00)
Dizziness	1	1 (2.94)	0	0 (0.00)
Headache	1	1 (2.94)	0	0 (0.00)
Seizure	1	1 (2.94)	1	1 (2.94)
Renal and urinary disorders				
- Total	3	2 (5.88)	1	1 (2.94)
Acute kidney injury	2	1 (2.94)	1	1 (2.94)
Haematuria	1	1 (2.94)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (2.94)	1	1 (2.94)

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Ovarian failure	1	1 (2.94)	1	1 (2.94)
Respiratory, thoracic and mediastinal disorders				
- Total	7	4 (11.76)	0	0 (0.00)
Cough	3	2 (5.88)	0	0 (0.00)
Epistaxis	1	1 (2.94)	0	0 (0.00)
Oropharyngeal pain	1	1 (2.94)	0	0 (0.00)
Rhinitis allergic	1	1 (2.94)	0	0 (0.00)
Rhinorrhoea	1	1 (2.94)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (8.82)	0	0 (0.00)
Acne	1	1 (2.94)	0	0 (0.00)
Papule	1	1 (2.94)	0	0 (0.00)
Pruritus	1	1 (2.94)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)

2 number of patients with Grade 3 or more AE

Table 220k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Total number of AE per patient	1750	64 (100.00)	552	59 (92.19)
Blood and lymphatic system disorders				
- Total	142	48 (75.00)	107	43 (67.19)
Anaemia	49	27 (42.19)	32	20 (31.25)
Thrombocytopenia	33	10 (15.63)	24	9 (14.06)
Febrile neutropenia	30	24 (37.50)	30	24 (37.50)
Neutropenia	15	11 (17.19)	14	11 (17.19)
Disseminated intravascular coagulation	5	4 (6.25)	2	2 (3.13)
Lymphopenia	4	4 (6.25)	2	2 (3.13)
Eosinophilia	2	1 (1.56)	1	1 (1.56)
Coagulopathy	1	1 (1.56)	0	0 (0.00)
Leukopenia	1	1 (1.56)	1	1 (1.56)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Lymphadenopathy	1	1 (1.56)	0	0 (0.00)
Pancytopenia	1	1 (1.56)	1	1 (1.56)
Cardiac disorders				
- Total	33	23 (35.94)	3	2 (3.13)
Tachycardia	17	15 (23.44)	2	2 (3.13)
Sinus tachycardia	6	6 (9.38)	0	0 (0.00)
Pericardial effusion	2	2 (3.13)	0	0 (0.00)
Sinus bradycardia	2	1 (1.56)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.56)	0	0 (0.00)
Bradycardia	1	1 (1.56)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.56)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.56)	1	1 (1.56)
Palpitations	1	1 (1.56)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.56)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	4	4 (6.25)	0	0 (0.00)
Ear pain	2	2 (3.13)	0	0 (0.00)
Hypoacusis	1	1 (1.56)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Tympanic membrane perforation	1	1 (1.56)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (3.13)	0	0 (0.00)
Adrenal insufficiency	2	2 (3.13)	0	0 (0.00)
Eye disorders				
- Total	30	18 (28.13)	0	0 (0.00)
Vision blurred	5	4 (6.25)	0	0 (0.00)
Eye pain	4	3 (4.69)	0	0 (0.00)
Periorbital oedema	4	4 (6.25)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (4.69)	0	0 (0.00)
Photophobia	3	2 (3.13)	0	0 (0.00)
Dry eye	2	2 (3.13)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.13)	0	0 (0.00)
Uveitis	2	2 (3.13)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.56)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.56)	0	0 (0.00)
Ocular hypertension	1	1 (1.56)	0	0 (0.00)
Papilloedema	1	1 (1.56)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Visual impairment	1	1 (1.56)	0	0 (0.00)
Gastrointestinal disorders				
- Total	168	43 (67.19)	23	13 (20.31)
Vomiting	48	27 (42.19)	5	3 (4.69)
Nausea	34	25 (39.06)	5	5 (7.81)
Diarrhoea	28	24 (37.50)	2	2 (3.13)
Abdominal pain	15	11 (17.19)	2	1 (1.56)
Constipation	8	7 (10.94)	0	0 (0.00)
Abdominal pain upper	3	3 (4.69)	0	0 (0.00)
Oral pain	3	2 (3.13)	1	1 (1.56)
Abdominal distension	2	2 (3.13)	0	0 (0.00)
Anal incontinence	2	1 (1.56)	0	0 (0.00)
Dysphagia	2	2 (3.13)	1	1 (1.56)
Haematemesis	2	2 (3.13)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.56)	2	1 (1.56)
Pancreatitis	2	2 (3.13)	1	1 (1.56)
Stomatitis	2	2 (3.13)	0	0 (0.00)
Abdominal discomfort	1	1 (1.56)	0	0 (0.00)
Abdominal pain lower	1	1 (1.56)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Abdominal tenderness	1	1 (1.56)	0	0 (0.00)
Ascites	1	1 (1.56)	1	1 (1.56)
Dyspepsia	1	1 (1.56)	0	0 (0.00)
Enterocolitis	1	1 (1.56)	1	1 (1.56)
Flatulence	1	1 (1.56)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.56)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.56)	0	0 (0.00)
Glossodynia	1	1 (1.56)	0	0 (0.00)
Ileus	1	1 (1.56)	1	1 (1.56)
Intestinal obstruction	1	1 (1.56)	1	1 (1.56)
Lip pain	1	1 (1.56)	0	0 (0.00)
Pigmentation lip	1	1 (1.56)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.56)	0	0 (0.00)
General disorders and administration site conditions				
- Total	107	42 (65.63)	16	12 (18.75)
Pyrexia	43	25 (39.06)	7	7 (10.94)
Fatigue	16	15 (23.44)	1	1 (1.56)
Chills	11	10 (15.63)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Catheter site pain	4	4 (6.25)	0	0 (0.00)
Generalised oedema	4	3 (4.69)	0	0 (0.00)
Malaise	4	4 (6.25)	0	0 (0.00)
Pain	4	4 (6.25)	2	2 (3.13)
Oedema peripheral	3	3 (4.69)	1	1 (1.56)
Face oedema	2	2 (3.13)	1	1 (1.56)
Influenza like illness	2	2 (3.13)	0	0 (0.00)
Acquired gene mutation	1	1 (1.56)	0	0 (0.00)
Asthenia	1	1 (1.56)	0	0 (0.00)
Catheter site extravasation	1	1 (1.56)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.56)	0	0 (0.00)
Crying	1	1 (1.56)	0	0 (0.00)
Cyst	1	1 (1.56)	1	1 (1.56)
Facial pain	1	1 (1.56)	0	0 (0.00)
Injection site haematoma	1	1 (1.56)	0	0 (0.00)
Localised oedema	1	1 (1.56)	1	1 (1.56)
Mucosal haemorrhage	1	1 (1.56)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.56)	1	1 (1.56)
Non-cardiac chest pain	1	1 (1.56)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Peripheral swelling	1	1 (1.56)	0	0 (0.00)
Physical deconditioning	1	1 (1.56)	1	1 (1.56)
Hepatobiliary disorders				
- Total	9	7 (10.94)	2	2 (3.13)
Hyperbilirubinaemia	4	3 (4.69)	2	2 (3.13)
Hepatomegaly	3	3 (4.69)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.56)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.56)	0	0 (0.00)
Immune system disorders				
- Total	135	58 (90.63)	34	22 (34.38)
Cytokine release syndrome	86	50 (78.13)	29	19 (29.69)
Hypogammaglobulinaemia	36	33 (51.56)	5	5 (7.81)
Graft versus host disease	3	2 (3.13)	0	0 (0.00)
Immunodeficiency common variable	2	2 (3.13)	0	0 (0.00)
Seasonal allergy	2	2 (3.13)	0	0 (0.00)
Chronic graft versus host disease	1	1 (1.56)	0	0 (0.00)
Drug hypersensitivity	1	1 (1.56)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.56)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Graft versus host disease in skin	1	1 (1.56)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.56)	0	0 (0.00)
Immunodeficiency	1	1 (1.56)	0	0 (0.00)
Infections and infestations				
- Total	134	46 (71.88)	31	18 (28.13)
Upper respiratory tract infection	12	9 (14.06)	1	1 (1.56)
Urinary tract infection	8	5 (7.81)	3	2 (3.13)
Otitis media	7	4 (6.25)	1	1 (1.56)
Rhinovirus infection	7	5 (7.81)	0	0 (0.00)
Cellulitis of male external genital organ	6	1 (1.56)	3	1 (1.56)
Clostridium difficile infection	5	5 (7.81)	1	1 (1.56)
Gastroenteritis	5	5 (7.81)	1	1 (1.56)
Otitis media acute	5	2 (3.13)	0	0 (0.00)
Sinusitis	5	4 (6.25)	0	0 (0.00)
Clostridium difficile colitis	4	4 (6.25)	1	1 (1.56)
Influenza	4	4 (6.25)	0	0 (0.00)
Pneumonia	4	4 (6.25)	1	1 (1.56)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Viral infection	3	3 (4.69)	0	0 (0.00)
Viral upper respiratory tract infection	3	3 (4.69)	1	1 (1.56)
Cytomegalovirus infection	2	2 (3.13)	0	0 (0.00)
Ear infection	2	2 (3.13)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (1.56)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.13)	1	1 (1.56)
Skin infection	2	2 (3.13)	0	0 (0.00)
Staphylococcal infection	2	2 (3.13)	1	1 (1.56)
Vulvovaginal candidiasis	2	2 (3.13)	0	0 (0.00)
Acute sinusitis	1	1 (1.56)	0	0 (0.00)
Bacterial sepsis	1	1 (1.56)	1	1 (1.56)
Body tinea	1	1 (1.56)	0	0 (0.00)
Campylobacter infection	1	1 (1.56)	1	1 (1.56)
Catheter site cellulitis	1	1 (1.56)	0	0 (0.00)
Catheter site infection	1	1 (1.56)	1	1 (1.56)
Cholecystitis infective	1	1 (1.56)	1	1 (1.56)
Corona virus infection	1	1 (1.56)	1	1 (1.56)
Enterococcal infection	1	1 (1.56)	0	0 (0.00)
Enterovirus infection	1	1 (1.56)	1	1 (1.56)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Escherichia urinary tract infection	1	1 (1.56)	1	1 (1.56)
Folliculitis	1	1 (1.56)	0	0 (0.00)
Fungal skin infection	1	1 (1.56)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.56)	0	0 (0.00)
Gingivitis	1	1 (1.56)	0	0 (0.00)
Haemophilus infection	1	1 (1.56)	0	0 (0.00)
Herpes simplex	1	1 (1.56)	0	0 (0.00)
Herpes zoster	1	1 (1.56)	1	1 (1.56)
Human herpesvirus 6 infection	1	1 (1.56)	0	0 (0.00)
Hypopyon	1	1 (1.56)	0	0 (0.00)
Meningitis aseptic	1	1 (1.56)	0	0 (0.00)
Molluscum contagiosum	1	1 (1.56)	0	0 (0.00)
Oral candidiasis	1	1 (1.56)	0	0 (0.00)
Oral herpes	1	1 (1.56)	0	0 (0.00)
Orchitis	1	1 (1.56)	0	0 (0.00)
Otitis externa	1	1 (1.56)	0	0 (0.00)
Paronychia	1	1 (1.56)	0	0 (0.00)
Pharyngitis	1	1 (1.56)	0	0 (0.00)
Rash pustular	1	1 (1.56)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Respiratory syncytial virus infection	1	1 (1.56)	1	1 (1.56)
Respiratory tract infection	1	1 (1.56)	1	1 (1.56)
Respiratory tract infection viral	1	1 (1.56)	1	1 (1.56)
Rhinitis	1	1 (1.56)	0	0 (0.00)
Rotavirus infection	1	1 (1.56)	1	1 (1.56)
Sepsis	1	1 (1.56)	1	1 (1.56)
Septic embolus	1	1 (1.56)	1	1 (1.56)
Streptococcal infection	1	1 (1.56)	0	0 (0.00)
Subcutaneous abscess	1	1 (1.56)	0	0 (0.00)
Tinea capitis	1	1 (1.56)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.56)	1	1 (1.56)
Vascular device infection	1	1 (1.56)	1	1 (1.56)
Vulvovaginal mycotic infection	1	1 (1.56)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	39	22 (34.38)	3	3 (4.69)
Procedural pain	6	5 (7.81)	1	1 (1.56)
Infusion related reaction	4	4 (6.25)	0	0 (0.00)
Transfusion reaction	4	3 (4.69)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Contusion	3	3 (4.69)	0	0 (0.00)
Skin abrasion	2	2 (3.13)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.56)	1	1 (1.56)
Arthropod bite	1	1 (1.56)	0	0 (0.00)
Foot fracture	1	1 (1.56)	0	0 (0.00)
Incision site pain	1	1 (1.56)	0	0 (0.00)
Limb injury	1	1 (1.56)	0	0 (0.00)
Mouth injury	1	1 (1.56)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.56)	0	0 (0.00)
Procedural complication	1	1 (1.56)	0	0 (0.00)
Procedural headache	1	1 (1.56)	0	0 (0.00)
Procedural nausea	1	1 (1.56)	0	0 (0.00)
Procedural site reaction	1	1 (1.56)	0	0 (0.00)
Radius fracture	1	1 (1.56)	0	0 (0.00)
Skin laceration	1	1 (1.56)	0	0 (0.00)
Stoma site irritation	1	1 (1.56)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.56)	0	0 (0.00)
Sunburn	1	1 (1.56)	0	0 (0.00)
Tibia fracture	1	1 (1.56)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Tongue injury	1	1 (1.56)	0	0 (0.00)
Transfusion related complication	1	1 (1.56)	1	1 (1.56)
Investigations				
- Total	402	56 (87.50)	202	49 (76.56)
White blood cell count decreased	67	35 (54.69)	43	30 (46.88)
Neutrophil count decreased	62	28 (43.75)	52	25 (39.06)
Platelet count decreased	49	20 (31.25)	38	15 (23.44)
Aspartate aminotransferase increased	37	20 (31.25)	19	12 (18.75)
Alanine aminotransferase increased	33	21 (32.81)	18	14 (21.88)
Lymphocyte count decreased	23	16 (25.00)	13	12 (18.75)
Prothrombin time prolonged	17	9 (14.06)	1	1 (1.56)
Blood fibrinogen decreased	15	4 (6.25)	4	3 (4.69)
Blood bilirubin increased	14	8 (12.50)	3	3 (4.69)
Blood creatinine increased	12	9 (14.06)	2	2 (3.13)
International normalised ratio increased	11	9 (14.06)	1	1 (1.56)
Activated partial thromboplastin time prolonged	8	5 (7.81)	0	0 (0.00)
Blood urea increased	5	3 (4.69)	1	1 (1.56)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Blood immunoglobulin M decreased	4	4 (6.25)	0	0 (0.00)
Weight decreased	4	4 (6.25)	0	0 (0.00)
Blood immunoglobulin A decreased	3	3 (4.69)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.13)	0	0 (0.00)
Blood uric acid increased	3	2 (3.13)	0	0 (0.00)
Haemoglobin decreased	3	3 (4.69)	1	1 (1.56)
Transaminases increased	3	3 (4.69)	0	0 (0.00)
Blood magnesium decreased	2	2 (3.13)	1	1 (1.56)
Blood sodium increased	2	1 (1.56)	0	0 (0.00)
C-reactive protein increased	2	2 (3.13)	1	1 (1.56)
Lipase increased	2	2 (3.13)	2	2 (3.13)
Serum ferritin increased	2	2 (3.13)	0	0 (0.00)
Weight increased	2	2 (3.13)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (1.56)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.56)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.56)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (1.56)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.56)	1	1 (1.56)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Blood phosphorus decreased	1	1 (1.56)	0	0 (0.00)
Cardiac murmur	1	1 (1.56)	0	0 (0.00)
Culture stool positive	1	1 (1.56)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.56)	0	0 (0.00)
Hepatic enzyme increased	1	1 (1.56)	0	0 (0.00)
Norovirus test positive	1	1 (1.56)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.56)	0	0 (0.00)
Protein total decreased	1	1 (1.56)	1	1 (1.56)
Pulmonary function test decreased	1	1 (1.56)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	133	43 (67.19)	50	27 (42.19)
Decreased appetite	26	22 (34.38)	13	12 (18.75)
Hypokalaemia	23	19 (29.69)	9	9 (14.06)
Hypophosphataemia	14	10 (15.63)	10	8 (12.50)
Hyperphosphataemia	12	8 (12.50)	0	0 (0.00)
Hypernatraemia	7	4 (6.25)	1	1 (1.56)
Hypoalbuminaemia	6	5 (7.81)	1	1 (1.56)
Hyperglycaemia	5	3 (4.69)	2	2 (3.13)
Dehydration	4	4 (6.25)	3	3 (4.69)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Hyperuricaemia	4	3 (4.69)	1	1 (1.56)
Hypocalcaemia	4	3 (4.69)	1	1 (1.56)
Fluid overload	3	3 (4.69)	0	0 (0.00)
Hyperalbuminaemia	3	1 (1.56)	0	0 (0.00)
Hypercalcaemia	3	1 (1.56)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.13)	1	1 (1.56)
Hyponatraemia	3	2 (3.13)	3	2 (3.13)
Acidosis	2	2 (3.13)	1	1 (1.56)
Tumour lysis syndrome	2	2 (3.13)	2	2 (3.13)
Vitamin D deficiency	2	2 (3.13)	0	0 (0.00)
Hyperchloraemia	1	1 (1.56)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.56)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.56)	0	0 (0.00)
Iron overload	1	1 (1.56)	1	1 (1.56)
Malnutrition	1	1 (1.56)	1	1 (1.56)
Metabolic acidosis	1	1 (1.56)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.56)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
- Total	45	25 (39.06)	1	1 (1.56)
Pain in extremity	12	11 (17.19)	0	0 (0.00)
Arthralgia	6	5 (7.81)	1	1 (1.56)
Myalgia	5	5 (7.81)	0	0 (0.00)
Musculoskeletal pain	4	3 (4.69)	0	0 (0.00)
Muscular weakness	3	3 (4.69)	0	0 (0.00)
Joint range of motion decreased	2	2 (3.13)	0	0 (0.00)
Muscle spasms	2	2 (3.13)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (3.13)	0	0 (0.00)
Back pain	1	1 (1.56)	0	0 (0.00)
Coccydynia	1	1 (1.56)	0	0 (0.00)
Flank pain	1	1 (1.56)	0	0 (0.00)
Limb discomfort	1	1 (1.56)	0	0 (0.00)
Neck pain	1	1 (1.56)	0	0 (0.00)
Osteonecrosis	1	1 (1.56)	0	0 (0.00)
Osteopenia	1	1 (1.56)	0	0 (0.00)
Pain in jaw	1	1 (1.56)	0	0 (0.00)
Toe walking	1	1 (1.56)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (4.69)	1	1 (1.56)
Glioblastoma multiforme	1	1 (1.56)	1	1 (1.56)
Myelodysplastic syndrome	1	1 (1.56)	0	0 (0.00)
Skin papilloma	1	1 (1.56)	0	0 (0.00)
Nervous system disorders				
- Total	74	35 (54.69)	7	6 (9.38)
Headache	39	24 (37.50)	2	2 (3.13)
Dizziness	8	6 (9.38)	0	0 (0.00)
Encephalopathy	6	4 (6.25)	2	2 (3.13)
Seizure	4	4 (6.25)	2	2 (3.13)
Dysarthria	2	2 (3.13)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.13)	0	0 (0.00)
Tremor	2	2 (3.13)	0	0 (0.00)
Asterixis	1	1 (1.56)	0	0 (0.00)
Ataxia	1	1 (1.56)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.56)	0	0 (0.00)
Disturbance in attention	1	1 (1.56)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Embolic stroke	1	1 (1.56)	1	1 (1.56)
Idiopathic intracranial hypertension	1	1 (1.56)	0	0 (0.00)
Migraine	1	1 (1.56)	0	0 (0.00)
Myoclonus	1	1 (1.56)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.56)	0	0 (0.00)
Pleocytosis	1	1 (1.56)	0	0 (0.00)
Somnolence	1	1 (1.56)	0	0 (0.00)
Product issues				
- Total	1	1 (1.56)	0	0 (0.00)
Device occlusion	1	1 (1.56)	0	0 (0.00)
Psychiatric disorders				
- Total	34	17 (26.56)	1	1 (1.56)
Anxiety	7	7 (10.94)	1	1 (1.56)
Confusional state	6	6 (9.38)	0	0 (0.00)
Delirium	4	4 (6.25)	0	0 (0.00)
Agitation	3	2 (3.13)	0	0 (0.00)
Hallucination	3	2 (3.13)	0	0 (0.00)
Depression	2	2 (3.13)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Irritability	2	2 (3.13)	0	0 (0.00)
Adjustment disorder	1	1 (1.56)	0	0 (0.00)
Insomnia	1	1 (1.56)	0	0 (0.00)
Listless	1	1 (1.56)	0	0 (0.00)
Mental status changes	1	1 (1.56)	0	0 (0.00)
Panic attack	1	1 (1.56)	0	0 (0.00)
Sleep disorder	1	1 (1.56)	0	0 (0.00)
Suicidal ideation	1	1 (1.56)	0	0 (0.00)
Renal and urinary disorders				
- Total	26	15 (23.44)	15	10 (15.63)
Acute kidney injury	10	9 (14.06)	7	7 (10.94)
Haematuria	6	5 (7.81)	3	3 (4.69)
Dysuria	2	2 (3.13)	0	0 (0.00)
Oliguria	2	2 (3.13)	2	2 (3.13)
Calculus urinary	1	1 (1.56)	0	0 (0.00)
Nephrolithiasis	1	1 (1.56)	1	1 (1.56)
Pollakiuria	1	1 (1.56)	0	0 (0.00)
Renal failure	1	1 (1.56)	1	1 (1.56)
Renal impairment	1	1 (1.56)	1	1 (1.56)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Urinary incontinence	1	1 (1.56)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	7	6 (9.38)	2	2 (3.13)
Oedema genital	2	1 (1.56)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.13)	0	0 (0.00)
Ovarian failure	1	1 (1.56)	1	1 (1.56)
Scrotal pain	1	1 (1.56)	0	0 (0.00)
Vaginal haemorrhage	1	1 (1.56)	1	1 (1.56)
Respiratory, thoracic and mediastinal disorders				
- Total	110	38 (59.38)	32	15 (23.44)
Cough	20	14 (21.88)	0	0 (0.00)
Epistaxis	14	10 (15.63)	5	5 (7.81)
Hypoxia	13	10 (15.63)	8	7 (10.94)
Pleural effusion	8	8 (12.50)	2	2 (3.13)
Pulmonary oedema	7	7 (10.94)	6	6 (9.38)
Oropharyngeal pain	6	6 (9.38)	0	0 (0.00)
Rhinorrhoea	6	6 (9.38)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Tachypnoea	6	5 (7.81)	1	1 (1.56)
Nasal congestion	5	5 (7.81)	0	0 (0.00)
Rhinitis allergic	5	4 (6.25)	0	0 (0.00)
Dyspnoea	3	2 (3.13)	2	2 (3.13)
Haemoptysis	3	2 (3.13)	1	1 (1.56)
Respiratory failure	3	3 (4.69)	3	3 (4.69)
Acute respiratory failure	1	1 (1.56)	1	1 (1.56)
Atelectasis	1	1 (1.56)	0	0 (0.00)
Dysphonia	1	1 (1.56)	0	0 (0.00)
Interstitial lung disease	1	1 (1.56)	1	1 (1.56)
Oropharyngeal plaque	1	1 (1.56)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.56)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.56)	1	1 (1.56)
Pharyngeal ulceration	1	1 (1.56)	0	0 (0.00)
Respiratory depression	1	1 (1.56)	0	0 (0.00)
Respiratory distress	1	1 (1.56)	1	1 (1.56)
Wheezing	1	1 (1.56)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
- Total	69	30 (46.88)	3	3 (4.69)
Rash	9	8 (12.50)	0	0 (0.00)
Erythema	6	5 (7.81)	0	0 (0.00)
Dry skin	5	5 (7.81)	0	0 (0.00)
Hyperhidrosis	5	4 (6.25)	0	0 (0.00)
Rash maculo-papular	5	5 (7.81)	1	1 (1.56)
Ingrowing nail	4	3 (4.69)	0	0 (0.00)
Petechiae	4	4 (6.25)	0	0 (0.00)
Pruritus	4	4 (6.25)	0	0 (0.00)
Rash erythematous	3	2 (3.13)	0	0 (0.00)
Macule	2	2 (3.13)	0	0 (0.00)
Papule	2	2 (3.13)	0	0 (0.00)
Rash papular	2	2 (3.13)	0	0 (0.00)
Acne	1	1 (1.56)	0	0 (0.00)
Alopecia	1	1 (1.56)	0	0 (0.00)
Dermatitis	1	1 (1.56)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.56)	1	1 (1.56)
Dermatitis atopic	1	1 (1.56)	0	0 (0.00)
Dermatitis diaper	1	1 (1.56)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Ecchymosis	1	1 (1.56)	1	1 (1.56)
Eczema	1	1 (1.56)	0	0 (0.00)
Keloid scar	1	1 (1.56)	0	0 (0.00)
Livedo reticularis	1	1 (1.56)	0	0 (0.00)
Night sweats	1	1 (1.56)	0	0 (0.00)
Rash follicular	1	1 (1.56)	0	0 (0.00)
Rash macular	1	1 (1.56)	0	0 (0.00)
Rash pruritic	1	1 (1.56)	0	0 (0.00)
Rash vesicular	1	1 (1.56)	0	0 (0.00)
Skin exfoliation	1	1 (1.56)	0	0 (0.00)
Skin fissures	1	1 (1.56)	0	0 (0.00)
Skin irritation	1	1 (1.56)	0	0 (0.00)
Vascular disorders				
- Total	43	25 (39.06)	19	16 (25.00)
Hypotension	19	16 (25.00)	16	15 (23.44)
Hypertension	14	12 (18.75)	1	1 (1.56)
Flushing	3	2 (3.13)	0	0 (0.00)
Orthostatic hypotension	2	2 (3.13)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.56)	1	1 (1.56)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Embolism	1	1 (1.56)	1	1 (1.56)
Haematoma	1	1 (1.56)	0	0 (0.00)
Hot flush	1	1 (1.56)	0	0 (0.00)
Secondary hypertension	1	1 (1.56)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Total number of AE per patient	611	27 (96.43)	180	22 (78.57)
Blood and lymphatic system disorders				
- Total	47	18 (64.29)	32	16 (57.14)
Anaemia	23	14 (50.00)	14	9 (32.14)
Febrile neutropenia	12	9 (32.14)	12	9 (32.14)
Thrombocytopenia	8	2 (7.14)	4	2 (7.14)
Lymphopenia	2	2 (7.14)	1	1 (3.57)
Disseminated intravascular coagulation	1	1 (3.57)	0	0 (0.00)
Neutropenia	1	1 (3.57)	1	1 (3.57)
Cardiac disorders				
- Total	15	10 (35.71)	1	1 (3.57)
Tachycardia	8	7 (25.00)	1	1 (3.57)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Sinus tachycardia	4	4 (14.29)	0	0 (0.00)
Sinus bradycardia	2	1 (3.57)	0	0 (0.00)
Cardiac dysfunction	1	1 (3.57)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (10.71)	0	0 (0.00)
Ear pain	2	2 (7.14)	0	0 (0.00)
Hypoacusis	1	1 (3.57)	0	0 (0.00)
Eye disorders				
- Total	12	7 (25.00)	0	0 (0.00)
Photophobia	3	2 (7.14)	0	0 (0.00)
Eye pain	2	2 (7.14)	0	0 (0.00)
Uveitis	2	2 (7.14)	0	0 (0.00)
Ocular hypertension	1	1 (3.57)	0	0 (0.00)
Papilloedema	1	1 (3.57)	0	0 (0.00)
Periorbital oedema	1	1 (3.57)	0	0 (0.00)
Vision blurred	1	1 (3.57)	0	0 (0.00)
Visual impairment	1	1 (3.57)	0	0 (0.00)
Gastrointestinal disorders				

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
- Total	65	17 (60.71)	5	4 (14.29)
Vomiting	16	10 (35.71)	2	2 (7.14)
Nausea	13	12 (42.86)	1	1 (3.57)
Diarrhoea	10	10 (35.71)	0	0 (0.00)
Abdominal pain	8	7 (25.00)	0	0 (0.00)
Constipation	3	2 (7.14)	0	0 (0.00)
Abdominal distension	2	2 (7.14)	0	0 (0.00)
Anal incontinence	2	1 (3.57)	0	0 (0.00)
Mouth haemorrhage	2	1 (3.57)	2	1 (3.57)
Stomatitis	2	2 (7.14)	0	0 (0.00)
Abdominal pain lower	1	1 (3.57)	0	0 (0.00)
Abdominal tenderness	1	1 (3.57)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (3.57)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (3.57)	0	0 (0.00)
Glossodynia	1	1 (3.57)	0	0 (0.00)
Haematemesis	1	1 (3.57)	0	0 (0.00)
Lip pain	1	1 (3.57)	0	0 (0.00)
General disorders and administration site conditions				
- Total	37	14 (50.00)	3	2 (7.14)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Pyrexia	10	6 (21.43)	1	1 (3.57)
Fatigue	9	8 (28.57)	1	1 (3.57)
Chills	4	3 (10.71)	0	0 (0.00)
Generalised oedema	2	1 (3.57)	0	0 (0.00)
Malaise	2	2 (7.14)	0	0 (0.00)
Catheter site extravasation	1	1 (3.57)	0	0 (0.00)
Catheter site haemorrhage	1	1 (3.57)	0	0 (0.00)
Catheter site pain	1	1 (3.57)	0	0 (0.00)
Face oedema	1	1 (3.57)	0	0 (0.00)
Facial pain	1	1 (3.57)	0	0 (0.00)
Injection site haematoma	1	1 (3.57)	0	0 (0.00)
Non-cardiac chest pain	1	1 (3.57)	0	0 (0.00)
Oedema peripheral	1	1 (3.57)	0	0 (0.00)
Pain	1	1 (3.57)	1	1 (3.57)
Peripheral swelling	1	1 (3.57)	0	0 (0.00)
Hepatobiliary disorders				
- Total	4	2 (7.14)	1	1 (3.57)
Hepatomegaly	2	2 (7.14)	0	0 (0.00)
Hyperbilirubinaemia	2	1 (3.57)	1	1 (3.57)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Immune system disorders				
- Total	41	23 (82.14)	9	7 (25.00)
Cytokine release syndrome	28	20 (71.43)	8	6 (21.43)
Hypogammaglobulinaemia	11	10 (35.71)	1	1 (3.57)
Graft versus host disease in skin	1	1 (3.57)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (3.57)	0	0 (0.00)
Infections and infestations				
- Total	20	13 (46.43)	1	1 (3.57)
Clostridium difficile infection	3	3 (10.71)	0	0 (0.00)
Acute sinusitis	1	1 (3.57)	0	0 (0.00)
Body tinea	1	1 (3.57)	0	0 (0.00)
Catheter site cellulitis	1	1 (3.57)	0	0 (0.00)
Clostridium difficile colitis	1	1 (3.57)	0	0 (0.00)
Cytomegalovirus infection	1	1 (3.57)	0	0 (0.00)
Enterococcal infection	1	1 (3.57)	0	0 (0.00)
Fungal skin infection	1	1 (3.57)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (3.57)	0	0 (0.00)
Herpes simplex	1	1 (3.57)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (3.57)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Hypopyon	1	1 (3.57)	0	0 (0.00)
Influenza	1	1 (3.57)	0	0 (0.00)
Oral candidiasis	1	1 (3.57)	0	0 (0.00)
Rhinovirus infection	1	1 (3.57)	0	0 (0.00)
Septic embolus	1	1 (3.57)	1	1 (3.57)
Skin infection	1	1 (3.57)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (3.57)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	16	8 (28.57)	1	1 (3.57)
Transfusion reaction	4	3 (10.71)	0	0 (0.00)
Infusion related reaction	2	2 (7.14)	0	0 (0.00)
Procedural pain	2	2 (7.14)	0	0 (0.00)
Contusion	1	1 (3.57)	0	0 (0.00)
Limb injury	1	1 (3.57)	0	0 (0.00)
Mouth injury	1	1 (3.57)	0	0 (0.00)
Procedural headache	1	1 (3.57)	0	0 (0.00)
Procedural site reaction	1	1 (3.57)	0	0 (0.00)
Skin abrasion	1	1 (3.57)	0	0 (0.00)
Tongue injury	1	1 (3.57)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Transfusion related complication	1	1 (3.57)	1	1 (3.57)
Investigations				
- Total	171	23 (82.14)	88	18 (64.29)
White blood cell count decreased	27	15 (53.57)	17	14 (50.00)
Platelet count decreased	26	11 (39.29)	23	8 (28.57)
Aspartate aminotransferase increased	21	12 (42.86)	10	7 (25.00)
Neutrophil count decreased	20	12 (42.86)	19	11 (39.29)
Alanine aminotransferase increased	19	12 (42.86)	8	6 (21.43)
Blood bilirubin increased	11	6 (21.43)	2	2 (7.14)
Prothrombin time prolonged	9	6 (21.43)	0	0 (0.00)
Blood creatinine increased	8	6 (21.43)	1	1 (3.57)
Lymphocyte count decreased	8	6 (21.43)	6	5 (17.86)
International normalised ratio increased	5	5 (17.86)	0	0 (0.00)
Blood immunoglobulin A decreased	3	3 (10.71)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (10.71)	0	0 (0.00)
Activated partial thromboplastin time prolonged	2	2 (7.14)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (3.57)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Blood lactic acid increased	1	1 (3.57)	1	1 (3.57)
Blood urea increased	1	1 (3.57)	0	0 (0.00)
Culture stool positive	1	1 (3.57)	0	0 (0.00)
Haemoglobin decreased	1	1 (3.57)	1	1 (3.57)
Hepatic enzyme increased	1	1 (3.57)	0	0 (0.00)
Norovirus test positive	1	1 (3.57)	0	0 (0.00)
Pulmonary function test decreased	1	1 (3.57)	0	0 (0.00)
Serum ferritin increased	1	1 (3.57)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	50	17 (60.71)	16	7 (25.00)
Decreased appetite	12	9 (32.14)	6	5 (17.86)
Hyperphosphataemia	9	7 (25.00)	0	0 (0.00)
Hypokalaemia	8	7 (25.00)	3	3 (10.71)
Hypophosphataemia	6	4 (14.29)	3	3 (10.71)
Hyperuricaemia	3	2 (7.14)	0	0 (0.00)
Hypocalcaemia	3	2 (7.14)	1	1 (3.57)
Hyponatraemia	3	2 (7.14)	3	2 (7.14)
Fluid overload	2	2 (7.14)	0	0 (0.00)
Hypoalbuminaemia	2	2 (7.14)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Dehydration	1	1 (3.57)	0	0 (0.00)
Hyperglycaemia	1	1 (3.57)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	15	10 (35.71)	0	0 (0.00)
Myalgia	5	5 (17.86)	0	0 (0.00)
Pain in extremity	3	3 (10.71)	0	0 (0.00)
Arthralgia	2	2 (7.14)	0	0 (0.00)
Musculoskeletal pain	2	2 (7.14)	0	0 (0.00)
Coccydynia	1	1 (3.57)	0	0 (0.00)
Muscle spasms	1	1 (3.57)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.57)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.57)	0	0 (0.00)
Skin papilloma	1	1 (3.57)	0	0 (0.00)
Nervous system disorders				
- Total	28	15 (53.57)	5	4 (14.29)
Headache	19	12 (42.86)	2	2 (7.14)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Dizziness	3	3 (10.71)	0	0 (0.00)
Encephalopathy	2	2 (7.14)	1	1 (3.57)
Embolic stroke	1	1 (3.57)	1	1 (3.57)
Idiopathic intracranial hypertension	1	1 (3.57)	0	0 (0.00)
Myoclonus	1	1 (3.57)	0	0 (0.00)
Seizure	1	1 (3.57)	1	1 (3.57)
Product issues				
- Total	1	1 (3.57)	0	0 (0.00)
Device occlusion	1	1 (3.57)	0	0 (0.00)
Psychiatric disorders				
- Total	11	4 (14.29)	1	1 (3.57)
Anxiety	3	3 (10.71)	1	1 (3.57)
Agitation	2	1 (3.57)	0	0 (0.00)
Confusional state	2	2 (7.14)	0	0 (0.00)
Hallucination	2	1 (3.57)	0	0 (0.00)
Irritability	1	1 (3.57)	0	0 (0.00)
Listless	1	1 (3.57)	0	0 (0.00)
Renal and urinary disorders				

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
- Total	4	2 (7.14)	2	1 (3.57)
Acute kidney injury	2	2 (7.14)	1	1 (3.57)
Haematuria	1	1 (3.57)	0	0 (0.00)
Oliguria	1	1 (3.57)	1	1 (3.57)
Reproductive system and breast disorders				
- Total	3	2 (7.14)	0	0 (0.00)
Oedema genital	2	1 (3.57)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (3.57)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	30	13 (46.43)	7	4 (14.29)
Epistaxis	7	3 (10.71)	2	2 (7.14)
Hypoxia	6	5 (17.86)	2	2 (7.14)
Cough	4	4 (14.29)	0	0 (0.00)
Pleural effusion	3	3 (10.71)	0	0 (0.00)
Dyspnoea	2	1 (3.57)	1	1 (3.57)
Tachypnoea	2	2 (7.14)	1	1 (3.57)
Atelectasis	1	1 (3.57)	0	0 (0.00)
Oropharyngeal pain	1	1 (3.57)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Pulmonary oedema	1	1 (3.57)	1	1 (3.57)
Rhinitis allergic	1	1 (3.57)	0	0 (0.00)
Rhinorrhoea	1	1 (3.57)	0	0 (0.00)
Wheezing	1	1 (3.57)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	18	8 (28.57)	1	1 (3.57)
Ingrowing nail	3	2 (7.14)	0	0 (0.00)
Erythema	2	1 (3.57)	0	0 (0.00)
Petechiae	2	2 (7.14)	0	0 (0.00)
Rash	2	2 (7.14)	0	0 (0.00)
Dry skin	1	1 (3.57)	0	0 (0.00)
Hyperhidrosis	1	1 (3.57)	0	0 (0.00)
Night sweats	1	1 (3.57)	0	0 (0.00)
Pruritus	1	1 (3.57)	0	0 (0.00)
Rash follicular	1	1 (3.57)	0	0 (0.00)
Rash maculo-papular	1	1 (3.57)	1	1 (3.57)
Rash papular	1	1 (3.57)	0	0 (0.00)
Rash vesicular	1	1 (3.57)	0	0 (0.00)
Skin irritation	1	1 (3.57)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes				
Primary system organ class Preferred term	**All grades Total events**	**All patients N=28 n (%)[1]**	**Grade >= 3 Total events**	**All patients N=28 n (%)[2]**
Vascular disorders				
- Total	19	11 (39.29)	7	6 (21.43)
Hypotension	8	6 (21.43)	5	5 (17.86)
Hypertension	7	5 (17.86)	1	1 (3.57)
Orthostatic hypotension	2	2 (7.14)	0	0 (0.00)
Embolism	1	1 (3.57)	1	1 (3.57)
Flushing	1	1 (3.57)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Total number of AE per patient	703	36 (100.00)	278	32 (88.89)
Blood and lymphatic system disorders				
- Total	75	25 (69.44)	61	22 (61.11)
Anaemia	24	13 (36.11)	17	10 (27.78)
Thrombocytopenia	22	6 (16.67)	19	6 (16.67)
Febrile neutropenia	14	13 (36.11)	14	13 (36.11)
Neutropenia	8	7 (19.44)	7	7 (19.44)
Disseminated intravascular coagulation	4	3 (8.33)	2	2 (5.56)
Coagulopathy	1	1 (2.78)	0	0 (0.00)
Lymphopenia	1	1 (2.78)	1	1 (2.78)
Pancytopenia	1	1 (2.78)	1	1 (2.78)
Cardiac disorders				
- Total	17	12 (33.33)	2	1 (2.78)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Tachycardia	9	8 (22.22)	1	1 (2.78)
Pericardial effusion	2	2 (5.56)	0	0 (0.00)
Atrioventricular block second degree	1	1 (2.78)	0	0 (0.00)
Bradycardia	1	1 (2.78)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.78)	1	1 (2.78)
Palpitations	1	1 (2.78)	0	0 (0.00)
Sinus tachycardia	1	1 (2.78)	0	0 (0.00)
Ventricular tachycardia	1	1 (2.78)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.78)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.78)	0	0 (0.00)
Eye disorders				
- Total	13	6 (16.67)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (8.33)	0	0 (0.00)
Periorbital oedema	3	3 (8.33)	0	0 (0.00)
Vision blurred	3	2 (5.56)	0	0 (0.00)
Eye pain	2	1 (2.78)	0	0 (0.00)
Retinal haemorrhage	2	2 (5.56)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Gastrointestinal disorders				
- Total	61	19 (52.78)	10	7 (19.44)
Vomiting	19	12 (33.33)	1	1 (2.78)
Nausea	13	9 (25.00)	2	2 (5.56)
Diarrhoea	8	8 (22.22)	1	1 (2.78)
Constipation	5	5 (13.89)	0	0 (0.00)
Abdominal pain	2	2 (5.56)	1	1 (2.78)
Abdominal pain upper	2	2 (5.56)	0	0 (0.00)
Dysphagia	2	2 (5.56)	1	1 (2.78)
Pancreatitis	2	2 (5.56)	1	1 (2.78)
Abdominal discomfort	1	1 (2.78)	0	0 (0.00)
Ascites	1	1 (2.78)	1	1 (2.78)
Dyspepsia	1	1 (2.78)	0	0 (0.00)
Flatulence	1	1 (2.78)	0	0 (0.00)
Haematemesis	1	1 (2.78)	0	0 (0.00)
Ileus	1	1 (2.78)	1	1 (2.78)
Intestinal obstruction	1	1 (2.78)	1	1 (2.78)
Tooth socket haemorrhage	1	1 (2.78)	0	0 (0.00)
General disorders and administration site conditions				

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
- Total	40	18 (50.00)	11	8 (22.22)
Pyrexia	17	10 (27.78)	5	5 (13.89)
Chills	5	5 (13.89)	0	0 (0.00)
Fatigue	5	5 (13.89)	0	0 (0.00)
Catheter site pain	2	2 (5.56)	0	0 (0.00)
Pain	2	2 (5.56)	1	1 (2.78)
Asthenia	1	1 (2.78)	0	0 (0.00)
Face oedema	1	1 (2.78)	1	1 (2.78)
Generalised oedema	1	1 (2.78)	0	0 (0.00)
Localised oedema	1	1 (2.78)	1	1 (2.78)
Malaise	1	1 (2.78)	0	0 (0.00)
Mucosal haemorrhage	1	1 (2.78)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.78)	1	1 (2.78)
Oedema peripheral	1	1 (2.78)	1	1 (2.78)
Physical deconditioning	1	1 (2.78)	1	1 (2.78)
Hepatobiliary disorders				
- Total	5	5 (13.89)	1	1 (2.78)
Hyperbilirubinaemia	2	2 (5.56)	1	1 (2.78)
Gallbladder enlargement	1	1 (2.78)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Hepatomegaly	1	1 (2.78)	0	0 (0.00)
Hepatosplenomegaly	1	1 (2.78)	0	0 (0.00)
Immune system disorders				
- Total	75	34 (94.44)	24	15 (41.67)
Cytokine release syndrome	58	30 (83.33)	21	13 (36.11)
Hypogammaglobulinaemia	16	16 (44.44)	3	3 (8.33)
Drug hypersensitivity	1	1 (2.78)	0	0 (0.00)
Infections and infestations				
- Total	21	13 (36.11)	6	6 (16.67)
Clostridium difficile colitis	3	3 (8.33)	1	1 (2.78)
Gastroenteritis	2	2 (5.56)	1	1 (2.78)
Pneumonia	2	2 (5.56)	1	1 (2.78)
Rhinovirus infection	2	2 (5.56)	0	0 (0.00)
Staphylococcal infection	2	2 (5.56)	1	1 (2.78)
Catheter site infection	1	1 (2.78)	1	1 (2.78)
Clostridium difficile infection	1	1 (2.78)	0	0 (0.00)
Folliculitis	1	1 (2.78)	0	0 (0.00)
Orchitis	1	1 (2.78)	0	0 (0.00)
Pharyngitis	1	1 (2.78)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Streptococcal infection	1	1 (2.78)	0	0 (0.00)
Upper respiratory tract infection	1	1 (2.78)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (2.78)	1	1 (2.78)
Viral infection	1	1 (2.78)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (2.78)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	9	7 (19.44)	1	1 (2.78)
Tracheal haemorrhage	2	1 (2.78)	1	1 (2.78)
Incision site pain	1	1 (2.78)	0	0 (0.00)
Post procedural haemorrhage	1	1 (2.78)	0	0 (0.00)
Procedural complication	1	1 (2.78)	0	0 (0.00)
Procedural pain	1	1 (2.78)	0	0 (0.00)
Stoma site irritation	1	1 (2.78)	0	0 (0.00)
Subdural haemorrhage	1	1 (2.78)	0	0 (0.00)
Tibia fracture	1	1 (2.78)	0	0 (0.00)
Investigations				
- Total	161	29 (80.56)	90	26 (72.22)
White blood cell count decreased	28	15 (41.67)	20	12 (33.33)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Neutrophil count decreased	27	13 (36.11)	25	12 (33.33)
Platelet count decreased	17	8 (22.22)	14	6 (16.67)
Blood fibrinogen decreased	15	4 (11.11)	4	3 (8.33)
Aspartate aminotransferase increased	11	6 (16.67)	6	4 (11.11)
Alanine aminotransferase increased	9	7 (19.44)	6	5 (13.89)
Lymphocyte count decreased	8	8 (22.22)	6	6 (16.67)
Prothrombin time prolonged	8	3 (8.33)	1	1 (2.78)
Activated partial thromboplastin time prolonged	6	3 (8.33)	0	0 (0.00)
International normalised ratio increased	6	4 (11.11)	1	1 (2.78)
Blood creatinine increased	3	3 (8.33)	1	1 (2.78)
Blood phosphorus increased	3	2 (5.56)	0	0 (0.00)
Blood bilirubin increased	2	1 (2.78)	0	0 (0.00)
Blood sodium increased	2	1 (2.78)	0	0 (0.00)
Blood urea increased	2	2 (5.56)	1	1 (2.78)
Blood uric acid increased	2	1 (2.78)	0	0 (0.00)
Lipase increased	2	2 (5.56)	2	2 (5.56)
Transaminases increased	2	2 (5.56)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.78)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Blood immunoglobulin M decreased	1	1 (2.78)	0	0 (0.00)
Blood magnesium decreased	1	1 (2.78)	1	1 (2.78)
Blood phosphorus decreased	1	1 (2.78)	0	0 (0.00)
C-reactive protein increased	1	1 (2.78)	1	1 (2.78)
Cardiac murmur	1	1 (2.78)	0	0 (0.00)
Fibrin D dimer increased	1	1 (2.78)	0	0 (0.00)
Protein total decreased	1	1 (2.78)	1	1 (2.78)
Metabolism and nutrition disorders				
- Total	66	22 (61.11)	27	17 (47.22)
Decreased appetite	12	11 (30.56)	7	7 (19.44)
Hypokalaemia	12	9 (25.00)	4	4 (11.11)
Hypernatraemia	7	4 (11.11)	1	1 (2.78)
Hypophosphataemia	7	5 (13.89)	6	4 (11.11)
Hypoalbuminaemia	4	3 (8.33)	1	1 (2.78)
Hyperglycaemia	3	2 (5.56)	1	1 (2.78)
Hypertriglyceridaemia	3	2 (5.56)	1	1 (2.78)
Acidosis	2	2 (5.56)	1	1 (2.78)
Dehydration	2	2 (5.56)	2	2 (5.56)
Hypercalcaemia	2	1 (2.78)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Fluid overload	1	1 (2.78)	0	0 (0.00)
Hyperalbuminaemia	1	1 (2.78)	0	0 (0.00)
Hyperchloraemia	1	1 (2.78)	0	0 (0.00)
Hypermagnesaemia	1	1 (2.78)	0	0 (0.00)
Hyperphosphataemia	1	1 (2.78)	0	0 (0.00)
Hyperuricaemia	1	1 (2.78)	1	1 (2.78)
Hypocalcaemia	1	1 (2.78)	0	0 (0.00)
Hypomagnesaemia	1	1 (2.78)	0	0 (0.00)
Malnutrition	1	1 (2.78)	1	1 (2.78)
Metabolic acidosis	1	1 (2.78)	0	0 (0.00)
Metabolic alkalosis	1	1 (2.78)	0	0 (0.00)
Tumour lysis syndrome	1	1 (2.78)	1	1 (2.78)
Musculoskeletal and connective tissue disorders				
- Total	8	5 (13.89)	1	1 (2.78)
Arthralgia	2	2 (5.56)	1	1 (2.78)
Musculoskeletal pain	2	1 (2.78)	0	0 (0.00)
Limb discomfort	1	1 (2.78)	0	0 (0.00)
Muscular weakness	1	1 (2.78)	0	0 (0.00)
Osteopenia	1	1 (2.78)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Pain in extremity	1	1 (2.78)	0	0 (0.00)
Nervous system disorders				
- Total	30	18 (50.00)	1	1 (2.78)
Headache	12	12 (33.33)	0	0 (0.00)
Encephalopathy	4	2 (5.56)	1	1 (2.78)
Dysarthria	2	2 (5.56)	0	0 (0.00)
Seizure	2	2 (5.56)	0	0 (0.00)
Tremor	2	2 (5.56)	0	0 (0.00)
Asterixis	1	1 (2.78)	0	0 (0.00)
Ataxia	1	1 (2.78)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.78)	0	0 (0.00)
Dizziness	1	1 (2.78)	0	0 (0.00)
Migraine	1	1 (2.78)	0	0 (0.00)
Neuropathy peripheral	1	1 (2.78)	0	0 (0.00)
Pleocytosis	1	1 (2.78)	0	0 (0.00)
Somnolence	1	1 (2.78)	0	0 (0.00)
Psychiatric disorders				
- Total	19	12 (33.33)	0	0 (0.00)
Confusional state	4	4 (11.11)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Delirium	4	4 (11.11)	0	0 (0.00)
Anxiety	3	3 (8.33)	0	0 (0.00)
Adjustment disorder	1	1 (2.78)	0	0 (0.00)
Agitation	1	1 (2.78)	0	0 (0.00)
Hallucination	1	1 (2.78)	0	0 (0.00)
Insomnia	1	1 (2.78)	0	0 (0.00)
Irritability	1	1 (2.78)	0	0 (0.00)
Mental status changes	1	1 (2.78)	0	0 (0.00)
Panic attack	1	1 (2.78)	0	0 (0.00)
Suicidal ideation	1	1 (2.78)	0	0 (0.00)
Renal and urinary disorders				
- Total	14	9 (25.00)	9	6 (16.67)
Acute kidney injury	5	5 (13.89)	4	4 (11.11)
Haematuria	3	3 (8.33)	2	2 (5.56)
Dysuria	2	2 (5.56)	0	0 (0.00)
Oliguria	1	1 (2.78)	1	1 (2.78)
Pollakiuria	1	1 (2.78)	0	0 (0.00)
Renal failure	1	1 (2.78)	1	1 (2.78)
Renal impairment	1	1 (2.78)	1	1 (2.78)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Reproductive system and breast disorders				
- Total	1	1 (2.78)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (2.78)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	43	15 (41.67)	21	8 (22.22)
Hypoxia	7	5 (13.89)	6	5 (13.89)
Pleural effusion	5	5 (13.89)	2	2 (5.56)
Pulmonary oedema	5	5 (13.89)	4	4 (11.11)
Cough	4	4 (11.11)	0	0 (0.00)
Epistaxis	4	4 (11.11)	2	2 (5.56)
Tachypnoea	4	3 (8.33)	0	0 (0.00)
Haemoptysis	3	2 (5.56)	1	1 (2.78)
Respiratory failure	3	3 (8.33)	3	3 (8.33)
Dyspnoea	1	1 (2.78)	1	1 (2.78)
Interstitial lung disease	1	1 (2.78)	1	1 (2.78)
Nasal congestion	1	1 (2.78)	0	0 (0.00)
Oropharyngeal pain	1	1 (2.78)	0	0 (0.00)
Oropharyngeal plaque	1	1 (2.78)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Pharyngeal ulceration	1	1 (2.78)	0	0 (0.00)
Respiratory depression	1	1 (2.78)	0	0 (0.00)
Respiratory distress	1	1 (2.78)	1	1 (2.78)
Skin and subcutaneous tissue disorders				
- Total	23	13 (36.11)	1	1 (2.78)
Dry skin	3	3 (8.33)	0	0 (0.00)
Hyperhidrosis	3	2 (5.56)	0	0 (0.00)
Erythema	2	2 (5.56)	0	0 (0.00)
Rash	2	2 (5.56)	0	0 (0.00)
Rash maculo-papular	2	2 (5.56)	0	0 (0.00)
Dermatitis diaper	1	1 (2.78)	0	0 (0.00)
Ecchymosis	1	1 (2.78)	1	1 (2.78)
Livedo reticularis	1	1 (2.78)	0	0 (0.00)
Macule	1	1 (2.78)	0	0 (0.00)
Petechiae	1	1 (2.78)	0	0 (0.00)
Pruritus	1	1 (2.78)	0	0 (0.00)
Rash erythematous	1	1 (2.78)	0	0 (0.00)
Rash macular	1	1 (2.78)	0	0 (0.00)
Rash papular	1	1 (2.78)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Skin exfoliation	1	1 (2.78)	0	0 (0.00)
Skin fissures	1	1 (2.78)	0	0 (0.00)
Vascular disorders				
- Total	21	13 (36.11)	12	10 (27.78)
Hypotension	11	10 (27.78)	11	10 (27.78)
Hypertension	5	5 (13.89)	0	0 (0.00)
Flushing	2	1 (2.78)	0	0 (0.00)
Capillary leak syndrome	1	1 (2.78)	1	1 (2.78)
Haematoma	1	1 (2.78)	0	0 (0.00)
Secondary hypertension	1	1 (2.78)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Total number of AE per patient	176	19 (76.00)	31	11 (44.00)
Blood and lymphatic system disorders				
- Total	8	5 (20.00)	5	3 (12.00)
Anaemia	2	2 (8.00)	1	1 (4.00)
Eosinophilia	2	1 (4.00)	1	1 (4.00)
Febrile neutropenia	1	1 (4.00)	1	1 (4.00)
Lymphopenia	1	1 (4.00)	0	0 (0.00)
Neutropenia	1	1 (4.00)	1	1 (4.00)
Thrombocytopenia	1	1 (4.00)	1	1 (4.00)
Cardiac disorders				
- Total	1	1 (4.00)	0	0 (0.00)
Sinus tachycardia	1	1 (4.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Eye disorders				
- Total	3	3 (12.00)	0	0 (0.00)
Dry eye	2	2 (8.00)	0	0 (0.00)
Ocular hyperaemia	1	1 (4.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	20	9 (36.00)	2	1 (4.00)
Vomiting	8	5 (20.00)	1	1 (4.00)
Nausea	5	4 (16.00)	1	1 (4.00)
Diarrhoea	3	3 (12.00)	0	0 (0.00)
Abdominal pain	2	2 (8.00)	0	0 (0.00)
Abdominal pain upper	1	1 (4.00)	0	0 (0.00)
Pigmentation lip	1	1 (4.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	19	10 (40.00)	0	0 (0.00)
Pyrexia	10	6 (24.00)	0	0 (0.00)
Influenza like illness	2	2 (8.00)	0	0 (0.00)
Acquired gene mutation	1	1 (4.00)	0	0 (0.00)
Chills	1	1 (4.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Crying	1	1 (4.00)	0	0 (0.00)
Fatigue	1	1 (4.00)	0	0 (0.00)
Generalised oedema	1	1 (4.00)	0	0 (0.00)
Oedema peripheral	1	1 (4.00)	0	0 (0.00)
Pain	1	1 (4.00)	0	0 (0.00)
Immune system disorders				
- Total	9	7 (28.00)	0	0 (0.00)
Hypogammaglobulinaemia	6	5 (20.00)	0	0 (0.00)
Graft versus host disease	1	1 (4.00)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (4.00)	0	0 (0.00)
Immunodeficiency common variable	1	1 (4.00)	0	0 (0.00)
Infections and infestations				
- Total	29	13 (52.00)	11	7 (28.00)
Cellulitis of male external genital organ	5	1 (4.00)	2	1 (4.00)
Urinary tract infection	4	3 (12.00)	2	2 (8.00)
Upper respiratory tract infection	3	3 (12.00)	1	1 (4.00)
Otitis media	2	1 (4.00)	0	0 (0.00)
Cholecystitis infective	1	1 (4.00)	1	1 (4.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Cytomegalovirus infection	1	1 (4.00)	0	0 (0.00)
Ear infection	1	1 (4.00)	0	0 (0.00)
Enterovirus infection	1	1 (4.00)	1	1 (4.00)
Escherichia urinary tract infection	1	1 (4.00)	1	1 (4.00)
Gastroenteritis norovirus	1	1 (4.00)	0	0 (0.00)
Influenza	1	1 (4.00)	0	0 (0.00)
Oral herpes	1	1 (4.00)	0	0 (0.00)
Otitis media acute	1	1 (4.00)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (4.00)	0	0 (0.00)
Rhinitis	1	1 (4.00)	0	0 (0.00)
Rotavirus infection	1	1 (4.00)	1	1 (4.00)
Sepsis	1	1 (4.00)	1	1 (4.00)
Sinusitis	1	1 (4.00)	0	0 (0.00)
Vascular device infection	1	1 (4.00)	1	1 (4.00)
Injury, poisoning and procedural complications				
- Total	3	3 (12.00)	0	0 (0.00)
Contusion	1	1 (4.00)	0	0 (0.00)
Foot fracture	1	1 (4.00)	0	0 (0.00)
Skin laceration	1	1 (4.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Investigations				
- Total	27	10 (40.00)	7	5 (20.00)
Neutrophil count decreased	6	5 (20.00)	4	3 (12.00)
Platelet count decreased	5	3 (12.00)	0	0 (0.00)
Aspartate aminotransferase increased	3	3 (12.00)	2	2 (8.00)
Haemoglobin decreased	2	2 (8.00)	0	0 (0.00)
Lymphocyte count decreased	2	2 (8.00)	0	0 (0.00)
Weight increased	2	2 (8.00)	0	0 (0.00)
White blood cell count decreased	2	2 (8.00)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (4.00)	1	1 (4.00)
Blood creatinine increased	1	1 (4.00)	0	0 (0.00)
Blood uric acid increased	1	1 (4.00)	0	0 (0.00)
Transaminases increased	1	1 (4.00)	0	0 (0.00)
Weight decreased	1	1 (4.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	10	7 (28.00)	4	2 (8.00)
Decreased appetite	2	2 (8.00)	0	0 (0.00)
Hyperphosphataemia	2	2 (8.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Hypokalaemia	2	2 (8.00)	1	1 (4.00)
Dehydration	1	1 (4.00)	1	1 (4.00)
Hyperglycaemia	1	1 (4.00)	1	1 (4.00)
Hypophosphataemia	1	1 (4.00)	1	1 (4.00)
Vitamin D deficiency	1	1 (4.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	10	7 (28.00)	0	0 (0.00)
Pain in extremity	3	3 (12.00)	0	0 (0.00)
Joint range of motion decreased	2	2 (8.00)	0	0 (0.00)
Back pain	1	1 (4.00)	0	0 (0.00)
Flank pain	1	1 (4.00)	0	0 (0.00)
Muscle spasms	1	1 (4.00)	0	0 (0.00)
Muscular weakness	1	1 (4.00)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (4.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (4.00)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (4.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Nervous system disorders				
- Total	8	4 (16.00)	0	0 (0.00)
Headache	5	3 (12.00)	0	0 (0.00)
Dizziness	2	2 (8.00)	0	0 (0.00)
Peroneal nerve palsy	1	1 (4.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	4	2 (8.00)	2	1 (4.00)
Calculus urinary	1	1 (4.00)	0	0 (0.00)
Haematuria	1	1 (4.00)	1	1 (4.00)
Nephrolithiasis	1	1 (4.00)	1	1 (4.00)
Urinary incontinence	1	1 (4.00)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (4.00)	0	0 (0.00)
Scrotal pain	1	1 (4.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	10	6 (24.00)	0	0 (0.00)
Cough	5	4 (16.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Rhinitis allergic	2	2 (8.00)	0	0 (0.00)
Epistaxis	1	1 (4.00)	0	0 (0.00)
Nasal congestion	1	1 (4.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (4.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	13	8 (32.00)	0	0 (0.00)
Rash	3	2 (8.00)	0	0 (0.00)
Rash maculo-papular	2	2 (8.00)	0	0 (0.00)
Dermatitis atopic	1	1 (4.00)	0	0 (0.00)
Dry skin	1	1 (4.00)	0	0 (0.00)
Erythema	1	1 (4.00)	0	0 (0.00)
Hyperhidrosis	1	1 (4.00)	0	0 (0.00)
Macule	1	1 (4.00)	0	0 (0.00)
Petechiae	1	1 (4.00)	0	0 (0.00)
Pruritus	1	1 (4.00)	0	0 (0.00)
Rash pruritic	1	1 (4.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Total number of AE per patient	170	27 (87.10)	40	15 (48.39)
Blood and lymphatic system disorders				
- Total	10	6 (19.35)	8	4 (12.90)
Neutropenia	5	3 (9.68)	5	3 (9.68)
Febrile neutropenia	2	2 (6.45)	2	2 (6.45)
Leukopenia	1	1 (3.23)	1	1 (3.23)
Lymphadenopathy	1	1 (3.23)	0	0 (0.00)
Thrombocytopenia	1	1 (3.23)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.23)	0	0 (0.00)
Eye disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
- Total	2	2 (6.45)	0	0 (0.00)
Conjunctivitis allergic	1	1 (3.23)	0	0 (0.00)
Vision blurred	1	1 (3.23)	0	0 (0.00)
Gastrointestinal disorders				
- Total	18	7 (22.58)	6	3 (9.68)
Diarrhoea	5	5 (16.13)	1	1 (3.23)
Vomiting	5	4 (12.90)	1	1 (3.23)
Oral pain	3	2 (6.45)	1	1 (3.23)
Abdominal pain	2	2 (6.45)	1	1 (3.23)
Nausea	2	2 (6.45)	1	1 (3.23)
Enterocolitis	1	1 (3.23)	1	1 (3.23)
General disorders and administration site conditions				
- Total	7	7 (22.58)	1	1 (3.23)
Pyrexia	4	4 (12.90)	1	1 (3.23)
Catheter site pain	1	1 (3.23)	0	0 (0.00)
Fatigue	1	1 (3.23)	0	0 (0.00)
Malaise	1	1 (3.23)	0	0 (0.00)
Immune system disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
- Total	8	7 (22.58)	1	1 (3.23)
Hypogammaglobulinaemia	3	3 (9.68)	1	1 (3.23)
Graft versus host disease	2	1 (3.23)	0	0 (0.00)
Seasonal allergy	2	2 (6.45)	0	0 (0.00)
Immunodeficiency common variable	1	1 (3.23)	0	0 (0.00)
Infections and infestations				
- Total	32	20 (64.52)	6	5 (16.13)
Rhinovirus infection	4	2 (6.45)	0	0 (0.00)
Upper respiratory tract infection	4	4 (12.90)	0	0 (0.00)
Gastroenteritis	3	3 (9.68)	0	0 (0.00)
Influenza	2	2 (6.45)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (6.45)	1	1 (3.23)
Bacterial sepsis	1	1 (3.23)	1	1 (3.23)
Corona virus infection	1	1 (3.23)	1	1 (3.23)
Ear infection	1	1 (3.23)	0	0 (0.00)
Gastroenteritis viral	1	1 (3.23)	0	0 (0.00)
Herpes zoster	1	1 (3.23)	1	1 (3.23)
Molluscum contagiosum	1	1 (3.23)	0	0 (0.00)
Otitis externa	1	1 (3.23)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Parainfluenzae virus infection	1	1 (3.23)	1	1 (3.23)
Paronychia	1	1 (3.23)	0	0 (0.00)
Rash pustular	1	1 (3.23)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (3.23)	1	1 (3.23)
Sinusitis	1	1 (3.23)	0	0 (0.00)
Subcutaneous abscess	1	1 (3.23)	0	0 (0.00)
Tinea capitis	1	1 (3.23)	0	0 (0.00)
Urinary tract infection	1	1 (3.23)	0	0 (0.00)
Viral infection	1	1 (3.23)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (3.23)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	10	5 (16.13)	0	0 (0.00)
Infusion related reaction	2	2 (6.45)	0	0 (0.00)
Procedural pain	2	2 (6.45)	0	0 (0.00)
Arthropod bite	1	1 (3.23)	0	0 (0.00)
Contusion	1	1 (3.23)	0	0 (0.00)
Procedural nausea	1	1 (3.23)	0	0 (0.00)
Radius fracture	1	1 (3.23)	0	0 (0.00)
Skin abrasion	1	1 (3.23)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Sunburn	1	1 (3.23)	0	0 (0.00)
Investigations				
- Total	21	13 (41.94)	9	7 (22.58)
Neutrophil count decreased	6	3 (9.68)	4	3 (9.68)
White blood cell count decreased	5	3 (9.68)	3	2 (6.45)
Weight decreased	3	3 (9.68)	0	0 (0.00)
Blood urea increased	2	1 (3.23)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (3.23)	1	1 (3.23)
Blood bilirubin increased	1	1 (3.23)	1	1 (3.23)
Blood magnesium decreased	1	1 (3.23)	0	0 (0.00)
Oxygen saturation decreased	1	1 (3.23)	0	0 (0.00)
Serum ferritin increased	1	1 (3.23)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	5	3 (9.68)	2	2 (6.45)
Hyperalbuminaemia	2	1 (3.23)	0	0 (0.00)
Hypercalcaemia	1	1 (3.23)	0	0 (0.00)
Iron overload	1	1 (3.23)	1	1 (3.23)
Tumour lysis syndrome	1	1 (3.23)	1	1 (3.23)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	11	9 (29.03)	0	0 (0.00)
Pain in extremity	5	5 (16.13)	0	0 (0.00)
Arthralgia	2	2 (6.45)	0	0 (0.00)
Muscular weakness	1	1 (3.23)	0	0 (0.00)
Osteonecrosis	1	1 (3.23)	0	0 (0.00)
Pain in jaw	1	1 (3.23)	0	0 (0.00)
Toe walking	1	1 (3.23)	0	0 (0.00)
Nervous system disorders				
- Total	4	4 (12.90)	0	0 (0.00)
Headache	2	2 (6.45)	0	0 (0.00)
Dizziness	1	1 (3.23)	0	0 (0.00)
Peroneal nerve palsy	1	1 (3.23)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (6.45)	0	0 (0.00)
Depression	2	2 (6.45)	0	0 (0.00)
Anxiety	1	1 (3.23)	0	0 (0.00)
Sleep disorder	1	1 (3.23)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Renal and urinary disorders				
- Total	1	1 (3.23)	1	1 (3.23)
Acute kidney injury	1	1 (3.23)	1	1 (3.23)
Reproductive system and breast disorders				
- Total	1	1 (3.23)	1	1 (3.23)
Vaginal haemorrhage	1	1 (3.23)	1	1 (3.23)
Respiratory, thoracic and mediastinal disorders				
- Total	20	12 (38.71)	4	3 (9.68)
Cough	4	3 (9.68)	0	0 (0.00)
Rhinorrhoea	4	4 (12.90)	0	0 (0.00)
Nasal congestion	3	3 (9.68)	0	0 (0.00)
Oropharyngeal pain	2	2 (6.45)	0	0 (0.00)
Acute respiratory failure	1	1 (3.23)	1	1 (3.23)
Dysphonia	1	1 (3.23)	0	0 (0.00)
Epistaxis	1	1 (3.23)	1	1 (3.23)
Pharyngeal erythema	1	1 (3.23)	0	0 (0.00)
Pharyngeal lesion	1	1 (3.23)	1	1 (3.23)
Pulmonary oedema	1	1 (3.23)	1	1 (3.23)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Rhinitis allergic	1	1 (3.23)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	12	8 (25.81)	1	1 (3.23)
Rash	2	2 (6.45)	0	0 (0.00)
Rash erythematous	2	1 (3.23)	0	0 (0.00)
Alopecia	1	1 (3.23)	0	0 (0.00)
Dermatitis	1	1 (3.23)	0	0 (0.00)
Dermatitis acneiform	1	1 (3.23)	1	1 (3.23)
Eczema	1	1 (3.23)	0	0 (0.00)
Erythema	1	1 (3.23)	0	0 (0.00)
Ingrowing nail	1	1 (3.23)	0	0 (0.00)
Keloid scar	1	1 (3.23)	0	0 (0.00)
Papule	1	1 (3.23)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (6.45)	0	0 (0.00)
Hypertension	2	2 (6.45)	0	0 (0.00)
Hot flush	1	1 (3.23)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Total number of AE per patient	53	11 (78.57)	12	6 (42.86)
Blood and lymphatic system disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Thrombocytopenia	1	1 (7.14)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Tympanic membrane perforation	1	1 (7.14)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	2 (14.29)	0	0 (0.00)
Diarrhoea	2	2 (14.29)	0	0 (0.00)
Abdominal pain	1	1 (7.14)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
General disorders and administration site conditions				
- Total	1	1 (7.14)	1	1 (7.14)
Cyst	1	1 (7.14)	1	1 (7.14)
Infections and infestations				
- Total	24	6 (42.86)	6	3 (21.43)
Otitis media	4	2 (14.29)	1	1 (7.14)
Otitis media acute	4	2 (14.29)	0	0 (0.00)
Upper respiratory tract infection	4	2 (14.29)	0	0 (0.00)
Urinary tract infection	3	2 (14.29)	1	1 (7.14)
Sinusitis	2	2 (14.29)	0	0 (0.00)
Campylobacter infection	1	1 (7.14)	1	1 (7.14)
Cellulitis of male external genital organ	1	1 (7.14)	1	1 (7.14)
Clostridium difficile infection	1	1 (7.14)	1	1 (7.14)
Haemophilus infection	1	1 (7.14)	0	0 (0.00)
Pneumonia	1	1 (7.14)	0	0 (0.00)
Respiratory tract infection viral	1	1 (7.14)	1	1 (7.14)
Vulvovaginal candidiasis	1	1 (7.14)	0	0 (0.00)
Investigations				

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=14** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=14** **n (%)[2]**
- Total	10	3 (21.43)	2	1 (7.14)
Lymphocyte count decreased	3	2 (14.29)	0	0 (0.00)
Neutrophil count decreased	3	2 (14.29)	0	0 (0.00)
White blood cell count decreased	2	1 (7.14)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (7.14)	1	1 (7.14)
Aspartate aminotransferase increased	1	1 (7.14)	1	1 (7.14)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Neck pain	1	1 (7.14)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (7.14)	1	1 (7.14)
Glioblastoma multiforme	1	1 (7.14)	1	1 (7.14)
Nervous system disorders				
- Total	3	2 (14.29)	1	1 (7.14)
Dizziness	1	1 (7.14)	0	0 (0.00)
Headache	1	1 (7.14)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Seizure	1	1 (7.14)	1	1 (7.14)
Renal and urinary disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Haematuria	1	1 (7.14)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (7.14)	1	1 (7.14)
Ovarian failure	1	1 (7.14)	1	1 (7.14)
Respiratory, thoracic and mediastinal disorders				
- Total	6	3 (21.43)	0	0 (0.00)
Cough	2	1 (7.14)	0	0 (0.00)
Epistaxis	1	1 (7.14)	0	0 (0.00)
Oropharyngeal pain	1	1 (7.14)	0	0 (0.00)
Rhinitis allergic	1	1 (7.14)	0	0 (0.00)
Rhinorrhoea	1	1 (7.14)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.

1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	37	11 (55.00)	11	6 (30.00)
Blood and lymphatic system disorders				
- Total	1	1 (5.00)	1	1 (5.00)
Febrile neutropenia	1	1 (5.00)	1	1 (5.00)
Gastrointestinal disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Nausea	1	1 (5.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	1 (5.00)	0	0 (0.00)
Pyrexia	2	1 (5.00)	0	0 (0.00)
Chills	1	1 (5.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=20** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=20** **n (%)[2]**
Immune system disorders				
- Total	2	2 (10.00)	0	0 (0.00)
Chronic graft versus host disease	1	1 (5.00)	0	0 (0.00)
Immunodeficiency	1	1 (5.00)	0	0 (0.00)
Infections and infestations				
- Total	8	5 (25.00)	1	1 (5.00)
Gingivitis	1	1 (5.00)	0	0 (0.00)
Meningitis aseptic	1	1 (5.00)	0	0 (0.00)
Otitis media	1	1 (5.00)	0	0 (0.00)
Pneumonia	1	1 (5.00)	0	0 (0.00)
Respiratory tract infection	1	1 (5.00)	1	1 (5.00)
Sinusitis	1	1 (5.00)	0	0 (0.00)
Skin infection	1	1 (5.00)	0	0 (0.00)
Viral infection	1	1 (5.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (5.00)	1	1 (5.00)
Procedural pain	1	1 (5.00)	1	1 (5.00)
Investigations				

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=20** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=20** **n (%)[2]**
- Total	12	5 (25.00)	6	4 (20.00)
White blood cell count decreased	3	3 (15.00)	3	3 (15.00)
Alanine aminotransferase increased	2	2 (10.00)	1	1 (5.00)
Lymphocyte count decreased	2	1 (5.00)	1	1 (5.00)
Aspartate aminotransferase increased	1	1 (5.00)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (5.00)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (5.00)	0	0 (0.00)
C-reactive protein increased	1	1 (5.00)	0	0 (0.00)
Platelet count decreased	1	1 (5.00)	1	1 (5.00)
Metabolism and nutrition disorders				
- Total	2	2 (10.00)	1	1 (5.00)
Hypokalaemia	1	1 (5.00)	1	1 (5.00)
Vitamin D deficiency	1	1 (5.00)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Disturbance in attention	1	1 (5.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Renal and urinary disorders				
- Total	2	1 (5.00)	1	1 (5.00)
Acute kidney injury	2	1 (5.00)	1	1 (5.00)
Respiratory, thoracic and mediastinal disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Cough	1	1 (5.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (15.00)	0	0 (0.00)
Acne	1	1 (5.00)	0	0 (0.00)
Papule	1	1 (5.00)	0	0 (0.00)
Pruritus	1	1 (5.00)	0	0 (0.00)

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Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Total number of AE per patient	840	28 (100.00)	223	26 (92.86)
Blood and lymphatic system disorders				
- Total	56	20 (71.43)	37	19 (67.86)
Anaemia	25	14 (50.00)	15	10 (35.71)
Febrile neutropenia	13	10 (35.71)	13	10 (35.71)
Thrombocytopenia	10	3 (10.71)	5	3 (10.71)
Lymphopenia	3	3 (10.71)	1	1 (3.57)
Eosinophilia	2	1 (3.57)	1	1 (3.57)
Neutropenia	2	2 (7.14)	2	2 (7.14)
Disseminated intravascular coagulation	1	1 (3.57)	0	0 (0.00)
Cardiac disorders				

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
- Total	16	11 (39.29)	1	1 (3.57)
Tachycardia	8	7 (25.00)	1	1 (3.57)
Sinus tachycardia	5	5 (17.86)	0	0 (0.00)
Sinus bradycardia	2	1 (3.57)	0	0 (0.00)
Cardiac dysfunction	1	1 (3.57)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	4	4 (14.29)	0	0 (0.00)
Ear pain	2	2 (7.14)	0	0 (0.00)
Hypoacusis	1	1 (3.57)	0	0 (0.00)
Tympanic membrane perforation	1	1 (3.57)	0	0 (0.00)
Eye disorders				
- Total	15	10 (35.71)	0	0 (0.00)
Photophobia	3	2 (7.14)	0	0 (0.00)
Dry eye	2	2 (7.14)	0	0 (0.00)
Eye pain	2	2 (7.14)	0	0 (0.00)
Uveitis	2	2 (7.14)	0	0 (0.00)
Ocular hyperaemia	1	1 (3.57)	0	0 (0.00)
Ocular hypertension	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Papilloedema	1	1 (3.57)	0	0 (0.00)
Periorbital oedema	1	1 (3.57)	0	0 (0.00)
Vision blurred	1	1 (3.57)	0	0 (0.00)
Visual impairment	1	1 (3.57)	0	0 (0.00)
Gastrointestinal disorders				
- Total	88	20 (71.43)	7	4 (14.29)
Vomiting	24	13 (46.43)	3	2 (7.14)
Nausea	18	14 (50.00)	2	2 (7.14)
Diarrhoea	15	12 (42.86)	0	0 (0.00)
Abdominal pain	11	8 (28.57)	0	0 (0.00)
Constipation	3	2 (7.14)	0	0 (0.00)
Abdominal distension	2	2 (7.14)	0	0 (0.00)
Anal incontinence	2	1 (3.57)	0	0 (0.00)
Mouth haemorrhage	2	1 (3.57)	2	1 (3.57)
Stomatitis	2	2 (7.14)	0	0 (0.00)
Abdominal pain lower	1	1 (3.57)	0	0 (0.00)
Abdominal pain upper	1	1 (3.57)	0	0 (0.00)
Abdominal tenderness	1	1 (3.57)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Gastrooesophageal reflux disease	1	1 (3.57)	0	0 (0.00)
Glossodynia	1	1 (3.57)	0	0 (0.00)
Haematemesis	1	1 (3.57)	0	0 (0.00)
Lip pain	1	1 (3.57)	0	0 (0.00)
Pigmentation lip	1	1 (3.57)	0	0 (0.00)
General disorders and administration site conditions				
- Total	57	20 (71.43)	4	3 (10.71)
Pyrexia	20	11 (39.29)	1	1 (3.57)
Fatigue	10	9 (32.14)	1	1 (3.57)
Chills	5	4 (14.29)	0	0 (0.00)
Generalised oedema	3	2 (7.14)	0	0 (0.00)
Influenza like illness	2	2 (7.14)	0	0 (0.00)
Malaise	2	2 (7.14)	0	0 (0.00)
Oedema peripheral	2	2 (7.14)	0	0 (0.00)
Pain	2	2 (7.14)	1	1 (3.57)
Acquired gene mutation	1	1 (3.57)	0	0 (0.00)
Catheter site extravasation	1	1 (3.57)	0	0 (0.00)
Catheter site haemorrhage	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Catheter site pain	1	1 (3.57)	0	0 (0.00)
Crying	1	1 (3.57)	0	0 (0.00)
Cyst	1	1 (3.57)	1	1 (3.57)
Face oedema	1	1 (3.57)	0	0 (0.00)
Facial pain	1	1 (3.57)	0	0 (0.00)
Injection site haematoma	1	1 (3.57)	0	0 (0.00)
Non-cardiac chest pain	1	1 (3.57)	0	0 (0.00)
Peripheral swelling	1	1 (3.57)	0	0 (0.00)
Hepatobiliary disorders				
- Total	4	2 (7.14)	1	1 (3.57)
Hepatomegaly	2	2 (7.14)	0	0 (0.00)
Hyperbilirubinaemia	2	1 (3.57)	1	1 (3.57)
Immune system disorders				
- Total	50	24 (85.71)	9	7 (25.00)
Cytokine release syndrome	28	20 (71.43)	8	6 (21.43)
Hypogammaglobulinaemia	17	14 (50.00)	1	1 (3.57)
Graft versus host disease	1	1 (3.57)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Graft versus host disease in skin	1	1 (3.57)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (3.57)	0	0 (0.00)
Immunodeficiency common variable	1	1 (3.57)	0	0 (0.00)
Infections and infestations				
- Total	73	21 (75.00)	18	9 (32.14)
Upper respiratory tract infection	7	5 (17.86)	1	1 (3.57)
Urinary tract infection	7	4 (14.29)	3	2 (7.14)
Cellulitis of male external genital organ	6	1 (3.57)	3	1 (3.57)
Otitis media	6	3 (10.71)	1	1 (3.57)
Otitis media acute	5	2 (7.14)	0	0 (0.00)
Clostridium difficile infection	4	4 (14.29)	1	1 (3.57)
Sinusitis	3	3 (10.71)	0	0 (0.00)
Cytomegalovirus infection	2	2 (7.14)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (3.57)	0	0 (0.00)
Influenza	2	2 (7.14)	0	0 (0.00)
Vulvovaginal candidiasis	2	2 (7.14)	0	0 (0.00)
Acute sinusitis	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Body tinea	1	1 (3.57)	0	0 (0.00)
Campylobacter infection	1	1 (3.57)	1	1 (3.57)
Catheter site cellulitis	1	1 (3.57)	0	0 (0.00)
Cholecystitis infective	1	1 (3.57)	1	1 (3.57)
Clostridium difficile colitis	1	1 (3.57)	0	0 (0.00)
Ear infection	1	1 (3.57)	0	0 (0.00)
Enterococcal infection	1	1 (3.57)	0	0 (0.00)
Enterovirus infection	1	1 (3.57)	1	1 (3.57)
Escherichia urinary tract infection	1	1 (3.57)	1	1 (3.57)
Fungal skin infection	1	1 (3.57)	0	0 (0.00)
Haemophilus infection	1	1 (3.57)	0	0 (0.00)
Herpes simplex	1	1 (3.57)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (3.57)	0	0 (0.00)
Hypopyon	1	1 (3.57)	0	0 (0.00)
Oral candidiasis	1	1 (3.57)	0	0 (0.00)
Oral herpes	1	1 (3.57)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (3.57)	0	0 (0.00)
Pneumonia	1	1 (3.57)	0	0 (0.00)
Respiratory tract infection viral	1	1 (3.57)	1	1 (3.57)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Rhinitis	1	1 (3.57)	0	0 (0.00)
Rhinovirus infection	1	1 (3.57)	0	0 (0.00)
Rotavirus infection	1	1 (3.57)	1	1 (3.57)
Sepsis	1	1 (3.57)	1	1 (3.57)
Septic embolus	1	1 (3.57)	1	1 (3.57)
Skin infection	1	1 (3.57)	0	0 (0.00)
Vascular device infection	1	1 (3.57)	1	1 (3.57)
Injury, poisoning and procedural complications				
- Total	19	11 (39.29)	1	1 (3.57)
Transfusion reaction	4	3 (10.71)	0	0 (0.00)
Contusion	2	2 (7.14)	0	0 (0.00)
Infusion related reaction	2	2 (7.14)	0	0 (0.00)
Procedural pain	2	2 (7.14)	0	0 (0.00)
Foot fracture	1	1 (3.57)	0	0 (0.00)
Limb injury	1	1 (3.57)	0	0 (0.00)
Mouth injury	1	1 (3.57)	0	0 (0.00)
Procedural headache	1	1 (3.57)	0	0 (0.00)
Procedural site reaction	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Skin abrasion	1	1 (3.57)	0	0 (0.00)
Skin laceration	1	1 (3.57)	0	0 (0.00)
Tongue injury	1	1 (3.57)	0	0 (0.00)
Transfusion related complication	1	1 (3.57)	1	1 (3.57)
Investigations				
- Total	208	24 (85.71)	97	19 (67.86)
Platelet count decreased	31	11 (39.29)	23	8 (28.57)
White blood cell count decreased	31	16 (57.14)	17	14 (50.00)
Neutrophil count decreased	29	14 (50.00)	23	12 (42.86)
Aspartate aminotransferase increased	25	13 (46.43)	13	8 (28.57)
Alanine aminotransferase increased	21	13 (46.43)	10	8 (28.57)
Lymphocyte count decreased	13	7 (25.00)	6	5 (17.86)
Blood bilirubin increased	11	6 (21.43)	2	2 (7.14)
Blood creatinine increased	9	6 (21.43)	1	1 (3.57)
Prothrombin time prolonged	9	6 (21.43)	0	0 (0.00)
International normalised ratio increased	5	5 (17.86)	0	0 (0.00)
Blood immunoglobulin A decreased	3	3 (10.71)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Blood immunoglobulin M decreased	3	3 (10.71)	0	0 (0.00)
Haemoglobin decreased	3	3 (10.71)	1	1 (3.57)
Activated partial thromboplastin time prolonged	2	2 (7.14)	0	0 (0.00)
Weight increased	2	2 (7.14)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (3.57)	0	0 (0.00)
Blood lactic acid increased	1	1 (3.57)	1	1 (3.57)
Blood urea increased	1	1 (3.57)	0	0 (0.00)
Blood uric acid increased	1	1 (3.57)	0	0 (0.00)
Culture stool positive	1	1 (3.57)	0	0 (0.00)
Hepatic enzyme increased	1	1 (3.57)	0	0 (0.00)
Norovirus test positive	1	1 (3.57)	0	0 (0.00)
Pulmonary function test decreased	1	1 (3.57)	0	0 (0.00)
Serum ferritin increased	1	1 (3.57)	0	0 (0.00)
Transaminases increased	1	1 (3.57)	0	0 (0.00)
Weight decreased	1	1 (3.57)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	60	19 (67.86)	20	9 (32.14)
Decreased appetite	14	11 (39.29)	6	5 (17.86)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Hyperphosphataemia	11	7 (25.00)	0	0 (0.00)
Hypokalaemia	10	9 (32.14)	4	4 (14.29)
Hypophosphataemia	7	5 (17.86)	4	4 (14.29)
Hyperuricaemia	3	2 (7.14)	0	0 (0.00)
Hypocalcaemia	3	2 (7.14)	1	1 (3.57)
Hyponatraemia	3	2 (7.14)	3	2 (7.14)
Dehydration	2	2 (7.14)	1	1 (3.57)
Fluid overload	2	2 (7.14)	0	0 (0.00)
Hyperglycaemia	2	1 (3.57)	1	1 (3.57)
Hypoalbuminaemia	2	2 (7.14)	0	0 (0.00)
Vitamin D deficiency	1	1 (3.57)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	26	13 (46.43)	0	0 (0.00)
Pain in extremity	6	5 (17.86)	0	0 (0.00)
Myalgia	5	5 (17.86)	0	0 (0.00)
Arthralgia	2	2 (7.14)	0	0 (0.00)
Joint range of motion decreased	2	2 (7.14)	0	0 (0.00)
Muscle spasms	2	2 (7.14)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Musculoskeletal chest pain	2	2 (7.14)	0	0 (0.00)
Musculoskeletal pain	2	2 (7.14)	0	0 (0.00)
Back pain	1	1 (3.57)	0	0 (0.00)
Coccydynia	1	1 (3.57)	0	0 (0.00)
Flank pain	1	1 (3.57)	0	0 (0.00)
Muscular weakness	1	1 (3.57)	0	0 (0.00)
Neck pain	1	1 (3.57)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (10.71)	1	1 (3.57)
Glioblastoma multiforme	1	1 (3.57)	1	1 (3.57)
Myelodysplastic syndrome	1	1 (3.57)	0	0 (0.00)
Skin papilloma	1	1 (3.57)	0	0 (0.00)
Nervous system disorders				
- Total	39	17 (60.71)	6	5 (17.86)
Headache	25	12 (42.86)	2	2 (7.14)
Dizziness	6	4 (14.29)	0	0 (0.00)
Encephalopathy	2	2 (7.14)	1	1 (3.57)
Seizure	2	2 (7.14)	2	2 (7.14)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Embolic stroke	1	1 (3.57)	1	1 (3.57)
Idiopathic intracranial hypertension	1	1 (3.57)	0	0 (0.00)
Myoclonus	1	1 (3.57)	0	0 (0.00)
Peroneal nerve palsy	1	1 (3.57)	0	0 (0.00)
Product issues				
- Total	1	1 (3.57)	0	0 (0.00)
Device occlusion	1	1 (3.57)	0	0 (0.00)
Psychiatric disorders				
- Total	11	4 (14.29)	1	1 (3.57)
Anxiety	3	3 (10.71)	1	1 (3.57)
Agitation	2	1 (3.57)	0	0 (0.00)
Confusional state	2	2 (7.14)	0	0 (0.00)
Hallucination	2	1 (3.57)	0	0 (0.00)
Irritability	1	1 (3.57)	0	0 (0.00)
Listless	1	1 (3.57)	0	0 (0.00)
Renal and urinary disorders				
- Total	9	4 (14.29)	4	2 (7.14)
Haematuria	3	2 (7.14)	1	1 (3.57)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Acute kidney injury	2	2 (7.14)	1	1 (3.57)
Calculus urinary	1	1 (3.57)	0	0 (0.00)
Nephrolithiasis	1	1 (3.57)	1	1 (3.57)
Oliguria	1	1 (3.57)	1	1 (3.57)
Urinary incontinence	1	1 (3.57)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	5	4 (14.29)	1	1 (3.57)
Oedema genital	2	1 (3.57)	0	0 (0.00)
Ovarian failure	1	1 (3.57)	1	1 (3.57)
Scrotal pain	1	1 (3.57)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (3.57)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	46	17 (60.71)	7	4 (14.29)
Cough	11	7 (25.00)	0	0 (0.00)
Epistaxis	9	5 (17.86)	2	2 (7.14)
Hypoxia	6	5 (17.86)	2	2 (7.14)
Rhinitis allergic	4	3 (10.71)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Oropharyngeal pain	3	3 (10.71)	0	0 (0.00)
Pleural effusion	3	3 (10.71)	0	0 (0.00)
Dyspnoea	2	1 (3.57)	1	1 (3.57)
Rhinorrhoea	2	2 (7.14)	0	0 (0.00)
Tachypnoea	2	2 (7.14)	1	1 (3.57)
Atelectasis	1	1 (3.57)	0	0 (0.00)
Nasal congestion	1	1 (3.57)	0	0 (0.00)
Pulmonary oedema	1	1 (3.57)	1	1 (3.57)
Wheezing	1	1 (3.57)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	31	12 (42.86)	1	1 (3.57)
Rash	5	4 (14.29)	0	0 (0.00)
Erythema	3	2 (7.14)	0	0 (0.00)
Ingrowing nail	3	2 (7.14)	0	0 (0.00)
Petechiae	3	3 (10.71)	0	0 (0.00)
Rash maculo-papular	3	3 (10.71)	1	1 (3.57)
Dry skin	2	2 (7.14)	0	0 (0.00)
Hyperhidrosis	2	2 (7.14)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Pruritus	2	2 (7.14)	0	0 (0.00)
Dermatitis atopic	1	1 (3.57)	0	0 (0.00)
Macule	1	1 (3.57)	0	0 (0.00)
Night sweats	1	1 (3.57)	0	0 (0.00)
Rash follicular	1	1 (3.57)	0	0 (0.00)
Rash papular	1	1 (3.57)	0	0 (0.00)
Rash pruritic	1	1 (3.57)	0	0 (0.00)
Rash vesicular	1	1 (3.57)	0	0 (0.00)
Skin irritation	1	1 (3.57)	0	0 (0.00)
Vascular disorders				
- Total	19	11 (39.29)	7	6 (21.43)
Hypotension	8	6 (21.43)	5	5 (17.86)
Hypertension	7	5 (17.86)	1	1 (3.57)
Orthostatic hypotension	2	2 (7.14)	0	0 (0.00)
Embolism	1	1 (3.57)	1	1 (3.57)
Flushing	1	1 (3.57)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Total number of AE per patient	910	36 (100.00)	329	33 (91.67)
Blood and lymphatic system disorders				
- Total	86	28 (77.78)	70	24 (66.67)
Anaemia	24	13 (36.11)	17	10 (27.78)
Thrombocytopenia	23	7 (19.44)	19	6 (16.67)
Febrile neutropenia	17	14 (38.89)	17	14 (38.89)
Neutropenia	13	9 (25.00)	12	9 (25.00)
Disseminated intravascular coagulation	4	3 (8.33)	2	2 (5.56)
Coagulopathy	1	1 (2.78)	0	0 (0.00)
Leukopenia	1	1 (2.78)	1	1 (2.78)
Lymphadenopathy	1	1 (2.78)	0	0 (0.00)
Lymphopenia	1	1 (2.78)	1	1 (2.78)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Pancytopenia	1	1 (2.78)	1	1 (2.78)
Cardiac disorders				
- Total	17	12 (33.33)	2	1 (2.78)
Tachycardia	9	8 (22.22)	1	1 (2.78)
Pericardial effusion	2	2 (5.56)	0	0 (0.00)
Atrioventricular block second degree	1	1 (2.78)	0	0 (0.00)
Bradycardia	1	1 (2.78)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.78)	1	1 (2.78)
Palpitations	1	1 (2.78)	0	0 (0.00)
Sinus tachycardia	1	1 (2.78)	0	0 (0.00)
Ventricular tachycardia	1	1 (2.78)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (5.56)	0	0 (0.00)
Adrenal insufficiency	2	2 (5.56)	0	0 (0.00)
Eye disorders				
- Total	15	8 (22.22)	0	0 (0.00)
Vision blurred	4	3 (8.33)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (8.33)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Periorbital oedema	3	3 (8.33)	0	0 (0.00)
Eye pain	2	1 (2.78)	0	0 (0.00)
Retinal haemorrhage	2	2 (5.56)	0	0 (0.00)
Conjunctivitis allergic	1	1 (2.78)	0	0 (0.00)
Gastrointestinal disorders				
- Total	80	23 (63.89)	16	9 (25.00)
Vomiting	24	14 (38.89)	2	1 (2.78)
Nausea	16	11 (30.56)	3	3 (8.33)
Diarrhoea	13	12 (33.33)	2	2 (5.56)
Constipation	5	5 (13.89)	0	0 (0.00)
Abdominal pain	4	3 (8.33)	2	1 (2.78)
Oral pain	3	2 (5.56)	1	1 (2.78)
Abdominal pain upper	2	2 (5.56)	0	0 (0.00)
Dysphagia	2	2 (5.56)	1	1 (2.78)
Pancreatitis	2	2 (5.56)	1	1 (2.78)
Abdominal discomfort	1	1 (2.78)	0	0 (0.00)
Ascites	1	1 (2.78)	1	1 (2.78)
Dyspepsia	1	1 (2.78)	0	0 (0.00)
Enterocolitis	1	1 (2.78)	1	1 (2.78)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Flatulence	1	1 (2.78)	0	0 (0.00)
Haematemesis	1	1 (2.78)	0	0 (0.00)
Ileus	1	1 (2.78)	1	1 (2.78)
Intestinal obstruction	1	1 (2.78)	1	1 (2.78)
Tooth socket haemorrhage	1	1 (2.78)	0	0 (0.00)
General disorders and administration site conditions				
- Total	50	22 (61.11)	12	9 (25.00)
Pyrexia	23	14 (38.89)	6	6 (16.67)
Chills	6	6 (16.67)	0	0 (0.00)
Fatigue	6	6 (16.67)	0	0 (0.00)
Catheter site pain	3	3 (8.33)	0	0 (0.00)
Malaise	2	2 (5.56)	0	0 (0.00)
Pain	2	2 (5.56)	1	1 (2.78)
Asthenia	1	1 (2.78)	0	0 (0.00)
Face oedema	1	1 (2.78)	1	1 (2.78)
Generalised oedema	1	1 (2.78)	0	0 (0.00)
Localised oedema	1	1 (2.78)	1	1 (2.78)
Mucosal haemorrhage	1	1 (2.78)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Multiple organ dysfunction syndrome	1	1 (2.78)	1	1 (2.78)
Oedema peripheral	1	1 (2.78)	1	1 (2.78)
Physical deconditioning	1	1 (2.78)	1	1 (2.78)
Hepatobiliary disorders				
- Total	5	5 (13.89)	1	1 (2.78)
Hyperbilirubinaemia	2	2 (5.56)	1	1 (2.78)
Gallbladder enlargement	1	1 (2.78)	0	0 (0.00)
Hepatomegaly	1	1 (2.78)	0	0 (0.00)
Hepatosplenomegaly	1	1 (2.78)	0	0 (0.00)
Immune system disorders				
- Total	85	34 (94.44)	25	15 (41.67)
Cytokine release syndrome	58	30 (83.33)	21	13 (36.11)
Hypogammaglobulinaemia	19	19 (52.78)	4	4 (11.11)
Graft versus host disease	2	1 (2.78)	0	0 (0.00)
Seasonal allergy	2	2 (5.56)	0	0 (0.00)
Chronic graft versus host disease	1	1 (2.78)	0	0 (0.00)
Drug hypersensitivity	1	1 (2.78)	0	0 (0.00)
Immunodeficiency	1	1 (2.78)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Immunodeficiency common variable	1	1 (2.78)	0	0 (0.00)
Infections and infestations				
- Total	61	25 (69.44)	13	9 (25.00)
Rhinovirus infection	6	4 (11.11)	0	0 (0.00)
Gastroenteritis	5	5 (13.89)	1	1 (2.78)
Upper respiratory tract infection	5	4 (11.11)	0	0 (0.00)
Clostridium difficile colitis	3	3 (8.33)	1	1 (2.78)
Pneumonia	3	3 (8.33)	1	1 (2.78)
Viral infection	3	3 (8.33)	0	0 (0.00)
Viral upper respiratory tract infection	3	3 (8.33)	1	1 (2.78)
Influenza	2	2 (5.56)	0	0 (0.00)
Sinusitis	2	1 (2.78)	0	0 (0.00)
Staphylococcal infection	2	2 (5.56)	1	1 (2.78)
Bacterial sepsis	1	1 (2.78)	1	1 (2.78)
Catheter site infection	1	1 (2.78)	1	1 (2.78)
Clostridium difficile infection	1	1 (2.78)	0	0 (0.00)
Corona virus infection	1	1 (2.78)	1	1 (2.78)
Ear infection	1	1 (2.78)	0	0 (0.00)
Folliculitis	1	1 (2.78)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Gastroenteritis viral	1	1 (2.78)	0	0 (0.00)
Gingivitis	1	1 (2.78)	0	0 (0.00)
Herpes zoster	1	1 (2.78)	1	1 (2.78)
Meningitis aseptic	1	1 (2.78)	0	0 (0.00)
Molluscum contagiosum	1	1 (2.78)	0	0 (0.00)
Orchitis	1	1 (2.78)	0	0 (0.00)
Otitis externa	1	1 (2.78)	0	0 (0.00)
Otitis media	1	1 (2.78)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.78)	1	1 (2.78)
Paronychia	1	1 (2.78)	0	0 (0.00)
Pharyngitis	1	1 (2.78)	0	0 (0.00)
Rash pustular	1	1 (2.78)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (2.78)	1	1 (2.78)
Respiratory tract infection	1	1 (2.78)	1	1 (2.78)
Skin infection	1	1 (2.78)	0	0 (0.00)
Streptococcal infection	1	1 (2.78)	0	0 (0.00)
Subcutaneous abscess	1	1 (2.78)	0	0 (0.00)
Tinea capitis	1	1 (2.78)	0	0 (0.00)
Urinary tract infection	1	1 (2.78)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Urinary tract infection enterococcal	1	1 (2.78)	1	1 (2.78)
Vulvovaginal mycotic infection	1	1 (2.78)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	20	11 (30.56)	2	2 (5.56)
Procedural pain	4	3 (8.33)	1	1 (2.78)
Infusion related reaction	2	2 (5.56)	0	0 (0.00)
Tracheal haemorrhage	2	1 (2.78)	1	1 (2.78)
Arthropod bite	1	1 (2.78)	0	0 (0.00)
Contusion	1	1 (2.78)	0	0 (0.00)
Incision site pain	1	1 (2.78)	0	0 (0.00)
Post procedural haemorrhage	1	1 (2.78)	0	0 (0.00)
Procedural complication	1	1 (2.78)	0	0 (0.00)
Procedural nausea	1	1 (2.78)	0	0 (0.00)
Radius fracture	1	1 (2.78)	0	0 (0.00)
Skin abrasion	1	1 (2.78)	0	0 (0.00)
Stoma site irritation	1	1 (2.78)	0	0 (0.00)
Subdural haemorrhage	1	1 (2.78)	0	0 (0.00)
Sunburn	1	1 (2.78)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Tibia fracture	1	1 (2.78)	0	0 (0.00)
Investigations				
- Total	194	32 (88.89)	105	30 (83.33)
White blood cell count decreased	36	19 (52.78)	26	16 (44.44)
Neutrophil count decreased	33	14 (38.89)	29	13 (36.11)
Platelet count decreased	18	9 (25.00)	15	7 (19.44)
Blood fibrinogen decreased	15	4 (11.11)	4	3 (8.33)
Alanine aminotransferase increased	12	8 (22.22)	8	6 (16.67)
Aspartate aminotransferase increased	12	7 (19.44)	6	4 (11.11)
Lymphocyte count decreased	10	9 (25.00)	7	7 (19.44)
Prothrombin time prolonged	8	3 (8.33)	1	1 (2.78)
Activated partial thromboplastin time prolonged	6	3 (8.33)	0	0 (0.00)
International normalised ratio increased	6	4 (11.11)	1	1 (2.78)
Blood urea increased	4	2 (5.56)	1	1 (2.78)
Blood bilirubin increased	3	2 (5.56)	1	1 (2.78)
Blood creatinine increased	3	3 (8.33)	1	1 (2.78)
Blood phosphorus increased	3	2 (5.56)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Weight decreased	3	3 (8.33)	0	0 (0.00)
Blood magnesium decreased	2	2 (5.56)	1	1 (2.78)
Blood sodium increased	2	1 (2.78)	0	0 (0.00)
Blood uric acid increased	2	1 (2.78)	0	0 (0.00)
C-reactive protein increased	2	2 (5.56)	1	1 (2.78)
Lipase increased	2	2 (5.56)	2	2 (5.56)
Transaminases increased	2	2 (5.56)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (2.78)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.78)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (2.78)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (2.78)	0	0 (0.00)
Blood phosphorus decreased	1	1 (2.78)	0	0 (0.00)
Cardiac murmur	1	1 (2.78)	0	0 (0.00)
Fibrin D dimer increased	1	1 (2.78)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.78)	0	0 (0.00)
Protein total decreased	1	1 (2.78)	1	1 (2.78)
Serum ferritin increased	1	1 (2.78)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Metabolism and nutrition disorders				
- Total	73	24 (66.67)	30	18 (50.00)
Hypokalaemia	13	10 (27.78)	5	5 (13.89)
Decreased appetite	12	11 (30.56)	7	7 (19.44)
Hypernatraemia	7	4 (11.11)	1	1 (2.78)
Hypophosphataemia	7	5 (13.89)	6	4 (11.11)
Hypoalbuminaemia	4	3 (8.33)	1	1 (2.78)
Hyperalbuminaemia	3	1 (2.78)	0	0 (0.00)
Hypercalcaemia	3	1 (2.78)	0	0 (0.00)
Hyperglycaemia	3	2 (5.56)	1	1 (2.78)
Hypertriglyceridaemia	3	2 (5.56)	1	1 (2.78)
Acidosis	2	2 (5.56)	1	1 (2.78)
Dehydration	2	2 (5.56)	2	2 (5.56)
Tumour lysis syndrome	2	2 (5.56)	2	2 (5.56)
Fluid overload	1	1 (2.78)	0	0 (0.00)
Hyperchloraemia	1	1 (2.78)	0	0 (0.00)
Hypermagnesaemia	1	1 (2.78)	0	0 (0.00)
Hyperphosphataemia	1	1 (2.78)	0	0 (0.00)
Hyperuricaemia	1	1 (2.78)	1	1 (2.78)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Hypocalcaemia	1	1 (2.78)	0	0 (0.00)
Hypomagnesaemia	1	1 (2.78)	0	0 (0.00)
Iron overload	1	1 (2.78)	1	1 (2.78)
Malnutrition	1	1 (2.78)	1	1 (2.78)
Metabolic acidosis	1	1 (2.78)	0	0 (0.00)
Metabolic alkalosis	1	1 (2.78)	0	0 (0.00)
Vitamin D deficiency	1	1 (2.78)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	19	12 (33.33)	1	1 (2.78)
Pain in extremity	6	6 (16.67)	0	0 (0.00)
Arthralgia	4	3 (8.33)	1	1 (2.78)
Muscular weakness	2	2 (5.56)	0	0 (0.00)
Musculoskeletal pain	2	1 (2.78)	0	0 (0.00)
Limb discomfort	1	1 (2.78)	0	0 (0.00)
Osteonecrosis	1	1 (2.78)	0	0 (0.00)
Osteopenia	1	1 (2.78)	0	0 (0.00)
Pain in jaw	1	1 (2.78)	0	0 (0.00)
Toe walking	1	1 (2.78)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Nervous system disorders				
- Total	35	18 (50.00)	1	1 (2.78)
Headache	14	12 (33.33)	0	0 (0.00)
Encephalopathy	4	2 (5.56)	1	1 (2.78)
Dizziness	2	2 (5.56)	0	0 (0.00)
Dysarthria	2	2 (5.56)	0	0 (0.00)
Seizure	2	2 (5.56)	0	0 (0.00)
Tremor	2	2 (5.56)	0	0 (0.00)
Asterixis	1	1 (2.78)	0	0 (0.00)
Ataxia	1	1 (2.78)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.78)	0	0 (0.00)
Disturbance in attention	1	1 (2.78)	0	0 (0.00)
Migraine	1	1 (2.78)	0	0 (0.00)
Neuropathy peripheral	1	1 (2.78)	0	0 (0.00)
Peroneal nerve palsy	1	1 (2.78)	0	0 (0.00)
Pleocytosis	1	1 (2.78)	0	0 (0.00)
Somnolence	1	1 (2.78)	0	0 (0.00)
Psychiatric disorders				
- Total	23	13 (36.11)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Anxiety	4	4 (11.11)	0	0 (0.00)
Confusional state	4	4 (11.11)	0	0 (0.00)
Delirium	4	4 (11.11)	0	0 (0.00)
Depression	2	2 (5.56)	0	0 (0.00)
Adjustment disorder	1	1 (2.78)	0	0 (0.00)
Agitation	1	1 (2.78)	0	0 (0.00)
Hallucination	1	1 (2.78)	0	0 (0.00)
Insomnia	1	1 (2.78)	0	0 (0.00)
Irritability	1	1 (2.78)	0	0 (0.00)
Mental status changes	1	1 (2.78)	0	0 (0.00)
Panic attack	1	1 (2.78)	0	0 (0.00)
Sleep disorder	1	1 (2.78)	0	0 (0.00)
Suicidal ideation	1	1 (2.78)	0	0 (0.00)
Renal and urinary disorders				
- Total	17	11 (30.56)	11	8 (22.22)
Acute kidney injury	8	7 (19.44)	6	6 (16.67)
Haematuria	3	3 (8.33)	2	2 (5.56)
Dysuria	2	2 (5.56)	0	0 (0.00)
Oliguria	1	1 (2.78)	1	1 (2.78)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Pollakiuria	1	1 (2.78)	0	0 (0.00)
Renal failure	1	1 (2.78)	1	1 (2.78)
Renal impairment	1	1 (2.78)	1	1 (2.78)
Reproductive system and breast disorders				
- Total	2	2 (5.56)	1	1 (2.78)
Vaginal haemorrhage	1	1 (2.78)	1	1 (2.78)
Vulvovaginal adhesion	1	1 (2.78)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	64	21 (58.33)	25	11 (30.56)
Cough	9	7 (19.44)	0	0 (0.00)
Hypoxia	7	5 (13.89)	6	5 (13.89)
Pulmonary oedema	6	6 (16.67)	5	5 (13.89)
Epistaxis	5	5 (13.89)	3	3 (8.33)
Pleural effusion	5	5 (13.89)	2	2 (5.56)
Nasal congestion	4	4 (11.11)	0	0 (0.00)
Rhinorrhoea	4	4 (11.11)	0	0 (0.00)
Tachypnoea	4	3 (8.33)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Haemoptysis	3	2 (5.56)	1	1 (2.78)
Oropharyngeal pain	3	3 (8.33)	0	0 (0.00)
Respiratory failure	3	3 (8.33)	3	3 (8.33)
Acute respiratory failure	1	1 (2.78)	1	1 (2.78)
Dysphonia	1	1 (2.78)	0	0 (0.00)
Dyspnoea	1	1 (2.78)	1	1 (2.78)
Interstitial lung disease	1	1 (2.78)	1	1 (2.78)
Oropharyngeal plaque	1	1 (2.78)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.78)	0	0 (0.00)
Pharyngeal lesion	1	1 (2.78)	1	1 (2.78)
Pharyngeal ulceration	1	1 (2.78)	0	0 (0.00)
Respiratory depression	1	1 (2.78)	0	0 (0.00)
Respiratory distress	1	1 (2.78)	1	1 (2.78)
Rhinitis allergic	1	1 (2.78)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	38	18 (50.00)	2	2 (5.56)
Rash	4	4 (11.11)	0	0 (0.00)
Dry skin	3	3 (8.33)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Erythema	3	3 (8.33)	0	0 (0.00)
Hyperhidrosis	3	2 (5.56)	0	0 (0.00)
Rash erythematous	3	2 (5.56)	0	0 (0.00)
Papule	2	2 (5.56)	0	0 (0.00)
Pruritus	2	2 (5.56)	0	0 (0.00)
Rash maculo-papular	2	2 (5.56)	0	0 (0.00)
Acne	1	1 (2.78)	0	0 (0.00)
Alopecia	1	1 (2.78)	0	0 (0.00)
Dermatitis	1	1 (2.78)	0	0 (0.00)
Dermatitis acneiform	1	1 (2.78)	1	1 (2.78)
Dermatitis diaper	1	1 (2.78)	0	0 (0.00)
Ecchymosis	1	1 (2.78)	1	1 (2.78)
Eczema	1	1 (2.78)	0	0 (0.00)
Ingrowing nail	1	1 (2.78)	0	0 (0.00)
Keloid scar	1	1 (2.78)	0	0 (0.00)
Livedo reticularis	1	1 (2.78)	0	0 (0.00)
Macule	1	1 (2.78)	0	0 (0.00)
Petechiae	1	1 (2.78)	0	0 (0.00)
Rash macular	1	1 (2.78)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Rash papular	1	1 (2.78)	0	0 (0.00)
Skin exfoliation	1	1 (2.78)	0	0 (0.00)
Skin fissures	1	1 (2.78)	0	0 (0.00)
Vascular disorders				
- Total	24	14 (38.89)	12	10 (27.78)
Hypotension	11	10 (27.78)	11	10 (27.78)
Hypertension	7	7 (19.44)	0	0 (0.00)
Flushing	2	1 (2.78)	0	0 (0.00)
Capillary leak syndrome	1	1 (2.78)	1	1 (2.78)
Haematoma	1	1 (2.78)	0	0 (0.00)
Hot flush	1	1 (2.78)	0	0 (0.00)
Secondary hypertension	1	1 (2.78)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Total number of AE per patient	228	14 (100.00)	102	13 (92.86)
Blood and lymphatic system disorders				
- Total	30	12 (85.71)	26	11 (78.57)
Febrile neutropenia	10	9 (64.29)	10	9 (64.29)
Thrombocytopenia	10	2 (14.29)	9	2 (14.29)
Anaemia	8	5 (35.71)	5	2 (14.29)
Neutropenia	1	1 (7.14)	1	1 (7.14)
Pancytopenia	1	1 (7.14)	1	1 (7.14)
Cardiac disorders				
- Total	4	4 (28.57)	0	0 (0.00)
Tachycardia	2	2 (14.29)	0	0 (0.00)
Atrioventricular block second degree	1	1 (7.14)	0	0 (0.00)
Sinus tachycardia	1	1 (7.14)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Eye disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Retinal haemorrhage	1	1 (7.14)	0	0 (0.00)
Gastrointestinal disorders				
- Total	20	5 (35.71)	6	3 (21.43)
Vomiting	5	2 (14.29)	1	1 (7.14)
Nausea	4	3 (21.43)	1	1 (7.14)
Abdominal pain	2	2 (14.29)	1	1 (7.14)
Constipation	2	2 (14.29)	0	0 (0.00)
Abdominal pain upper	1	1 (7.14)	0	0 (0.00)
Ascites	1	1 (7.14)	1	1 (7.14)
Diarrhoea	1	1 (7.14)	0	0 (0.00)
Dyspepsia	1	1 (7.14)	0	0 (0.00)
Intestinal obstruction	1	1 (7.14)	1	1 (7.14)
Pancreatitis	1	1 (7.14)	1	1 (7.14)
Tooth socket haemorrhage	1	1 (7.14)	0	0 (0.00)
General disorders and administration site conditions				
- Total	5	4 (28.57)	1	1 (7.14)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Pyrexia	2	2 (14.29)	1	1 (7.14)
Catheter site pain	1	1 (7.14)	0	0 (0.00)
Chills	1	1 (7.14)	0	0 (0.00)
Fatigue	1	1 (7.14)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Hepatosplenomegaly	1	1 (7.14)	0	0 (0.00)
Immune system disorders				
- Total	25	14 (100.00)	5	4 (28.57)
Cytokine release syndrome	17	13 (92.86)	4	3 (21.43)
Hypogammaglobulinaemia	8	8 (57.14)	1	1 (7.14)
Infections and infestations				
- Total	10	6 (42.86)	3	3 (21.43)
Catheter site infection	1	1 (7.14)	1	1 (7.14)
Clostridium difficile infection	1	1 (7.14)	0	0 (0.00)
Cytomegalovirus infection	1	1 (7.14)	0	0 (0.00)
Folliculitis	1	1 (7.14)	0	0 (0.00)
Fungal skin infection	1	1 (7.14)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Pneumonia	1	1 (7.14)	1	1 (7.14)
Rhinovirus infection	1	1 (7.14)	0	0 (0.00)
Staphylococcal infection	1	1 (7.14)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (7.14)	1	1 (7.14)
Viral infection	1	1 (7.14)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (7.14)	0	0 (0.00)
Procedural pain	1	1 (7.14)	0	0 (0.00)
Investigations				
- Total	73	12 (85.71)	44	11 (78.57)
Neutrophil count decreased	18	7 (50.00)	18	7 (50.00)
White blood cell count decreased	16	8 (57.14)	12	7 (50.00)
Platelet count decreased	7	4 (28.57)	6	3 (21.43)
Blood fibrinogen decreased	5	1 (7.14)	1	1 (7.14)
Lymphocyte count decreased	5	5 (35.71)	4	4 (28.57)
Alanine aminotransferase increased	3	2 (14.29)	1	1 (7.14)
Blood bilirubin increased	3	2 (14.29)	0	0 (0.00)
Prothrombin time prolonged	3	1 (7.14)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Blood creatinine increased	2	1 (7.14)	0	0 (0.00)
Blood sodium increased	2	1 (7.14)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (7.14)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (7.14)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (7.14)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (7.14)	0	0 (0.00)
Blood urea increased	1	1 (7.14)	0	0 (0.00)
C-reactive protein increased	1	1 (7.14)	1	1 (7.14)
Fibrin D dimer increased	1	1 (7.14)	0	0 (0.00)
International normalised ratio increased	1	1 (7.14)	0	0 (0.00)
Lipase increased	1	1 (7.14)	1	1 (7.14)
Metabolism and nutrition disorders				
- Total	19	8 (57.14)	10	6 (42.86)
Decreased appetite	4	4 (28.57)	2	2 (14.29)
Hypokalaemia	4	4 (28.57)	2	2 (14.29)
Hypophosphataemia	3	1 (7.14)	3	1 (7.14)
Hyperphosphataemia	2	2 (14.29)	0	0 (0.00)
Hypoalbuminaemia	2	1 (7.14)	1	1 (7.14)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Dehydration	1	1 (7.14)	1	1 (7.14)
Hypertriglyceridaemia	1	1 (7.14)	0	0 (0.00)
Hyperuricaemia	1	1 (7.14)	1	1 (7.14)
Hypomagnesaemia	1	1 (7.14)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	3	2 (14.29)	0	0 (0.00)
Arthralgia	1	1 (7.14)	0	0 (0.00)
Muscular weakness	1	1 (7.14)	0	0 (0.00)
Pain in extremity	1	1 (7.14)	0	0 (0.00)
Nervous system disorders				
- Total	8	5 (35.71)	0	0 (0.00)
Headache	4	3 (21.43)	0	0 (0.00)
Depressed level of consciousness	1	1 (7.14)	0	0 (0.00)
Dysarthria	1	1 (7.14)	0	0 (0.00)
Migraine	1	1 (7.14)	0	0 (0.00)
Somnolence	1	1 (7.14)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (7.14)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Panic attack	1	1 (7.14)	0	0 (0.00)
Renal and urinary disorders				
- Total	2	2 (14.29)	1	1 (7.14)
Acute kidney injury	1	1 (7.14)	1	1 (7.14)
Dysuria	1	1 (7.14)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (7.14)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	10	6 (42.86)	4	2 (14.29)
Hypoxia	2	2 (14.29)	1	1 (7.14)
Pleural effusion	2	2 (14.29)	1	1 (7.14)
Cough	1	1 (7.14)	0	0 (0.00)
Nasal congestion	1	1 (7.14)	0	0 (0.00)
Oropharyngeal plaque	1	1 (7.14)	0	0 (0.00)
Pulmonary oedema	1	1 (7.14)	1	1 (7.14)
Respiratory failure	1	1 (7.14)	1	1 (7.14)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Tachypnoea	1	1 (7.14)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	9	4 (28.57)	0	0 (0.00)
Dermatitis diaper	1	1 (7.14)	0	0 (0.00)
Erythema	1	1 (7.14)	0	0 (0.00)
Hyperhidrosis	1	1 (7.14)	0	0 (0.00)
Macule	1	1 (7.14)	0	0 (0.00)
Petechiae	1	1 (7.14)	0	0 (0.00)
Pruritus	1	1 (7.14)	0	0 (0.00)
Rash	1	1 (7.14)	0	0 (0.00)
Rash erythematous	1	1 (7.14)	0	0 (0.00)
Rash macular	1	1 (7.14)	0	0 (0.00)
Vascular disorders				
- Total	5	5 (35.71)	2	2 (14.29)
Hypertension	2	2 (14.29)	0	0 (0.00)
Hypotension	2	2 (14.29)	2	2 (14.29)
Orthostatic hypotension	1	1 (7.14)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Total number of AE per patient	1086	49 (98.00)	356	41 (82.00)
Blood and lymphatic system disorders				
- Total	92	31 (62.00)	67	27 (54.00)
Anaemia	39	22 (44.00)	26	17 (34.00)
Thrombocytopenia	20	6 (12.00)	14	6 (12.00)
Febrile neutropenia	16	13 (26.00)	16	13 (26.00)
Neutropenia	8	7 (14.00)	7	7 (14.00)
Disseminated intravascular coagulation	5	4 (8.00)	2	2 (4.00)
Lymphopenia	3	3 (6.00)	2	2 (4.00)
Coagulopathy	1	1 (2.00)	0	0 (0.00)
Cardiac disorders				
- Total	28	18 (36.00)	3	2 (4.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Tachycardia	15	13 (26.00)	2	2 (4.00)
Sinus tachycardia	4	4 (8.00)	0	0 (0.00)
Pericardial effusion	2	2 (4.00)	0	0 (0.00)
Sinus bradycardia	2	1 (2.00)	0	0 (0.00)
Bradycardia	1	1 (2.00)	0	0 (0.00)
Cardiac dysfunction	1	1 (2.00)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.00)	1	1 (2.00)
Palpitations	1	1 (2.00)	0	0 (0.00)
Ventricular tachycardia	1	1 (2.00)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (6.00)	0	0 (0.00)
Ear pain	2	2 (4.00)	0	0 (0.00)
Hypoacusis	1	1 (2.00)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.00)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.00)	0	0 (0.00)
Eye disorders				
- Total	24	12 (24.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Eye pain	4	3 (6.00)	0	0 (0.00)
Periorbital oedema	4	4 (8.00)	0	0 (0.00)
Vision blurred	4	3 (6.00)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (6.00)	0	0 (0.00)
Photophobia	3	2 (4.00)	0	0 (0.00)
Uveitis	2	2 (4.00)	0	0 (0.00)
Ocular hypertension	1	1 (2.00)	0	0 (0.00)
Papilloedema	1	1 (2.00)	0	0 (0.00)
Retinal haemorrhage	1	1 (2.00)	0	0 (0.00)
Visual impairment	1	1 (2.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	106	31 (62.00)	9	8 (16.00)
Vomiting	30	20 (40.00)	2	2 (4.00)
Nausea	22	18 (36.00)	2	2 (4.00)
Diarrhoea	17	17 (34.00)	1	1 (2.00)
Abdominal pain	8	7 (14.00)	0	0 (0.00)
Constipation	6	5 (10.00)	0	0 (0.00)
Abdominal distension	2	2 (4.00)	0	0 (0.00)
Anal incontinence	2	1 (2.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Dysphagia	2	2 (4.00)	1	1 (2.00)
Haematemesis	2	2 (4.00)	0	0 (0.00)
Mouth haemorrhage	2	1 (2.00)	2	1 (2.00)
Stomatitis	2	2 (4.00)	0	0 (0.00)
Abdominal discomfort	1	1 (2.00)	0	0 (0.00)
Abdominal pain lower	1	1 (2.00)	0	0 (0.00)
Abdominal pain upper	1	1 (2.00)	0	0 (0.00)
Abdominal tenderness	1	1 (2.00)	0	0 (0.00)
Flatulence	1	1 (2.00)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (2.00)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.00)	0	0 (0.00)
Glossodynia	1	1 (2.00)	0	0 (0.00)
Ileus	1	1 (2.00)	1	1 (2.00)
Lip pain	1	1 (2.00)	0	0 (0.00)
Pancreatitis	1	1 (2.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	72	28 (56.00)	13	9 (18.00)
Pyrexia	25	14 (28.00)	5	5 (10.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Fatigue	13	12 (24.00)	1	1 (2.00)
Chills	8	7 (14.00)	0	0 (0.00)
Generalised oedema	3	2 (4.00)	0	0 (0.00)
Malaise	3	3 (6.00)	0	0 (0.00)
Pain	3	3 (6.00)	2	2 (4.00)
Catheter site pain	2	2 (4.00)	0	0 (0.00)
Face oedema	2	2 (4.00)	1	1 (2.00)
Oedema peripheral	2	2 (4.00)	1	1 (2.00)
Asthenia	1	1 (2.00)	0	0 (0.00)
Catheter site extravasation	1	1 (2.00)	0	0 (0.00)
Catheter site haemorrhage	1	1 (2.00)	0	0 (0.00)
Facial pain	1	1 (2.00)	0	0 (0.00)
Injection site haematoma	1	1 (2.00)	0	0 (0.00)
Localised oedema	1	1 (2.00)	1	1 (2.00)
Mucosal haemorrhage	1	1 (2.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.00)	1	1 (2.00)
Non-cardiac chest pain	1	1 (2.00)	0	0 (0.00)
Peripheral swelling	1	1 (2.00)	0	0 (0.00)
Physical deconditioning	1	1 (2.00)	1	1 (2.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Hepatobiliary disorders				
- Total	8	6 (12.00)	2	2 (4.00)
Hyperbilirubinaemia	4	3 (6.00)	2	2 (4.00)
Hepatomegaly	3	3 (6.00)	0	0 (0.00)
Gallbladder enlargement	1	1 (2.00)	0	0 (0.00)
Immune system disorders				
- Total	91	43 (86.00)	28	18 (36.00)
Cytokine release syndrome	69	37 (74.00)	25	16 (32.00)
Hypogammaglobulinaemia	19	18 (36.00)	3	3 (6.00)
Drug hypersensitivity	1	1 (2.00)	0	0 (0.00)
Graft versus host disease in skin	1	1 (2.00)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (2.00)	0	0 (0.00)
Infections and infestations				
- Total	31	20 (40.00)	4	4 (8.00)
Clostridium difficile colitis	4	4 (8.00)	1	1 (2.00)
Clostridium difficile infection	3	3 (6.00)	0	0 (0.00)
Gastroenteritis	2	2 (4.00)	1	1 (2.00)
Rhinovirus infection	2	2 (4.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Acute sinusitis	1	1 (2.00)	0	0 (0.00)
Body tinea	1	1 (2.00)	0	0 (0.00)
Catheter site cellulitis	1	1 (2.00)	0	0 (0.00)
Enterococcal infection	1	1 (2.00)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (2.00)	0	0 (0.00)
Herpes simplex	1	1 (2.00)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (2.00)	0	0 (0.00)
Hypopyon	1	1 (2.00)	0	0 (0.00)
Influenza	1	1 (2.00)	0	0 (0.00)
Oral candidiasis	1	1 (2.00)	0	0 (0.00)
Orchitis	1	1 (2.00)	0	0 (0.00)
Pharyngitis	1	1 (2.00)	0	0 (0.00)
Pneumonia	1	1 (2.00)	0	0 (0.00)
Septic embolus	1	1 (2.00)	1	1 (2.00)
Skin infection	1	1 (2.00)	0	0 (0.00)
Staphylococcal infection	1	1 (2.00)	1	1 (2.00)
Streptococcal infection	1	1 (2.00)	0	0 (0.00)
Upper respiratory tract infection	1	1 (2.00)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (2.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Vulvovaginal candidiasis	1	1 (2.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	24	14 (28.00)	2	2 (4.00)
Transfusion reaction	4	3 (6.00)	0	0 (0.00)
Infusion related reaction	2	2 (4.00)	0	0 (0.00)
Procedural pain	2	2 (4.00)	0	0 (0.00)
Tracheal haemorrhage	2	1 (2.00)	1	1 (2.00)
Contusion	1	1 (2.00)	0	0 (0.00)
Incision site pain	1	1 (2.00)	0	0 (0.00)
Limb injury	1	1 (2.00)	0	0 (0.00)
Mouth injury	1	1 (2.00)	0	0 (0.00)
Post procedural haemorrhage	1	1 (2.00)	0	0 (0.00)
Procedural complication	1	1 (2.00)	0	0 (0.00)
Procedural headache	1	1 (2.00)	0	0 (0.00)
Procedural site reaction	1	1 (2.00)	0	0 (0.00)
Skin abrasion	1	1 (2.00)	0	0 (0.00)
Stoma site irritation	1	1 (2.00)	0	0 (0.00)
Subdural haemorrhage	1	1 (2.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Tibia fracture	1	1 (2.00)	0	0 (0.00)
Tongue injury	1	1 (2.00)	0	0 (0.00)
Transfusion related complication	1	1 (2.00)	1	1 (2.00)
Investigations				
- Total	259	40 (80.00)	134	33 (66.00)
White blood cell count decreased	39	22 (44.00)	25	19 (38.00)
Platelet count decreased	36	15 (30.00)	31	11 (22.00)
Aspartate aminotransferase increased	31	17 (34.00)	16	11 (22.00)
Neutrophil count decreased	29	18 (36.00)	26	16 (32.00)
Alanine aminotransferase increased	25	17 (34.00)	13	10 (20.00)
Prothrombin time prolonged	14	8 (16.00)	1	1 (2.00)
Lymphocyte count decreased	11	9 (18.00)	8	7 (14.00)
Blood bilirubin increased	10	5 (10.00)	2	2 (4.00)
Blood fibrinogen decreased	10	3 (6.00)	3	2 (4.00)
International normalised ratio increased	10	8 (16.00)	1	1 (2.00)
Blood creatinine increased	9	8 (16.00)	2	2 (4.00)
Activated partial thromboplastin time prolonged	8	5 (10.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Blood immunoglobulin M decreased	3	3 (6.00)	0	0 (0.00)
Blood phosphorus increased	3	2 (4.00)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (4.00)	0	0 (0.00)
Blood urea increased	2	2 (4.00)	1	1 (2.00)
Blood uric acid increased	2	1 (2.00)	0	0 (0.00)
Transaminases increased	2	2 (4.00)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (2.00)	0	0 (0.00)
Blood lactic acid increased	1	1 (2.00)	1	1 (2.00)
Blood magnesium decreased	1	1 (2.00)	1	1 (2.00)
Blood phosphorus decreased	1	1 (2.00)	0	0 (0.00)
Cardiac murmur	1	1 (2.00)	0	0 (0.00)
Culture stool positive	1	1 (2.00)	0	0 (0.00)
Haemoglobin decreased	1	1 (2.00)	1	1 (2.00)
Hepatic enzyme increased	1	1 (2.00)	0	0 (0.00)
Lipase increased	1	1 (2.00)	1	1 (2.00)
Norovirus test positive	1	1 (2.00)	0	0 (0.00)
Protein total decreased	1	1 (2.00)	1	1 (2.00)
Pulmonary function test decreased	1	1 (2.00)	0	0 (0.00)
Serum ferritin increased	1	1 (2.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Metabolism and nutrition disorders				
- Total	97	31 (62.00)	33	18 (36.00)
Decreased appetite	20	16 (32.00)	11	10 (20.00)
Hypokalaemia	16	12 (24.00)	5	5 (10.00)
Hypophosphataemia	10	8 (16.00)	6	6 (12.00)
Hyperphosphataemia	8	6 (12.00)	0	0 (0.00)
Hypernatraemia	7	4 (8.00)	1	1 (2.00)
Hyperglycaemia	4	3 (6.00)	1	1 (2.00)
Hypoalbuminaemia	4	4 (8.00)	0	0 (0.00)
Hypocalcaemia	4	3 (6.00)	1	1 (2.00)
Fluid overload	3	3 (6.00)	0	0 (0.00)
Hyperuricaemia	3	2 (4.00)	0	0 (0.00)
Hyponatraemia	3	2 (4.00)	3	2 (4.00)
Acidosis	2	2 (4.00)	1	1 (2.00)
Dehydration	2	2 (4.00)	1	1 (2.00)
Hypercalcaemia	2	1 (2.00)	0	0 (0.00)
Hypertriglyceridaemia	2	1 (2.00)	1	1 (2.00)
Hyperalbuminaemia	1	1 (2.00)	0	0 (0.00)
Hyperchloraemia	1	1 (2.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Hypermagnesaemia	1	1 (2.00)	0	0 (0.00)
Malnutrition	1	1 (2.00)	1	1 (2.00)
Metabolic acidosis	1	1 (2.00)	0	0 (0.00)
Metabolic alkalosis	1	1 (2.00)	0	0 (0.00)
Tumour lysis syndrome	1	1 (2.00)	1	1 (2.00)
Musculoskeletal and connective tissue disorders				
- Total	20	13 (26.00)	1	1 (2.00)
Myalgia	5	5 (10.00)	0	0 (0.00)
Musculoskeletal pain	4	3 (6.00)	0	0 (0.00)
Arthralgia	3	3 (6.00)	1	1 (2.00)
Pain in extremity	3	3 (6.00)	0	0 (0.00)
Coccydynia	1	1 (2.00)	0	0 (0.00)
Limb discomfort	1	1 (2.00)	0	0 (0.00)
Muscle spasms	1	1 (2.00)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.00)	0	0 (0.00)
Osteopenia	1	1 (2.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
- Total	1	1 (2.00)	0	0 (0.00)
Skin papilloma	1	1 (2.00)	0	0 (0.00)
Nervous system disorders				
- Total	50	28 (56.00)	6	5 (10.00)
Headache	27	21 (42.00)	2	2 (4.00)
Encephalopathy	6	4 (8.00)	2	2 (4.00)
Dizziness	4	4 (8.00)	0	0 (0.00)
Seizure	3	3 (6.00)	1	1 (2.00)
Tremor	2	2 (4.00)	0	0 (0.00)
Asterixis	1	1 (2.00)	0	0 (0.00)
Ataxia	1	1 (2.00)	0	0 (0.00)
Dysarthria	1	1 (2.00)	0	0 (0.00)
Embolic stroke	1	1 (2.00)	1	1 (2.00)
Idiopathic intracranial hypertension	1	1 (2.00)	0	0 (0.00)
Myoclonus	1	1 (2.00)	0	0 (0.00)
Neuropathy peripheral	1	1 (2.00)	0	0 (0.00)
Pleocytosis	1	1 (2.00)	0	0 (0.00)
Product issues				

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
- Total	1	1 (2.00)	0	0 (0.00)
Device occlusion	1	1 (2.00)	0	0 (0.00)
Psychiatric disorders				
- Total	29	15 (30.00)	1	1 (2.00)
Anxiety	6	6 (12.00)	1	1 (2.00)
Confusional state	6	6 (12.00)	0	0 (0.00)
Delirium	4	4 (8.00)	0	0 (0.00)
Agitation	3	2 (4.00)	0	0 (0.00)
Hallucination	3	2 (4.00)	0	0 (0.00)
Irritability	2	2 (4.00)	0	0 (0.00)
Adjustment disorder	1	1 (2.00)	0	0 (0.00)
Insomnia	1	1 (2.00)	0	0 (0.00)
Listless	1	1 (2.00)	0	0 (0.00)
Mental status changes	1	1 (2.00)	0	0 (0.00)
Suicidal ideation	1	1 (2.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	16	9 (18.00)	10	6 (12.00)
Acute kidney injury	6	6 (12.00)	4	4 (8.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Haematuria	4	4 (8.00)	2	2 (4.00)
Oliguria	2	2 (4.00)	2	2 (4.00)
Dysuria	1	1 (2.00)	0	0 (0.00)
Pollakiuria	1	1 (2.00)	0	0 (0.00)
Renal failure	1	1 (2.00)	1	1 (2.00)
Renal impairment	1	1 (2.00)	1	1 (2.00)
Reproductive system and breast disorders				
- Total	3	2 (4.00)	0	0 (0.00)
Oedema genital	2	1 (2.00)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (2.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	63	22 (44.00)	24	10 (20.00)
Epistaxis	11	7 (14.00)	4	4 (8.00)
Hypoxia	11	8 (16.00)	7	6 (12.00)
Cough	7	7 (14.00)	0	0 (0.00)
Pleural effusion	6	6 (12.00)	1	1 (2.00)
Pulmonary oedema	5	5 (10.00)	4	4 (8.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Tachypnoea	5	4 (8.00)	1	1 (2.00)
Dyspnoea	3	2 (4.00)	2	2 (4.00)
Haemoptysis	3	2 (4.00)	1	1 (2.00)
Oropharyngeal pain	2	2 (4.00)	0	0 (0.00)
Respiratory failure	2	2 (4.00)	2	2 (4.00)
Atelectasis	1	1 (2.00)	0	0 (0.00)
Interstitial lung disease	1	1 (2.00)	1	1 (2.00)
Pharyngeal ulceration	1	1 (2.00)	0	0 (0.00)
Respiratory depression	1	1 (2.00)	0	0 (0.00)
Respiratory distress	1	1 (2.00)	1	1 (2.00)
Rhinitis allergic	1	1 (2.00)	0	0 (0.00)
Rhinorrhoea	1	1 (2.00)	0	0 (0.00)
Wheezing	1	1 (2.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	32	17 (34.00)	2	2 (4.00)
Dry skin	4	4 (8.00)	0	0 (0.00)
Erythema	3	2 (4.00)	0	0 (0.00)
Hyperhidrosis	3	2 (4.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Ingrowing nail	3	2 (4.00)	0	0 (0.00)
Rash	3	3 (6.00)	0	0 (0.00)
Rash maculo-papular	3	3 (6.00)	1	1 (2.00)
Petechiae	2	2 (4.00)	0	0 (0.00)
Rash papular	2	2 (4.00)	0	0 (0.00)
Ecchymosis	1	1 (2.00)	1	1 (2.00)
Livedo reticularis	1	1 (2.00)	0	0 (0.00)
Night sweats	1	1 (2.00)	0	0 (0.00)
Pruritus	1	1 (2.00)	0	0 (0.00)
Rash follicular	1	1 (2.00)	0	0 (0.00)
Rash vesicular	1	1 (2.00)	0	0 (0.00)
Skin exfoliation	1	1 (2.00)	0	0 (0.00)
Skin fissures	1	1 (2.00)	0	0 (0.00)
Skin irritation	1	1 (2.00)	0	0 (0.00)
Vascular disorders				
- Total	35	19 (38.00)	17	14 (28.00)
Hypotension	17	14 (28.00)	14	13 (26.00)
Hypertension	10	8 (16.00)	1	1 (2.00)
Flushing	3	2 (4.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Capillary leak syndrome	1	1 (2.00)	1	1 (2.00)
Embolism	1	1 (2.00)	1	1 (2.00)
Haematoma	1	1 (2.00)	0	0 (0.00)
Orthostatic hypotension	1	1 (2.00)	0	0 (0.00)
Secondary hypertension	1	1 (2.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=12 n (%)[1]	Grade >= 3 Total events	All patients N=12 n (%)[2]
Total number of AE per patient	81	12 (100.00)	19	9 (75.00)
Blood and lymphatic system disorders				
- Total	4	3 (25.00)	2	1 (8.33)
Anaemia	2	2 (16.67)	1	1 (8.33)
Febrile neutropenia	1	1 (8.33)	1	1 (8.33)
Thrombocytopenia	1	1 (8.33)	0	0 (0.00)
Eye disorders				
- Total	3	3 (25.00)	0	0 (0.00)
Conjunctivitis allergic	1	1 (8.33)	0	0 (0.00)
Dry eye	1	1 (8.33)	0	0 (0.00)
Ocular hyperaemia	1	1 (8.33)	0	0 (0.00)
Gastrointestinal disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=12 n (%)[1]	Grade >= 3 Total events	All patients N=12 n (%)[2]
- Total	10	4 (33.33)	5	2 (16.67)
Vomiting	4	3 (25.00)	1	1 (8.33)
Diarrhoea	2	2 (16.67)	1	1 (8.33)
Nausea	2	2 (16.67)	1	1 (8.33)
Abdominal pain	1	1 (8.33)	1	1 (8.33)
Enterocolitis	1	1 (8.33)	1	1 (8.33)
General disorders and administration site conditions				
- Total	4	4 (33.33)	0	0 (0.00)
Pyrexia	2	2 (16.67)	0	0 (0.00)
Influenza like illness	1	1 (8.33)	0	0 (0.00)
Malaise	1	1 (8.33)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (8.33)	0	0 (0.00)
Immunodeficiency common variable	1	1 (8.33)	0	0 (0.00)
Infections and infestations				
- Total	16	9 (75.00)	5	4 (33.33)
Influenza	2	2 (16.67)	0	0 (0.00)
Urinary tract infection	2	2 (16.67)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=12 n (%)[1]	Grade >= 3 Total events	All patients N=12 n (%)[2]
Viral upper respiratory tract infection	2	2 (16.67)	1	1 (8.33)
Bacterial sepsis	1	1 (8.33)	1	1 (8.33)
Corona virus infection	1	1 (8.33)	1	1 (8.33)
Gastroenteritis	1	1 (8.33)	0	0 (0.00)
Gastroenteritis viral	1	1 (8.33)	0	0 (0.00)
Molluscum contagiosum	1	1 (8.33)	0	0 (0.00)
Otitis externa	1	1 (8.33)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (8.33)	1	1 (8.33)
Paronychia	1	1 (8.33)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (8.33)	1	1 (8.33)
Subcutaneous abscess	1	1 (8.33)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	4	3 (25.00)	0	0 (0.00)
Infusion related reaction	1	1 (8.33)	0	0 (0.00)
Procedural pain	1	1 (8.33)	0	0 (0.00)
Skin abrasion	1	1 (8.33)	0	0 (0.00)
Skin laceration	1	1 (8.33)	0	0 (0.00)
Investigations				

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=12 n (%)[1]	Grade >= 3 Total events	All patients N=12 n (%)[2]
- Total	12	5 (41.67)	3	3 (25.00)
Neutrophil count decreased	5	3 (25.00)	2	2 (16.67)
Platelet count decreased	2	1 (8.33)	0	0 (0.00)
White blood cell count decreased	2	2 (16.67)	1	1 (8.33)
Lymphocyte count decreased	1	1 (8.33)	0	0 (0.00)
Oxygen saturation decreased	1	1 (8.33)	0	0 (0.00)
Serum ferritin increased	1	1 (8.33)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	4	4 (33.33)	2	2 (16.67)
Hyperphosphataemia	1	1 (8.33)	0	0 (0.00)
Hypokalaemia	1	1 (8.33)	0	0 (0.00)
Iron overload	1	1 (8.33)	1	1 (8.33)
Tumour lysis syndrome	1	1 (8.33)	1	1 (8.33)
Musculoskeletal and connective tissue disorders				
- Total	6	6 (50.00)	0	0 (0.00)
Pain in extremity	3	3 (25.00)	0	0 (0.00)
Arthralgia	1	1 (8.33)	0	0 (0.00)
Muscular weakness	1	1 (8.33)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=12 n (%)[1]	Grade >= 3 Total events	All patients N=12 n (%)[2]
Toe walking	1	1 (8.33)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (8.33)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (8.33)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (8.33)	0	0 (0.00)
Dizziness	1	1 (8.33)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (8.33)	0	0 (0.00)
Depression	1	1 (8.33)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (8.33)	1	1 (8.33)
Vaginal haemorrhage	1	1 (8.33)	1	1 (8.33)
Respiratory, thoracic and mediastinal disorders				
- Total	9	5 (41.67)	0	0 (0.00)
Cough	3	2 (16.67)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=12 n (%)[1]	Grade >= 3 Total events	All patients N=12 n (%)[2]
Nasal congestion	2	2 (16.67)	0	0 (0.00)
Rhinorrhoea	2	2 (16.67)	0	0 (0.00)
Oropharyngeal pain	1	1 (8.33)	0	0 (0.00)
Rhinitis allergic	1	1 (8.33)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	4	4 (33.33)	1	1 (8.33)
Dermatitis acneiform	1	1 (8.33)	1	1 (8.33)
Dry skin	1	1 (8.33)	0	0 (0.00)
Keloid scar	1	1 (8.33)	0	0 (0.00)
Rash maculo-papular	1	1 (8.33)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Total number of AE per patient	265	34 (77.27)	52	17 (38.64)
Blood and lymphatic system disorders				
- Total	14	8 (18.18)	11	6 (13.64)
Neutropenia	6	4 (9.09)	6	4 (9.09)
Eosinophilia	2	1 (2.27)	1	1 (2.27)
Febrile neutropenia	2	2 (4.55)	2	2 (4.55)
Leukopenia	1	1 (2.27)	1	1 (2.27)
Lymphadenopathy	1	1 (2.27)	0	0 (0.00)
Lymphopenia	1	1 (2.27)	0	0 (0.00)
Thrombocytopenia	1	1 (2.27)	1	1 (2.27)
Cardiac disorders				
- Total	1	1 (2.27)	0	0 (0.00)
Sinus tachycardia	1	1 (2.27)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Endocrine disorders				
- Total	1	1 (2.27)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.27)	0	0 (0.00)
Eye disorders				
- Total	2	2 (4.55)	0	0 (0.00)
Dry eye	1	1 (2.27)	0	0 (0.00)
Vision blurred	1	1 (2.27)	0	0 (0.00)
Gastrointestinal disorders				
- Total	28	12 (27.27)	3	2 (4.55)
Vomiting	9	6 (13.64)	1	1 (2.27)
Diarrhoea	6	6 (13.64)	0	0 (0.00)
Nausea	5	4 (9.09)	1	1 (2.27)
Abdominal pain	3	3 (6.82)	0	0 (0.00)
Oral pain	3	2 (4.55)	1	1 (2.27)
Abdominal pain upper	1	1 (2.27)	0	0 (0.00)
Pigmentation lip	1	1 (2.27)	0	0 (0.00)
General disorders and administration site conditions				

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
- Total	22	13 (29.55)	1	1 (2.27)
Pyrexia	12	8 (18.18)	1	1 (2.27)
Fatigue	2	2 (4.55)	0	0 (0.00)
Acquired gene mutation	1	1 (2.27)	0	0 (0.00)
Catheter site pain	1	1 (2.27)	0	0 (0.00)
Chills	1	1 (2.27)	0	0 (0.00)
Crying	1	1 (2.27)	0	0 (0.00)
Generalised oedema	1	1 (2.27)	0	0 (0.00)
Influenza like illness	1	1 (2.27)	0	0 (0.00)
Oedema peripheral	1	1 (2.27)	0	0 (0.00)
Pain	1	1 (2.27)	0	0 (0.00)
Immune system disorders				
- Total	16	13 (29.55)	1	1 (2.27)
Hypogammaglobulinaemia	9	8 (18.18)	1	1 (2.27)
Graft versus host disease	3	2 (4.55)	0	0 (0.00)
Seasonal allergy	2	2 (4.55)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (2.27)	0	0 (0.00)
Immunodeficiency common variable	1	1 (2.27)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Infections and infestations				
- Total	45	24 (54.55)	12	8 (18.18)
Upper respiratory tract infection	7	7 (15.91)	1	1 (2.27)
Cellulitis of male external genital organ	5	1 (2.27)	2	1 (2.27)
Rhinovirus infection	4	2 (4.55)	0	0 (0.00)
Urinary tract infection	3	2 (4.55)	2	2 (4.55)
Ear infection	2	2 (4.55)	0	0 (0.00)
Gastroenteritis	2	2 (4.55)	0	0 (0.00)
Otitis media	2	1 (2.27)	0	0 (0.00)
Sinusitis	2	2 (4.55)	0	0 (0.00)
Cholecystitis infective	1	1 (2.27)	1	1 (2.27)
Cytomegalovirus infection	1	1 (2.27)	0	0 (0.00)
Enterovirus infection	1	1 (2.27)	1	1 (2.27)
Escherichia urinary tract infection	1	1 (2.27)	1	1 (2.27)
Gastroenteritis norovirus	1	1 (2.27)	0	0 (0.00)
Herpes zoster	1	1 (2.27)	1	1 (2.27)
Influenza	1	1 (2.27)	0	0 (0.00)
Oral herpes	1	1 (2.27)	0	0 (0.00)
Otitis media acute	1	1 (2.27)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Parainfluenzae virus infection	1	1 (2.27)	0	0 (0.00)
Rash pustular	1	1 (2.27)	0	0 (0.00)
Rhinitis	1	1 (2.27)	0	0 (0.00)
Rotavirus infection	1	1 (2.27)	1	1 (2.27)
Sepsis	1	1 (2.27)	1	1 (2.27)
Tinea capitis	1	1 (2.27)	0	0 (0.00)
Vascular device infection	1	1 (2.27)	1	1 (2.27)
Viral infection	1	1 (2.27)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (2.27)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	9	5 (11.36)	0	0 (0.00)
Contusion	2	2 (4.55)	0	0 (0.00)
Arthropod bite	1	1 (2.27)	0	0 (0.00)
Foot fracture	1	1 (2.27)	0	0 (0.00)
Infusion related reaction	1	1 (2.27)	0	0 (0.00)
Procedural nausea	1	1 (2.27)	0	0 (0.00)
Procedural pain	1	1 (2.27)	0	0 (0.00)
Radius fracture	1	1 (2.27)	0	0 (0.00)
Sunburn	1	1 (2.27)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Investigations				
- Total	36	18 (40.91)	13	9 (20.45)
Neutrophil count decreased	7	5 (11.36)	6	4 (9.09)
White blood cell count decreased	5	3 (6.82)	2	1 (2.27)
Weight decreased	4	4 (9.09)	0	0 (0.00)
Aspartate aminotransferase increased	3	3 (6.82)	2	2 (4.55)
Platelet count decreased	3	2 (4.55)	0	0 (0.00)
Alanine aminotransferase increased	2	2 (4.55)	2	2 (4.55)
Blood urea increased	2	1 (2.27)	0	0 (0.00)
Haemoglobin decreased	2	2 (4.55)	0	0 (0.00)
Weight increased	2	2 (4.55)	0	0 (0.00)
Blood bilirubin increased	1	1 (2.27)	1	1 (2.27)
Blood creatinine increased	1	1 (2.27)	0	0 (0.00)
Blood magnesium decreased	1	1 (2.27)	0	0 (0.00)
Blood uric acid increased	1	1 (2.27)	0	0 (0.00)
Lymphocyte count decreased	1	1 (2.27)	0	0 (0.00)
Transaminases increased	1	1 (2.27)	0	0 (0.00)
Metabolism and nutrition disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
- Total	11	6 (13.64)	4	2 (4.55)
Decreased appetite	2	2 (4.55)	0	0 (0.00)
Hyperalbuminaemia	2	1 (2.27)	0	0 (0.00)
Dehydration	1	1 (2.27)	1	1 (2.27)
Hypercalcaemia	1	1 (2.27)	0	0 (0.00)
Hyperglycaemia	1	1 (2.27)	1	1 (2.27)
Hyperphosphataemia	1	1 (2.27)	0	0 (0.00)
Hypokalaemia	1	1 (2.27)	1	1 (2.27)
Hypophosphataemia	1	1 (2.27)	1	1 (2.27)
Vitamin D deficiency	1	1 (2.27)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	15	10 (22.73)	0	0 (0.00)
Pain in extremity	5	5 (11.36)	0	0 (0.00)
Joint range of motion decreased	2	2 (4.55)	0	0 (0.00)
Arthralgia	1	1 (2.27)	0	0 (0.00)
Back pain	1	1 (2.27)	0	0 (0.00)
Flank pain	1	1 (2.27)	0	0 (0.00)
Muscle spasms	1	1 (2.27)	0	0 (0.00)
Muscular weakness	1	1 (2.27)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Musculoskeletal chest pain	1	1 (2.27)	0	0 (0.00)
Osteonecrosis	1	1 (2.27)	0	0 (0.00)
Pain in jaw	1	1 (2.27)	0	0 (0.00)
Nervous system disorders				
- Total	11	7 (15.91)	0	0 (0.00)
Headache	7	5 (11.36)	0	0 (0.00)
Dizziness	2	2 (4.55)	0	0 (0.00)
Peroneal nerve palsy	2	2 (4.55)	0	0 (0.00)
Psychiatric disorders				
- Total	3	1 (2.27)	0	0 (0.00)
Anxiety	1	1 (2.27)	0	0 (0.00)
Depression	1	1 (2.27)	0	0 (0.00)
Sleep disorder	1	1 (2.27)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	3 (6.82)	3	2 (4.55)
Acute kidney injury	1	1 (2.27)	1	1 (2.27)
Calculus urinary	1	1 (2.27)	0	0 (0.00)
Haematuria	1	1 (2.27)	1	1 (2.27)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Nephrolithiasis	1	1 (2.27)	1	1 (2.27)
Urinary incontinence	1	1 (2.27)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (2.27)	0	0 (0.00)
Scrotal pain	1	1 (2.27)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	21	13 (29.55)	4	3 (6.82)
Cough	6	5 (11.36)	0	0 (0.00)
Epistaxis	2	2 (4.55)	1	1 (2.27)
Nasal congestion	2	2 (4.55)	0	0 (0.00)
Oropharyngeal pain	2	2 (4.55)	0	0 (0.00)
Rhinitis allergic	2	2 (4.55)	0	0 (0.00)
Rhinorrhoea	2	2 (4.55)	0	0 (0.00)
Acute respiratory failure	1	1 (2.27)	1	1 (2.27)
Dysphonia	1	1 (2.27)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.27)	0	0 (0.00)
Pharyngeal lesion	1	1 (2.27)	1	1 (2.27)
Pulmonary oedema	1	1 (2.27)	1	1 (2.27)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	21	12 (27.27)	0	0 (0.00)
Rash	5	4 (9.09)	0	0 (0.00)
Erythema	2	2 (4.55)	0	0 (0.00)
Rash erythematous	2	1 (2.27)	0	0 (0.00)
Alopecia	1	1 (2.27)	0	0 (0.00)
Dermatitis	1	1 (2.27)	0	0 (0.00)
Dermatitis atopic	1	1 (2.27)	0	0 (0.00)
Eczema	1	1 (2.27)	0	0 (0.00)
Hyperhidrosis	1	1 (2.27)	0	0 (0.00)
Ingrowing nail	1	1 (2.27)	0	0 (0.00)
Macule	1	1 (2.27)	0	0 (0.00)
Papule	1	1 (2.27)	0	0 (0.00)
Petechiae	1	1 (2.27)	0	0 (0.00)
Pruritus	1	1 (2.27)	0	0 (0.00)
Rash maculo-papular	1	1 (2.27)	0	0 (0.00)
Rash pruritic	1	1 (2.27)	0	0 (0.00)
Vascular disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
- Total	3	2 (4.55)	0	0 (0.00)
Hypertension	2	2 (4.55)	0	0 (0.00)
Hot flush	1	1 (2.27)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=9 n (%)[1]	Grade >= 3 Total events	All patients N=9 n (%)[2]
Total number of AE per patient	6	4 (44.44)	2	2 (22.22)
Infections and infestations				
- Total	1	1 (11.11)	1	1 (11.11)
Respiratory tract infection	1	1 (11.11)	1	1 (11.11)
Investigations				
- Total	2	1 (11.11)	0	0 (0.00)
Lymphocyte count decreased	1	1 (11.11)	0	0 (0.00)
Neutrophil count decreased	1	1 (11.11)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (11.11)	1	1 (11.11)
Ovarian failure	1	1 (11.11)	1	1 (11.11)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=9 n (%)[1]	Grade >= 3 Total events	All patients N=9 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	1	1 (11.11)	0	0 (0.00)
Epistaxis	1	1 (11.11)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (11.11)	0	0 (0.00)
Papule	1	1 (11.11)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Total number of AE per patient	84	18 (72.00)	21	10 (40.00)
Blood and lymphatic system disorders				
- Total	2	2 (8.00)	1	1 (4.00)
Febrile neutropenia	1	1 (4.00)	1	1 (4.00)
Thrombocytopenia	1	1 (4.00)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (4.00)	0	0 (0.00)
Tympanic membrane perforation	1	1 (4.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	3 (12.00)	0	0 (0.00)
Diarrhoea	2	2 (8.00)	0	0 (0.00)
Abdominal pain	1	1 (4.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Nausea	1	1 (4.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	2 (8.00)	1	1 (4.00)
Pyrexia	2	1 (4.00)	0	0 (0.00)
Chills	1	1 (4.00)	0	0 (0.00)
Cyst	1	1 (4.00)	1	1 (4.00)
Immune system disorders				
- Total	2	2 (8.00)	0	0 (0.00)
Chronic graft versus host disease	1	1 (4.00)	0	0 (0.00)
Immunodeficiency	1	1 (4.00)	0	0 (0.00)
Infections and infestations				
- Total	31	10 (40.00)	6	3 (12.00)
Otitis media	5	3 (12.00)	1	1 (4.00)
Otitis media acute	4	2 (8.00)	0	0 (0.00)
Upper respiratory tract infection	4	2 (8.00)	0	0 (0.00)
Sinusitis	3	3 (12.00)	0	0 (0.00)
Urinary tract infection	3	2 (8.00)	1	1 (4.00)
Pneumonia	2	2 (8.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Campylobacter infection	1	1 (4.00)	1	1 (4.00)
Cellulitis of male external genital organ	1	1 (4.00)	1	1 (4.00)
Clostridium difficile infection	1	1 (4.00)	1	1 (4.00)
Gingivitis	1	1 (4.00)	0	0 (0.00)
Haemophilus infection	1	1 (4.00)	0	0 (0.00)
Meningitis aseptic	1	1 (4.00)	0	0 (0.00)
Respiratory tract infection viral	1	1 (4.00)	1	1 (4.00)
Skin infection	1	1 (4.00)	0	0 (0.00)
Viral infection	1	1 (4.00)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (4.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (4.00)	1	1 (4.00)
Procedural pain	1	1 (4.00)	1	1 (4.00)
Investigations				
- Total	20	7 (28.00)	8	5 (20.00)
White blood cell count decreased	5	4 (16.00)	3	3 (12.00)
Lymphocyte count decreased	4	2 (8.00)	1	1 (4.00)
Alanine aminotransferase increased	3	3 (12.00)	2	2 (8.00)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Aspartate aminotransferase increased	2	2 (8.00)	1	1 (4.00)
Neutrophil count decreased	2	1 (4.00)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (4.00)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (4.00)	0	0 (0.00)
C-reactive protein increased	1	1 (4.00)	0	0 (0.00)
Platelet count decreased	1	1 (4.00)	1	1 (4.00)
Metabolism and nutrition disorders				
- Total	2	2 (8.00)	1	1 (4.00)
Hypokalaemia	1	1 (4.00)	1	1 (4.00)
Vitamin D deficiency	1	1 (4.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (4.00)	0	0 (0.00)
Neck pain	1	1 (4.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (4.00)	1	1 (4.00)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Glioblastoma multiforme	1	1 (4.00)	1	1 (4.00)
Nervous system disorders				
- Total	4	3 (12.00)	1	1 (4.00)
Disturbance in attention	1	1 (4.00)	0	0 (0.00)
Dizziness	1	1 (4.00)	0	0 (0.00)
Headache	1	1 (4.00)	0	0 (0.00)
Seizure	1	1 (4.00)	1	1 (4.00)
Renal and urinary disorders				
- Total	3	2 (8.00)	1	1 (4.00)
Acute kidney injury	2	1 (4.00)	1	1 (4.00)
Haematuria	1	1 (4.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	6	3 (12.00)	0	0 (0.00)
Cough	3	2 (8.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (4.00)	0	0 (0.00)
Rhinitis allergic	1	1 (4.00)	0	0 (0.00)
Rhinorrhoea	1	1 (4.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	2	2 (8.00)	0	0 (0.00)
Acne	1	1 (4.00)	0	0 (0.00)
Pruritus	1	1 (4.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Total number of AE per patient	315	14 (100.00)	123	14 (100.00)
Blood and lymphatic system disorders				
- Total	34	13 (92.86)	28	12 (85.71)
Febrile neutropenia	11	10 (71.43)	11	10 (71.43)
Thrombocytopenia	11	3 (21.43)	9	2 (14.29)
Anaemia	10	5 (35.71)	6	3 (21.43)
Neutropenia	1	1 (7.14)	1	1 (7.14)
Pancytopenia	1	1 (7.14)	1	1 (7.14)
Cardiac disorders				
- Total	4	4 (28.57)	0	0 (0.00)
Tachycardia	2	2 (14.29)	0	0 (0.00)
Atrioventricular block second degree	1	1 (7.14)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Sinus tachycardia	1	1 (7.14)	0	0 (0.00)
Eye disorders				
- Total	4	4 (28.57)	0	0 (0.00)
Conjunctivitis allergic	1	1 (7.14)	0	0 (0.00)
Dry eye	1	1 (7.14)	0	0 (0.00)
Ocular hyperaemia	1	1 (7.14)	0	0 (0.00)
Retinal haemorrhage	1	1 (7.14)	0	0 (0.00)
Gastrointestinal disorders				
- Total	30	7 (50.00)	11	4 (28.57)
Vomiting	9	4 (28.57)	2	1 (7.14)
Nausea	6	4 (28.57)	2	2 (14.29)
Abdominal pain	3	2 (14.29)	2	1 (7.14)
Diarrhoea	3	3 (21.43)	1	1 (7.14)
Constipation	2	2 (14.29)	0	0 (0.00)
Abdominal pain upper	1	1 (7.14)	0	0 (0.00)
Ascites	1	1 (7.14)	1	1 (7.14)
Dyspepsia	1	1 (7.14)	0	0 (0.00)
Enterocolitis	1	1 (7.14)	1	1 (7.14)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Intestinal obstruction	1	1 (7.14)	1	1 (7.14)
Pancreatitis	1	1 (7.14)	1	1 (7.14)
Tooth socket haemorrhage	1	1 (7.14)	0	0 (0.00)
General disorders and administration site conditions				
- Total	9	6 (42.86)	1	1 (7.14)
Pyrexia	4	3 (21.43)	1	1 (7.14)
Catheter site pain	1	1 (7.14)	0	0 (0.00)
Chills	1	1 (7.14)	0	0 (0.00)
Fatigue	1	1 (7.14)	0	0 (0.00)
Influenza like illness	1	1 (7.14)	0	0 (0.00)
Malaise	1	1 (7.14)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Hepatosplenomegaly	1	1 (7.14)	0	0 (0.00)
Immune system disorders				
- Total	26	14 (100.00)	5	4 (28.57)
Cytokine release syndrome	17	13 (92.86)	4	3 (21.43)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Hypogammaglobulinaemia	8	8 (57.14)	1	1 (7.14)
Immunodeficiency common variable	1	1 (7.14)	0	0 (0.00)
Infections and infestations				
- Total	27	11 (78.57)	9	6 (42.86)
Influenza	2	2 (14.29)	0	0 (0.00)
Urinary tract infection	2	2 (14.29)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (14.29)	1	1 (7.14)
Bacterial sepsis	1	1 (7.14)	1	1 (7.14)
Catheter site infection	1	1 (7.14)	1	1 (7.14)
Clostridium difficile infection	1	1 (7.14)	0	0 (0.00)
Corona virus infection	1	1 (7.14)	1	1 (7.14)
Cytomegalovirus infection	1	1 (7.14)	0	0 (0.00)
Folliculitis	1	1 (7.14)	0	0 (0.00)
Fungal skin infection	1	1 (7.14)	0	0 (0.00)
Gastroenteritis	1	1 (7.14)	0	0 (0.00)
Gastroenteritis viral	1	1 (7.14)	0	0 (0.00)
Molluscum contagiosum	1	1 (7.14)	0	0 (0.00)
Otitis externa	1	1 (7.14)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (7.14)	1	1 (7.14)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Paronychia	1	1 (7.14)	0	0 (0.00)
Pneumonia	1	1 (7.14)	1	1 (7.14)
Respiratory syncytial virus infection	1	1 (7.14)	1	1 (7.14)
Respiratory tract infection	1	1 (7.14)	1	1 (7.14)
Rhinovirus infection	1	1 (7.14)	0	0 (0.00)
Staphylococcal infection	1	1 (7.14)	0	0 (0.00)
Subcutaneous abscess	1	1 (7.14)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (7.14)	1	1 (7.14)
Viral infection	1	1 (7.14)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	5	4 (28.57)	0	0 (0.00)
Procedural pain	2	2 (14.29)	0	0 (0.00)
Infusion related reaction	1	1 (7.14)	0	0 (0.00)
Skin abrasion	1	1 (7.14)	0	0 (0.00)
Skin laceration	1	1 (7.14)	0	0 (0.00)
Investigations				
- Total	87	13 (92.86)	47	12 (85.71)
Neutrophil count decreased	24	8 (57.14)	20	7 (50.00)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
White blood cell count decreased	18	10 (71.43)	13	8 (57.14)
Platelet count decreased	9	4 (28.57)	6	3 (21.43)
Lymphocyte count decreased	7	6 (42.86)	4	4 (28.57)
Blood fibrinogen decreased	5	1 (7.14)	1	1 (7.14)
Alanine aminotransferase increased	3	2 (14.29)	1	1 (7.14)
Blood bilirubin increased	3	2 (14.29)	0	0 (0.00)
Prothrombin time prolonged	3	1 (7.14)	0	0 (0.00)
Blood creatinine increased	2	1 (7.14)	0	0 (0.00)
Blood sodium increased	2	1 (7.14)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (7.14)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (7.14)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (7.14)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (7.14)	0	0 (0.00)
Blood urea increased	1	1 (7.14)	0	0 (0.00)
C-reactive protein increased	1	1 (7.14)	1	1 (7.14)
Fibrin D dimer increased	1	1 (7.14)	0	0 (0.00)
International normalised ratio increased	1	1 (7.14)	0	0 (0.00)
Lipase increased	1	1 (7.14)	1	1 (7.14)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Oxygen saturation decreased	1	1 (7.14)	0	0 (0.00)
Serum ferritin increased	1	1 (7.14)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	23	9 (64.29)	12	6 (42.86)
Hypokalaemia	5	5 (35.71)	2	2 (14.29)
Decreased appetite	4	4 (28.57)	2	2 (14.29)
Hyperphosphataemia	3	2 (14.29)	0	0 (0.00)
Hypophosphataemia	3	1 (7.14)	3	1 (7.14)
Hypoalbuminaemia	2	1 (7.14)	1	1 (7.14)
Dehydration	1	1 (7.14)	1	1 (7.14)
Hypertriglyceridaemia	1	1 (7.14)	0	0 (0.00)
Hyperuricaemia	1	1 (7.14)	1	1 (7.14)
Hypomagnesaemia	1	1 (7.14)	0	0 (0.00)
Iron overload	1	1 (7.14)	1	1 (7.14)
Tumour lysis syndrome	1	1 (7.14)	1	1 (7.14)
Musculoskeletal and connective tissue disorders				
- Total	9	7 (50.00)	0	0 (0.00)
Pain in extremity	4	4 (28.57)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Arthralgia	2	2 (14.29)	0	0 (0.00)
Muscular weakness	2	2 (14.29)	0	0 (0.00)
Toe walking	1	1 (7.14)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (7.14)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (7.14)	0	0 (0.00)
Nervous system disorders				
- Total	9	5 (35.71)	0	0 (0.00)
Headache	4	3 (21.43)	0	0 (0.00)
Depressed level of consciousness	1	1 (7.14)	0	0 (0.00)
Dizziness	1	1 (7.14)	0	0 (0.00)
Dysarthria	1	1 (7.14)	0	0 (0.00)
Migraine	1	1 (7.14)	0	0 (0.00)
Somnolence	1	1 (7.14)	0	0 (0.00)
Psychiatric disorders				
- Total	2	2 (14.29)	0	0 (0.00)
Depression	1	1 (7.14)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Panic attack	1	1 (7.14)	0	0 (0.00)
Renal and urinary disorders				
- Total	2	2 (14.29)	1	1 (7.14)
Acute kidney injury	1	1 (7.14)	1	1 (7.14)
Dysuria	1	1 (7.14)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	3	3 (21.43)	2	2 (14.29)
Ovarian failure	1	1 (7.14)	1	1 (7.14)
Vaginal haemorrhage	1	1 (7.14)	1	1 (7.14)
Vulvovaginal adhesion	1	1 (7.14)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	20	9 (64.29)	4	2 (14.29)
Cough	4	3 (21.43)	0	0 (0.00)
Nasal congestion	3	3 (21.43)	0	0 (0.00)
Hypoxia	2	2 (14.29)	1	1 (7.14)
Pleural effusion	2	2 (14.29)	1	1 (7.14)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Rhinorrhoea	2	2 (14.29)	0	0 (0.00)
Epistaxis	1	1 (7.14)	0	0 (0.00)
Oropharyngeal pain	1	1 (7.14)	0	0 (0.00)
Oropharyngeal plaque	1	1 (7.14)	0	0 (0.00)
Pulmonary oedema	1	1 (7.14)	1	1 (7.14)
Respiratory failure	1	1 (7.14)	1	1 (7.14)
Rhinitis allergic	1	1 (7.14)	0	0 (0.00)
Tachypnoea	1	1 (7.14)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	14	8 (57.14)	1	1 (7.14)
Dermatitis acneiform	1	1 (7.14)	1	1 (7.14)
Dermatitis diaper	1	1 (7.14)	0	0 (0.00)
Dry skin	1	1 (7.14)	0	0 (0.00)
Erythema	1	1 (7.14)	0	0 (0.00)
Hyperhidrosis	1	1 (7.14)	0	0 (0.00)
Keloid scar	1	1 (7.14)	0	0 (0.00)
Macule	1	1 (7.14)	0	0 (0.00)
Papule	1	1 (7.14)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Petechiae	1	1 (7.14)	0	0 (0.00)
Pruritus	1	1 (7.14)	0	0 (0.00)
Rash	1	1 (7.14)	0	0 (0.00)
Rash erythematous	1	1 (7.14)	0	0 (0.00)
Rash macular	1	1 (7.14)	0	0 (0.00)
Rash maculo-papular	1	1 (7.14)	0	0 (0.00)
Vascular disorders				
- Total	5	5 (35.71)	2	2 (14.29)
Hypertension	2	2 (14.29)	0	0 (0.00)
Hypotension	2	2 (14.29)	2	2 (14.29)
Orthostatic hypotension	1	1 (7.14)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Total number of AE per patient	1435	50 (100.00)	429	45 (90.00)
Blood and lymphatic system disorders				
- Total	108	35 (70.00)	79	31 (62.00)
Anaemia	39	22 (44.00)	26	17 (34.00)
Thrombocytopenia	22	7 (14.00)	15	7 (14.00)
Febrile neutropenia	19	14 (28.00)	19	14 (28.00)
Neutropenia	14	10 (20.00)	13	10 (20.00)
Disseminated intravascular coagulation	5	4 (8.00)	2	2 (4.00)
Lymphopenia	4	4 (8.00)	2	2 (4.00)
Eosinophilia	2	1 (2.00)	1	1 (2.00)
Coagulopathy	1	1 (2.00)	0	0 (0.00)
Leukopenia	1	1 (2.00)	1	1 (2.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Lymphadenopathy	1	1 (2.00)	0	0 (0.00)
Cardiac disorders				
- Total	29	19 (38.00)	3	2 (4.00)
Tachycardia	15	13 (26.00)	2	2 (4.00)
Sinus tachycardia	5	5 (10.00)	0	0 (0.00)
Pericardial effusion	2	2 (4.00)	0	0 (0.00)
Sinus bradycardia	2	1 (2.00)	0	0 (0.00)
Bradycardia	1	1 (2.00)	0	0 (0.00)
Cardiac dysfunction	1	1 (2.00)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.00)	1	1 (2.00)
Palpitations	1	1 (2.00)	0	0 (0.00)
Ventricular tachycardia	1	1 (2.00)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	4	4 (8.00)	0	0 (0.00)
Ear pain	2	2 (4.00)	0	0 (0.00)
Hypoacusis	1	1 (2.00)	0	0 (0.00)
Tympanic membrane perforation	1	1 (2.00)	0	0 (0.00)
Endocrine disorders				

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
- Total	2	2 (4.00)	0	0 (0.00)
Adrenal insufficiency	2	2 (4.00)	0	0 (0.00)
Eye disorders				
- Total	26	14 (28.00)	0	0 (0.00)
Vision blurred	5	4 (8.00)	0	0 (0.00)
Eye pain	4	3 (6.00)	0	0 (0.00)
Periorbital oedema	4	4 (8.00)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (6.00)	0	0 (0.00)
Photophobia	3	2 (4.00)	0	0 (0.00)
Uveitis	2	2 (4.00)	0	0 (0.00)
Dry eye	1	1 (2.00)	0	0 (0.00)
Ocular hypertension	1	1 (2.00)	0	0 (0.00)
Papilloedema	1	1 (2.00)	0	0 (0.00)
Retinal haemorrhage	1	1 (2.00)	0	0 (0.00)
Visual impairment	1	1 (2.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	138	36 (72.00)	12	9 (18.00)
Vomiting	39	23 (46.00)	3	2 (4.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Nausea	28	21 (42.00)	3	3 (6.00)
Diarrhoea	25	21 (42.00)	1	1 (2.00)
Abdominal pain	12	9 (18.00)	0	0 (0.00)
Constipation	6	5 (10.00)	0	0 (0.00)
Oral pain	3	2 (4.00)	1	1 (2.00)
Abdominal distension	2	2 (4.00)	0	0 (0.00)
Abdominal pain upper	2	2 (4.00)	0	0 (0.00)
Anal incontinence	2	1 (2.00)	0	0 (0.00)
Dysphagia	2	2 (4.00)	1	1 (2.00)
Haematemesis	2	2 (4.00)	0	0 (0.00)
Mouth haemorrhage	2	1 (2.00)	2	1 (2.00)
Stomatitis	2	2 (4.00)	0	0 (0.00)
Abdominal discomfort	1	1 (2.00)	0	0 (0.00)
Abdominal pain lower	1	1 (2.00)	0	0 (0.00)
Abdominal tenderness	1	1 (2.00)	0	0 (0.00)
Flatulence	1	1 (2.00)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (2.00)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.00)	0	0 (0.00)
Glossodynia	1	1 (2.00)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Ileus	1	1 (2.00)	1	1 (2.00)
Lip pain	1	1 (2.00)	0	0 (0.00)
Pancreatitis	1	1 (2.00)	0	0 (0.00)
Pigmentation lip	1	1 (2.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	98	36 (72.00)	15	11 (22.00)
Pyrexia	39	22 (44.00)	6	6 (12.00)
Fatigue	15	14 (28.00)	1	1 (2.00)
Chills	10	9 (18.00)	0	0 (0.00)
Generalised oedema	4	3 (6.00)	0	0 (0.00)
Pain	4	4 (8.00)	2	2 (4.00)
Catheter site pain	3	3 (6.00)	0	0 (0.00)
Malaise	3	3 (6.00)	0	0 (0.00)
Oedema peripheral	3	3 (6.00)	1	1 (2.00)
Face oedema	2	2 (4.00)	1	1 (2.00)
Acquired gene mutation	1	1 (2.00)	0	0 (0.00)
Asthenia	1	1 (2.00)	0	0 (0.00)
Catheter site extravasation	1	1 (2.00)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Catheter site haemorrhage	1	1 (2.00)	0	0 (0.00)
Crying	1	1 (2.00)	0	0 (0.00)
Cyst	1	1 (2.00)	1	1 (2.00)
Facial pain	1	1 (2.00)	0	0 (0.00)
Influenza like illness	1	1 (2.00)	0	0 (0.00)
Injection site haematoma	1	1 (2.00)	0	0 (0.00)
Localised oedema	1	1 (2.00)	1	1 (2.00)
Mucosal haemorrhage	1	1 (2.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.00)	1	1 (2.00)
Non-cardiac chest pain	1	1 (2.00)	0	0 (0.00)
Peripheral swelling	1	1 (2.00)	0	0 (0.00)
Physical deconditioning	1	1 (2.00)	1	1 (2.00)
Hepatobiliary disorders				
- Total	8	6 (12.00)	2	2 (4.00)
Hyperbilirubinaemia	4	3 (6.00)	2	2 (4.00)
Hepatomegaly	3	3 (6.00)	0	0 (0.00)
Gallbladder enlargement	1	1 (2.00)	0	0 (0.00)
Immune system disorders				

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
- Total	109	44 (88.00)	29	18 (36.00)
Cytokine release syndrome	69	37 (74.00)	25	16 (32.00)
Hypogammaglobulinaemia	28	25 (50.00)	4	4 (8.00)
Graft versus host disease	3	2 (4.00)	0	0 (0.00)
Seasonal allergy	2	2 (4.00)	0	0 (0.00)
Chronic graft versus host disease	1	1 (2.00)	0	0 (0.00)
Drug hypersensitivity	1	1 (2.00)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (2.00)	0	0 (0.00)
Graft versus host disease in skin	1	1 (2.00)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (2.00)	0	0 (0.00)
Immunodeficiency	1	1 (2.00)	0	0 (0.00)
Immunodeficiency common variable	1	1 (2.00)	0	0 (0.00)
Infections and infestations				
- Total	107	35 (70.00)	22	12 (24.00)
Upper respiratory tract infection	12	9 (18.00)	1	1 (2.00)
Otitis media	7	4 (8.00)	1	1 (2.00)
Cellulitis of male external genital organ	6	1 (2.00)	3	1 (2.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Rhinovirus infection	6	4 (8.00)	0	0 (0.00)
Urinary tract infection	6	3 (6.00)	3	2 (4.00)
Otitis media acute	5	2 (4.00)	0	0 (0.00)
Sinusitis	5	4 (8.00)	0	0 (0.00)
Clostridium difficile colitis	4	4 (8.00)	1	1 (2.00)
Clostridium difficile infection	4	4 (8.00)	1	1 (2.00)
Gastroenteritis	4	4 (8.00)	1	1 (2.00)
Pneumonia	3	3 (6.00)	0	0 (0.00)
Ear infection	2	2 (4.00)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (2.00)	0	0 (0.00)
Influenza	2	2 (4.00)	0	0 (0.00)
Skin infection	2	2 (4.00)	0	0 (0.00)
Viral infection	2	2 (4.00)	0	0 (0.00)
Vulvovaginal candidiasis	2	2 (4.00)	0	0 (0.00)
Acute sinusitis	1	1 (2.00)	0	0 (0.00)
Body tinea	1	1 (2.00)	0	0 (0.00)
Campylobacter infection	1	1 (2.00)	1	1 (2.00)
Catheter site cellulitis	1	1 (2.00)	0	0 (0.00)
Cholecystitis infective	1	1 (2.00)	1	1 (2.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Cytomegalovirus infection	1	1 (2.00)	0	0 (0.00)
Enterococcal infection	1	1 (2.00)	0	0 (0.00)
Enterovirus infection	1	1 (2.00)	1	1 (2.00)
Escherichia urinary tract infection	1	1 (2.00)	1	1 (2.00)
Gingivitis	1	1 (2.00)	0	0 (0.00)
Haemophilus infection	1	1 (2.00)	0	0 (0.00)
Herpes simplex	1	1 (2.00)	0	0 (0.00)
Herpes zoster	1	1 (2.00)	1	1 (2.00)
Human herpesvirus 6 infection	1	1 (2.00)	0	0 (0.00)
Hypopyon	1	1 (2.00)	0	0 (0.00)
Meningitis aseptic	1	1 (2.00)	0	0 (0.00)
Oral candidiasis	1	1 (2.00)	0	0 (0.00)
Oral herpes	1	1 (2.00)	0	0 (0.00)
Orchitis	1	1 (2.00)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.00)	0	0 (0.00)
Pharyngitis	1	1 (2.00)	0	0 (0.00)
Rash pustular	1	1 (2.00)	0	0 (0.00)
Respiratory tract infection viral	1	1 (2.00)	1	1 (2.00)
Rhinitis	1	1 (2.00)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Rotavirus infection	1	1 (2.00)	1	1 (2.00)
Sepsis	1	1 (2.00)	1	1 (2.00)
Septic embolus	1	1 (2.00)	1	1 (2.00)
Staphylococcal infection	1	1 (2.00)	1	1 (2.00)
Streptococcal infection	1	1 (2.00)	0	0 (0.00)
Tinea capitis	1	1 (2.00)	0	0 (0.00)
Vascular device infection	1	1 (2.00)	1	1 (2.00)
Viral upper respiratory tract infection	1	1 (2.00)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (2.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	34	18 (36.00)	3	3 (6.00)
Procedural pain	4	3 (6.00)	1	1 (2.00)
Transfusion reaction	4	3 (6.00)	0	0 (0.00)
Contusion	3	3 (6.00)	0	0 (0.00)
Infusion related reaction	3	3 (6.00)	0	0 (0.00)
Tracheal haemorrhage	2	1 (2.00)	1	1 (2.00)
Arthropod bite	1	1 (2.00)	0	0 (0.00)
Foot fracture	1	1 (2.00)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Incision site pain	1	1 (2.00)	0	0 (0.00)
Limb injury	1	1 (2.00)	0	0 (0.00)
Mouth injury	1	1 (2.00)	0	0 (0.00)
Post procedural haemorrhage	1	1 (2.00)	0	0 (0.00)
Procedural complication	1	1 (2.00)	0	0 (0.00)
Procedural headache	1	1 (2.00)	0	0 (0.00)
Procedural nausea	1	1 (2.00)	0	0 (0.00)
Procedural site reaction	1	1 (2.00)	0	0 (0.00)
Radius fracture	1	1 (2.00)	0	0 (0.00)
Skin abrasion	1	1 (2.00)	0	0 (0.00)
Stoma site irritation	1	1 (2.00)	0	0 (0.00)
Subdural haemorrhage	1	1 (2.00)	0	0 (0.00)
Sunburn	1	1 (2.00)	0	0 (0.00)
Tibia fracture	1	1 (2.00)	0	0 (0.00)
Tongue injury	1	1 (2.00)	0	0 (0.00)
Transfusion related complication	1	1 (2.00)	1	1 (2.00)
Investigations				
- Total	315	43 (86.00)	155	37 (74.00)
White blood cell count decreased	49	25 (50.00)	30	22 (44.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Platelet count decreased	40	16 (32.00)	32	12 (24.00)
Neutrophil count decreased	38	20 (40.00)	32	18 (36.00)
Aspartate aminotransferase increased	36	19 (38.00)	19	12 (24.00)
Alanine aminotransferase increased	30	19 (38.00)	17	13 (26.00)
Lymphocyte count decreased	16	10 (20.00)	9	8 (16.00)
Prothrombin time prolonged	14	8 (16.00)	1	1 (2.00)
Blood bilirubin increased	11	6 (12.00)	3	3 (6.00)
Blood creatinine increased	10	8 (16.00)	2	2 (4.00)
Blood fibrinogen decreased	10	3 (6.00)	3	2 (4.00)
International normalised ratio increased	10	8 (16.00)	1	1 (2.00)
Activated partial thromboplastin time prolonged	8	5 (10.00)	0	0 (0.00)
Blood urea increased	4	2 (4.00)	1	1 (2.00)
Weight decreased	4	4 (8.00)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (6.00)	0	0 (0.00)
Blood phosphorus increased	3	2 (4.00)	0	0 (0.00)
Blood uric acid increased	3	2 (4.00)	0	0 (0.00)
Haemoglobin decreased	3	3 (6.00)	1	1 (2.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Transaminases increased	3	3 (6.00)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (4.00)	0	0 (0.00)
Blood magnesium decreased	2	2 (4.00)	1	1 (2.00)
Weight increased	2	2 (4.00)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (2.00)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (2.00)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (2.00)	0	0 (0.00)
Blood lactic acid increased	1	1 (2.00)	1	1 (2.00)
Blood phosphorus decreased	1	1 (2.00)	0	0 (0.00)
C-reactive protein increased	1	1 (2.00)	0	0 (0.00)
Cardiac murmur	1	1 (2.00)	0	0 (0.00)
Culture stool positive	1	1 (2.00)	0	0 (0.00)
Hepatic enzyme increased	1	1 (2.00)	0	0 (0.00)
Lipase increased	1	1 (2.00)	1	1 (2.00)
Norovirus test positive	1	1 (2.00)	0	0 (0.00)
Protein total decreased	1	1 (2.00)	1	1 (2.00)
Pulmonary function test decreased	1	1 (2.00)	0	0 (0.00)
Serum ferritin increased	1	1 (2.00)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Metabolism and nutrition disorders				
- Total	110	34 (68.00)	38	21 (42.00)
Decreased appetite	22	18 (36.00)	11	10 (20.00)
Hypokalaemia	18	14 (28.00)	7	7 (14.00)
Hypophosphataemia	11	9 (18.00)	7	7 (14.00)
Hyperphosphataemia	9	6 (12.00)	0	0 (0.00)
Hypernatraemia	7	4 (8.00)	1	1 (2.00)
Hyperglycaemia	5	3 (6.00)	2	2 (4.00)
Hypoalbuminaemia	4	4 (8.00)	0	0 (0.00)
Hypocalcaemia	4	3 (6.00)	1	1 (2.00)
Dehydration	3	3 (6.00)	2	2 (4.00)
Fluid overload	3	3 (6.00)	0	0 (0.00)
Hyperalbuminaemia	3	1 (2.00)	0	0 (0.00)
Hypercalcaemia	3	1 (2.00)	0	0 (0.00)
Hyperuricaemia	3	2 (4.00)	0	0 (0.00)
Hyponatraemia	3	2 (4.00)	3	2 (4.00)
Acidosis	2	2 (4.00)	1	1 (2.00)
Hypertriglyceridaemia	2	1 (2.00)	1	1 (2.00)
Vitamin D deficiency	2	2 (4.00)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Hyperchloraemia	1	1 (2.00)	0	0 (0.00)
Hypermagnesaemia	1	1 (2.00)	0	0 (0.00)
Malnutrition	1	1 (2.00)	1	1 (2.00)
Metabolic acidosis	1	1 (2.00)	0	0 (0.00)
Metabolic alkalosis	1	1 (2.00)	0	0 (0.00)
Tumour lysis syndrome	1	1 (2.00)	1	1 (2.00)
Musculoskeletal and connective tissue disorders				
- Total	36	18 (36.00)	1	1 (2.00)
Pain in extremity	8	7 (14.00)	0	0 (0.00)
Myalgia	5	5 (10.00)	0	0 (0.00)
Arthralgia	4	3 (6.00)	1	1 (2.00)
Musculoskeletal pain	4	3 (6.00)	0	0 (0.00)
Joint range of motion decreased	2	2 (4.00)	0	0 (0.00)
Muscle spasms	2	2 (4.00)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (4.00)	0	0 (0.00)
Back pain	1	1 (2.00)	0	0 (0.00)
Coccydynia	1	1 (2.00)	0	0 (0.00)
Flank pain	1	1 (2.00)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Limb discomfort	1	1 (2.00)	0	0 (0.00)
Muscular weakness	1	1 (2.00)	0	0 (0.00)
Neck pain	1	1 (2.00)	0	0 (0.00)
Osteonecrosis	1	1 (2.00)	0	0 (0.00)
Osteopenia	1	1 (2.00)	0	0 (0.00)
Pain in jaw	1	1 (2.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	2 (4.00)	1	1 (2.00)
Glioblastoma multiforme	1	1 (2.00)	1	1 (2.00)
Skin papilloma	1	1 (2.00)	0	0 (0.00)
Nervous system disorders				
- Total	65	30 (60.00)	7	6 (12.00)
Headache	35	21 (42.00)	2	2 (4.00)
Dizziness	7	5 (10.00)	0	0 (0.00)
Encephalopathy	6	4 (8.00)	2	2 (4.00)
Seizure	4	4 (8.00)	2	2 (4.00)
Peroneal nerve palsy	2	2 (4.00)	0	0 (0.00)
Tremor	2	2 (4.00)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Asterixis	1	1 (2.00)	0	0 (0.00)
Ataxia	1	1 (2.00)	0	0 (0.00)
Disturbance in attention	1	1 (2.00)	0	0 (0.00)
Dysarthria	1	1 (2.00)	0	0 (0.00)
Embolic stroke	1	1 (2.00)	1	1 (2.00)
Idiopathic intracranial hypertension	1	1 (2.00)	0	0 (0.00)
Myoclonus	1	1 (2.00)	0	0 (0.00)
Neuropathy peripheral	1	1 (2.00)	0	0 (0.00)
Pleocytosis	1	1 (2.00)	0	0 (0.00)
Product issues				
- Total	1	1 (2.00)	0	0 (0.00)
Device occlusion	1	1 (2.00)	0	0 (0.00)
Psychiatric disorders				
- Total	32	15 (30.00)	1	1 (2.00)
Anxiety	7	7 (14.00)	1	1 (2.00)
Confusional state	6	6 (12.00)	0	0 (0.00)
Delirium	4	4 (8.00)	0	0 (0.00)
Agitation	3	2 (4.00)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Hallucination	3	2 (4.00)	0	0 (0.00)
Irritability	2	2 (4.00)	0	0 (0.00)
Adjustment disorder	1	1 (2.00)	0	0 (0.00)
Depression	1	1 (2.00)	0	0 (0.00)
Insomnia	1	1 (2.00)	0	0 (0.00)
Listless	1	1 (2.00)	0	0 (0.00)
Mental status changes	1	1 (2.00)	0	0 (0.00)
Sleep disorder	1	1 (2.00)	0	0 (0.00)
Suicidal ideation	1	1 (2.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	24	13 (26.00)	14	9 (18.00)
Acute kidney injury	9	8 (16.00)	6	6 (12.00)
Haematuria	6	5 (10.00)	3	3 (6.00)
Oliguria	2	2 (4.00)	2	2 (4.00)
Calculus urinary	1	1 (2.00)	0	0 (0.00)
Dysuria	1	1 (2.00)	0	0 (0.00)
Nephrolithiasis	1	1 (2.00)	1	1 (2.00)
Pollakiuria	1	1 (2.00)	0	0 (0.00)
Renal failure	1	1 (2.00)	1	1 (2.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Renal impairment	1	1 (2.00)	1	1 (2.00)
Urinary incontinence	1	1 (2.00)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	4	3 (6.00)	0	0 (0.00)
Oedema genital	2	1 (2.00)	0	0 (0.00)
Scrotal pain	1	1 (2.00)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (2.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	90	29 (58.00)	28	13 (26.00)
Cough	16	11 (22.00)	0	0 (0.00)
Epistaxis	13	9 (18.00)	5	5 (10.00)
Hypoxia	11	8 (16.00)	7	6 (12.00)
Pleural effusion	6	6 (12.00)	1	1 (2.00)
Pulmonary oedema	6	6 (12.00)	5	5 (10.00)
Oropharyngeal pain	5	5 (10.00)	0	0 (0.00)
Tachypnoea	5	4 (8.00)	1	1 (2.00)
Rhinitis allergic	4	3 (6.00)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Rhinorrhoea	4	4 (8.00)	0	0 (0.00)
Dyspnoea	3	2 (4.00)	2	2 (4.00)
Haemoptysis	3	2 (4.00)	1	1 (2.00)
Nasal congestion	2	2 (4.00)	0	0 (0.00)
Respiratory failure	2	2 (4.00)	2	2 (4.00)
Acute respiratory failure	1	1 (2.00)	1	1 (2.00)
Atelectasis	1	1 (2.00)	0	0 (0.00)
Dysphonia	1	1 (2.00)	0	0 (0.00)
Interstitial lung disease	1	1 (2.00)	1	1 (2.00)
Pharyngeal erythema	1	1 (2.00)	0	0 (0.00)
Pharyngeal lesion	1	1 (2.00)	1	1 (2.00)
Pharyngeal ulceration	1	1 (2.00)	0	0 (0.00)
Respiratory depression	1	1 (2.00)	0	0 (0.00)
Respiratory distress	1	1 (2.00)	1	1 (2.00)
Wheezing	1	1 (2.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	55	22 (44.00)	2	2 (4.00)
Rash	8	7 (14.00)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Erythema	5	4 (8.00)	0	0 (0.00)
Dry skin	4	4 (8.00)	0	0 (0.00)
Hyperhidrosis	4	3 (6.00)	0	0 (0.00)
Ingrowing nail	4	3 (6.00)	0	0 (0.00)
Rash maculo-papular	4	4 (8.00)	1	1 (2.00)
Petechiae	3	3 (6.00)	0	0 (0.00)
Pruritus	3	3 (6.00)	0	0 (0.00)
Rash erythematous	2	1 (2.00)	0	0 (0.00)
Rash papular	2	2 (4.00)	0	0 (0.00)
Acne	1	1 (2.00)	0	0 (0.00)
Alopecia	1	1 (2.00)	0	0 (0.00)
Dermatitis	1	1 (2.00)	0	0 (0.00)
Dermatitis atopic	1	1 (2.00)	0	0 (0.00)
Ecchymosis	1	1 (2.00)	1	1 (2.00)
Eczema	1	1 (2.00)	0	0 (0.00)
Livedo reticularis	1	1 (2.00)	0	0 (0.00)
Macule	1	1 (2.00)	0	0 (0.00)
Night sweats	1	1 (2.00)	0	0 (0.00)
Papule	1	1 (2.00)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Rash follicular	1	1 (2.00)	0	0 (0.00)
Rash pruritic	1	1 (2.00)	0	0 (0.00)
Rash vesicular	1	1 (2.00)	0	0 (0.00)
Skin exfoliation	1	1 (2.00)	0	0 (0.00)
Skin fissures	1	1 (2.00)	0	0 (0.00)
Skin irritation	1	1 (2.00)	0	0 (0.00)
Vascular disorders				
- Total	38	20 (40.00)	17	14 (28.00)
Hypotension	17	14 (28.00)	14	13 (26.00)
Hypertension	12	10 (20.00)	1	1 (2.00)
Flushing	3	2 (4.00)	0	0 (0.00)
Capillary leak syndrome	1	1 (2.00)	1	1 (2.00)
Embolism	1	1 (2.00)	1	1 (2.00)
Haematoma	1	1 (2.00)	0	0 (0.00)
Hot flush	1	1 (2.00)	0	0 (0.00)
Orthostatic hypotension	1	1 (2.00)	0	0 (0.00)
Secondary hypertension	1	1 (2.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	286	19 (95.00)	97	18 (90.00)
Blood and lymphatic system disorders				
- Total	25	14 (70.00)	20	14 (70.00)
Febrile neutropenia	10	9 (45.00)	10	9 (45.00)
Anaemia	9	9 (45.00)	5	5 (25.00)
Neutropenia	3	3 (15.00)	3	3 (15.00)
Disseminated intravascular coagulation	1	1 (5.00)	0	0 (0.00)
Lymphopenia	1	1 (5.00)	1	1 (5.00)
Pancytopenia	1	1 (5.00)	1	1 (5.00)
Cardiac disorders				
- Total	4	2 (10.00)	0	0 (0.00)
Sinus bradycardia	2	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Tachycardia	2	2 (10.00)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Hypoacusis	1	1 (5.00)	0	0 (0.00)
Eye disorders				
- Total	5	3 (15.00)	0	0 (0.00)
Eye pain	3	2 (10.00)	0	0 (0.00)
Retinal haemorrhage	1	1 (5.00)	0	0 (0.00)
Vision blurred	1	1 (5.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	36	11 (55.00)	3	1 (5.00)
Vomiting	11	7 (35.00)	1	1 (5.00)
Nausea	7	7 (35.00)	0	0 (0.00)
Abdominal pain	3	3 (15.00)	1	1 (5.00)
Constipation	3	3 (15.00)	0	0 (0.00)
Diarrhoea	3	3 (15.00)	0	0 (0.00)
Anal incontinence	2	1 (5.00)	0	0 (0.00)
Abdominal pain upper	1	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Dyspepsia	1	1 (5.00)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (5.00)	0	0 (0.00)
Haematemesis	1	1 (5.00)	0	0 (0.00)
Intestinal obstruction	1	1 (5.00)	1	1 (5.00)
Lip pain	1	1 (5.00)	0	0 (0.00)
Stomatitis	1	1 (5.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	12	7 (35.00)	2	2 (10.00)
Fatigue	4	4 (20.00)	0	0 (0.00)
Chills	2	2 (10.00)	0	0 (0.00)
Pain	2	2 (10.00)	1	1 (5.00)
Pyrexia	2	2 (10.00)	1	1 (5.00)
Catheter site pain	1	1 (5.00)	0	0 (0.00)
Non-cardiac chest pain	1	1 (5.00)	0	0 (0.00)
Hepatobiliary disorders				
- Total	2	2 (10.00)	0	0 (0.00)
Hepatomegaly	1	1 (5.00)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Immune system disorders				
- Total	35	17 (85.00)	8	6 (30.00)
Cytokine release syndrome	24	16 (80.00)	7	5 (25.00)
Hypogammaglobulinaemia	10	9 (45.00)	1	1 (5.00)
Drug hypersensitivity	1	1 (5.00)	0	0 (0.00)
Infections and infestations				
- Total	15	9 (45.00)	2	2 (10.00)
Gastroenteritis	2	2 (10.00)	1	1 (5.00)
Acute sinusitis	1	1 (5.00)	0	0 (0.00)
Clostridium difficile colitis	1	1 (5.00)	0	0 (0.00)
Folliculitis	1	1 (5.00)	0	0 (0.00)
Fungal skin infection	1	1 (5.00)	0	0 (0.00)
Herpes simplex	1	1 (5.00)	0	0 (0.00)
Oral candidiasis	1	1 (5.00)	0	0 (0.00)
Orchitis	1	1 (5.00)	0	0 (0.00)
Pharyngitis	1	1 (5.00)	0	0 (0.00)
Streptococcal infection	1	1 (5.00)	0	0 (0.00)
Upper respiratory tract infection	1	1 (5.00)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (5.00)	1	1 (5.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Viral infection	1	1 (5.00)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (5.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (5.00)	0	0 (0.00)
Procedural pain	1	1 (5.00)	0	0 (0.00)
Investigations				
- Total	81	16 (80.00)	43	13 (65.00)
Neutrophil count decreased	15	8 (40.00)	15	8 (40.00)
White blood cell count decreased	15	9 (45.00)	11	8 (40.00)
Platelet count decreased	8	6 (30.00)	6	4 (20.00)
Aspartate aminotransferase increased	6	5 (25.00)	2	2 (10.00)
Lymphocyte count decreased	6	6 (30.00)	5	5 (25.00)
Alanine aminotransferase increased	4	4 (20.00)	2	2 (10.00)
Blood bilirubin increased	4	3 (15.00)	1	1 (5.00)
Blood creatinine increased	4	3 (15.00)	0	0 (0.00)
International normalised ratio increased	4	3 (15.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Activated partial thromboplastin time prolonged	3	1 (5.00)	0	0 (0.00)
Prothrombin time prolonged	3	2 (10.00)	0	0 (0.00)
Blood phosphorus increased	2	1 (5.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (5.00)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (5.00)	0	0 (0.00)
Blood lactic acid increased	1	1 (5.00)	1	1 (5.00)
Cardiac murmur	1	1 (5.00)	0	0 (0.00)
Culture stool positive	1	1 (5.00)	0	0 (0.00)
Fibrin D dimer increased	1	1 (5.00)	0	0 (0.00)
Serum ferritin increased	1	1 (5.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	16	10 (50.00)	10	8 (40.00)
Decreased appetite	6	5 (25.00)	3	3 (15.00)
Dehydration	2	2 (10.00)	2	2 (10.00)
Hyperphosphataemia	2	2 (10.00)	0	0 (0.00)
Hypophosphataemia	2	2 (10.00)	2	2 (10.00)
Fluid overload	1	1 (5.00)	0	0 (0.00)
Hyperuricaemia	1	1 (5.00)	1	1 (5.00)
Hypokalaemia	1	1 (5.00)	1	1 (5.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Hyponatraemia	1	1 (5.00)	1	1 (5.00)
Musculoskeletal and connective tissue disorders				
- Total	5	5 (25.00)	1	1 (5.00)
Myalgia	2	2 (10.00)	0	0 (0.00)
Pain in extremity	2	2 (10.00)	0	0 (0.00)
Arthralgia	1	1 (5.00)	1	1 (5.00)
Nervous system disorders				
- Total	14	9 (45.00)	2	1 (5.00)
Headache	8	6 (30.00)	1	1 (5.00)
Encephalopathy	3	3 (15.00)	1	1 (5.00)
Myoclonus	1	1 (5.00)	0	0 (0.00)
Seizure	1	1 (5.00)	0	0 (0.00)
Tremor	1	1 (5.00)	0	0 (0.00)
Psychiatric disorders				
- Total	5	4 (20.00)	0	0 (0.00)
Anxiety	1	1 (5.00)	0	0 (0.00)
Confusional state	1	1 (5.00)	0	0 (0.00)
Delirium	1	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Mental status changes	1	1 (5.00)	0	0 (0.00)
Panic attack	1	1 (5.00)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (5.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	11	6 (30.00)	0	0 (0.00)
Hypoxia	3	3 (15.00)	0	0 (0.00)
Cough	2	2 (10.00)	0	0 (0.00)
Atelectasis	1	1 (5.00)	0	0 (0.00)
Nasal congestion	1	1 (5.00)	0	0 (0.00)
Pharyngeal ulceration	1	1 (5.00)	0	0 (0.00)
Pleural effusion	1	1 (5.00)	0	0 (0.00)
Respiratory depression	1	1 (5.00)	0	0 (0.00)
Rhinitis allergic	1	1 (5.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	9	6 (30.00)	1	1 (5.00)
Dry skin	2	2 (10.00)	0	0 (0.00)
Erythema	2	2 (10.00)	0	0 (0.00)
Ingrowing nail	2	1 (5.00)	0	0 (0.00)
Dermatitis diaper	1	1 (5.00)	0	0 (0.00)
Livedo reticularis	1	1 (5.00)	0	0 (0.00)
Rash maculo-papular	1	1 (5.00)	1	1 (5.00)
Vascular disorders				
- Total	8	5 (25.00)	5	5 (25.00)
Hypotension	4	4 (20.00)	4	4 (20.00)
Hypertension	3	2 (10.00)	0	0 (0.00)
Embolism	1	1 (5.00)	1	1 (5.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Total number of AE per patient	1028	44 (100.00)	361	36 (81.82)
Blood and lymphatic system disorders				
- Total	97	29 (65.91)	73	24 (54.55)
Anaemia	38	18 (40.91)	26	14 (31.82)
Thrombocytopenia	30	8 (18.18)	23	8 (18.18)
Febrile neutropenia	16	13 (29.55)	16	13 (29.55)
Neutropenia	6	5 (11.36)	5	5 (11.36)
Disseminated intravascular coagulation	4	3 (6.82)	2	2 (4.55)
Lymphopenia	2	2 (4.55)	1	1 (2.27)
Coagulopathy	1	1 (2.27)	0	0 (0.00)
Cardiac disorders				
- Total	28	20 (45.45)	3	2 (4.55)
Tachycardia	15	13 (29.55)	2	2 (4.55)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Sinus tachycardia	5	5 (11.36)	0	0 (0.00)
Pericardial effusion	2	2 (4.55)	0	0 (0.00)
Atrioventricular block second degree	1	1 (2.27)	0	0 (0.00)
Bradycardia	1	1 (2.27)	0	0 (0.00)
Cardiac dysfunction	1	1 (2.27)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.27)	1	1 (2.27)
Palpitations	1	1 (2.27)	0	0 (0.00)
Ventricular tachycardia	1	1 (2.27)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (4.55)	0	0 (0.00)
Ear pain	2	2 (4.55)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.27)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.27)	0	0 (0.00)
Eye disorders				
- Total	20	10 (22.73)	0	0 (0.00)
Periorbital oedema	4	4 (9.09)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (6.82)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Photophobia	3	2 (4.55)	0	0 (0.00)
Vision blurred	3	2 (4.55)	0	0 (0.00)
Uveitis	2	2 (4.55)	0	0 (0.00)
Eye pain	1	1 (2.27)	0	0 (0.00)
Ocular hypertension	1	1 (2.27)	0	0 (0.00)
Papilloedema	1	1 (2.27)	0	0 (0.00)
Retinal haemorrhage	1	1 (2.27)	0	0 (0.00)
Visual impairment	1	1 (2.27)	0	0 (0.00)
Gastrointestinal disorders				
- Total	90	25 (56.82)	12	10 (22.73)
Vomiting	24	15 (34.09)	2	2 (4.55)
Nausea	19	14 (31.82)	3	3 (6.82)
Diarrhoea	15	15 (34.09)	1	1 (2.27)
Abdominal pain	7	6 (13.64)	0	0 (0.00)
Constipation	5	4 (9.09)	0	0 (0.00)
Abdominal distension	2	2 (4.55)	0	0 (0.00)
Dysphagia	2	2 (4.55)	1	1 (2.27)
Mouth haemorrhage	2	1 (2.27)	2	1 (2.27)
Pancreatitis	2	2 (4.55)	1	1 (2.27)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Abdominal discomfort	1	1 (2.27)	0	0 (0.00)
Abdominal pain lower	1	1 (2.27)	0	0 (0.00)
Abdominal pain upper	1	1 (2.27)	0	0 (0.00)
Abdominal tenderness	1	1 (2.27)	0	0 (0.00)
Ascites	1	1 (2.27)	1	1 (2.27)
Flatulence	1	1 (2.27)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.27)	0	0 (0.00)
Glossodynia	1	1 (2.27)	0	0 (0.00)
Haematemesis	1	1 (2.27)	0	0 (0.00)
Ileus	1	1 (2.27)	1	1 (2.27)
Stomatitis	1	1 (2.27)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (2.27)	0	0 (0.00)
General disorders and administration site conditions				
- Total	65	25 (56.82)	12	8 (18.18)
Pyrexia	25	14 (31.82)	5	5 (11.36)
Fatigue	10	9 (20.45)	1	1 (2.27)
Chills	7	6 (13.64)	0	0 (0.00)
Generalised oedema	3	2 (4.55)	0	0 (0.00)
Malaise	3	3 (6.82)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Catheter site pain	2	2 (4.55)	0	0 (0.00)
Face oedema	2	2 (4.55)	1	1 (2.27)
Oedema peripheral	2	2 (4.55)	1	1 (2.27)
Asthenia	1	1 (2.27)	0	0 (0.00)
Catheter site extravasation	1	1 (2.27)	0	0 (0.00)
Catheter site haemorrhage	1	1 (2.27)	0	0 (0.00)
Facial pain	1	1 (2.27)	0	0 (0.00)
Injection site haematoma	1	1 (2.27)	0	0 (0.00)
Localised oedema	1	1 (2.27)	1	1 (2.27)
Mucosal haemorrhage	1	1 (2.27)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.27)	1	1 (2.27)
Pain	1	1 (2.27)	1	1 (2.27)
Peripheral swelling	1	1 (2.27)	0	0 (0.00)
Physical deconditioning	1	1 (2.27)	1	1 (2.27)
Hepatobiliary disorders				
- Total	7	5 (11.36)	2	2 (4.55)
Hyperbilirubinaemia	3	2 (4.55)	2	2 (4.55)
Hepatomegaly	2	2 (4.55)	0	0 (0.00)
Gallbladder enlargement	1	1 (2.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Hepatosplenomegaly	1	1 (2.27)	0	0 (0.00)
Immune system disorders				
- Total	81	40 (90.91)	25	16 (36.36)
Cytokine release syndrome	62	34 (77.27)	22	14 (31.82)
Hypogammaglobulinaemia	17	17 (38.64)	3	3 (6.82)
Graft versus host disease in skin	1	1 (2.27)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (2.27)	0	0 (0.00)
Infections and infestations				
- Total	26	17 (38.64)	5	5 (11.36)
Clostridium difficile infection	4	4 (9.09)	0	0 (0.00)
Clostridium difficile colitis	3	3 (6.82)	1	1 (2.27)
Rhinovirus infection	3	3 (6.82)	0	0 (0.00)
Pneumonia	2	2 (4.55)	1	1 (2.27)
Staphylococcal infection	2	2 (4.55)	1	1 (2.27)
Body tinea	1	1 (2.27)	0	0 (0.00)
Catheter site cellulitis	1	1 (2.27)	0	0 (0.00)
Catheter site infection	1	1 (2.27)	1	1 (2.27)
Cytomegalovirus infection	1	1 (2.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Enterococcal infection	1	1 (2.27)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (2.27)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (2.27)	0	0 (0.00)
Hypopyon	1	1 (2.27)	0	0 (0.00)
Influenza	1	1 (2.27)	0	0 (0.00)
Septic embolus	1	1 (2.27)	1	1 (2.27)
Skin infection	1	1 (2.27)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (2.27)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	24	14 (31.82)	2	2 (4.55)
Transfusion reaction	4	3 (6.82)	0	0 (0.00)
Infusion related reaction	2	2 (4.55)	0	0 (0.00)
Procedural pain	2	2 (4.55)	0	0 (0.00)
Tracheal haemorrhage	2	1 (2.27)	1	1 (2.27)
Contusion	1	1 (2.27)	0	0 (0.00)
Incision site pain	1	1 (2.27)	0	0 (0.00)
Limb injury	1	1 (2.27)	0	0 (0.00)
Mouth injury	1	1 (2.27)	0	0 (0.00)
Post procedural haemorrhage	1	1 (2.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Procedural complication	1	1 (2.27)	0	0 (0.00)
Procedural headache	1	1 (2.27)	0	0 (0.00)
Procedural site reaction	1	1 (2.27)	0	0 (0.00)
Skin abrasion	1	1 (2.27)	0	0 (0.00)
Stoma site irritation	1	1 (2.27)	0	0 (0.00)
Subdural haemorrhage	1	1 (2.27)	0	0 (0.00)
Tibia fracture	1	1 (2.27)	0	0 (0.00)
Tongue injury	1	1 (2.27)	0	0 (0.00)
Transfusion related complication	1	1 (2.27)	1	1 (2.27)
Investigations				
- Total	251	36 (81.82)	135	31 (70.45)
White blood cell count decreased	40	21 (47.73)	26	18 (40.91)
Platelet count decreased	35	13 (29.55)	31	10 (22.73)
Neutrophil count decreased	32	17 (38.64)	29	15 (34.09)
Aspartate aminotransferase increased	26	13 (29.55)	14	9 (20.45)
Alanine aminotransferase increased	24	15 (34.09)	12	9 (20.45)
Blood fibrinogen decreased	15	4 (9.09)	4	3 (6.82)
Prothrombin time prolonged	14	7 (15.91)	1	1 (2.27)
Lymphocyte count decreased	10	8 (18.18)	7	6 (13.64)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Blood bilirubin increased	9	4 (9.09)	1	1 (2.27)
Blood creatinine increased	7	6 (13.64)	2	2 (4.55)
International normalised ratio increased	7	6 (13.64)	1	1 (2.27)
Activated partial thromboplastin time prolonged	5	4 (9.09)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (6.82)	0	0 (0.00)
Blood urea increased	3	3 (6.82)	1	1 (2.27)
Blood immunoglobulin A decreased	2	2 (4.55)	0	0 (0.00)
Blood sodium increased	2	1 (2.27)	0	0 (0.00)
Blood uric acid increased	2	1 (2.27)	0	0 (0.00)
Lipase increased	2	2 (4.55)	2	2 (4.55)
Transaminases increased	2	2 (4.55)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (2.27)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.27)	0	0 (0.00)
Blood magnesium decreased	1	1 (2.27)	1	1 (2.27)
Blood phosphorus decreased	1	1 (2.27)	0	0 (0.00)
Blood phosphorus increased	1	1 (2.27)	0	0 (0.00)
C-reactive protein increased	1	1 (2.27)	1	1 (2.27)
Haemoglobin decreased	1	1 (2.27)	1	1 (2.27)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Hepatic enzyme increased	1	1 (2.27)	0	0 (0.00)
Norovirus test positive	1	1 (2.27)	0	0 (0.00)
Protein total decreased	1	1 (2.27)	1	1 (2.27)
Pulmonary function test decreased	1	1 (2.27)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	100	29 (65.91)	33	16 (36.36)
Hypokalaemia	19	15 (34.09)	6	6 (13.64)
Decreased appetite	18	15 (34.09)	10	9 (20.45)
Hypophosphataemia	11	7 (15.91)	7	5 (11.36)
Hyperphosphataemia	8	6 (13.64)	0	0 (0.00)
Hypernatraemia	7	4 (9.09)	1	1 (2.27)
Hypoalbuminaemia	6	5 (11.36)	1	1 (2.27)
Hyperglycaemia	4	3 (6.82)	1	1 (2.27)
Hypocalcaemia	4	3 (6.82)	1	1 (2.27)
Hypertriglyceridaemia	3	2 (4.55)	1	1 (2.27)
Hyperuricaemia	3	2 (4.55)	0	0 (0.00)
Acidosis	2	2 (4.55)	1	1 (2.27)
Fluid overload	2	2 (4.55)	0	0 (0.00)
Hypercalcaemia	2	1 (2.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Hyponatraemia	2	1 (2.27)	2	1 (2.27)
Dehydration	1	1 (2.27)	0	0 (0.00)
Hyperalbuminaemia	1	1 (2.27)	0	0 (0.00)
Hyperchloraemia	1	1 (2.27)	0	0 (0.00)
Hypermagnesaemia	1	1 (2.27)	0	0 (0.00)
Hypomagnesaemia	1	1 (2.27)	0	0 (0.00)
Malnutrition	1	1 (2.27)	1	1 (2.27)
Metabolic acidosis	1	1 (2.27)	0	0 (0.00)
Metabolic alkalosis	1	1 (2.27)	0	0 (0.00)
Tumour lysis syndrome	1	1 (2.27)	1	1 (2.27)
Musculoskeletal and connective tissue disorders				
- Total	18	10 (22.73)	0	0 (0.00)
Musculoskeletal pain	4	3 (6.82)	0	0 (0.00)
Arthralgia	3	3 (6.82)	0	0 (0.00)
Myalgia	3	3 (6.82)	0	0 (0.00)
Pain in extremity	2	2 (4.55)	0	0 (0.00)
Coccydynia	1	1 (2.27)	0	0 (0.00)
Limb discomfort	1	1 (2.27)	0	0 (0.00)
Muscle spasms	1	1 (2.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Muscular weakness	1	1 (2.27)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.27)	0	0 (0.00)
Osteopenia	1	1 (2.27)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (2.27)	0	0 (0.00)
Skin papilloma	1	1 (2.27)	0	0 (0.00)
Nervous system disorders				
- Total	44	24 (54.55)	4	4 (9.09)
Headache	23	18 (40.91)	1	1 (2.27)
Dizziness	4	4 (9.09)	0	0 (0.00)
Encephalopathy	3	1 (2.27)	1	1 (2.27)
Dysarthria	2	2 (4.55)	0	0 (0.00)
Seizure	2	2 (4.55)	1	1 (2.27)
Asterixis	1	1 (2.27)	0	0 (0.00)
Ataxia	1	1 (2.27)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.27)	0	0 (0.00)
Embolic stroke	1	1 (2.27)	1	1 (2.27)
Idiopathic intracranial hypertension	1	1 (2.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Migraine	1	1 (2.27)	0	0 (0.00)
Neuropathy peripheral	1	1 (2.27)	0	0 (0.00)
Pleocytosis	1	1 (2.27)	0	0 (0.00)
Somnolence	1	1 (2.27)	0	0 (0.00)
Tremor	1	1 (2.27)	0	0 (0.00)
Product issues				
- Total	1	1 (2.27)	0	0 (0.00)
Device occlusion	1	1 (2.27)	0	0 (0.00)
Psychiatric disorders				
- Total	25	12 (27.27)	1	1 (2.27)
Anxiety	5	5 (11.36)	1	1 (2.27)
Confusional state	5	5 (11.36)	0	0 (0.00)
Agitation	3	2 (4.55)	0	0 (0.00)
Delirium	3	3 (6.82)	0	0 (0.00)
Hallucination	3	2 (4.55)	0	0 (0.00)
Irritability	2	2 (4.55)	0	0 (0.00)
Adjustment disorder	1	1 (2.27)	0	0 (0.00)
Insomnia	1	1 (2.27)	0	0 (0.00)
Listless	1	1 (2.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Suicidal ideation	1	1 (2.27)	0	0 (0.00)
Renal and urinary disorders				
- Total	18	11 (25.00)	11	7 (15.91)
Acute kidney injury	7	7 (15.91)	5	5 (11.36)
Haematuria	4	4 (9.09)	2	2 (4.55)
Dysuria	2	2 (4.55)	0	0 (0.00)
Oliguria	2	2 (4.55)	2	2 (4.55)
Pollakiuria	1	1 (2.27)	0	0 (0.00)
Renal failure	1	1 (2.27)	1	1 (2.27)
Renal impairment	1	1 (2.27)	1	1 (2.27)
Reproductive system and breast disorders				
- Total	3	2 (4.55)	0	0 (0.00)
Oedema genital	2	1 (2.27)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (2.27)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	62	22 (50.00)	28	12 (27.27)
Epistaxis	11	7 (15.91)	4	4 (9.09)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Hypoxia	10	7 (15.91)	8	7 (15.91)
Pleural effusion	7	7 (15.91)	2	2 (4.55)
Cough	6	6 (13.64)	0	0 (0.00)
Pulmonary oedema	6	6 (13.64)	5	5 (11.36)
Tachypnoea	6	5 (11.36)	1	1 (2.27)
Dyspnoea	3	2 (4.55)	2	2 (4.55)
Haemoptysis	3	2 (4.55)	1	1 (2.27)
Respiratory failure	3	3 (6.82)	3	3 (6.82)
Oropharyngeal pain	2	2 (4.55)	0	0 (0.00)
Interstitial lung disease	1	1 (2.27)	1	1 (2.27)
Oropharyngeal plaque	1	1 (2.27)	0	0 (0.00)
Respiratory distress	1	1 (2.27)	1	1 (2.27)
Rhinorrhoea	1	1 (2.27)	0	0 (0.00)
Wheezing	1	1 (2.27)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	32	15 (34.09)	1	1 (2.27)
Hyperhidrosis	4	3 (6.82)	0	0 (0.00)
Rash	4	4 (9.09)	0	0 (0.00)
Petechiae	3	3 (6.82)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Dry skin	2	2 (4.55)	0	0 (0.00)
Erythema	2	1 (2.27)	0	0 (0.00)
Pruritus	2	2 (4.55)	0	0 (0.00)
Rash maculo-papular	2	2 (4.55)	0	0 (0.00)
Rash papular	2	2 (4.55)	0	0 (0.00)
Ecchymosis	1	1 (2.27)	1	1 (2.27)
Ingrowing nail	1	1 (2.27)	0	0 (0.00)
Macule	1	1 (2.27)	0	0 (0.00)
Night sweats	1	1 (2.27)	0	0 (0.00)
Rash erythematous	1	1 (2.27)	0	0 (0.00)
Rash follicular	1	1 (2.27)	0	0 (0.00)
Rash macular	1	1 (2.27)	0	0 (0.00)
Rash vesicular	1	1 (2.27)	0	0 (0.00)
Skin exfoliation	1	1 (2.27)	0	0 (0.00)
Skin fissures	1	1 (2.27)	0	0 (0.00)
Skin irritation	1	1 (2.27)	0	0 (0.00)
Vascular disorders				
- Total	32	19 (43.18)	14	11 (25.00)
Hypotension	15	12 (27.27)	12	11 (25.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Hypertension	9	8 (18.18)	1	1 (2.27)
Flushing	3	2 (4.55)	0	0 (0.00)
Orthostatic hypotension	2	2 (4.55)	0	0 (0.00)
Capillary leak syndrome	1	1 (2.27)	1	1 (2.27)
Haematoma	1	1 (2.27)	0	0 (0.00)
Secondary hypertension	1	1 (2.27)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	136	18 (90.00)	34	11 (55.00)
Blood and lymphatic system disorders				
- Total	9	5 (25.00)	8	4 (20.00)
Neutropenia	5	3 (15.00)	5	3 (15.00)
Febrile neutropenia	2	2 (10.00)	2	2 (10.00)
Anaemia	1	1 (5.00)	0	0 (0.00)
Thrombocytopenia	1	1 (5.00)	1	1 (5.00)
Endocrine disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Adrenal insufficiency	1	1 (5.00)	0	0 (0.00)
Eye disorders				
- Total	1	1 (5.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Ocular hyperaemia	1	1 (5.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	17	7 (35.00)	6	3 (15.00)
Vomiting	5	4 (20.00)	1	1 (5.00)
Diarrhoea	3	3 (15.00)	1	1 (5.00)
Oral pain	3	2 (10.00)	1	1 (5.00)
Abdominal pain	2	2 (10.00)	1	1 (5.00)
Nausea	2	2 (10.00)	1	1 (5.00)
Abdominal pain upper	1	1 (5.00)	0	0 (0.00)
Enterocolitis	1	1 (5.00)	1	1 (5.00)
General disorders and administration site conditions				
- Total	10	10 (50.00)	1	1 (5.00)
Pyrexia	6	6 (30.00)	1	1 (5.00)
Acquired gene mutation	1	1 (5.00)	0	0 (0.00)
Catheter site pain	1	1 (5.00)	0	0 (0.00)
Fatigue	1	1 (5.00)	0	0 (0.00)
Influenza like illness	1	1 (5.00)	0	0 (0.00)
Immune system disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	5	4 (20.00)	0	0 (0.00)
Hypogammaglobulinaemia	3	3 (15.00)	0	0 (0.00)
Graft versus host disease	2	1 (5.00)	0	0 (0.00)
Infections and infestations				
- Total	17	11 (55.00)	6	5 (25.00)
Rhinovirus infection	3	1 (5.00)	0	0 (0.00)
Upper respiratory tract infection	3	3 (15.00)	0	0 (0.00)
Influenza	2	2 (10.00)	0	0 (0.00)
Bacterial sepsis	1	1 (5.00)	1	1 (5.00)
Cholecystitis infective	1	1 (5.00)	1	1 (5.00)
Corona virus infection	1	1 (5.00)	1	1 (5.00)
Ear infection	1	1 (5.00)	0	0 (0.00)
Herpes zoster	1	1 (5.00)	1	1 (5.00)
Respiratory syncytial virus infection	1	1 (5.00)	1	1 (5.00)
Tinea capitis	1	1 (5.00)	0	0 (0.00)
Vascular device infection	1	1 (5.00)	1	1 (5.00)
Viral infection	1	1 (5.00)	0	0 (0.00)
Injury, poisoning and procedural complications				

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	6	3 (15.00)	0	0 (0.00)
Contusion	1	1 (5.00)	0	0 (0.00)
Foot fracture	1	1 (5.00)	0	0 (0.00)
Infusion related reaction	1	1 (5.00)	0	0 (0.00)
Procedural nausea	1	1 (5.00)	0	0 (0.00)
Skin laceration	1	1 (5.00)	0	0 (0.00)
Sunburn	1	1 (5.00)	0	0 (0.00)
Investigations				
- Total	22	9 (45.00)	9	6 (30.00)
Neutrophil count decreased	8	4 (20.00)	5	3 (15.00)
White blood cell count decreased	4	2 (10.00)	2	1 (5.00)
Lymphocyte count decreased	2	2 (10.00)	0	0 (0.00)
Platelet count decreased	2	1 (5.00)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (5.00)	1	1 (5.00)
Blood bilirubin increased	1	1 (5.00)	1	1 (5.00)
Blood magnesium decreased	1	1 (5.00)	0	0 (0.00)
Haemoglobin decreased	1	1 (5.00)	0	0 (0.00)
Transaminases increased	1	1 (5.00)	0	0 (0.00)
Weight decreased	1	1 (5.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Metabolism and nutrition disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Hyperphosphataemia	1	1 (5.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	8	6 (30.00)	0	0 (0.00)
Pain in extremity	3	3 (15.00)	0	0 (0.00)
Arthralgia	2	2 (10.00)	0	0 (0.00)
Muscular weakness	1	1 (5.00)	0	0 (0.00)
Osteonecrosis	1	1 (5.00)	0	0 (0.00)
Pain in jaw	1	1 (5.00)	0	0 (0.00)
Nervous system disorders				
- Total	4	4 (20.00)	0	0 (0.00)
Headache	2	2 (10.00)	0	0 (0.00)
Peroneal nerve palsy	2	2 (10.00)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (10.00)	0	0 (0.00)
Depression	2	2 (10.00)	0	0 (0.00)
Anxiety	1	1 (5.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Sleep disorder	1	1 (5.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Urinary incontinence	1	1 (5.00)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (5.00)	1	1 (5.00)
Vaginal haemorrhage	1	1 (5.00)	1	1 (5.00)
Respiratory, thoracic and mediastinal disorders				
- Total	15	8 (40.00)	3	2 (10.00)
Cough	4	3 (15.00)	0	0 (0.00)
Nasal congestion	2	2 (10.00)	0	0 (0.00)
Rhinorrhoea	2	2 (10.00)	0	0 (0.00)
Dysphonia	1	1 (5.00)	0	0 (0.00)
Epistaxis	1	1 (5.00)	1	1 (5.00)
Oropharyngeal pain	1	1 (5.00)	0	0 (0.00)
Pharyngeal erythema	1	1 (5.00)	0	0 (0.00)
Pharyngeal lesion	1	1 (5.00)	1	1 (5.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Pulmonary oedema	1	1 (5.00)	1	1 (5.00)
Rhinitis allergic	1	1 (5.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	11	7 (35.00)	0	0 (0.00)
Erythema	2	2 (10.00)	0	0 (0.00)
Rash erythematous	2	1 (5.00)	0	0 (0.00)
Alopecia	1	1 (5.00)	0	0 (0.00)
Dermatitis atopic	1	1 (5.00)	0	0 (0.00)
Hyperhidrosis	1	1 (5.00)	0	0 (0.00)
Ingrowing nail	1	1 (5.00)	0	0 (0.00)
Keloid scar	1	1 (5.00)	0	0 (0.00)
Rash	1	1 (5.00)	0	0 (0.00)
Rash maculo-papular	1	1 (5.00)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (10.00)	0	0 (0.00)
Hypertension	2	2 (10.00)	0	0 (0.00)
Hot flush	1	1 (5.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Total number of AE per patient	210	28 (77.78)	37	15 (41.67)
Blood and lymphatic system disorders				
- Total	9	6 (16.67)	5	3 (8.33)
Eosinophilia	2	1 (2.78)	1	1 (2.78)
Anaemia	1	1 (2.78)	1	1 (2.78)
Febrile neutropenia	1	1 (2.78)	1	1 (2.78)
Leukopenia	1	1 (2.78)	1	1 (2.78)
Lymphadenopathy	1	1 (2.78)	0	0 (0.00)
Lymphopenia	1	1 (2.78)	0	0 (0.00)
Neutropenia	1	1 (2.78)	1	1 (2.78)
Thrombocytopenia	1	1 (2.78)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (2.78)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Sinus tachycardia	1	1 (2.78)	0	0 (0.00)
Eye disorders				
- Total	4	4 (11.11)	0	0 (0.00)
Dry eye	2	2 (5.56)	0	0 (0.00)
Conjunctivitis allergic	1	1 (2.78)	0	0 (0.00)
Vision blurred	1	1 (2.78)	0	0 (0.00)
Gastrointestinal disorders				
- Total	21	9 (25.00)	2	1 (2.78)
Vomiting	8	5 (13.89)	1	1 (2.78)
Diarrhoea	5	5 (13.89)	0	0 (0.00)
Nausea	5	4 (11.11)	1	1 (2.78)
Abdominal pain	2	2 (5.56)	0	0 (0.00)
Pigmentation lip	1	1 (2.78)	0	0 (0.00)
General disorders and administration site conditions				
- Total	16	7 (19.44)	0	0 (0.00)
Pyrexia	8	4 (11.11)	0	0 (0.00)
Chills	1	1 (2.78)	0	0 (0.00)
Crying	1	1 (2.78)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Fatigue	1	1 (2.78)	0	0 (0.00)
Generalised oedema	1	1 (2.78)	0	0 (0.00)
Influenza like illness	1	1 (2.78)	0	0 (0.00)
Malaise	1	1 (2.78)	0	0 (0.00)
Oedema peripheral	1	1 (2.78)	0	0 (0.00)
Pain	1	1 (2.78)	0	0 (0.00)
Immune system disorders				
- Total	12	10 (27.78)	1	1 (2.78)
Hypogammaglobulinaemia	6	5 (13.89)	1	1 (2.78)
Immunodeficiency common variable	2	2 (5.56)	0	0 (0.00)
Seasonal allergy	2	2 (5.56)	0	0 (0.00)
Graft versus host disease	1	1 (2.78)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (2.78)	0	0 (0.00)
Infections and infestations				
- Total	44	22 (61.11)	11	7 (19.44)
Cellulitis of male external genital organ	5	1 (2.78)	2	1 (2.78)
Urinary tract infection	5	4 (11.11)	2	2 (5.56)
Upper respiratory tract infection	4	4 (11.11)	1	1 (2.78)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Gastroenteritis	3	3 (8.33)	0	0 (0.00)
Otitis media	2	1 (2.78)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (5.56)	1	1 (2.78)
Sinusitis	2	2 (5.56)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (5.56)	1	1 (2.78)
Cytomegalovirus infection	1	1 (2.78)	0	0 (0.00)
Ear infection	1	1 (2.78)	0	0 (0.00)
Enterovirus infection	1	1 (2.78)	1	1 (2.78)
Escherichia urinary tract infection	1	1 (2.78)	1	1 (2.78)
Gastroenteritis norovirus	1	1 (2.78)	0	0 (0.00)
Gastroenteritis viral	1	1 (2.78)	0	0 (0.00)
Influenza	1	1 (2.78)	0	0 (0.00)
Molluscum contagiosum	1	1 (2.78)	0	0 (0.00)
Oral herpes	1	1 (2.78)	0	0 (0.00)
Otitis externa	1	1 (2.78)	0	0 (0.00)
Otitis media acute	1	1 (2.78)	0	0 (0.00)
Paronychia	1	1 (2.78)	0	0 (0.00)
Rash pustular	1	1 (2.78)	0	0 (0.00)
Rhinitis	1	1 (2.78)	0	0 (0.00)
Rhinovirus infection	1	1 (2.78)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Rotavirus infection	1	1 (2.78)	1	1 (2.78)
Sepsis	1	1 (2.78)	1	1 (2.78)
Subcutaneous abscess	1	1 (2.78)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (2.78)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	7	5 (13.89)	0	0 (0.00)
Procedural pain	2	2 (5.56)	0	0 (0.00)
Arthropod bite	1	1 (2.78)	0	0 (0.00)
Contusion	1	1 (2.78)	0	0 (0.00)
Infusion related reaction	1	1 (2.78)	0	0 (0.00)
Radius fracture	1	1 (2.78)	0	0 (0.00)
Skin abrasion	1	1 (2.78)	0	0 (0.00)
Investigations				
- Total	26	14 (38.89)	7	6 (16.67)
Neutrophil count decreased	4	4 (11.11)	3	3 (8.33)
Aspartate aminotransferase increased	3	3 (8.33)	2	2 (5.56)
Platelet count decreased	3	2 (5.56)	0	0 (0.00)
Weight decreased	3	3 (8.33)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
White blood cell count decreased	3	3 (8.33)	1	1 (2.78)
Blood urea increased	2	1 (2.78)	0	0 (0.00)
Weight increased	2	2 (5.56)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (2.78)	1	1 (2.78)
Blood creatinine increased	1	1 (2.78)	0	0 (0.00)
Blood uric acid increased	1	1 (2.78)	0	0 (0.00)
Haemoglobin decreased	1	1 (2.78)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.78)	0	0 (0.00)
Serum ferritin increased	1	1 (2.78)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	14	9 (25.00)	6	4 (11.11)
Decreased appetite	2	2 (5.56)	0	0 (0.00)
Hyperalbuminaemia	2	1 (2.78)	0	0 (0.00)
Hypokalaemia	2	2 (5.56)	1	1 (2.78)
Dehydration	1	1 (2.78)	1	1 (2.78)
Hypercalcaemia	1	1 (2.78)	0	0 (0.00)
Hyperglycaemia	1	1 (2.78)	1	1 (2.78)
Hyperphosphataemia	1	1 (2.78)	0	0 (0.00)
Hypophosphataemia	1	1 (2.78)	1	1 (2.78)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Iron overload	1	1 (2.78)	1	1 (2.78)
Tumour lysis syndrome	1	1 (2.78)	1	1 (2.78)
Vitamin D deficiency	1	1 (2.78)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	13	10 (27.78)	0	0 (0.00)
Pain in extremity	5	5 (13.89)	0	0 (0.00)
Joint range of motion decreased	2	2 (5.56)	0	0 (0.00)
Back pain	1	1 (2.78)	0	0 (0.00)
Flank pain	1	1 (2.78)	0	0 (0.00)
Muscle spasms	1	1 (2.78)	0	0 (0.00)
Muscular weakness	1	1 (2.78)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.78)	0	0 (0.00)
Toe walking	1	1 (2.78)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (2.78)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (2.78)	0	0 (0.00)
Nervous system disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
- Total	8	4 (11.11)	0	0 (0.00)
Headache	5	3 (8.33)	0	0 (0.00)
Dizziness	3	3 (8.33)	0	0 (0.00)
Renal and urinary disorders				
- Total	4	2 (5.56)	3	2 (5.56)
Acute kidney injury	1	1 (2.78)	1	1 (2.78)
Calculus urinary	1	1 (2.78)	0	0 (0.00)
Haematuria	1	1 (2.78)	1	1 (2.78)
Nephrolithiasis	1	1 (2.78)	1	1 (2.78)
Reproductive system and breast disorders				
- Total	1	1 (2.78)	0	0 (0.00)
Scrotal pain	1	1 (2.78)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	15	10 (27.78)	1	1 (2.78)
Cough	5	4 (11.11)	0	0 (0.00)
Nasal congestion	2	2 (5.56)	0	0 (0.00)
Oropharyngeal pain	2	2 (5.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=36 n (%)[1]	Grade >= 3 Total events	All patients N=36 n (%)[2]
Rhinitis allergic	2	2 (5.56)	0	0 (0.00)
Rhinorrhoea	2	2 (5.56)	0	0 (0.00)
Acute respiratory failure	1	1 (2.78)	1	1 (2.78)
Epistaxis	1	1 (2.78)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	14	9 (25.00)	1	1 (2.78)
Rash	4	3 (8.33)	0	0 (0.00)
Dermatitis	1	1 (2.78)	0	0 (0.00)
Dermatitis acneiform	1	1 (2.78)	1	1 (2.78)
Dry skin	1	1 (2.78)	0	0 (0.00)
Eczema	1	1 (2.78)	0	0 (0.00)
Macule	1	1 (2.78)	0	0 (0.00)
Papule	1	1 (2.78)	0	0 (0.00)
Petechiae	1	1 (2.78)	0	0 (0.00)
Pruritus	1	1 (2.78)	0	0 (0.00)
Rash maculo-papular	1	1 (2.78)	0	0 (0.00)
Rash pruritic	1	1 (2.78)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Total number of AE per patient	42	11 (78.57)	8	5 (35.71)
Blood and lymphatic system disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Thrombocytopenia	1	1 (7.14)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Tympanic membrane perforation	1	1 (7.14)	0	0 (0.00)
Infections and infestations				
- Total	17	5 (35.71)	1	1 (7.14)
Upper respiratory tract infection	4	2 (14.29)	0	0 (0.00)
Otitis media	3	1 (7.14)	1	1 (7.14)
Otitis media acute	3	1 (7.14)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Sinusitis	2	2 (14.29)	0	0 (0.00)
Gingivitis	1	1 (7.14)	0	0 (0.00)
Haemophilus infection	1	1 (7.14)	0	0 (0.00)
Pneumonia	1	1 (7.14)	0	0 (0.00)
Skin infection	1	1 (7.14)	0	0 (0.00)
Viral infection	1	1 (7.14)	0	0 (0.00)
Investigations				
- Total	15	7 (50.00)	5	4 (28.57)
Lymphocyte count decreased	5	3 (21.43)	1	1 (7.14)
White blood cell count decreased	4	3 (21.43)	2	2 (14.29)
Neutrophil count decreased	3	2 (14.29)	0	0 (0.00)
Alanine aminotransferase increased	2	2 (14.29)	1	1 (7.14)
Aspartate aminotransferase increased	1	1 (7.14)	1	1 (7.14)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (7.14)	1	1 (7.14)
Glioblastoma multiforme	1	1 (7.14)	1	1 (7.14)
Nervous system disorders				

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
- Total	2	2 (14.29)	1	1 (7.14)
Disturbance in attention	1	1 (7.14)	0	0 (0.00)
Seizure	1	1 (7.14)	1	1 (7.14)
Respiratory, thoracic and mediastinal disorders				
- Total	3	1 (7.14)	0	0 (0.00)
Cough	2	1 (7.14)	0	0 (0.00)
Rhinitis allergic	1	1 (7.14)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	2 (14.29)	0	0 (0.00)
Acne	1	1 (7.14)	0	0 (0.00)
Papule	1	1 (7.14)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	48	11 (55.00)	15	7 (35.00)
Blood and lymphatic system disorders				
- Total	1	1 (5.00)	1	1 (5.00)
Febrile neutropenia	1	1 (5.00)	1	1 (5.00)
Gastrointestinal disorders				
- Total	4	3 (15.00)	0	0 (0.00)
Diarrhoea	2	2 (10.00)	0	0 (0.00)
Abdominal pain	1	1 (5.00)	0	0 (0.00)
Nausea	1	1 (5.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	2 (10.00)	1	1 (5.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Pyrexia	2	1 (5.00)	0	0 (0.00)
Chills	1	1 (5.00)	0	0 (0.00)
Cyst	1	1 (5.00)	1	1 (5.00)
Immune system disorders				
- Total	2	2 (10.00)	0	0 (0.00)
Chronic graft versus host disease	1	1 (5.00)	0	0 (0.00)
Immunodeficiency	1	1 (5.00)	0	0 (0.00)
Infections and infestations				
- Total	15	6 (30.00)	6	3 (15.00)
Urinary tract infection	3	2 (10.00)	1	1 (5.00)
Otitis media	2	2 (10.00)	0	0 (0.00)
Campylobacter infection	1	1 (5.00)	1	1 (5.00)
Cellulitis of male external genital organ	1	1 (5.00)	1	1 (5.00)
Clostridium difficile infection	1	1 (5.00)	1	1 (5.00)
Meningitis aseptic	1	1 (5.00)	0	0 (0.00)
Otitis media acute	1	1 (5.00)	0	0 (0.00)
Pneumonia	1	1 (5.00)	0	0 (0.00)
Respiratory tract infection	1	1 (5.00)	1	1 (5.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Respiratory tract infection viral	1	1 (5.00)	1	1 (5.00)
Sinusitis	1	1 (5.00)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (5.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (5.00)	1	1 (5.00)
Procedural pain	1	1 (5.00)	1	1 (5.00)
Investigations				
- Total	7	1 (5.00)	3	1 (5.00)
Alanine aminotransferase increased	1	1 (5.00)	1	1 (5.00)
Aspartate aminotransferase increased	1	1 (5.00)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (5.00)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (5.00)	0	0 (0.00)
C-reactive protein increased	1	1 (5.00)	0	0 (0.00)
Platelet count decreased	1	1 (5.00)	1	1 (5.00)
White blood cell count decreased	1	1 (5.00)	1	1 (5.00)
Metabolism and nutrition disorders				

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	2	2 (10.00)	1	1 (5.00)
Hypokalaemia	1	1 (5.00)	1	1 (5.00)
Vitamin D deficiency	1	1 (5.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Neck pain	1	1 (5.00)	0	0 (0.00)
Nervous system disorders				
- Total	2	1 (5.00)	0	0 (0.00)
Dizziness	1	1 (5.00)	0	0 (0.00)
Headache	1	1 (5.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	3	2 (10.00)	1	1 (5.00)
Acute kidney injury	2	1 (5.00)	1	1 (5.00)
Haematuria	1	1 (5.00)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (5.00)	1	1 (5.00)
Ovarian failure	1	1 (5.00)	1	1 (5.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	4	3 (15.00)	0	0 (0.00)
Cough	1	1 (5.00)	0	0 (0.00)
Epistaxis	1	1 (5.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (5.00)	0	0 (0.00)
Rhinorrhoea	1	1 (5.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Pruritus	1	1 (5.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	464	20 (100.00)	139	20 (100.00)
Blood and lymphatic system disorders				
- Total	35	16 (80.00)	28	16 (80.00)
Febrile neutropenia	12	9 (45.00)	12	9 (45.00)
Anaemia	10	9 (45.00)	5	5 (25.00)
Neutropenia	8	5 (25.00)	8	5 (25.00)
Thrombocytopenia	2	1 (5.00)	1	1 (5.00)
Disseminated intravascular coagulation	1	1 (5.00)	0	0 (0.00)
Lymphopenia	1	1 (5.00)	1	1 (5.00)
Pancytopenia	1	1 (5.00)	1	1 (5.00)
Cardiac disorders				
- Total	4	2 (10.00)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Sinus bradycardia	2	1 (5.00)	0	0 (0.00)
Tachycardia	2	2 (10.00)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (10.00)	0	0 (0.00)
Hypoacusis	1	1 (5.00)	0	0 (0.00)
Tympanic membrane perforation	1	1 (5.00)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Adrenal insufficiency	1	1 (5.00)	0	0 (0.00)
Eye disorders				
- Total	6	4 (20.00)	0	0 (0.00)
Eye pain	3	2 (10.00)	0	0 (0.00)
Ocular hyperaemia	1	1 (5.00)	0	0 (0.00)
Retinal haemorrhage	1	1 (5.00)	0	0 (0.00)
Vision blurred	1	1 (5.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	53	15 (75.00)	9	3 (15.00)
Vomiting	16	10 (50.00)	2	1 (5.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Nausea	9	8 (40.00)	1	1 (5.00)
Diarrhoea	6	5 (25.00)	1	1 (5.00)
Abdominal pain	5	4 (20.00)	2	1 (5.00)
Constipation	3	3 (15.00)	0	0 (0.00)
Oral pain	3	2 (10.00)	1	1 (5.00)
Abdominal pain upper	2	2 (10.00)	0	0 (0.00)
Anal incontinence	2	1 (5.00)	0	0 (0.00)
Dyspepsia	1	1 (5.00)	0	0 (0.00)
Enterocolitis	1	1 (5.00)	1	1 (5.00)
Gastrointestinal haemorrhage	1	1 (5.00)	0	0 (0.00)
Haematemesis	1	1 (5.00)	0	0 (0.00)
Intestinal obstruction	1	1 (5.00)	1	1 (5.00)
Lip pain	1	1 (5.00)	0	0 (0.00)
Stomatitis	1	1 (5.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	22	14 (70.00)	3	3 (15.00)
Pyrexia	8	8 (40.00)	2	2 (10.00)
Fatigue	5	5 (25.00)	0	0 (0.00)
Catheter site pain	2	2 (10.00)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Chills	2	2 (10.00)	0	0 (0.00)
Pain	2	2 (10.00)	1	1 (5.00)
Acquired gene mutation	1	1 (5.00)	0	0 (0.00)
Influenza like illness	1	1 (5.00)	0	0 (0.00)
Non-cardiac chest pain	1	1 (5.00)	0	0 (0.00)
Hepatobiliary disorders				
- Total	2	2 (10.00)	0	0 (0.00)
Hepatomegaly	1	1 (5.00)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (5.00)	0	0 (0.00)
Immune system disorders				
- Total	40	17 (85.00)	8	6 (30.00)
Cytokine release syndrome	24	16 (80.00)	7	5 (25.00)
Hypogammaglobulinaemia	13	12 (60.00)	1	1 (5.00)
Graft versus host disease	2	1 (5.00)	0	0 (0.00)
Drug hypersensitivity	1	1 (5.00)	0	0 (0.00)
Infections and infestations				
- Total	49	15 (75.00)	9	6 (30.00)
Upper respiratory tract infection	8	5 (25.00)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Otitis media	3	1 (5.00)	1	1 (5.00)
Otitis media acute	3	1 (5.00)	0	0 (0.00)
Rhinovirus infection	3	1 (5.00)	0	0 (0.00)
Viral infection	3	3 (15.00)	0	0 (0.00)
Gastroenteritis	2	2 (10.00)	1	1 (5.00)
Influenza	2	2 (10.00)	0	0 (0.00)
Sinusitis	2	2 (10.00)	0	0 (0.00)
Acute sinusitis	1	1 (5.00)	0	0 (0.00)
Bacterial sepsis	1	1 (5.00)	1	1 (5.00)
Cholecystitis infective	1	1 (5.00)	1	1 (5.00)
Clostridium difficile colitis	1	1 (5.00)	0	0 (0.00)
Corona virus infection	1	1 (5.00)	1	1 (5.00)
Ear infection	1	1 (5.00)	0	0 (0.00)
Folliculitis	1	1 (5.00)	0	0 (0.00)
Fungal skin infection	1	1 (5.00)	0	0 (0.00)
Gingivitis	1	1 (5.00)	0	0 (0.00)
Haemophilus infection	1	1 (5.00)	0	0 (0.00)
Herpes simplex	1	1 (5.00)	0	0 (0.00)
Herpes zoster	1	1 (5.00)	1	1 (5.00)
Oral candidiasis	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Orchitis	1	1 (5.00)	0	0 (0.00)
Pharyngitis	1	1 (5.00)	0	0 (0.00)
Pneumonia	1	1 (5.00)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (5.00)	1	1 (5.00)
Skin infection	1	1 (5.00)	0	0 (0.00)
Streptococcal infection	1	1 (5.00)	0	0 (0.00)
Tinea capitis	1	1 (5.00)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (5.00)	1	1 (5.00)
Vascular device infection	1	1 (5.00)	1	1 (5.00)
Vulvovaginal candidiasis	1	1 (5.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	7	4 (20.00)	0	0 (0.00)
Contusion	1	1 (5.00)	0	0 (0.00)
Foot fracture	1	1 (5.00)	0	0 (0.00)
Infusion related reaction	1	1 (5.00)	0	0 (0.00)
Procedural nausea	1	1 (5.00)	0	0 (0.00)
Procedural pain	1	1 (5.00)	0	0 (0.00)
Skin laceration	1	1 (5.00)	0	0 (0.00)
Sunburn	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Investigations				
- Total	118	19 (95.00)	57	17 (85.00)
Neutrophil count decreased	26	10 (50.00)	20	9 (45.00)
White blood cell count decreased	23	12 (60.00)	15	10 (50.00)
Lymphocyte count decreased	13	8 (40.00)	6	6 (30.00)
Platelet count decreased	10	6 (30.00)	6	4 (20.00)
Alanine aminotransferase increased	7	5 (25.00)	4	3 (15.00)
Aspartate aminotransferase increased	7	6 (30.00)	3	3 (15.00)
Blood bilirubin increased	5	4 (20.00)	2	2 (10.00)
Blood creatinine increased	4	3 (15.00)	0	0 (0.00)
International normalised ratio increased	4	3 (15.00)	0	0 (0.00)
Activated partial thromboplastin time prolonged	3	1 (5.00)	0	0 (0.00)
Prothrombin time prolonged	3	2 (10.00)	0	0 (0.00)
Blood phosphorus increased	2	1 (5.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (5.00)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (5.00)	0	0 (0.00)
Blood lactic acid increased	1	1 (5.00)	1	1 (5.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Blood magnesium decreased	1	1 (5.00)	0	0 (0.00)
Cardiac murmur	1	1 (5.00)	0	0 (0.00)
Culture stool positive	1	1 (5.00)	0	0 (0.00)
Fibrin D dimer increased	1	1 (5.00)	0	0 (0.00)
Haemoglobin decreased	1	1 (5.00)	0	0 (0.00)
Serum ferritin increased	1	1 (5.00)	0	0 (0.00)
Transaminases increased	1	1 (5.00)	0	0 (0.00)
Weight decreased	1	1 (5.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	17	10 (50.00)	10	8 (40.00)
Decreased appetite	6	5 (25.00)	3	3 (15.00)
Hyperphosphataemia	3	2 (10.00)	0	0 (0.00)
Dehydration	2	2 (10.00)	2	2 (10.00)
Hypophosphataemia	2	2 (10.00)	2	2 (10.00)
Fluid overload	1	1 (5.00)	0	0 (0.00)
Hyperuricaemia	1	1 (5.00)	1	1 (5.00)
Hypokalaemia	1	1 (5.00)	1	1 (5.00)
Hyponatraemia	1	1 (5.00)	1	1 (5.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	13	8 (40.00)	1	1 (5.00)
Pain in extremity	5	5 (25.00)	0	0 (0.00)
Arthralgia	3	2 (10.00)	1	1 (5.00)
Myalgia	2	2 (10.00)	0	0 (0.00)
Muscular weakness	1	1 (5.00)	0	0 (0.00)
Osteonecrosis	1	1 (5.00)	0	0 (0.00)
Pain in jaw	1	1 (5.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (5.00)	1	1 (5.00)
Glioblastoma multiforme	1	1 (5.00)	1	1 (5.00)
Nervous system disorders				
- Total	20	11 (55.00)	3	2 (10.00)
Headache	10	6 (30.00)	1	1 (5.00)
Encephalopathy	3	3 (15.00)	1	1 (5.00)
Peroneal nerve palsy	2	2 (10.00)	0	0 (0.00)
Seizure	2	2 (10.00)	1	1 (5.00)
Disturbance in attention	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Myoclonus	1	1 (5.00)	0	0 (0.00)
Tremor	1	1 (5.00)	0	0 (0.00)
Psychiatric disorders				
- Total	9	5 (25.00)	0	0 (0.00)
Anxiety	2	2 (10.00)	0	0 (0.00)
Depression	2	2 (10.00)	0	0 (0.00)
Confusional state	1	1 (5.00)	0	0 (0.00)
Delirium	1	1 (5.00)	0	0 (0.00)
Mental status changes	1	1 (5.00)	0	0 (0.00)
Panic attack	1	1 (5.00)	0	0 (0.00)
Sleep disorder	1	1 (5.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Urinary incontinence	1	1 (5.00)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	2 (10.00)	1	1 (5.00)
Vaginal haemorrhage	1	1 (5.00)	1	1 (5.00)
Vulvovaginal adhesion	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	29	11 (55.00)	3	2 (10.00)
Cough	8	5 (25.00)	0	0 (0.00)
Hypoxia	3	3 (15.00)	0	0 (0.00)
Nasal congestion	3	3 (15.00)	0	0 (0.00)
Rhinitis allergic	3	2 (10.00)	0	0 (0.00)
Rhinorrhoea	2	2 (10.00)	0	0 (0.00)
Atelectasis	1	1 (5.00)	0	0 (0.00)
Dysphonia	1	1 (5.00)	0	0 (0.00)
Epistaxis	1	1 (5.00)	1	1 (5.00)
Oropharyngeal pain	1	1 (5.00)	0	0 (0.00)
Pharyngeal erythema	1	1 (5.00)	0	0 (0.00)
Pharyngeal lesion	1	1 (5.00)	1	1 (5.00)
Pharyngeal ulceration	1	1 (5.00)	0	0 (0.00)
Pleural effusion	1	1 (5.00)	0	0 (0.00)
Pulmonary oedema	1	1 (5.00)	1	1 (5.00)
Respiratory depression	1	1 (5.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	22	11 (55.00)	1	1 (5.00)
Erythema	4	4 (20.00)	0	0 (0.00)
Ingrowing nail	3	2 (10.00)	0	0 (0.00)
Dry skin	2	2 (10.00)	0	0 (0.00)
Rash erythematous	2	1 (5.00)	0	0 (0.00)
Rash maculo-papular	2	2 (10.00)	1	1 (5.00)
Acne	1	1 (5.00)	0	0 (0.00)
Alopecia	1	1 (5.00)	0	0 (0.00)
Dermatitis atopic	1	1 (5.00)	0	0 (0.00)
Dermatitis diaper	1	1 (5.00)	0	0 (0.00)
Hyperhidrosis	1	1 (5.00)	0	0 (0.00)
Keloid scar	1	1 (5.00)	0	0 (0.00)
Livedo reticularis	1	1 (5.00)	0	0 (0.00)
Papule	1	1 (5.00)	0	0 (0.00)
Rash	1	1 (5.00)	0	0 (0.00)
Vascular disorders				
- Total	11	6 (30.00)	5	5 (25.00)
Hypertension	5	4 (20.00)	0	0 (0.00)
Hypotension	4	4 (20.00)	4	4 (20.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Embolism	1	1 (5.00)	1	1 (5.00)
Hot flush	1	1 (5.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Total number of AE per patient	1286	44 (100.00)	413	39 (88.64)
Blood and lymphatic system disorders				
- Total	107	32 (72.73)	79	27 (61.36)
Anaemia	39	18 (40.91)	27	15 (34.09)
Thrombocytopenia	31	9 (20.45)	23	8 (18.18)
Febrile neutropenia	18	15 (34.09)	18	15 (34.09)
Neutropenia	7	6 (13.64)	6	6 (13.64)
Disseminated intravascular coagulation	4	3 (6.82)	2	2 (4.55)
Lymphopenia	3	3 (6.82)	1	1 (2.27)
Eosinophilia	2	1 (2.27)	1	1 (2.27)
Coagulopathy	1	1 (2.27)	0	0 (0.00)
Leukopenia	1	1 (2.27)	1	1 (2.27)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Lymphadenopathy	1	1 (2.27)	0	0 (0.00)
Cardiac disorders				
- Total	29	21 (47.73)	3	2 (4.55)
Tachycardia	15	13 (29.55)	2	2 (4.55)
Sinus tachycardia	6	6 (13.64)	0	0 (0.00)
Pericardial effusion	2	2 (4.55)	0	0 (0.00)
Atrioventricular block second degree	1	1 (2.27)	0	0 (0.00)
Bradycardia	1	1 (2.27)	0	0 (0.00)
Cardiac dysfunction	1	1 (2.27)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.27)	1	1 (2.27)
Palpitations	1	1 (2.27)	0	0 (0.00)
Ventricular tachycardia	1	1 (2.27)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (4.55)	0	0 (0.00)
Ear pain	2	2 (4.55)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.27)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.27)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Eye disorders				
- Total	24	14 (31.82)	0	0 (0.00)
Periorbital oedema	4	4 (9.09)	0	0 (0.00)
Vision blurred	4	3 (6.82)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (6.82)	0	0 (0.00)
Photophobia	3	2 (4.55)	0	0 (0.00)
Dry eye	2	2 (4.55)	0	0 (0.00)
Uveitis	2	2 (4.55)	0	0 (0.00)
Conjunctivitis allergic	1	1 (2.27)	0	0 (0.00)
Eye pain	1	1 (2.27)	0	0 (0.00)
Ocular hypertension	1	1 (2.27)	0	0 (0.00)
Papilloedema	1	1 (2.27)	0	0 (0.00)
Retinal haemorrhage	1	1 (2.27)	0	0 (0.00)
Visual impairment	1	1 (2.27)	0	0 (0.00)
Gastrointestinal disorders				
- Total	115	28 (63.64)	14	10 (22.73)
Vomiting	32	17 (38.64)	3	2 (4.55)
Nausea	25	17 (38.64)	4	4 (9.09)
Diarrhoea	22	19 (43.18)	1	1 (2.27)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Abdominal pain	10	7 (15.91)	0	0 (0.00)
Constipation	5	4 (9.09)	0	0 (0.00)
Abdominal distension	2	2 (4.55)	0	0 (0.00)
Dysphagia	2	2 (4.55)	1	1 (2.27)
Mouth haemorrhage	2	1 (2.27)	2	1 (2.27)
Pancreatitis	2	2 (4.55)	1	1 (2.27)
Abdominal discomfort	1	1 (2.27)	0	0 (0.00)
Abdominal pain lower	1	1 (2.27)	0	0 (0.00)
Abdominal pain upper	1	1 (2.27)	0	0 (0.00)
Abdominal tenderness	1	1 (2.27)	0	0 (0.00)
Ascites	1	1 (2.27)	1	1 (2.27)
Flatulence	1	1 (2.27)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.27)	0	0 (0.00)
Glossodynia	1	1 (2.27)	0	0 (0.00)
Haematemesis	1	1 (2.27)	0	0 (0.00)
Ileus	1	1 (2.27)	1	1 (2.27)
Pigmentation lip	1	1 (2.27)	0	0 (0.00)
Stomatitis	1	1 (2.27)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (2.27)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
General disorders and administration site conditions				
- Total	85	28 (63.64)	13	9 (20.45)
Pyrexia	35	17 (38.64)	5	5 (11.36)
Fatigue	11	10 (22.73)	1	1 (2.27)
Chills	9	8 (18.18)	0	0 (0.00)
Generalised oedema	4	3 (6.82)	0	0 (0.00)
Malaise	4	4 (9.09)	0	0 (0.00)
Oedema peripheral	3	3 (6.82)	1	1 (2.27)
Catheter site pain	2	2 (4.55)	0	0 (0.00)
Face oedema	2	2 (4.55)	1	1 (2.27)
Pain	2	2 (4.55)	1	1 (2.27)
Asthenia	1	1 (2.27)	0	0 (0.00)
Catheter site extravasation	1	1 (2.27)	0	0 (0.00)
Catheter site haemorrhage	1	1 (2.27)	0	0 (0.00)
Crying	1	1 (2.27)	0	0 (0.00)
Cyst	1	1 (2.27)	1	1 (2.27)
Facial pain	1	1 (2.27)	0	0 (0.00)
Influenza like illness	1	1 (2.27)	0	0 (0.00)
Injection site haematoma	1	1 (2.27)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Localised oedema	1	1 (2.27)	1	1 (2.27)
Mucosal haemorrhage	1	1 (2.27)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.27)	1	1 (2.27)
Peripheral swelling	1	1 (2.27)	0	0 (0.00)
Physical deconditioning	1	1 (2.27)	1	1 (2.27)
Hepatobiliary disorders				
- Total	7	5 (11.36)	2	2 (4.55)
Hyperbilirubinaemia	3	2 (4.55)	2	2 (4.55)
Hepatomegaly	2	2 (4.55)	0	0 (0.00)
Gallbladder enlargement	1	1 (2.27)	0	0 (0.00)
Hepatosplenomegaly	1	1 (2.27)	0	0 (0.00)
Immune system disorders				
- Total	95	41 (93.18)	26	16 (36.36)
Cytokine release syndrome	62	34 (77.27)	22	14 (31.82)
Hypogammaglobulinaemia	23	21 (47.73)	4	4 (9.09)
Immunodeficiency common variable	2	2 (4.55)	0	0 (0.00)
Seasonal allergy	2	2 (4.55)	0	0 (0.00)
Chronic graft versus host disease	1	1 (2.27)	0	0 (0.00)
Graft versus host disease	1	1 (2.27)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=44** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=44** **n (%)[2]**
Graft versus host disease in gastrointestinal tract	1	1 (2.27)	0	0 (0.00)
Graft versus host disease in skin	1	1 (2.27)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (2.27)	0	0 (0.00)
Immunodeficiency	1	1 (2.27)	0	0 (0.00)
Infections and infestations				
- Total	85	31 (70.45)	22	12 (27.27)
Urinary tract infection	8	5 (11.36)	3	2 (4.55)
Cellulitis of male external genital organ	6	1 (2.27)	3	1 (2.27)
Clostridium difficile infection	5	5 (11.36)	1	1 (2.27)
Otitis media	4	3 (6.82)	0	0 (0.00)
Rhinovirus infection	4	4 (9.09)	0	0 (0.00)
Upper respiratory tract infection	4	4 (9.09)	1	1 (2.27)
Clostridium difficile colitis	3	3 (6.82)	1	1 (2.27)
Gastroenteritis	3	3 (6.82)	0	0 (0.00)
Pneumonia	3	3 (6.82)	1	1 (2.27)
Sinusitis	3	2 (4.55)	0	0 (0.00)
Viral upper respiratory tract infection	3	3 (6.82)	1	1 (2.27)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Cytomegalovirus infection	2	2 (4.55)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (2.27)	0	0 (0.00)
Influenza	2	2 (4.55)	0	0 (0.00)
Otitis media acute	2	1 (2.27)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (4.55)	1	1 (2.27)
Staphylococcal infection	2	2 (4.55)	1	1 (2.27)
Body tinea	1	1 (2.27)	0	0 (0.00)
Campylobacter infection	1	1 (2.27)	1	1 (2.27)
Catheter site cellulitis	1	1 (2.27)	0	0 (0.00)
Catheter site infection	1	1 (2.27)	1	1 (2.27)
Ear infection	1	1 (2.27)	0	0 (0.00)
Enterococcal infection	1	1 (2.27)	0	0 (0.00)
Enterovirus infection	1	1 (2.27)	1	1 (2.27)
Escherichia urinary tract infection	1	1 (2.27)	1	1 (2.27)
Gastroenteritis viral	1	1 (2.27)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (2.27)	0	0 (0.00)
Hypopyon	1	1 (2.27)	0	0 (0.00)
Meningitis aseptic	1	1 (2.27)	0	0 (0.00)
Molluscum contagiosum	1	1 (2.27)	0	0 (0.00)
Oral herpes	1	1 (2.27)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Otitis externa	1	1 (2.27)	0	0 (0.00)
Paronychia	1	1 (2.27)	0	0 (0.00)
Rash pustular	1	1 (2.27)	0	0 (0.00)
Respiratory tract infection	1	1 (2.27)	1	1 (2.27)
Respiratory tract infection viral	1	1 (2.27)	1	1 (2.27)
Rhinitis	1	1 (2.27)	0	0 (0.00)
Rotavirus infection	1	1 (2.27)	1	1 (2.27)
Sepsis	1	1 (2.27)	1	1 (2.27)
Septic embolus	1	1 (2.27)	1	1 (2.27)
Skin infection	1	1 (2.27)	0	0 (0.00)
Subcutaneous abscess	1	1 (2.27)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (2.27)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (2.27)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	32	18 (40.91)	3	3 (6.82)
Procedural pain	5	4 (9.09)	1	1 (2.27)
Transfusion reaction	4	3 (6.82)	0	0 (0.00)
Infusion related reaction	3	3 (6.82)	0	0 (0.00)
Contusion	2	2 (4.55)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Skin abrasion	2	2 (4.55)	0	0 (0.00)
Tracheal haemorrhage	2	1 (2.27)	1	1 (2.27)
Arthropod bite	1	1 (2.27)	0	0 (0.00)
Incision site pain	1	1 (2.27)	0	0 (0.00)
Limb injury	1	1 (2.27)	0	0 (0.00)
Mouth injury	1	1 (2.27)	0	0 (0.00)
Post procedural haemorrhage	1	1 (2.27)	0	0 (0.00)
Procedural complication	1	1 (2.27)	0	0 (0.00)
Procedural headache	1	1 (2.27)	0	0 (0.00)
Procedural site reaction	1	1 (2.27)	0	0 (0.00)
Radius fracture	1	1 (2.27)	0	0 (0.00)
Stoma site irritation	1	1 (2.27)	0	0 (0.00)
Subdural haemorrhage	1	1 (2.27)	0	0 (0.00)
Tibia fracture	1	1 (2.27)	0	0 (0.00)
Tongue injury	1	1 (2.27)	0	0 (0.00)
Transfusion related complication	1	1 (2.27)	1	1 (2.27)
Investigations				
- Total	284	37 (84.09)	145	32 (72.73)
White blood cell count decreased	44	23 (52.27)	28	20 (45.45)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Platelet count decreased	39	14 (31.82)	32	11 (25.00)
Neutrophil count decreased	36	18 (40.91)	32	16 (36.36)
Aspartate aminotransferase increased	30	14 (31.82)	16	9 (20.45)
Alanine aminotransferase increased	26	16 (36.36)	14	11 (25.00)
Blood fibrinogen decreased	15	4 (9.09)	4	3 (6.82)
Prothrombin time prolonged	14	7 (15.91)	1	1 (2.27)
Lymphocyte count decreased	10	8 (18.18)	7	6 (13.64)
Blood bilirubin increased	9	4 (9.09)	1	1 (2.27)
Blood creatinine increased	8	6 (13.64)	2	2 (4.55)
International normalised ratio increased	7	6 (13.64)	1	1 (2.27)
Activated partial thromboplastin time prolonged	5	4 (9.09)	0	0 (0.00)
Blood urea increased	5	3 (6.82)	1	1 (2.27)
Blood immunoglobulin M decreased	3	3 (6.82)	0	0 (0.00)
Blood uric acid increased	3	2 (4.55)	0	0 (0.00)
Weight decreased	3	3 (6.82)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (4.55)	0	0 (0.00)
Blood sodium increased	2	1 (2.27)	0	0 (0.00)
C-reactive protein increased	2	2 (4.55)	1	1 (2.27)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Haemoglobin decreased	2	2 (4.55)	1	1 (2.27)
Lipase increased	2	2 (4.55)	2	2 (4.55)
Transaminases increased	2	2 (4.55)	0	0 (0.00)
Weight increased	2	2 (4.55)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (2.27)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (2.27)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.27)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (2.27)	0	0 (0.00)
Blood magnesium decreased	1	1 (2.27)	1	1 (2.27)
Blood phosphorus decreased	1	1 (2.27)	0	0 (0.00)
Blood phosphorus increased	1	1 (2.27)	0	0 (0.00)
Hepatic enzyme increased	1	1 (2.27)	0	0 (0.00)
Norovirus test positive	1	1 (2.27)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.27)	0	0 (0.00)
Protein total decreased	1	1 (2.27)	1	1 (2.27)
Pulmonary function test decreased	1	1 (2.27)	0	0 (0.00)
Serum ferritin increased	1	1 (2.27)	0	0 (0.00)
Metabolism and nutrition disorders				

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
- Total	116	33 (75.00)	40	19 (43.18)
Hypokalaemia	22	18 (40.91)	8	8 (18.18)
Decreased appetite	20	17 (38.64)	10	9 (20.45)
Hypophosphataemia	12	8 (18.18)	8	6 (13.64)
Hyperphosphataemia	9	6 (13.64)	0	0 (0.00)
Hypernatraemia	7	4 (9.09)	1	1 (2.27)
Hypoalbuminaemia	6	5 (11.36)	1	1 (2.27)
Hyperglycaemia	5	3 (6.82)	2	2 (4.55)
Hypocalcaemia	4	3 (6.82)	1	1 (2.27)
Hyperalbuminaemia	3	1 (2.27)	0	0 (0.00)
Hypercalcaemia	3	1 (2.27)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (4.55)	1	1 (2.27)
Hyperuricaemia	3	2 (4.55)	0	0 (0.00)
Acidosis	2	2 (4.55)	1	1 (2.27)
Dehydration	2	2 (4.55)	1	1 (2.27)
Fluid overload	2	2 (4.55)	0	0 (0.00)
Hyponatraemia	2	1 (2.27)	2	1 (2.27)
Tumour lysis syndrome	2	2 (4.55)	2	2 (4.55)
Vitamin D deficiency	2	2 (4.55)	0	0 (0.00)
Hyperchloraemia	1	1 (2.27)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Hypermagnesaemia	1	1 (2.27)	0	0 (0.00)
Hypomagnesaemia	1	1 (2.27)	0	0 (0.00)
Iron overload	1	1 (2.27)	1	1 (2.27)
Malnutrition	1	1 (2.27)	1	1 (2.27)
Metabolic acidosis	1	1 (2.27)	0	0 (0.00)
Metabolic alkalosis	1	1 (2.27)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	32	17 (38.64)	0	0 (0.00)
Pain in extremity	7	6 (13.64)	0	0 (0.00)
Musculoskeletal pain	4	3 (6.82)	0	0 (0.00)
Arthralgia	3	3 (6.82)	0	0 (0.00)
Myalgia	3	3 (6.82)	0	0 (0.00)
Joint range of motion decreased	2	2 (4.55)	0	0 (0.00)
Muscle spasms	2	2 (4.55)	0	0 (0.00)
Muscular weakness	2	2 (4.55)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (4.55)	0	0 (0.00)
Back pain	1	1 (2.27)	0	0 (0.00)
Coccydynia	1	1 (2.27)	0	0 (0.00)
Flank pain	1	1 (2.27)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Limb discomfort	1	1 (2.27)	0	0 (0.00)
Neck pain	1	1 (2.27)	0	0 (0.00)
Osteopenia	1	1 (2.27)	0	0 (0.00)
Toe walking	1	1 (2.27)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	2 (4.55)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (2.27)	0	0 (0.00)
Skin papilloma	1	1 (2.27)	0	0 (0.00)
Nervous system disorders				
- Total	54	24 (54.55)	4	4 (9.09)
Headache	29	18 (40.91)	1	1 (2.27)
Dizziness	8	6 (13.64)	0	0 (0.00)
Encephalopathy	3	1 (2.27)	1	1 (2.27)
Dysarthria	2	2 (4.55)	0	0 (0.00)
Seizure	2	2 (4.55)	1	1 (2.27)
Asterixis	1	1 (2.27)	0	0 (0.00)
Ataxia	1	1 (2.27)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.27)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Embolic stroke	1	1 (2.27)	1	1 (2.27)
Idiopathic intracranial hypertension	1	1 (2.27)	0	0 (0.00)
Migraine	1	1 (2.27)	0	0 (0.00)
Neuropathy peripheral	1	1 (2.27)	0	0 (0.00)
Pleocytosis	1	1 (2.27)	0	0 (0.00)
Somnolence	1	1 (2.27)	0	0 (0.00)
Tremor	1	1 (2.27)	0	0 (0.00)
Product issues				
- Total	1	1 (2.27)	0	0 (0.00)
Device occlusion	1	1 (2.27)	0	0 (0.00)
Psychiatric disorders				
- Total	25	12 (27.27)	1	1 (2.27)
Anxiety	5	5 (11.36)	1	1 (2.27)
Confusional state	5	5 (11.36)	0	0 (0.00)
Agitation	3	2 (4.55)	0	0 (0.00)
Delirium	3	3 (6.82)	0	0 (0.00)
Hallucination	3	2 (4.55)	0	0 (0.00)
Irritability	2	2 (4.55)	0	0 (0.00)
Adjustment disorder	1	1 (2.27)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Insomnia	1	1 (2.27)	0	0 (0.00)
Listless	1	1 (2.27)	0	0 (0.00)
Suicidal ideation	1	1 (2.27)	0	0 (0.00)
Renal and urinary disorders				
- Total	25	14 (31.82)	15	10 (22.73)
Acute kidney injury	10	9 (20.45)	7	7 (15.91)
Haematuria	6	5 (11.36)	3	3 (6.82)
Dysuria	2	2 (4.55)	0	0 (0.00)
Oliguria	2	2 (4.55)	2	2 (4.55)
Calculus urinary	1	1 (2.27)	0	0 (0.00)
Nephrolithiasis	1	1 (2.27)	1	1 (2.27)
Pollakiuria	1	1 (2.27)	0	0 (0.00)
Renal failure	1	1 (2.27)	1	1 (2.27)
Renal impairment	1	1 (2.27)	1	1 (2.27)
Reproductive system and breast disorders				
- Total	5	4 (9.09)	1	1 (2.27)
Oedema genital	2	1 (2.27)	0	0 (0.00)
Ovarian failure	1	1 (2.27)	1	1 (2.27)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Scrotal pain	1	1 (2.27)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (2.27)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	81	27 (61.36)	29	13 (29.55)
Epistaxis	13	9 (20.45)	4	4 (9.09)
Cough	12	9 (20.45)	0	0 (0.00)
Hypoxia	10	7 (15.91)	8	7 (15.91)
Pleural effusion	7	7 (15.91)	2	2 (4.55)
Pulmonary oedema	6	6 (13.64)	5	5 (11.36)
Tachypnoea	6	5 (11.36)	1	1 (2.27)
Oropharyngeal pain	5	5 (11.36)	0	0 (0.00)
Rhinorrhoea	4	4 (9.09)	0	0 (0.00)
Dyspnoea	3	2 (4.55)	2	2 (4.55)
Haemoptysis	3	2 (4.55)	1	1 (2.27)
Respiratory failure	3	3 (6.82)	3	3 (6.82)
Nasal congestion	2	2 (4.55)	0	0 (0.00)
Rhinitis allergic	2	2 (4.55)	0	0 (0.00)
Acute respiratory failure	1	1 (2.27)	1	1 (2.27)
Interstitial lung disease	1	1 (2.27)	1	1 (2.27)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Oropharyngeal plaque	1	1 (2.27)	0	0 (0.00)
Respiratory distress	1	1 (2.27)	1	1 (2.27)
Wheezing	1	1 (2.27)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	47	19 (43.18)	2	2 (4.55)
Rash	8	7 (15.91)	0	0 (0.00)
Hyperhidrosis	4	3 (6.82)	0	0 (0.00)
Petechiae	4	4 (9.09)	0	0 (0.00)
Pruritus	4	4 (9.09)	0	0 (0.00)
Dry skin	3	3 (6.82)	0	0 (0.00)
Rash maculo-papular	3	3 (6.82)	0	0 (0.00)
Erythema	2	1 (2.27)	0	0 (0.00)
Macule	2	2 (4.55)	0	0 (0.00)
Rash papular	2	2 (4.55)	0	0 (0.00)
Dermatitis	1	1 (2.27)	0	0 (0.00)
Dermatitis acneiform	1	1 (2.27)	1	1 (2.27)
Ecchymosis	1	1 (2.27)	1	1 (2.27)
Eczema	1	1 (2.27)	0	0 (0.00)
Ingrowing nail	1	1 (2.27)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=44 n (%)[1]	Grade >= 3 Total events	All patients N=44 n (%)[2]
Night sweats	1	1 (2.27)	0	0 (0.00)
Papule	1	1 (2.27)	0	0 (0.00)
Rash erythematous	1	1 (2.27)	0	0 (0.00)
Rash follicular	1	1 (2.27)	0	0 (0.00)
Rash macular	1	1 (2.27)	0	0 (0.00)
Rash pruritic	1	1 (2.27)	0	0 (0.00)
Rash vesicular	1	1 (2.27)	0	0 (0.00)
Skin exfoliation	1	1 (2.27)	0	0 (0.00)
Skin fissures	1	1 (2.27)	0	0 (0.00)
Skin irritation	1	1 (2.27)	0	0 (0.00)
Vascular disorders				
- Total	32	19 (43.18)	14	11 (25.00)
Hypotension	15	12 (27.27)	12	11 (25.00)
Hypertension	9	8 (18.18)	1	1 (2.27)
Flushing	3	2 (4.55)	0	0 (0.00)
Orthostatic hypotension	2	2 (4.55)	0	0 (0.00)
Capillary leak syndrome	1	1 (2.27)	1	1 (2.27)
Haematoma	1	1 (2.27)	0	0 (0.00)
Secondary hypertension	1	1 (2.27)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	102	4 (80.00)	50	4 (80.00)
Blood and lymphatic system disorders				
- Total	5	2 (40.00)	5	2 (40.00)
Anaemia	4	2 (40.00)	4	2 (40.00)
Febrile neutropenia	1	1 (20.00)	1	1 (20.00)
Cardiac disorders				
- Total	3	2 (40.00)	0	0 (0.00)
Bradycardia	1	1 (20.00)	0	0 (0.00)
Pericardial effusion	1	1 (20.00)	0	0 (0.00)
Tachycardia	1	1 (20.00)	0	0 (0.00)
Eye disorders				
- Total	2	1 (20.00)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (20.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Periorbital oedema	1	1 (20.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	3 (60.00)	1	1 (20.00)
Abdominal pain	1	1 (20.00)	0	0 (0.00)
Dysphagia	1	1 (20.00)	1	1 (20.00)
Nausea	1	1 (20.00)	0	0 (0.00)
Vomiting	1	1 (20.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	6	2 (40.00)	4	1 (20.00)
Face oedema	1	1 (20.00)	1	1 (20.00)
Localised oedema	1	1 (20.00)	1	1 (20.00)
Malaise	1	1 (20.00)	0	0 (0.00)
Mucosal haemorrhage	1	1 (20.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (20.00)	1	1 (20.00)
Oedema peripheral	1	1 (20.00)	1	1 (20.00)
Hepatobiliary disorders				
- Total	1	1 (20.00)	1	1 (20.00)
Hyperbilirubinaemia	1	1 (20.00)	1	1 (20.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Immune system disorders				
- Total	12	4 (80.00)	3	1 (20.00)
Cytokine release syndrome	10	4 (80.00)	3	1 (20.00)
Hypogammaglobulinaemia	2	2 (40.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (20.00)	0	0 (0.00)
Procedural complication	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	32	4 (80.00)	27	4 (80.00)
Neutrophil count decreased	10	2 (40.00)	10	2 (40.00)
Aspartate aminotransferase increased	7	2 (40.00)	4	2 (40.00)
Alanine aminotransferase increased	3	2 (40.00)	3	2 (40.00)
White blood cell count decreased	3	2 (40.00)	3	2 (40.00)
Platelet count decreased	2	1 (20.00)	2	1 (20.00)
Activated partial thromboplastin time prolonged	1	1 (20.00)	0	0 (0.00)
Blood creatinine increased	1	1 (20.00)	1	1 (20.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Blood fibrinogen decreased	1	1 (20.00)	1	1 (20.00)
Blood phosphorus decreased	1	1 (20.00)	0	0 (0.00)
Blood urea increased	1	1 (20.00)	1	1 (20.00)
Lymphocyte count decreased	1	1 (20.00)	1	1 (20.00)
Protein total decreased	1	1 (20.00)	1	1 (20.00)
Metabolism and nutrition disorders				
- Total	14	2 (40.00)	3	2 (40.00)
Hypercalcaemia	2	1 (20.00)	0	0 (0.00)
Hypernatraemia	2	1 (20.00)	0	0 (0.00)
Hypokalaemia	2	2 (40.00)	2	2 (40.00)
Acidosis	1	1 (20.00)	1	1 (20.00)
Decreased appetite	1	1 (20.00)	0	0 (0.00)
Hyperalbuminaemia	1	1 (20.00)	0	0 (0.00)
Hyperchloraemia	1	1 (20.00)	0	0 (0.00)
Hypermagnesaemia	1	1 (20.00)	0	0 (0.00)
Hypoalbuminaemia	1	1 (20.00)	0	0 (0.00)
Hypophosphataemia	1	1 (20.00)	0	0 (0.00)
Metabolic alkalosis	1	1 (20.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	2	1 (20.00)	0	0 (0.00)
Arthralgia	1	1 (20.00)	0	0 (0.00)
Muscular weakness	1	1 (20.00)	0	0 (0.00)
Nervous system disorders				
- Total	3	2 (40.00)	0	0 (0.00)
Dysarthria	1	1 (20.00)	0	0 (0.00)
Headache	1	1 (20.00)	0	0 (0.00)
Somnolence	1	1 (20.00)	0	0 (0.00)
Psychiatric disorders				
- Total	3	1 (20.00)	0	0 (0.00)
Delirium	1	1 (20.00)	0	0 (0.00)
Insomnia	1	1 (20.00)	0	0 (0.00)
Irritability	1	1 (20.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (20.00)	1	1 (20.00)
Renal impairment	1	1 (20.00)	1	1 (20.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	5	2 (40.00)	3	1 (20.00)
Epistaxis	1	1 (20.00)	0	0 (0.00)
Oropharyngeal plaque	1	1 (20.00)	0	0 (0.00)
Pleural effusion	1	1 (20.00)	1	1 (20.00)
Pulmonary oedema	1	1 (20.00)	1	1 (20.00)
Respiratory distress	1	1 (20.00)	1	1 (20.00)
Skin and subcutaneous tissue disorders				
- Total	3	1 (20.00)	0	0 (0.00)
Hyperhidrosis	2	1 (20.00)	0	0 (0.00)
Rash papular	1	1 (20.00)	0	0 (0.00)
Vascular disorders				
- Total	5	1 (20.00)	2	1 (20.00)
Flushing	2	1 (20.00)	0	0 (0.00)
Capillary leak syndrome	1	1 (20.00)	1	1 (20.00)
Hypertension	1	1 (20.00)	0	0 (0.00)
Hypotension	1	1 (20.00)	1	1 (20.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Total number of AE per patient	1212	59 (100.00)	408	50 (84.75)
Blood and lymphatic system disorders				
- Total	117	41 (69.49)	88	36 (61.02)
Anaemia	43	25 (42.37)	27	17 (28.81)
Thrombocytopenia	30	8 (13.56)	23	8 (13.56)
Febrile neutropenia	25	21 (35.59)	25	21 (35.59)
Neutropenia	9	8 (13.56)	8	8 (13.56)
Disseminated intravascular coagulation	5	4 (6.78)	2	2 (3.39)
Lymphopenia	3	3 (5.08)	2	2 (3.39)
Coagulopathy	1	1 (1.69)	0	0 (0.00)
Pancytopenia	1	1 (1.69)	1	1 (1.69)
Cardiac disorders				
- Total	29	20 (33.90)	3	2 (3.39)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Tachycardia	16	14 (23.73)	2	2 (3.39)
Sinus tachycardia	5	5 (8.47)	0	0 (0.00)
Sinus bradycardia	2	1 (1.69)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.69)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.69)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.69)	1	1 (1.69)
Palpitations	1	1 (1.69)	0	0 (0.00)
Pericardial effusion	1	1 (1.69)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.69)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (5.08)	0	0 (0.00)
Ear pain	2	2 (3.39)	0	0 (0.00)
Hypoacusis	1	1 (1.69)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.69)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.69)	0	0 (0.00)
Eye disorders				
- Total	23	12 (20.34)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Eye pain	4	3 (5.08)	0	0 (0.00)
Vision blurred	4	3 (5.08)	0	0 (0.00)
Periorbital oedema	3	3 (5.08)	0	0 (0.00)
Photophobia	3	2 (3.39)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (3.39)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.39)	0	0 (0.00)
Uveitis	2	2 (3.39)	0	0 (0.00)
Ocular hypertension	1	1 (1.69)	0	0 (0.00)
Papilloedema	1	1 (1.69)	0	0 (0.00)
Visual impairment	1	1 (1.69)	0	0 (0.00)
Gastrointestinal disorders				
- Total	122	33 (55.93)	14	10 (16.95)
Vomiting	34	21 (35.59)	3	3 (5.08)
Nausea	25	20 (33.90)	3	3 (5.08)
Diarrhoea	18	18 (30.51)	1	1 (1.69)
Abdominal pain	9	8 (13.56)	1	1 (1.69)
Constipation	8	7 (11.86)	0	0 (0.00)
Abdominal distension	2	2 (3.39)	0	0 (0.00)
Abdominal pain upper	2	2 (3.39)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Anal incontinence	2	1 (1.69)	0	0 (0.00)
Haematemesis	2	2 (3.39)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.69)	2	1 (1.69)
Pancreatitis	2	2 (3.39)	1	1 (1.69)
Stomatitis	2	2 (3.39)	0	0 (0.00)
Abdominal discomfort	1	1 (1.69)	0	0 (0.00)
Abdominal pain lower	1	1 (1.69)	0	0 (0.00)
Abdominal tenderness	1	1 (1.69)	0	0 (0.00)
Ascites	1	1 (1.69)	1	1 (1.69)
Dyspepsia	1	1 (1.69)	0	0 (0.00)
Dysphagia	1	1 (1.69)	0	0 (0.00)
Flatulence	1	1 (1.69)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.69)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.69)	0	0 (0.00)
Glossodynia	1	1 (1.69)	0	0 (0.00)
Ileus	1	1 (1.69)	1	1 (1.69)
Intestinal obstruction	1	1 (1.69)	1	1 (1.69)
Lip pain	1	1 (1.69)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
General disorders and administration site conditions				
- Total	71	30 (50.85)	10	9 (15.25)
Pyrexia	27	16 (27.12)	6	6 (10.17)
Fatigue	14	13 (22.03)	1	1 (1.69)
Chills	9	8 (13.56)	0	0 (0.00)
Catheter site pain	3	3 (5.08)	0	0 (0.00)
Generalised oedema	3	2 (3.39)	0	0 (0.00)
Pain	3	3 (5.08)	2	2 (3.39)
Malaise	2	2 (3.39)	0	0 (0.00)
Asthenia	1	1 (1.69)	0	0 (0.00)
Catheter site extravasation	1	1 (1.69)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.69)	0	0 (0.00)
Face oedema	1	1 (1.69)	0	0 (0.00)
Facial pain	1	1 (1.69)	0	0 (0.00)
Injection site haematoma	1	1 (1.69)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.69)	0	0 (0.00)
Oedema peripheral	1	1 (1.69)	0	0 (0.00)
Peripheral swelling	1	1 (1.69)	0	0 (0.00)
Physical deconditioning	1	1 (1.69)	1	1 (1.69)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Hepatobiliary disorders				
- Total	8	6 (10.17)	1	1 (1.69)
Hepatomegaly	3	3 (5.08)	0	0 (0.00)
Hyperbilirubinaemia	3	2 (3.39)	1	1 (1.69)
Gallbladder enlargement	1	1 (1.69)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.69)	0	0 (0.00)
Immune system disorders				
- Total	104	53 (89.83)	30	21 (35.59)
Cytokine release syndrome	76	46 (77.97)	26	18 (30.51)
Hypogammaglobulinaemia	25	24 (40.68)	4	4 (6.78)
Drug hypersensitivity	1	1 (1.69)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.69)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.69)	0	0 (0.00)
Infections and infestations				
- Total	41	26 (44.07)	7	7 (11.86)
Clostridium difficile colitis	4	4 (6.78)	1	1 (1.69)
Clostridium difficile infection	4	4 (6.78)	0	0 (0.00)
Rhinovirus infection	3	3 (5.08)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Gastroenteritis	2	2 (3.39)	1	1 (1.69)
Pneumonia	2	2 (3.39)	1	1 (1.69)
Staphylococcal infection	2	2 (3.39)	1	1 (1.69)
Acute sinusitis	1	1 (1.69)	0	0 (0.00)
Body tinea	1	1 (1.69)	0	0 (0.00)
Catheter site cellulitis	1	1 (1.69)	0	0 (0.00)
Catheter site infection	1	1 (1.69)	1	1 (1.69)
Cytomegalovirus infection	1	1 (1.69)	0	0 (0.00)
Enterococcal infection	1	1 (1.69)	0	0 (0.00)
Folliculitis	1	1 (1.69)	0	0 (0.00)
Fungal skin infection	1	1 (1.69)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.69)	0	0 (0.00)
Herpes simplex	1	1 (1.69)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (1.69)	0	0 (0.00)
Hypopyon	1	1 (1.69)	0	0 (0.00)
Influenza	1	1 (1.69)	0	0 (0.00)
Oral candidiasis	1	1 (1.69)	0	0 (0.00)
Orchitis	1	1 (1.69)	0	0 (0.00)
Pharyngitis	1	1 (1.69)	0	0 (0.00)
Septic embolus	1	1 (1.69)	1	1 (1.69)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Skin infection	1	1 (1.69)	0	0 (0.00)
Streptococcal infection	1	1 (1.69)	0	0 (0.00)
Upper respiratory tract infection	1	1 (1.69)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.69)	1	1 (1.69)
Viral infection	1	1 (1.69)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.69)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (1.69)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	24	14 (23.73)	2	2 (3.39)
Transfusion reaction	4	3 (5.08)	0	0 (0.00)
Procedural pain	3	3 (5.08)	0	0 (0.00)
Infusion related reaction	2	2 (3.39)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.69)	1	1 (1.69)
Contusion	1	1 (1.69)	0	0 (0.00)
Incision site pain	1	1 (1.69)	0	0 (0.00)
Limb injury	1	1 (1.69)	0	0 (0.00)
Mouth injury	1	1 (1.69)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.69)	0	0 (0.00)
Procedural headache	1	1 (1.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Procedural site reaction	1	1 (1.69)	0	0 (0.00)
Skin abrasion	1	1 (1.69)	0	0 (0.00)
Stoma site irritation	1	1 (1.69)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.69)	0	0 (0.00)
Tibia fracture	1	1 (1.69)	0	0 (0.00)
Tongue injury	1	1 (1.69)	0	0 (0.00)
Transfusion related complication	1	1 (1.69)	1	1 (1.69)
Investigations				
- Total	300	48 (81.36)	151	40 (67.80)
White blood cell count decreased	52	28 (47.46)	34	24 (40.68)
Platelet count decreased	41	18 (30.51)	35	13 (22.03)
Neutrophil count decreased	37	23 (38.98)	34	21 (35.59)
Alanine aminotransferase increased	25	17 (28.81)	11	9 (15.25)
Aspartate aminotransferase increased	25	16 (27.12)	12	9 (15.25)
Prothrombin time prolonged	17	9 (15.25)	1	1 (1.69)
Lymphocyte count decreased	15	13 (22.03)	11	10 (16.95)
Blood fibrinogen decreased	14	3 (5.08)	3	2 (3.39)
Blood bilirubin increased	13	7 (11.86)	2	2 (3.39)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
International normalised ratio increased	11	9 (15.25)	1	1 (1.69)
Blood creatinine increased	10	8 (13.56)	1	1 (1.69)
Activated partial thromboplastin time prolonged	7	4 (6.78)	0	0 (0.00)
Blood immunoglobulin M decreased	4	4 (6.78)	0	0 (0.00)
Blood immunoglobulin A decreased	3	3 (5.08)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.39)	0	0 (0.00)
Blood sodium increased	2	1 (1.69)	0	0 (0.00)
Blood urea increased	2	2 (3.39)	0	0 (0.00)
Blood uric acid increased	2	1 (1.69)	0	0 (0.00)
Lipase increased	2	2 (3.39)	2	2 (3.39)
Transaminases increased	2	2 (3.39)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.69)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.69)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.69)	1	1 (1.69)
Blood magnesium decreased	1	1 (1.69)	1	1 (1.69)
C-reactive protein increased	1	1 (1.69)	1	1 (1.69)
Cardiac murmur	1	1 (1.69)	0	0 (0.00)
Culture stool positive	1	1 (1.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Fibrin D dimer increased	1	1 (1.69)	0	0 (0.00)
Haemoglobin decreased	1	1 (1.69)	1	1 (1.69)
Hepatic enzyme increased	1	1 (1.69)	0	0 (0.00)
Norovirus test positive	1	1 (1.69)	0	0 (0.00)
Pulmonary function test decreased	1	1 (1.69)	0	0 (0.00)
Serum ferritin increased	1	1 (1.69)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	102	37 (62.71)	40	22 (37.29)
Decreased appetite	23	19 (32.20)	13	12 (20.34)
Hypokalaemia	18	14 (23.73)	5	5 (8.47)
Hypophosphataemia	12	8 (13.56)	9	7 (11.86)
Hyperphosphataemia	10	8 (13.56)	0	0 (0.00)
Hypernatraemia	5	3 (5.08)	1	1 (1.69)
Hypoalbuminaemia	5	4 (6.78)	1	1 (1.69)
Hyperglycaemia	4	3 (5.08)	1	1 (1.69)
Hyperuricaemia	4	3 (5.08)	1	1 (1.69)
Hypocalcaemia	4	3 (5.08)	1	1 (1.69)
Dehydration	3	3 (5.08)	2	2 (3.39)
Fluid overload	3	3 (5.08)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Hypertriglyceridaemia	3	2 (3.39)	1	1 (1.69)
Hyponatraemia	3	2 (3.39)	3	2 (3.39)
Acidosis	1	1 (1.69)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.69)	0	0 (0.00)
Malnutrition	1	1 (1.69)	1	1 (1.69)
Metabolic acidosis	1	1 (1.69)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.69)	1	1 (1.69)
Musculoskeletal and connective tissue disorders				
- Total	21	14 (23.73)	1	1 (1.69)
Myalgia	5	5 (8.47)	0	0 (0.00)
Musculoskeletal pain	4	3 (5.08)	0	0 (0.00)
Pain in extremity	4	4 (6.78)	0	0 (0.00)
Arthralgia	3	3 (5.08)	1	1 (1.69)
Coccydynia	1	1 (1.69)	0	0 (0.00)
Limb discomfort	1	1 (1.69)	0	0 (0.00)
Muscle spasms	1	1 (1.69)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.69)	0	0 (0.00)
Osteopenia	1	1 (1.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.69)	0	0 (0.00)
Skin papilloma	1	1 (1.69)	0	0 (0.00)
Nervous system disorders				
- Total	55	31 (52.54)	6	5 (8.47)
Headache	30	23 (38.98)	2	2 (3.39)
Encephalopathy	6	4 (6.78)	2	2 (3.39)
Dizziness	4	4 (6.78)	0	0 (0.00)
Seizure	3	3 (5.08)	1	1 (1.69)
Tremor	2	2 (3.39)	0	0 (0.00)
Asterixis	1	1 (1.69)	0	0 (0.00)
Ataxia	1	1 (1.69)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.69)	0	0 (0.00)
Dysarthria	1	1 (1.69)	0	0 (0.00)
Embolic stroke	1	1 (1.69)	1	1 (1.69)
Idiopathic intracranial hypertension	1	1 (1.69)	0	0 (0.00)
Migraine	1	1 (1.69)	0	0 (0.00)
Myoclonus	1	1 (1.69)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Pleocytosis	1	1 (1.69)	0	0 (0.00)
Product issues				
- Total	1	1 (1.69)	0	0 (0.00)
Device occlusion	1	1 (1.69)	0	0 (0.00)
Psychiatric disorders				
- Total	27	15 (25.42)	1	1 (1.69)
Anxiety	6	6 (10.17)	1	1 (1.69)
Confusional state	6	6 (10.17)	0	0 (0.00)
Agitation	3	2 (3.39)	0	0 (0.00)
Delirium	3	3 (5.08)	0	0 (0.00)
Hallucination	3	2 (3.39)	0	0 (0.00)
Adjustment disorder	1	1 (1.69)	0	0 (0.00)
Irritability	1	1 (1.69)	0	0 (0.00)
Listless	1	1 (1.69)	0	0 (0.00)
Mental status changes	1	1 (1.69)	0	0 (0.00)
Panic attack	1	1 (1.69)	0	0 (0.00)
Suicidal ideation	1	1 (1.69)	0	0 (0.00)
Renal and urinary disorders				

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
- Total	17	10 (16.95)	10	6 (10.17)
Acute kidney injury	7	7 (11.86)	5	5 (8.47)
Haematuria	4	4 (6.78)	2	2 (3.39)
Dysuria	2	2 (3.39)	0	0 (0.00)
Oliguria	2	2 (3.39)	2	2 (3.39)
Pollakiuria	1	1 (1.69)	0	0 (0.00)
Renal failure	1	1 (1.69)	1	1 (1.69)
Reproductive system and breast disorders				
- Total	4	3 (5.08)	0	0 (0.00)
Oedema genital	2	1 (1.69)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.39)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	68	26 (44.07)	25	11 (18.64)
Hypoxia	13	10 (16.95)	8	7 (11.86)
Epistaxis	10	6 (10.17)	4	4 (6.78)
Cough	8	8 (13.56)	0	0 (0.00)
Pleural effusion	7	7 (11.86)	1	1 (1.69)
Tachypnoea	6	5 (8.47)	1	1 (1.69)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Pulmonary oedema	5	5 (8.47)	4	4 (6.78)
Dyspnoea	3	2 (3.39)	2	2 (3.39)
Haemoptysis	3	2 (3.39)	1	1 (1.69)
Respiratory failure	3	3 (5.08)	3	3 (5.08)
Oropharyngeal pain	2	2 (3.39)	0	0 (0.00)
Atelectasis	1	1 (1.69)	0	0 (0.00)
Interstitial lung disease	1	1 (1.69)	1	1 (1.69)
Nasal congestion	1	1 (1.69)	0	0 (0.00)
Pharyngeal ulceration	1	1 (1.69)	0	0 (0.00)
Respiratory depression	1	1 (1.69)	0	0 (0.00)
Rhinitis allergic	1	1 (1.69)	0	0 (0.00)
Rhinorrhoea	1	1 (1.69)	0	0 (0.00)
Wheezing	1	1 (1.69)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	38	20 (33.90)	2	2 (3.39)
Dry skin	4	4 (6.78)	0	0 (0.00)
Erythema	4	3 (5.08)	0	0 (0.00)
Rash	4	4 (6.78)	0	0 (0.00)
Ingrowing nail	3	2 (3.39)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Petechiae	3	3 (5.08)	0	0 (0.00)
Rash maculo-papular	3	3 (5.08)	1	1 (1.69)
Hyperhidrosis	2	2 (3.39)	0	0 (0.00)
Pruritus	2	2 (3.39)	0	0 (0.00)
Dermatitis diaper	1	1 (1.69)	0	0 (0.00)
Ecchymosis	1	1 (1.69)	1	1 (1.69)
Livedo reticularis	1	1 (1.69)	0	0 (0.00)
Macule	1	1 (1.69)	0	0 (0.00)
Night sweats	1	1 (1.69)	0	0 (0.00)
Rash erythematous	1	1 (1.69)	0	0 (0.00)
Rash follicular	1	1 (1.69)	0	0 (0.00)
Rash macular	1	1 (1.69)	0	0 (0.00)
Rash papular	1	1 (1.69)	0	0 (0.00)
Rash vesicular	1	1 (1.69)	0	0 (0.00)
Skin exfoliation	1	1 (1.69)	0	0 (0.00)
Skin fissures	1	1 (1.69)	0	0 (0.00)
Skin irritation	1	1 (1.69)	0	0 (0.00)
Vascular disorders				
- Total	35	23 (38.98)	17	15 (25.42)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Hypotension	18	15 (25.42)	15	14 (23.73)
Hypertension	11	9 (15.25)	1	1 (1.69)
Orthostatic hypotension	2	2 (3.39)	0	0 (0.00)
Embolism	1	1 (1.69)	1	1 (1.69)
Flushing	1	1 (1.69)	0	0 (0.00)
Haematoma	1	1 (1.69)	0	0 (0.00)
Secondary hypertension	1	1 (1.69)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	23	4 (80.00)	4	2 (40.00)
Blood and lymphatic system disorders				
- Total	2	2 (40.00)	1	1 (20.00)
Leukopenia	1	1 (20.00)	1	1 (20.00)
Lymphadenopathy	1	1 (20.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (20.00)	0	0 (0.00)
Acquired gene mutation	1	1 (20.00)	0	0 (0.00)
Immune system disorders				
- Total	2	2 (40.00)	1	1 (20.00)
Hypogammaglobulinaemia	1	1 (20.00)	1	1 (20.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Seasonal allergy	1	1 (20.00)	0	0 (0.00)
Infections and infestations				
- Total	4	2 (40.00)	1	1 (20.00)
Gastroenteritis	1	1 (20.00)	0	0 (0.00)
Subcutaneous abscess	1	1 (20.00)	0	0 (0.00)
Upper respiratory tract infection	1	1 (20.00)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (20.00)	1	1 (20.00)
Injury, poisoning and procedural complications				
- Total	2	1 (20.00)	0	0 (0.00)
Arthropod bite	1	1 (20.00)	0	0 (0.00)
Procedural pain	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	3	2 (40.00)	0	0 (0.00)
Blood urea increased	2	1 (20.00)	0	0 (0.00)
Serum ferritin increased	1	1 (20.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	4	2 (40.00)	1	1 (20.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Hyperalbuminaemia	2	1 (20.00)	0	0 (0.00)
Hypercalcaemia	1	1 (20.00)	0	0 (0.00)
Iron overload	1	1 (20.00)	1	1 (20.00)
Respiratory, thoracic and mediastinal disorders				
- Total	2	1 (20.00)	0	0 (0.00)
Cough	1	1 (20.00)	0	0 (0.00)
Rhinorrhoea	1	1 (20.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	2 (40.00)	0	0 (0.00)
Dermatitis	1	1 (20.00)	0	0 (0.00)
Papule	1	1 (20.00)	0	0 (0.00)
Rash	1	1 (20.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Total number of AE per patient	323	42 (82.35)	67	24 (47.06)
Blood and lymphatic system disorders				
- Total	16	9 (17.65)	12	6 (11.76)
Neutropenia	6	4 (7.84)	6	4 (7.84)
Febrile neutropenia	3	3 (5.88)	3	3 (5.88)
Anaemia	2	2 (3.92)	1	1 (1.96)
Eosinophilia	2	1 (1.96)	1	1 (1.96)
Thrombocytopenia	2	2 (3.92)	1	1 (1.96)
Lymphopenia	1	1 (1.96)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (1.96)	0	0 (0.00)
Sinus tachycardia	1	1 (1.96)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Endocrine disorders				
- Total	1	1 (1.96)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.96)	0	0 (0.00)
Eye disorders				
- Total	5	5 (9.80)	0	0 (0.00)
Dry eye	2	2 (3.92)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.96)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.96)	0	0 (0.00)
Vision blurred	1	1 (1.96)	0	0 (0.00)
Gastrointestinal disorders				
- Total	38	16 (31.37)	8	4 (7.84)
Vomiting	13	9 (17.65)	2	2 (3.92)
Diarrhoea	8	8 (15.69)	1	1 (1.96)
Nausea	7	6 (11.76)	2	2 (3.92)
Abdominal pain	4	4 (7.84)	1	1 (1.96)
Oral pain	3	2 (3.92)	1	1 (1.96)
Abdominal pain upper	1	1 (1.96)	0	0 (0.00)
Enterocolitis	1	1 (1.96)	1	1 (1.96)
Pigmentation lip	1	1 (1.96)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
General disorders and administration site conditions				
- Total	25	16 (31.37)	1	1 (1.96)
Pyrexia	14	10 (19.61)	1	1 (1.96)
Fatigue	2	2 (3.92)	0	0 (0.00)
Influenza like illness	2	2 (3.92)	0	0 (0.00)
Catheter site pain	1	1 (1.96)	0	0 (0.00)
Chills	1	1 (1.96)	0	0 (0.00)
Crying	1	1 (1.96)	0	0 (0.00)
Generalised oedema	1	1 (1.96)	0	0 (0.00)
Malaise	1	1 (1.96)	0	0 (0.00)
Oedema peripheral	1	1 (1.96)	0	0 (0.00)
Pain	1	1 (1.96)	0	0 (0.00)
Immune system disorders				
- Total	15	12 (23.53)	0	0 (0.00)
Hypogammaglobulinaemia	8	7 (13.73)	0	0 (0.00)
Graft versus host disease	3	2 (3.92)	0	0 (0.00)
Immunodeficiency common variable	2	2 (3.92)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.96)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Seasonal allergy	1	1 (1.96)	0	0 (0.00)
Infections and infestations				
- Total	57	31 (60.78)	16	11 (21.57)
Upper respiratory tract infection	6	6 (11.76)	1	1 (1.96)
Cellulitis of male external genital organ	5	1 (1.96)	2	1 (1.96)
Urinary tract infection	5	4 (7.84)	2	2 (3.92)
Rhinovirus infection	4	2 (3.92)	0	0 (0.00)
Influenza	3	3 (5.88)	0	0 (0.00)
Ear infection	2	2 (3.92)	0	0 (0.00)
Gastroenteritis	2	2 (3.92)	0	0 (0.00)
Otitis media	2	1 (1.96)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.92)	1	1 (1.96)
Sinusitis	2	2 (3.92)	0	0 (0.00)
Bacterial sepsis	1	1 (1.96)	1	1 (1.96)
Cholecystitis infective	1	1 (1.96)	1	1 (1.96)
Corona virus infection	1	1 (1.96)	1	1 (1.96)
Cytomegalovirus infection	1	1 (1.96)	0	0 (0.00)
Enterovirus infection	1	1 (1.96)	1	1 (1.96)
Escherichia urinary tract infection	1	1 (1.96)	1	1 (1.96)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Gastroenteritis norovirus	1	1 (1.96)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.96)	0	0 (0.00)
Herpes zoster	1	1 (1.96)	1	1 (1.96)
Molluscum contagiosum	1	1 (1.96)	0	0 (0.00)
Oral herpes	1	1 (1.96)	0	0 (0.00)
Otitis externa	1	1 (1.96)	0	0 (0.00)
Otitis media acute	1	1 (1.96)	0	0 (0.00)
Paronychia	1	1 (1.96)	0	0 (0.00)
Rash pustular	1	1 (1.96)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (1.96)	1	1 (1.96)
Rhinitis	1	1 (1.96)	0	0 (0.00)
Rotavirus infection	1	1 (1.96)	1	1 (1.96)
Sepsis	1	1 (1.96)	1	1 (1.96)
Tinea capitis	1	1 (1.96)	0	0 (0.00)
Vascular device infection	1	1 (1.96)	1	1 (1.96)
Viral infection	1	1 (1.96)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.96)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (1.96)	0	0 (0.00)
Injury, poisoning and procedural complications				

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
- Total	11	7 (13.73)	0	0 (0.00)
Contusion	2	2 (3.92)	0	0 (0.00)
Infusion related reaction	2	2 (3.92)	0	0 (0.00)
Foot fracture	1	1 (1.96)	0	0 (0.00)
Procedural nausea	1	1 (1.96)	0	0 (0.00)
Procedural pain	1	1 (1.96)	0	0 (0.00)
Radius fracture	1	1 (1.96)	0	0 (0.00)
Skin abrasion	1	1 (1.96)	0	0 (0.00)
Skin laceration	1	1 (1.96)	0	0 (0.00)
Sunburn	1	1 (1.96)	0	0 (0.00)
Investigations				
- Total	45	21 (41.18)	16	12 (23.53)
Neutrophil count decreased	12	8 (15.69)	8	6 (11.76)
White blood cell count decreased	7	5 (9.80)	3	2 (3.92)
Platelet count decreased	5	3 (5.88)	0	0 (0.00)
Weight decreased	4	4 (7.84)	0	0 (0.00)
Aspartate aminotransferase increased	3	3 (5.88)	2	2 (3.92)
Alanine aminotransferase increased	2	2 (3.92)	2	2 (3.92)
Haemoglobin decreased	2	2 (3.92)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Lymphocyte count decreased	2	2 (3.92)	0	0 (0.00)
Weight increased	2	2 (3.92)	0	0 (0.00)
Blood bilirubin increased	1	1 (1.96)	1	1 (1.96)
Blood creatinine increased	1	1 (1.96)	0	0 (0.00)
Blood magnesium decreased	1	1 (1.96)	0	0 (0.00)
Blood uric acid increased	1	1 (1.96)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.96)	0	0 (0.00)
Transaminases increased	1	1 (1.96)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	11	8 (15.69)	5	3 (5.88)
Decreased appetite	2	2 (3.92)	0	0 (0.00)
Hyperphosphataemia	2	2 (3.92)	0	0 (0.00)
Hypokalaemia	2	2 (3.92)	1	1 (1.96)
Dehydration	1	1 (1.96)	1	1 (1.96)
Hyperglycaemia	1	1 (1.96)	1	1 (1.96)
Hypophosphataemia	1	1 (1.96)	1	1 (1.96)
Tumour lysis syndrome	1	1 (1.96)	1	1 (1.96)
Vitamin D deficiency	1	1 (1.96)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	21	16 (31.37)	0	0 (0.00)
Pain in extremity	8	8 (15.69)	0	0 (0.00)
Arthralgia	2	2 (3.92)	0	0 (0.00)
Joint range of motion decreased	2	2 (3.92)	0	0 (0.00)
Muscular weakness	2	2 (3.92)	0	0 (0.00)
Back pain	1	1 (1.96)	0	0 (0.00)
Flank pain	1	1 (1.96)	0	0 (0.00)
Muscle spasms	1	1 (1.96)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.96)	0	0 (0.00)
Osteonecrosis	1	1 (1.96)	0	0 (0.00)
Pain in jaw	1	1 (1.96)	0	0 (0.00)
Toe walking	1	1 (1.96)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.96)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.96)	0	0 (0.00)
Nervous system disorders				
- Total	12	8 (15.69)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Headache	7	5 (9.80)	0	0 (0.00)
Dizziness	3	3 (5.88)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.92)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (3.92)	0	0 (0.00)
Depression	2	2 (3.92)	0	0 (0.00)
Anxiety	1	1 (1.96)	0	0 (0.00)
Sleep disorder	1	1 (1.96)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	3 (5.88)	3	2 (3.92)
Acute kidney injury	1	1 (1.96)	1	1 (1.96)
Calculus urinary	1	1 (1.96)	0	0 (0.00)
Haematuria	1	1 (1.96)	1	1 (1.96)
Nephrolithiasis	1	1 (1.96)	1	1 (1.96)
Urinary incontinence	1	1 (1.96)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	2 (3.92)	1	1 (1.96)
Scrotal pain	1	1 (1.96)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Vaginal haemorrhage	1	1 (1.96)	1	1 (1.96)
Respiratory, thoracic and mediastinal disorders				
- Total	28	17 (33.33)	4	3 (5.88)
Cough	8	6 (11.76)	0	0 (0.00)
Nasal congestion	4	4 (7.84)	0	0 (0.00)
Oropharyngeal pain	3	3 (5.88)	0	0 (0.00)
Rhinitis allergic	3	3 (5.88)	0	0 (0.00)
Rhinorrhoea	3	3 (5.88)	0	0 (0.00)
Epistaxis	2	2 (3.92)	1	1 (1.96)
Acute respiratory failure	1	1 (1.96)	1	1 (1.96)
Dysphonia	1	1 (1.96)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.96)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.96)	1	1 (1.96)
Pulmonary oedema	1	1 (1.96)	1	1 (1.96)
Skin and subcutaneous tissue disorders				
- Total	22	14 (27.45)	1	1 (1.96)
Rash	4	3 (5.88)	0	0 (0.00)
Erythema	2	2 (3.92)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=51 n (%)[1]	Grade >= 3 Total events	All patients N=51 n (%)[2]
Rash erythematous	2	1 (1.96)	0	0 (0.00)
Rash maculo-papular	2	2 (3.92)	0	0 (0.00)
Alopecia	1	1 (1.96)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.96)	1	1 (1.96)
Dermatitis atopic	1	1 (1.96)	0	0 (0.00)
Dry skin	1	1 (1.96)	0	0 (0.00)
Eczema	1	1 (1.96)	0	0 (0.00)
Hyperhidrosis	1	1 (1.96)	0	0 (0.00)
Ingrowing nail	1	1 (1.96)	0	0 (0.00)
Keloid scar	1	1 (1.96)	0	0 (0.00)
Macule	1	1 (1.96)	0	0 (0.00)
Petechiae	1	1 (1.96)	0	0 (0.00)
Pruritus	1	1 (1.96)	0	0 (0.00)
Rash pruritic	1	1 (1.96)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (3.92)	0	0 (0.00)
Hypertension	2	2 (3.92)	0	0 (0.00)
Hot flush	1	1 (1.96)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Total number of AE per patient	28	2 (66.67)	8	2 (66.67)
Blood and lymphatic system disorders				
- Total	1	1 (33.33)	1	1 (33.33)
Febrile neutropenia	1	1 (33.33)	1	1 (33.33)
Ear and labyrinth disorders				
- Total	1	1 (33.33)	0	0 (0.00)
Tympanic membrane perforation	1	1 (33.33)	0	0 (0.00)
Gastrointestinal disorders				
- Total	1	1 (33.33)	0	0 (0.00)
Nausea	1	1 (33.33)	0	0 (0.00)
General disorders and administration site conditions				

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
- Total	3	1 (33.33)	0	0 (0.00)
Pyrexia	2	1 (33.33)	0	0 (0.00)
Chills	1	1 (33.33)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (33.33)	0	0 (0.00)
Immunodeficiency	1	1 (33.33)	0	0 (0.00)
Infections and infestations				
- Total	9	1 (33.33)	1	1 (33.33)
Otitis media	3	1 (33.33)	1	1 (33.33)
Otitis media acute	3	1 (33.33)	0	0 (0.00)
Haemophilus infection	1	1 (33.33)	0	0 (0.00)
Pneumonia	1	1 (33.33)	0	0 (0.00)
Sinusitis	1	1 (33.33)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (33.33)	1	1 (33.33)
Procedural pain	1	1 (33.33)	1	1 (33.33)
Investigations				

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
- Total	7	1 (33.33)	3	1 (33.33)
Alanine aminotransferase increased	1	1 (33.33)	1	1 (33.33)
Aspartate aminotransferase increased	1	1 (33.33)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (33.33)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (33.33)	0	0 (0.00)
C-reactive protein increased	1	1 (33.33)	0	0 (0.00)
Platelet count decreased	1	1 (33.33)	1	1 (33.33)
White blood cell count decreased	1	1 (33.33)	1	1 (33.33)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (33.33)	1	1 (33.33)
Glioblastoma multiforme	1	1 (33.33)	1	1 (33.33)
Nervous system disorders				
- Total	1	1 (33.33)	1	1 (33.33)
Seizure	1	1 (33.33)	1	1 (33.33)
Respiratory, thoracic and mediastinal disorders				

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
- Total	1	1 (33.33)	0	0 (0.00)
Cough	1	1 (33.33)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (33.33)	0	0 (0.00)
Pruritus	1	1 (33.33)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Total number of AE per patient	62	20 (64.52)	15	10 (32.26)
Blood and lymphatic system disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Thrombocytopenia	1	1 (3.23)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	2 (6.45)	0	0 (0.00)
Diarrhoea	2	2 (6.45)	0	0 (0.00)
Abdominal pain	1	1 (3.23)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (3.23)	1	1 (3.23)
Cyst	1	1 (3.23)	1	1 (3.23)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Immune system disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Chronic graft versus host disease	1	1 (3.23)	0	0 (0.00)
Infections and infestations				
- Total	23	10 (32.26)	6	3 (9.68)
Upper respiratory tract infection	4	2 (6.45)	0	0 (0.00)
Urinary tract infection	3	2 (6.45)	1	1 (3.23)
Otitis media	2	2 (6.45)	0	0 (0.00)
Sinusitis	2	2 (6.45)	0	0 (0.00)
Campylobacter infection	1	1 (3.23)	1	1 (3.23)
Cellulitis of male external genital organ	1	1 (3.23)	1	1 (3.23)
Clostridium difficile infection	1	1 (3.23)	1	1 (3.23)
Gingivitis	1	1 (3.23)	0	0 (0.00)
Meningitis aseptic	1	1 (3.23)	0	0 (0.00)
Otitis media acute	1	1 (3.23)	0	0 (0.00)
Pneumonia	1	1 (3.23)	0	0 (0.00)
Respiratory tract infection	1	1 (3.23)	1	1 (3.23)
Respiratory tract infection viral	1	1 (3.23)	1	1 (3.23)
Skin infection	1	1 (3.23)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Viral infection	1	1 (3.23)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (3.23)	0	0 (0.00)
Investigations				
- Total	15	7 (22.58)	5	4 (12.90)
Lymphocyte count decreased	5	3 (9.68)	1	1 (3.23)
White blood cell count decreased	4	3 (9.68)	2	2 (6.45)
Neutrophil count decreased	3	2 (6.45)	0	0 (0.00)
Alanine aminotransferase increased	2	2 (6.45)	1	1 (3.23)
Aspartate aminotransferase increased	1	1 (3.23)	1	1 (3.23)
Metabolism and nutrition disorders				
- Total	2	2 (6.45)	1	1 (3.23)
Hypokalaemia	1	1 (3.23)	1	1 (3.23)
Vitamin D deficiency	1	1 (3.23)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Neck pain	1	1 (3.23)	0	0 (0.00)
Nervous system disorders				

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
- Total	3	2 (6.45)	0	0 (0.00)
Disturbance in attention	1	1 (3.23)	0	0 (0.00)
Dizziness	1	1 (3.23)	0	0 (0.00)
Headache	1	1 (3.23)	0	0 (0.00)
Renal and urinary disorders				
- Total	3	2 (6.45)	1	1 (3.23)
Acute kidney injury	2	1 (3.23)	1	1 (3.23)
Haematuria	1	1 (3.23)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.23)	1	1 (3.23)
Ovarian failure	1	1 (3.23)	1	1 (3.23)
Respiratory, thoracic and mediastinal disorders				
- Total	6	3 (9.68)	0	0 (0.00)
Cough	2	1 (3.23)	0	0 (0.00)
Epistaxis	1	1 (3.23)	0	0 (0.00)
Oropharyngeal pain	1	1 (3.23)	0	0 (0.00)
Rhinitis allergic	1	1 (3.23)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Rhinorrhoea	1	1 (3.23)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	2 (6.45)	0	0 (0.00)
Acne	1	1 (3.23)	0	0 (0.00)
Papule	1	1 (3.23)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	153	5 (100.00)	62	5 (100.00)
Blood and lymphatic system disorders				
- Total	8	3 (60.00)	7	3 (60.00)
Anaemia	4	2 (40.00)	4	2 (40.00)
Febrile neutropenia	2	2 (40.00)	2	2 (40.00)
Leukopenia	1	1 (20.00)	1	1 (20.00)
Lymphadenopathy	1	1 (20.00)	0	0 (0.00)
Cardiac disorders				
- Total	3	2 (40.00)	0	0 (0.00)
Bradycardia	1	1 (20.00)	0	0 (0.00)
Pericardial effusion	1	1 (20.00)	0	0 (0.00)
Tachycardia	1	1 (20.00)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Tympanic membrane perforation	1	1 (20.00)	0	0 (0.00)
Eye disorders				
- Total	2	1 (20.00)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (20.00)	0	0 (0.00)
Periorbital oedema	1	1 (20.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	5	4 (80.00)	1	1 (20.00)
Nausea	2	2 (40.00)	0	0 (0.00)
Abdominal pain	1	1 (20.00)	0	0 (0.00)
Dysphagia	1	1 (20.00)	1	1 (20.00)
Vomiting	1	1 (20.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	10	4 (80.00)	4	1 (20.00)
Pyrexia	2	1 (20.00)	0	0 (0.00)
Acquired gene mutation	1	1 (20.00)	0	0 (0.00)
Chills	1	1 (20.00)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Face oedema	1	1 (20.00)	1	1 (20.00)
Localised oedema	1	1 (20.00)	1	1 (20.00)
Malaise	1	1 (20.00)	0	0 (0.00)
Mucosal haemorrhage	1	1 (20.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (20.00)	1	1 (20.00)
Oedema peripheral	1	1 (20.00)	1	1 (20.00)
Hepatobiliary disorders				
- Total	1	1 (20.00)	1	1 (20.00)
Hyperbilirubinaemia	1	1 (20.00)	1	1 (20.00)
Immune system disorders				
- Total	15	4 (80.00)	4	1 (20.00)
Cytokine release syndrome	10	4 (80.00)	3	1 (20.00)
Hypogammaglobulinaemia	3	3 (60.00)	1	1 (20.00)
Immunodeficiency	1	1 (20.00)	0	0 (0.00)
Seasonal allergy	1	1 (20.00)	0	0 (0.00)
Infections and infestations				
- Total	13	3 (60.00)	2	2 (40.00)
Otitis media	3	1 (20.00)	1	1 (20.00)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Otitis media acute	3	1 (20.00)	0	0 (0.00)
Gastroenteritis	1	1 (20.00)	0	0 (0.00)
Haemophilus infection	1	1 (20.00)	0	0 (0.00)
Pneumonia	1	1 (20.00)	0	0 (0.00)
Sinusitis	1	1 (20.00)	0	0 (0.00)
Subcutaneous abscess	1	1 (20.00)	0	0 (0.00)
Upper respiratory tract infection	1	1 (20.00)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (20.00)	1	1 (20.00)
Injury, poisoning and procedural complications				
- Total	4	2 (40.00)	1	1 (20.00)
Procedural pain	2	1 (20.00)	1	1 (20.00)
Arthropod bite	1	1 (20.00)	0	0 (0.00)
Procedural complication	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	42	4 (80.00)	30	4 (80.00)
Neutrophil count decreased	10	2 (40.00)	10	2 (40.00)
Aspartate aminotransferase increased	8	3 (60.00)	4	2 (40.00)
Alanine aminotransferase increased	4	3 (60.00)	4	3 (60.00)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
White blood cell count decreased	4	3 (60.00)	4	3 (60.00)
Blood urea increased	3	1 (20.00)	1	1 (20.00)
Platelet count decreased	3	2 (40.00)	3	2 (40.00)
Activated partial thromboplastin time prolonged	1	1 (20.00)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (20.00)	0	0 (0.00)
Blood creatinine increased	1	1 (20.00)	1	1 (20.00)
Blood fibrinogen decreased	1	1 (20.00)	1	1 (20.00)
Blood lactate dehydrogenase increased	1	1 (20.00)	0	0 (0.00)
Blood phosphorus decreased	1	1 (20.00)	0	0 (0.00)
C-reactive protein increased	1	1 (20.00)	0	0 (0.00)
Lymphocyte count decreased	1	1 (20.00)	1	1 (20.00)
Protein total decreased	1	1 (20.00)	1	1 (20.00)
Serum ferritin increased	1	1 (20.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	18	2 (40.00)	4	2 (40.00)
Hyperalbuminaemia	3	1 (20.00)	0	0 (0.00)
Hypercalcaemia	3	1 (20.00)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Hypernatraemia	2	1 (20.00)	0	0 (0.00)
Hypokalaemia	2	2 (40.00)	2	2 (40.00)
Acidosis	1	1 (20.00)	1	1 (20.00)
Decreased appetite	1	1 (20.00)	0	0 (0.00)
Hyperchloraemia	1	1 (20.00)	0	0 (0.00)
Hypermagnesaemia	1	1 (20.00)	0	0 (0.00)
Hypoalbuminaemia	1	1 (20.00)	0	0 (0.00)
Hypophosphataemia	1	1 (20.00)	0	0 (0.00)
Iron overload	1	1 (20.00)	1	1 (20.00)
Metabolic alkalosis	1	1 (20.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	2	1 (20.00)	0	0 (0.00)
Arthralgia	1	1 (20.00)	0	0 (0.00)
Muscular weakness	1	1 (20.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (20.00)	1	1 (20.00)
Glioblastoma multiforme	1	1 (20.00)	1	1 (20.00)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Nervous system disorders				
- Total	4	3 (60.00)	1	1 (20.00)
Dysarthria	1	1 (20.00)	0	0 (0.00)
Headache	1	1 (20.00)	0	0 (0.00)
Seizure	1	1 (20.00)	1	1 (20.00)
Somnolence	1	1 (20.00)	0	0 (0.00)
Psychiatric disorders				
- Total	3	1 (20.00)	0	0 (0.00)
Delirium	1	1 (20.00)	0	0 (0.00)
Insomnia	1	1 (20.00)	0	0 (0.00)
Irritability	1	1 (20.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (20.00)	1	1 (20.00)
Renal impairment	1	1 (20.00)	1	1 (20.00)
Respiratory, thoracic and mediastinal disorders				
- Total	8	3 (60.00)	3	1 (20.00)
Cough	2	1 (20.00)	0	0 (0.00)
Epistaxis	1	1 (20.00)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Oropharyngeal plaque	1	1 (20.00)	0	0 (0.00)
Pleural effusion	1	1 (20.00)	1	1 (20.00)
Pulmonary oedema	1	1 (20.00)	1	1 (20.00)
Respiratory distress	1	1 (20.00)	1	1 (20.00)
Rhinorrhoea	1	1 (20.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	7	2 (40.00)	0	0 (0.00)
Hyperhidrosis	2	1 (20.00)	0	0 (0.00)
Dermatitis	1	1 (20.00)	0	0 (0.00)
Papule	1	1 (20.00)	0	0 (0.00)
Pruritus	1	1 (20.00)	0	0 (0.00)
Rash	1	1 (20.00)	0	0 (0.00)
Rash papular	1	1 (20.00)	0	0 (0.00)
Vascular disorders				
- Total	5	1 (20.00)	2	1 (20.00)
Flushing	2	1 (20.00)	0	0 (0.00)
Capillary leak syndrome	1	1 (20.00)	1	1 (20.00)
Hypertension	1	1 (20.00)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Hypotension	1	1 (20.00)	1	1 (20.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Total number of AE per patient	1597	59 (100.00)	490	54 (91.53)
Blood and lymphatic system disorders				
- Total	134	45 (76.27)	100	40 (67.80)
Anaemia	45	25 (42.37)	28	18 (30.51)
Thrombocytopenia	33	10 (16.95)	24	9 (15.25)
Febrile neutropenia	28	22 (37.29)	28	22 (37.29)
Neutropenia	15	11 (18.64)	14	11 (18.64)
Disseminated intravascular coagulation	5	4 (6.78)	2	2 (3.39)
Lymphopenia	4	4 (6.78)	2	2 (3.39)
Eosinophilia	2	1 (1.69)	1	1 (1.69)
Coagulopathy	1	1 (1.69)	0	0 (0.00)
Pancytopenia	1	1 (1.69)	1	1 (1.69)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Cardiac disorders				
- Total	30	21 (35.59)	3	2 (3.39)
Tachycardia	16	14 (23.73)	2	2 (3.39)
Sinus tachycardia	6	6 (10.17)	0	0 (0.00)
Sinus bradycardia	2	1 (1.69)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.69)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.69)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.69)	1	1 (1.69)
Palpitations	1	1 (1.69)	0	0 (0.00)
Pericardial effusion	1	1 (1.69)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.69)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (5.08)	0	0 (0.00)
Ear pain	2	2 (3.39)	0	0 (0.00)
Hypoacusis	1	1 (1.69)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (3.39)	0	0 (0.00)
Adrenal insufficiency	2	2 (3.39)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Eye disorders				
- Total	28	17 (28.81)	0	0 (0.00)
Vision blurred	5	4 (6.78)	0	0 (0.00)
Eye pain	4	3 (5.08)	0	0 (0.00)
Periorbital oedema	3	3 (5.08)	0	0 (0.00)
Photophobia	3	2 (3.39)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (3.39)	0	0 (0.00)
Dry eye	2	2 (3.39)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.39)	0	0 (0.00)
Uveitis	2	2 (3.39)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.69)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.69)	0	0 (0.00)
Ocular hypertension	1	1 (1.69)	0	0 (0.00)
Papilloedema	1	1 (1.69)	0	0 (0.00)
Visual impairment	1	1 (1.69)	0	0 (0.00)
Gastrointestinal disorders				
- Total	163	39 (66.10)	22	12 (20.34)
Vomiting	47	26 (44.07)	5	3 (5.08)
Nausea	32	23 (38.98)	5	5 (8.47)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Diarrhoea	28	24 (40.68)	2	2 (3.39)
Abdominal pain	14	10 (16.95)	2	1 (1.69)
Constipation	8	7 (11.86)	0	0 (0.00)
Abdominal pain upper	3	3 (5.08)	0	0 (0.00)
Oral pain	3	2 (3.39)	1	1 (1.69)
Abdominal distension	2	2 (3.39)	0	0 (0.00)
Anal incontinence	2	1 (1.69)	0	0 (0.00)
Haematemesis	2	2 (3.39)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.69)	2	1 (1.69)
Pancreatitis	2	2 (3.39)	1	1 (1.69)
Stomatitis	2	2 (3.39)	0	0 (0.00)
Abdominal discomfort	1	1 (1.69)	0	0 (0.00)
Abdominal pain lower	1	1 (1.69)	0	0 (0.00)
Abdominal tenderness	1	1 (1.69)	0	0 (0.00)
Ascites	1	1 (1.69)	1	1 (1.69)
Dyspepsia	1	1 (1.69)	0	0 (0.00)
Dysphagia	1	1 (1.69)	0	0 (0.00)
Enterocolitis	1	1 (1.69)	1	1 (1.69)
Flatulence	1	1 (1.69)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Gastrooesophageal reflux disease	1	1 (1.69)	0	0 (0.00)
Glossodynia	1	1 (1.69)	0	0 (0.00)
Ileus	1	1 (1.69)	1	1 (1.69)
Intestinal obstruction	1	1 (1.69)	1	1 (1.69)
Lip pain	1	1 (1.69)	0	0 (0.00)
Pigmentation lip	1	1 (1.69)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.69)	0	0 (0.00)
General disorders and administration site conditions				
- Total	97	38 (64.41)	12	11 (18.64)
Pyrexia	41	24 (40.68)	7	7 (11.86)
Fatigue	16	15 (25.42)	1	1 (1.69)
Chills	10	9 (15.25)	0	0 (0.00)
Catheter site pain	4	4 (6.78)	0	0 (0.00)
Generalised oedema	4	3 (5.08)	0	0 (0.00)
Pain	4	4 (6.78)	2	2 (3.39)
Malaise	3	3 (5.08)	0	0 (0.00)
Influenza like illness	2	2 (3.39)	0	0 (0.00)
Oedema peripheral	2	2 (3.39)	0	0 (0.00)
Asthenia	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Catheter site extravasation	1	1 (1.69)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.69)	0	0 (0.00)
Crying	1	1 (1.69)	0	0 (0.00)
Cyst	1	1 (1.69)	1	1 (1.69)
Face oedema	1	1 (1.69)	0	0 (0.00)
Facial pain	1	1 (1.69)	0	0 (0.00)
Injection site haematoma	1	1 (1.69)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.69)	0	0 (0.00)
Peripheral swelling	1	1 (1.69)	0	0 (0.00)
Physical deconditioning	1	1 (1.69)	1	1 (1.69)
Hepatobiliary disorders				
- Total	8	6 (10.17)	1	1 (1.69)
Hepatomegaly	3	3 (5.08)	0	0 (0.00)
Hyperbilirubinaemia	3	2 (3.39)	1	1 (1.69)
Gallbladder enlargement	1	1 (1.69)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.69)	0	0 (0.00)
Immune system disorders				
- Total	120	54 (91.53)	30	21 (35.59)
Cytokine release syndrome	76	46 (77.97)	26	18 (30.51)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Hypogammaglobulinaemia	33	30 (50.85)	4	4 (6.78)
Graft versus host disease	3	2 (3.39)	0	0 (0.00)
Immunodeficiency common variable	2	2 (3.39)	0	0 (0.00)
Chronic graft versus host disease	1	1 (1.69)	0	0 (0.00)
Drug hypersensitivity	1	1 (1.69)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.69)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.69)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (1.69)	0	0 (0.00)
Seasonal allergy	1	1 (1.69)	0	0 (0.00)
Infections and infestations				
- Total	121	43 (72.88)	29	16 (27.12)
Upper respiratory tract infection	11	8 (13.56)	1	1 (1.69)
Urinary tract infection	8	5 (8.47)	3	2 (3.39)
Rhinovirus infection	7	5 (8.47)	0	0 (0.00)
Cellulitis of male external genital organ	6	1 (1.69)	3	1 (1.69)
Clostridium difficile infection	5	5 (8.47)	1	1 (1.69)
Clostridium difficile colitis	4	4 (6.78)	1	1 (1.69)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Gastroenteritis	4	4 (6.78)	1	1 (1.69)
Influenza	4	4 (6.78)	0	0 (0.00)
Otitis media	4	3 (5.08)	0	0 (0.00)
Sinusitis	4	3 (5.08)	0	0 (0.00)
Pneumonia	3	3 (5.08)	1	1 (1.69)
Viral infection	3	3 (5.08)	0	0 (0.00)
Cytomegalovirus infection	2	2 (3.39)	0	0 (0.00)
Ear infection	2	2 (3.39)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (1.69)	0	0 (0.00)
Otitis media acute	2	1 (1.69)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.39)	1	1 (1.69)
Skin infection	2	2 (3.39)	0	0 (0.00)
Staphylococcal infection	2	2 (3.39)	1	1 (1.69)
Viral upper respiratory tract infection	2	2 (3.39)	0	0 (0.00)
Vulvovaginal candidiasis	2	2 (3.39)	0	0 (0.00)
Acute sinusitis	1	1 (1.69)	0	0 (0.00)
Bacterial sepsis	1	1 (1.69)	1	1 (1.69)
Body tinea	1	1 (1.69)	0	0 (0.00)
Campylobacter infection	1	1 (1.69)	1	1 (1.69)
Catheter site cellulitis	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Catheter site infection	1	1 (1.69)	1	1 (1.69)
Cholecystitis infective	1	1 (1.69)	1	1 (1.69)
Corona virus infection	1	1 (1.69)	1	1 (1.69)
Enterococcal infection	1	1 (1.69)	0	0 (0.00)
Enterovirus infection	1	1 (1.69)	1	1 (1.69)
Escherichia urinary tract infection	1	1 (1.69)	1	1 (1.69)
Folliculitis	1	1 (1.69)	0	0 (0.00)
Fungal skin infection	1	1 (1.69)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.69)	0	0 (0.00)
Gingivitis	1	1 (1.69)	0	0 (0.00)
Herpes simplex	1	1 (1.69)	0	0 (0.00)
Herpes zoster	1	1 (1.69)	1	1 (1.69)
Human herpesvirus 6 infection	1	1 (1.69)	0	0 (0.00)
Hypopyon	1	1 (1.69)	0	0 (0.00)
Meningitis aseptic	1	1 (1.69)	0	0 (0.00)
Molluscum contagiosum	1	1 (1.69)	0	0 (0.00)
Oral candidiasis	1	1 (1.69)	0	0 (0.00)
Oral herpes	1	1 (1.69)	0	0 (0.00)
Orchitis	1	1 (1.69)	0	0 (0.00)
Otitis externa	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Paronychia	1	1 (1.69)	0	0 (0.00)
Pharyngitis	1	1 (1.69)	0	0 (0.00)
Rash pustular	1	1 (1.69)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (1.69)	1	1 (1.69)
Respiratory tract infection	1	1 (1.69)	1	1 (1.69)
Respiratory tract infection viral	1	1 (1.69)	1	1 (1.69)
Rhinitis	1	1 (1.69)	0	0 (0.00)
Rotavirus infection	1	1 (1.69)	1	1 (1.69)
Sepsis	1	1 (1.69)	1	1 (1.69)
Septic embolus	1	1 (1.69)	1	1 (1.69)
Streptococcal infection	1	1 (1.69)	0	0 (0.00)
Tinea capitis	1	1 (1.69)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.69)	1	1 (1.69)
Vascular device infection	1	1 (1.69)	1	1 (1.69)
Vulvovaginal mycotic infection	1	1 (1.69)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	35	20 (33.90)	2	2 (3.39)
Infusion related reaction	4	4 (6.78)	0	0 (0.00)
Procedural pain	4	4 (6.78)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Transfusion reaction	4	3 (5.08)	0	0 (0.00)
Contusion	3	3 (5.08)	0	0 (0.00)
Skin abrasion	2	2 (3.39)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.69)	1	1 (1.69)
Foot fracture	1	1 (1.69)	0	0 (0.00)
Incision site pain	1	1 (1.69)	0	0 (0.00)
Limb injury	1	1 (1.69)	0	0 (0.00)
Mouth injury	1	1 (1.69)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.69)	0	0 (0.00)
Procedural headache	1	1 (1.69)	0	0 (0.00)
Procedural nausea	1	1 (1.69)	0	0 (0.00)
Procedural site reaction	1	1 (1.69)	0	0 (0.00)
Radius fracture	1	1 (1.69)	0	0 (0.00)
Skin laceration	1	1 (1.69)	0	0 (0.00)
Stoma site irritation	1	1 (1.69)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.69)	0	0 (0.00)
Sunburn	1	1 (1.69)	0	0 (0.00)
Tibia fracture	1	1 (1.69)	0	0 (0.00)
Tongue injury	1	1 (1.69)	0	0 (0.00)
Transfusion related complication	1	1 (1.69)	1	1 (1.69)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Investigations				
- Total	360	52 (88.14)	172	45 (76.27)
White blood cell count decreased	63	32 (54.24)	39	27 (45.76)
Neutrophil count decreased	52	26 (44.07)	42	23 (38.98)
Platelet count decreased	46	18 (30.51)	35	13 (22.03)
Alanine aminotransferase increased	29	18 (30.51)	14	11 (18.64)
Aspartate aminotransferase increased	29	17 (28.81)	15	10 (16.95)
Lymphocyte count decreased	22	15 (25.42)	12	11 (18.64)
Prothrombin time prolonged	17	9 (15.25)	1	1 (1.69)
Blood bilirubin increased	14	8 (13.56)	3	3 (5.08)
Blood fibrinogen decreased	14	3 (5.08)	3	2 (3.39)
Blood creatinine increased	11	8 (13.56)	1	1 (1.69)
International normalised ratio increased	11	9 (15.25)	1	1 (1.69)
Activated partial thromboplastin time prolonged	7	4 (6.78)	0	0 (0.00)
Blood immunoglobulin M decreased	4	4 (6.78)	0	0 (0.00)
Weight decreased	4	4 (6.78)	0	0 (0.00)
Blood immunoglobulin A decreased	3	3 (5.08)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Blood phosphorus increased	3	2 (3.39)	0	0 (0.00)
Blood uric acid increased	3	2 (3.39)	0	0 (0.00)
Haemoglobin decreased	3	3 (5.08)	1	1 (1.69)
Transaminases increased	3	3 (5.08)	0	0 (0.00)
Blood magnesium decreased	2	2 (3.39)	1	1 (1.69)
Blood sodium increased	2	1 (1.69)	0	0 (0.00)
Blood urea increased	2	2 (3.39)	0	0 (0.00)
Lipase increased	2	2 (3.39)	2	2 (3.39)
Weight increased	2	2 (3.39)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.69)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.69)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.69)	1	1 (1.69)
C-reactive protein increased	1	1 (1.69)	1	1 (1.69)
Cardiac murmur	1	1 (1.69)	0	0 (0.00)
Culture stool positive	1	1 (1.69)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.69)	0	0 (0.00)
Hepatic enzyme increased	1	1 (1.69)	0	0 (0.00)
Norovirus test positive	1	1 (1.69)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.69)	0	0 (0.00)
Pulmonary function test decreased	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Serum ferritin increased	1	1 (1.69)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	115	41 (69.49)	46	25 (42.37)
Decreased appetite	25	21 (35.59)	13	12 (20.34)
Hypokalaemia	21	17 (28.81)	7	7 (11.86)
Hypophosphataemia	13	9 (15.25)	10	8 (13.56)
Hyperphosphataemia	12	8 (13.56)	0	0 (0.00)
Hyperglycaemia	5	3 (5.08)	2	2 (3.39)
Hypernatraemia	5	3 (5.08)	1	1 (1.69)
Hypoalbuminaemia	5	4 (6.78)	1	1 (1.69)
Dehydration	4	4 (6.78)	3	3 (5.08)
Hyperuricaemia	4	3 (5.08)	1	1 (1.69)
Hypocalcaemia	4	3 (5.08)	1	1 (1.69)
Fluid overload	3	3 (5.08)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.39)	1	1 (1.69)
Hyponatraemia	3	2 (3.39)	3	2 (3.39)
Tumour lysis syndrome	2	2 (3.39)	2	2 (3.39)
Vitamin D deficiency	2	2 (3.39)	0	0 (0.00)
Acidosis	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Hypomagnesaemia	1	1 (1.69)	0	0 (0.00)
Malnutrition	1	1 (1.69)	1	1 (1.69)
Metabolic acidosis	1	1 (1.69)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	43	24 (40.68)	1	1 (1.69)
Pain in extremity	12	11 (18.64)	0	0 (0.00)
Arthralgia	5	4 (6.78)	1	1 (1.69)
Myalgia	5	5 (8.47)	0	0 (0.00)
Musculoskeletal pain	4	3 (5.08)	0	0 (0.00)
Joint range of motion decreased	2	2 (3.39)	0	0 (0.00)
Muscle spasms	2	2 (3.39)	0	0 (0.00)
Muscular weakness	2	2 (3.39)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (3.39)	0	0 (0.00)
Back pain	1	1 (1.69)	0	0 (0.00)
Coccydynia	1	1 (1.69)	0	0 (0.00)
Flank pain	1	1 (1.69)	0	0 (0.00)
Limb discomfort	1	1 (1.69)	0	0 (0.00)
Neck pain	1	1 (1.69)	0	0 (0.00)
Osteonecrosis	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Osteopenia	1	1 (1.69)	0	0 (0.00)
Pain in jaw	1	1 (1.69)	0	0 (0.00)
Toe walking	1	1 (1.69)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	2 (3.39)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.69)	0	0 (0.00)
Skin papilloma	1	1 (1.69)	0	0 (0.00)
Nervous system disorders				
- Total	70	32 (54.24)	6	5 (8.47)
Headache	38	23 (38.98)	2	2 (3.39)
Dizziness	8	6 (10.17)	0	0 (0.00)
Encephalopathy	6	4 (6.78)	2	2 (3.39)
Seizure	3	3 (5.08)	1	1 (1.69)
Peroneal nerve palsy	2	2 (3.39)	0	0 (0.00)
Tremor	2	2 (3.39)	0	0 (0.00)
Asterixis	1	1 (1.69)	0	0 (0.00)
Ataxia	1	1 (1.69)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Disturbance in attention	1	1 (1.69)	0	0 (0.00)
Dysarthria	1	1 (1.69)	0	0 (0.00)
Embolic stroke	1	1 (1.69)	1	1 (1.69)
Idiopathic intracranial hypertension	1	1 (1.69)	0	0 (0.00)
Migraine	1	1 (1.69)	0	0 (0.00)
Myoclonus	1	1 (1.69)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.69)	0	0 (0.00)
Pleocytosis	1	1 (1.69)	0	0 (0.00)
Product issues				
- Total	1	1 (1.69)	0	0 (0.00)
Device occlusion	1	1 (1.69)	0	0 (0.00)
Psychiatric disorders				
- Total	31	16 (27.12)	1	1 (1.69)
Anxiety	7	7 (11.86)	1	1 (1.69)
Confusional state	6	6 (10.17)	0	0 (0.00)
Agitation	3	2 (3.39)	0	0 (0.00)
Delirium	3	3 (5.08)	0	0 (0.00)
Hallucination	3	2 (3.39)	0	0 (0.00)
Depression	2	2 (3.39)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Adjustment disorder	1	1 (1.69)	0	0 (0.00)
Irritability	1	1 (1.69)	0	0 (0.00)
Listless	1	1 (1.69)	0	0 (0.00)
Mental status changes	1	1 (1.69)	0	0 (0.00)
Panic attack	1	1 (1.69)	0	0 (0.00)
Sleep disorder	1	1 (1.69)	0	0 (0.00)
Suicidal ideation	1	1 (1.69)	0	0 (0.00)
Renal and urinary disorders				
- Total	25	14 (23.73)	14	9 (15.25)
Acute kidney injury	10	9 (15.25)	7	7 (11.86)
Haematuria	6	5 (8.47)	3	3 (5.08)
Dysuria	2	2 (3.39)	0	0 (0.00)
Oliguria	2	2 (3.39)	2	2 (3.39)
Calculus urinary	1	1 (1.69)	0	0 (0.00)
Nephrolithiasis	1	1 (1.69)	1	1 (1.69)
Pollakiuria	1	1 (1.69)	0	0 (0.00)
Renal failure	1	1 (1.69)	1	1 (1.69)
Urinary incontinence	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Reproductive system and breast disorders				
- Total	7	6 (10.17)	2	2 (3.39)
Oedema genital	2	1 (1.69)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.39)	0	0 (0.00)
Ovarian failure	1	1 (1.69)	1	1 (1.69)
Scrotal pain	1	1 (1.69)	0	0 (0.00)
Vaginal haemorrhage	1	1 (1.69)	1	1 (1.69)
Respiratory, thoracic and mediastinal disorders				
- Total	102	35 (59.32)	29	14 (23.73)
Cough	18	13 (22.03)	0	0 (0.00)
Epistaxis	13	9 (15.25)	5	5 (8.47)
Hypoxia	13	10 (16.95)	8	7 (11.86)
Pleural effusion	7	7 (11.86)	1	1 (1.69)
Oropharyngeal pain	6	6 (10.17)	0	0 (0.00)
Pulmonary oedema	6	6 (10.17)	5	5 (8.47)
Tachypnoea	6	5 (8.47)	1	1 (1.69)
Nasal congestion	5	5 (8.47)	0	0 (0.00)
Rhinitis allergic	5	4 (6.78)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Rhinorrhoea	5	5 (8.47)	0	0 (0.00)
Dyspnoea	3	2 (3.39)	2	2 (3.39)
Haemoptysis	3	2 (3.39)	1	1 (1.69)
Respiratory failure	3	3 (5.08)	3	3 (5.08)
Acute respiratory failure	1	1 (1.69)	1	1 (1.69)
Atelectasis	1	1 (1.69)	0	0 (0.00)
Dysphonia	1	1 (1.69)	0	0 (0.00)
Interstitial lung disease	1	1 (1.69)	1	1 (1.69)
Pharyngeal erythema	1	1 (1.69)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.69)	1	1 (1.69)
Pharyngeal ulceration	1	1 (1.69)	0	0 (0.00)
Respiratory depression	1	1 (1.69)	0	0 (0.00)
Wheezing	1	1 (1.69)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	62	28 (47.46)	3	3 (5.08)
Rash	8	7 (11.86)	0	0 (0.00)
Erythema	6	5 (8.47)	0	0 (0.00)
Dry skin	5	5 (8.47)	0	0 (0.00)
Rash maculo-papular	5	5 (8.47)	1	1 (1.69)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Ingrowing nail	4	3 (5.08)	0	0 (0.00)
Petechiae	4	4 (6.78)	0	0 (0.00)
Hyperhidrosis	3	3 (5.08)	0	0 (0.00)
Pruritus	3	3 (5.08)	0	0 (0.00)
Rash erythematous	3	2 (3.39)	0	0 (0.00)
Macule	2	2 (3.39)	0	0 (0.00)
Acne	1	1 (1.69)	0	0 (0.00)
Alopecia	1	1 (1.69)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.69)	1	1 (1.69)
Dermatitis atopic	1	1 (1.69)	0	0 (0.00)
Dermatitis diaper	1	1 (1.69)	0	0 (0.00)
Ecchymosis	1	1 (1.69)	1	1 (1.69)
Eczema	1	1 (1.69)	0	0 (0.00)
Keloid scar	1	1 (1.69)	0	0 (0.00)
Livedo reticularis	1	1 (1.69)	0	0 (0.00)
Night sweats	1	1 (1.69)	0	0 (0.00)
Papule	1	1 (1.69)	0	0 (0.00)
Rash follicular	1	1 (1.69)	0	0 (0.00)
Rash macular	1	1 (1.69)	0	0 (0.00)
Rash papular	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Rash pruritic	1	1 (1.69)	0	0 (0.00)
Rash vesicular	1	1 (1.69)	0	0 (0.00)
Skin exfoliation	1	1 (1.69)	0	0 (0.00)
Skin fissures	1	1 (1.69)	0	0 (0.00)
Skin irritation	1	1 (1.69)	0	0 (0.00)
Vascular disorders				
- Total	38	24 (40.68)	17	15 (25.42)
Hypotension	18	15 (25.42)	15	14 (23.73)
Hypertension	13	11 (18.64)	1	1 (1.69)
Orthostatic hypotension	2	2 (3.39)	0	0 (0.00)
Embolism	1	1 (1.69)	1	1 (1.69)
Flushing	1	1 (1.69)	0	0 (0.00)
Haematoma	1	1 (1.69)	0	0 (0.00)
Hot flush	1	1 (1.69)	0	0 (0.00)
Secondary hypertension	1	1 (1.69)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Total number of AE per patient	39	4 (100.00)	10	3 (75.00)
Blood and lymphatic system disorders				
- Total	5	3 (75.00)	3	3 (75.00)
Anaemia	2	2 (50.00)	0	0 (0.00)
Febrile neutropenia	2	2 (50.00)	2	2 (50.00)
Neutropenia	1	1 (25.00)	1	1 (25.00)
Gastrointestinal disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Constipation	1	1 (25.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (25.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Fatigue	1	1 (25.00)	0	0 (0.00)
Immune system disorders				
- Total	4	3 (75.00)	0	0 (0.00)
Cytokine release syndrome	3	3 (75.00)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (25.00)	0	0 (0.00)
Infections and infestations				
- Total	2	2 (50.00)	0	0 (0.00)
Fungal skin infection	1	1 (25.00)	0	0 (0.00)
Viral infection	1	1 (25.00)	0	0 (0.00)
Investigations				
- Total	17	3 (75.00)	6	2 (50.00)
White blood cell count decreased	5	1 (25.00)	2	1 (25.00)
Neutrophil count decreased	3	1 (25.00)	3	1 (25.00)
Blood creatinine increased	2	1 (25.00)	0	0 (0.00)
Lymphocyte count decreased	2	2 (50.00)	1	1 (25.00)
Blood bilirubin increased	1	1 (25.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (25.00)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (25.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Fibrin D dimer increased	1	1 (25.00)	0	0 (0.00)
Platelet count decreased	1	1 (25.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	2	1 (25.00)	0	0 (0.00)
Decreased appetite	1	1 (25.00)	0	0 (0.00)
Hyperphosphataemia	1	1 (25.00)	0	0 (0.00)
Nervous system disorders				
- Total	2	1 (25.00)	0	0 (0.00)
Headache	1	1 (25.00)	0	0 (0.00)
Tremor	1	1 (25.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Hypoxia	1	1 (25.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	2 (50.00)	0	0 (0.00)
Dermatitis diaper	1	1 (25.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Dry skin	1	1 (25.00)	0	0 (0.00)
Erythema	1	1 (25.00)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (25.00)	1	1 (25.00)
Hypotension	1	1 (25.00)	1	1 (25.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Total number of AE per patient	1275	59 (98.33)	448	51 (85.00)
Blood and lymphatic system disorders				
- Total	117	40 (66.67)	90	35 (58.33)
Anaemia	45	25 (41.67)	31	19 (31.67)
Thrombocytopenia	30	8 (13.33)	23	8 (13.33)
Febrile neutropenia	24	20 (33.33)	24	20 (33.33)
Neutropenia	8	7 (11.67)	7	7 (11.67)
Disseminated intravascular coagulation	5	4 (6.67)	2	2 (3.33)
Lymphopenia	3	3 (5.00)	2	2 (3.33)
Coagulopathy	1	1 (1.67)	0	0 (0.00)
Pancytopenia	1	1 (1.67)	1	1 (1.67)
Cardiac disorders				

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
- Total	32	22 (36.67)	3	2 (3.33)
Tachycardia	17	15 (25.00)	2	2 (3.33)
Sinus tachycardia	5	5 (8.33)	0	0 (0.00)
Pericardial effusion	2	2 (3.33)	0	0 (0.00)
Sinus bradycardia	2	1 (1.67)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.67)	0	0 (0.00)
Bradycardia	1	1 (1.67)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.67)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.67)	1	1 (1.67)
Palpitations	1	1 (1.67)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.67)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (5.00)	0	0 (0.00)
Ear pain	2	2 (3.33)	0	0 (0.00)
Hypoacusis	1	1 (1.67)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.67)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Eye disorders				
- Total	25	13 (21.67)	0	0 (0.00)
Eye pain	4	3 (5.00)	0	0 (0.00)
Periorbital oedema	4	4 (6.67)	0	0 (0.00)
Vision blurred	4	3 (5.00)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (5.00)	0	0 (0.00)
Photophobia	3	2 (3.33)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.33)	0	0 (0.00)
Uveitis	2	2 (3.33)	0	0 (0.00)
Ocular hypertension	1	1 (1.67)	0	0 (0.00)
Papilloedema	1	1 (1.67)	0	0 (0.00)
Visual impairment	1	1 (1.67)	0	0 (0.00)
Gastrointestinal disorders				
- Total	125	35 (58.33)	15	11 (18.33)
Vomiting	35	22 (36.67)	3	3 (5.00)
Nausea	26	21 (35.00)	3	3 (5.00)
Diarrhoea	18	18 (30.00)	1	1 (1.67)
Abdominal pain	10	9 (15.00)	1	1 (1.67)
Constipation	7	6 (10.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Abdominal distension	2	2 (3.33)	0	0 (0.00)
Abdominal pain upper	2	2 (3.33)	0	0 (0.00)
Anal incontinence	2	1 (1.67)	0	0 (0.00)
Dysphagia	2	2 (3.33)	1	1 (1.67)
Haematemesis	2	2 (3.33)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.67)	2	1 (1.67)
Pancreatitis	2	2 (3.33)	1	1 (1.67)
Stomatitis	2	2 (3.33)	0	0 (0.00)
Abdominal discomfort	1	1 (1.67)	0	0 (0.00)
Abdominal pain lower	1	1 (1.67)	0	0 (0.00)
Abdominal tenderness	1	1 (1.67)	0	0 (0.00)
Ascites	1	1 (1.67)	1	1 (1.67)
Dyspepsia	1	1 (1.67)	0	0 (0.00)
Flatulence	1	1 (1.67)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.67)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.67)	0	0 (0.00)
Glossodynia	1	1 (1.67)	0	0 (0.00)
Ileus	1	1 (1.67)	1	1 (1.67)
Intestinal obstruction	1	1 (1.67)	1	1 (1.67)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Lip pain	1	1 (1.67)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.67)	0	0 (0.00)
General disorders and administration site conditions				
- Total	76	31 (51.67)	14	10 (16.67)
Pyrexia	27	16 (26.67)	6	6 (10.00)
Fatigue	13	12 (20.00)	1	1 (1.67)
Chills	9	8 (13.33)	0	0 (0.00)
Catheter site pain	3	3 (5.00)	0	0 (0.00)
Generalised oedema	3	2 (3.33)	0	0 (0.00)
Malaise	3	3 (5.00)	0	0 (0.00)
Pain	3	3 (5.00)	2	2 (3.33)
Face oedema	2	2 (3.33)	1	1 (1.67)
Oedema peripheral	2	2 (3.33)	1	1 (1.67)
Asthenia	1	1 (1.67)	0	0 (0.00)
Catheter site extravasation	1	1 (1.67)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.67)	0	0 (0.00)
Facial pain	1	1 (1.67)	0	0 (0.00)
Injection site haematoma	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Localised oedema	1	1 (1.67)	1	1 (1.67)
Mucosal haemorrhage	1	1 (1.67)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.67)	1	1 (1.67)
Non-cardiac chest pain	1	1 (1.67)	0	0 (0.00)
Peripheral swelling	1	1 (1.67)	0	0 (0.00)
Physical deconditioning	1	1 (1.67)	1	1 (1.67)
Hepatobiliary disorders				
- Total	9	7 (11.67)	2	2 (3.33)
Hyperbilirubinaemia	4	3 (5.00)	2	2 (3.33)
Hepatomegaly	3	3 (5.00)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.67)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.67)	0	0 (0.00)
Immune system disorders				
- Total	112	54 (90.00)	33	22 (36.67)
Cytokine release syndrome	83	47 (78.33)	29	19 (31.67)
Hypogammaglobulinaemia	26	25 (41.67)	4	4 (6.67)
Drug hypersensitivity	1	1 (1.67)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Haemophagocytic lymphohistiocytosis	1	1 (1.67)	0	0 (0.00)
Infections and infestations				
- Total	39	24 (40.00)	7	7 (11.67)
Clostridium difficile colitis	4	4 (6.67)	1	1 (1.67)
Clostridium difficile infection	4	4 (6.67)	0	0 (0.00)
Rhinovirus infection	3	3 (5.00)	0	0 (0.00)
Gastroenteritis	2	2 (3.33)	1	1 (1.67)
Pneumonia	2	2 (3.33)	1	1 (1.67)
Staphylococcal infection	2	2 (3.33)	1	1 (1.67)
Acute sinusitis	1	1 (1.67)	0	0 (0.00)
Body tinea	1	1 (1.67)	0	0 (0.00)
Catheter site cellulitis	1	1 (1.67)	0	0 (0.00)
Catheter site infection	1	1 (1.67)	1	1 (1.67)
Cytomegalovirus infection	1	1 (1.67)	0	0 (0.00)
Enterococcal infection	1	1 (1.67)	0	0 (0.00)
Folliculitis	1	1 (1.67)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.67)	0	0 (0.00)
Herpes simplex	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Human herpesvirus 6 infection	1	1 (1.67)	0	0 (0.00)
Hypopyon	1	1 (1.67)	0	0 (0.00)
Influenza	1	1 (1.67)	0	0 (0.00)
Oral candidiasis	1	1 (1.67)	0	0 (0.00)
Orchitis	1	1 (1.67)	0	0 (0.00)
Pharyngitis	1	1 (1.67)	0	0 (0.00)
Septic embolus	1	1 (1.67)	1	1 (1.67)
Skin infection	1	1 (1.67)	0	0 (0.00)
Streptococcal infection	1	1 (1.67)	0	0 (0.00)
Upper respiratory tract infection	1	1 (1.67)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.67)	1	1 (1.67)
Viral upper respiratory tract infection	1	1 (1.67)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (1.67)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	25	15 (25.00)	2	2 (3.33)
Transfusion reaction	4	3 (5.00)	0	0 (0.00)
Procedural pain	3	3 (5.00)	0	0 (0.00)
Infusion related reaction	2	2 (3.33)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Tracheal haemorrhage	2	1 (1.67)	1	1 (1.67)
Contusion	1	1 (1.67)	0	0 (0.00)
Incision site pain	1	1 (1.67)	0	0 (0.00)
Limb injury	1	1 (1.67)	0	0 (0.00)
Mouth injury	1	1 (1.67)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.67)	0	0 (0.00)
Procedural complication	1	1 (1.67)	0	0 (0.00)
Procedural headache	1	1 (1.67)	0	0 (0.00)
Procedural site reaction	1	1 (1.67)	0	0 (0.00)
Skin abrasion	1	1 (1.67)	0	0 (0.00)
Stoma site irritation	1	1 (1.67)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.67)	0	0 (0.00)
Tibia fracture	1	1 (1.67)	0	0 (0.00)
Tongue injury	1	1 (1.67)	0	0 (0.00)
Transfusion related complication	1	1 (1.67)	1	1 (1.67)
Investigations				
- Total	315	49 (81.67)	172	42 (70.00)
White blood cell count decreased	50	29 (48.33)	35	25 (41.67)
Neutrophil count decreased	44	24 (40.00)	41	22 (36.67)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Platelet count decreased	42	18 (30.00)	37	14 (23.33)
Aspartate aminotransferase increased	32	18 (30.00)	16	11 (18.33)
Alanine aminotransferase increased	28	19 (31.67)	14	11 (18.33)
Prothrombin time prolonged	17	9 (15.00)	1	1 (1.67)
Blood fibrinogen decreased	15	4 (6.67)	4	3 (5.00)
Lymphocyte count decreased	14	12 (20.00)	11	10 (16.67)
Blood bilirubin increased	12	6 (10.00)	2	2 (3.33)
International normalised ratio increased	11	9 (15.00)	1	1 (1.67)
Blood creatinine increased	9	8 (13.33)	2	2 (3.33)
Activated partial thromboplastin time prolonged	8	5 (8.33)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (5.00)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.33)	0	0 (0.00)
Blood urea increased	3	3 (5.00)	1	1 (1.67)
Blood immunoglobulin A decreased	2	2 (3.33)	0	0 (0.00)
Blood sodium increased	2	1 (1.67)	0	0 (0.00)
Blood uric acid increased	2	1 (1.67)	0	0 (0.00)
Lipase increased	2	2 (3.33)	2	2 (3.33)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Transaminases increased	2	2 (3.33)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.67)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.67)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.67)	1	1 (1.67)
Blood magnesium decreased	1	1 (1.67)	1	1 (1.67)
Blood phosphorus decreased	1	1 (1.67)	0	0 (0.00)
C-reactive protein increased	1	1 (1.67)	1	1 (1.67)
Cardiac murmur	1	1 (1.67)	0	0 (0.00)
Culture stool positive	1	1 (1.67)	0	0 (0.00)
Haemoglobin decreased	1	1 (1.67)	1	1 (1.67)
Hepatic enzyme increased	1	1 (1.67)	0	0 (0.00)
Norovirus test positive	1	1 (1.67)	0	0 (0.00)
Protein total decreased	1	1 (1.67)	1	1 (1.67)
Pulmonary function test decreased	1	1 (1.67)	0	0 (0.00)
Serum ferritin increased	1	1 (1.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	114	38 (63.33)	43	24 (40.00)
Decreased appetite	23	19 (31.67)	13	12 (20.00)
Hypokalaemia	20	16 (26.67)	7	7 (11.67)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Hypophosphataemia	13	9 (15.00)	9	7 (11.67)
Hyperphosphataemia	9	7 (11.67)	0	0 (0.00)
Hypernatraemia	7	4 (6.67)	1	1 (1.67)
Hypoalbuminaemia	6	5 (8.33)	1	1 (1.67)
Hyperglycaemia	4	3 (5.00)	1	1 (1.67)
Hyperuricaemia	4	3 (5.00)	1	1 (1.67)
Hypocalcaemia	4	3 (5.00)	1	1 (1.67)
Dehydration	3	3 (5.00)	2	2 (3.33)
Fluid overload	3	3 (5.00)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.33)	1	1 (1.67)
Hyponatraemia	3	2 (3.33)	3	2 (3.33)
Acidosis	2	2 (3.33)	1	1 (1.67)
Hypercalcaemia	2	1 (1.67)	0	0 (0.00)
Hyperalbuminaemia	1	1 (1.67)	0	0 (0.00)
Hyperchloraemia	1	1 (1.67)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.67)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.67)	0	0 (0.00)
Malnutrition	1	1 (1.67)	1	1 (1.67)
Metabolic acidosis	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Metabolic alkalosis	1	1 (1.67)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.67)	1	1 (1.67)
Musculoskeletal and connective tissue disorders				
- Total	23	15 (25.00)	1	1 (1.67)
Myalgia	5	5 (8.33)	0	0 (0.00)
Arthralgia	4	4 (6.67)	1	1 (1.67)
Musculoskeletal pain	4	3 (5.00)	0	0 (0.00)
Pain in extremity	4	4 (6.67)	0	0 (0.00)
Coccydynia	1	1 (1.67)	0	0 (0.00)
Limb discomfort	1	1 (1.67)	0	0 (0.00)
Muscle spasms	1	1 (1.67)	0	0 (0.00)
Muscular weakness	1	1 (1.67)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.67)	0	0 (0.00)
Osteopenia	1	1 (1.67)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.67)	0	0 (0.00)
Skin papilloma	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Nervous system disorders				
- Total	56	32 (53.33)	6	5 (8.33)
Headache	30	23 (38.33)	2	2 (3.33)
Encephalopathy	6	4 (6.67)	2	2 (3.33)
Dizziness	4	4 (6.67)	0	0 (0.00)
Seizure	3	3 (5.00)	1	1 (1.67)
Dysarthria	2	2 (3.33)	0	0 (0.00)
Asterixis	1	1 (1.67)	0	0 (0.00)
Ataxia	1	1 (1.67)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.67)	0	0 (0.00)
Embolic stroke	1	1 (1.67)	1	1 (1.67)
Idiopathic intracranial hypertension	1	1 (1.67)	0	0 (0.00)
Migraine	1	1 (1.67)	0	0 (0.00)
Myoclonus	1	1 (1.67)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.67)	0	0 (0.00)
Pleocytosis	1	1 (1.67)	0	0 (0.00)
Somnolence	1	1 (1.67)	0	0 (0.00)
Tremor	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Product issues				
- Total	1	1 (1.67)	0	0 (0.00)
Device occlusion	1	1 (1.67)	0	0 (0.00)
Psychiatric disorders				
- Total	30	16 (26.67)	1	1 (1.67)
Anxiety	6	6 (10.00)	1	1 (1.67)
Confusional state	6	6 (10.00)	0	0 (0.00)
Delirium	4	4 (6.67)	0	0 (0.00)
Agitation	3	2 (3.33)	0	0 (0.00)
Hallucination	3	2 (3.33)	0	0 (0.00)
Irritability	2	2 (3.33)	0	0 (0.00)
Adjustment disorder	1	1 (1.67)	0	0 (0.00)
Insomnia	1	1 (1.67)	0	0 (0.00)
Listless	1	1 (1.67)	0	0 (0.00)
Mental status changes	1	1 (1.67)	0	0 (0.00)
Panic attack	1	1 (1.67)	0	0 (0.00)
Suicidal ideation	1	1 (1.67)	0	0 (0.00)
Renal and urinary disorders				

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
- Total	18	11 (18.33)	11	7 (11.67)
Acute kidney injury	7	7 (11.67)	5	5 (8.33)
Haematuria	4	4 (6.67)	2	2 (3.33)
Dysuria	2	2 (3.33)	0	0 (0.00)
Oliguria	2	2 (3.33)	2	2 (3.33)
Pollakiuria	1	1 (1.67)	0	0 (0.00)
Renal failure	1	1 (1.67)	1	1 (1.67)
Renal impairment	1	1 (1.67)	1	1 (1.67)
Reproductive system and breast disorders				
- Total	4	3 (5.00)	0	0 (0.00)
Oedema genital	2	1 (1.67)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.33)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	72	27 (45.00)	28	12 (20.00)
Hypoxia	12	9 (15.00)	8	7 (11.67)
Epistaxis	11	7 (11.67)	4	4 (6.67)
Cough	8	8 (13.33)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Pleural effusion	8	8 (13.33)	2	2 (3.33)
Pulmonary oedema	6	6 (10.00)	5	5 (8.33)
Tachypnoea	6	5 (8.33)	1	1 (1.67)
Dyspnoea	3	2 (3.33)	2	2 (3.33)
Haemoptysis	3	2 (3.33)	1	1 (1.67)
Respiratory failure	3	3 (5.00)	3	3 (5.00)
Oropharyngeal pain	2	2 (3.33)	0	0 (0.00)
Atelectasis	1	1 (1.67)	0	0 (0.00)
Interstitial lung disease	1	1 (1.67)	1	1 (1.67)
Nasal congestion	1	1 (1.67)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.67)	0	0 (0.00)
Pharyngeal ulceration	1	1 (1.67)	0	0 (0.00)
Respiratory depression	1	1 (1.67)	0	0 (0.00)
Respiratory distress	1	1 (1.67)	1	1 (1.67)
Rhinitis allergic	1	1 (1.67)	0	0 (0.00)
Rhinorrhoea	1	1 (1.67)	0	0 (0.00)
Wheezing	1	1 (1.67)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
- Total	38	19 (31.67)	2	2 (3.33)
Hyperhidrosis	4	3 (5.00)	0	0 (0.00)
Rash	4	4 (6.67)	0	0 (0.00)
Dry skin	3	3 (5.00)	0	0 (0.00)
Erythema	3	2 (3.33)	0	0 (0.00)
Ingrowing nail	3	2 (3.33)	0	0 (0.00)
Petechiae	3	3 (5.00)	0	0 (0.00)
Rash maculo-papular	3	3 (5.00)	1	1 (1.67)
Pruritus	2	2 (3.33)	0	0 (0.00)
Rash papular	2	2 (3.33)	0	0 (0.00)
Ecchymosis	1	1 (1.67)	1	1 (1.67)
Livedo reticularis	1	1 (1.67)	0	0 (0.00)
Macule	1	1 (1.67)	0	0 (0.00)
Night sweats	1	1 (1.67)	0	0 (0.00)
Rash erythematous	1	1 (1.67)	0	0 (0.00)
Rash follicular	1	1 (1.67)	0	0 (0.00)
Rash macular	1	1 (1.67)	0	0 (0.00)
Rash vesicular	1	1 (1.67)	0	0 (0.00)
Skin exfoliation	1	1 (1.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Skin fissures	1	1 (1.67)	0	0 (0.00)
Skin irritation	1	1 (1.67)	0	0 (0.00)
Vascular disorders				
- Total	39	23 (38.33)	18	15 (25.00)
Hypotension	18	15 (25.00)	15	14 (23.33)
Hypertension	12	10 (16.67)	1	1 (1.67)
Flushing	3	2 (3.33)	0	0 (0.00)
Orthostatic hypotension	2	2 (3.33)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.67)	1	1 (1.67)
Embolism	1	1 (1.67)	1	1 (1.67)
Haematoma	1	1 (1.67)	0	0 (0.00)
Secondary hypertension	1	1 (1.67)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Total number of AE per patient	24	4 (100.00)	4	2 (50.00)
Blood and lymphatic system disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Anaemia	1	1 (25.00)	0	0 (0.00)
Eye disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Ocular hyperaemia	1	1 (25.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	5	2 (50.00)	1	1 (25.00)
Vomiting	3	2 (50.00)	0	0 (0.00)
Enterocolitis	1	1 (25.00)	1	1 (25.00)
Nausea	1	1 (25.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
General disorders and administration site conditions				
- Total	2	2 (50.00)	1	1 (25.00)
Influenza like illness	1	1 (25.00)	0	0 (0.00)
Pyrexia	1	1 (25.00)	1	1 (25.00)
Infections and infestations				
- Total	3	2 (50.00)	2	1 (25.00)
Corona virus infection	1	1 (25.00)	1	1 (25.00)
Rash pustular	1	1 (25.00)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (25.00)	1	1 (25.00)
Injury, poisoning and procedural complications				
- Total	1	1 (25.00)	0	0 (0.00)
Skin laceration	1	1 (25.00)	0	0 (0.00)
Investigations				
- Total	5	1 (25.00)	0	0 (0.00)
Platelet count decreased	2	1 (25.00)	0	0 (0.00)
Lymphocyte count decreased	1	1 (25.00)	0	0 (0.00)
Neutrophil count decreased	1	1 (25.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
White blood cell count decreased	1	1 (25.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Hyperphosphataemia	1	1 (25.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Pain in extremity	1	1 (25.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	3	2 (50.00)	0	0 (0.00)
Cough	1	1 (25.00)	0	0 (0.00)
Nasal congestion	1	1 (25.00)	0	0 (0.00)
Rhinorrhoea	1	1 (25.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Rash maculo-papular	1	1 (25.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Total number of AE per patient	322	42 (80.77)	67	24 (46.15)
Blood and lymphatic system disorders				
- Total	17	10 (19.23)	13	7 (13.46)
Neutropenia	6	4 (7.69)	6	4 (7.69)
Febrile neutropenia	3	3 (5.77)	3	3 (5.77)
Eosinophilia	2	1 (1.92)	1	1 (1.92)
Thrombocytopenia	2	2 (3.85)	1	1 (1.92)
Anaemia	1	1 (1.92)	1	1 (1.92)
Leukopenia	1	1 (1.92)	1	1 (1.92)
Lymphadenopathy	1	1 (1.92)	0	0 (0.00)
Lymphopenia	1	1 (1.92)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (1.92)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Sinus tachycardia	1	1 (1.92)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.92)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.92)	0	0 (0.00)
Eye disorders				
- Total	4	4 (7.69)	0	0 (0.00)
Dry eye	2	2 (3.85)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.92)	0	0 (0.00)
Vision blurred	1	1 (1.92)	0	0 (0.00)
Gastrointestinal disorders				
- Total	33	14 (26.92)	7	3 (5.77)
Vomiting	10	7 (13.46)	2	2 (3.85)
Diarrhoea	8	8 (15.38)	1	1 (1.92)
Nausea	6	5 (9.62)	2	2 (3.85)
Abdominal pain	4	4 (7.69)	1	1 (1.92)
Oral pain	3	2 (3.85)	1	1 (1.92)
Abdominal pain upper	1	1 (1.92)	0	0 (0.00)
Pigmentation lip	1	1 (1.92)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
General disorders and administration site conditions				
- Total	24	15 (28.85)	0	0 (0.00)
Pyrexia	13	9 (17.31)	0	0 (0.00)
Fatigue	2	2 (3.85)	0	0 (0.00)
Acquired gene mutation	1	1 (1.92)	0	0 (0.00)
Catheter site pain	1	1 (1.92)	0	0 (0.00)
Chills	1	1 (1.92)	0	0 (0.00)
Crying	1	1 (1.92)	0	0 (0.00)
Generalised oedema	1	1 (1.92)	0	0 (0.00)
Influenza like illness	1	1 (1.92)	0	0 (0.00)
Malaise	1	1 (1.92)	0	0 (0.00)
Oedema peripheral	1	1 (1.92)	0	0 (0.00)
Pain	1	1 (1.92)	0	0 (0.00)
Immune system disorders				
- Total	17	14 (26.92)	1	1 (1.92)
Hypogammaglobulinaemia	9	8 (15.38)	1	1 (1.92)
Graft versus host disease	3	2 (3.85)	0	0 (0.00)
Immunodeficiency common variable	2	2 (3.85)	0	0 (0.00)
Seasonal allergy	2	2 (3.85)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Graft versus host disease in gastrointestinal tract	1	1 (1.92)	0	0 (0.00)
Infections and infestations				
- Total	58	31 (59.62)	15	11 (21.15)
Upper respiratory tract infection	7	7 (13.46)	1	1 (1.92)
Cellulitis of male external genital organ	5	1 (1.92)	2	1 (1.92)
Urinary tract infection	5	4 (7.69)	2	2 (3.85)
Rhinovirus infection	4	2 (3.85)	0	0 (0.00)
Gastroenteritis	3	3 (5.77)	0	0 (0.00)
Influenza	3	3 (5.77)	0	0 (0.00)
Ear infection	2	2 (3.85)	0	0 (0.00)
Otitis media	2	1 (1.92)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.85)	1	1 (1.92)
Sinusitis	2	2 (3.85)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (3.85)	1	1 (1.92)
Bacterial sepsis	1	1 (1.92)	1	1 (1.92)
Cholecystitis infective	1	1 (1.92)	1	1 (1.92)
Cytomegalovirus infection	1	1 (1.92)	0	0 (0.00)
Enterovirus infection	1	1 (1.92)	1	1 (1.92)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Escherichia urinary tract infection	1	1 (1.92)	1	1 (1.92)
Gastroenteritis norovirus	1	1 (1.92)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.92)	0	0 (0.00)
Herpes zoster	1	1 (1.92)	1	1 (1.92)
Molluscum contagiosum	1	1 (1.92)	0	0 (0.00)
Oral herpes	1	1 (1.92)	0	0 (0.00)
Otitis externa	1	1 (1.92)	0	0 (0.00)
Otitis media acute	1	1 (1.92)	0	0 (0.00)
Paronychia	1	1 (1.92)	0	0 (0.00)
Rhinitis	1	1 (1.92)	0	0 (0.00)
Rotavirus infection	1	1 (1.92)	1	1 (1.92)
Sepsis	1	1 (1.92)	1	1 (1.92)
Subcutaneous abscess	1	1 (1.92)	0	0 (0.00)
Tinea capitis	1	1 (1.92)	0	0 (0.00)
Vascular device infection	1	1 (1.92)	1	1 (1.92)
Viral infection	1	1 (1.92)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (1.92)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	12	7 (13.46)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Contusion	2	2 (3.85)	0	0 (0.00)
Infusion related reaction	2	2 (3.85)	0	0 (0.00)
Procedural pain	2	2 (3.85)	0	0 (0.00)
Arthropod bite	1	1 (1.92)	0	0 (0.00)
Foot fracture	1	1 (1.92)	0	0 (0.00)
Procedural nausea	1	1 (1.92)	0	0 (0.00)
Radius fracture	1	1 (1.92)	0	0 (0.00)
Skin abrasion	1	1 (1.92)	0	0 (0.00)
Sunburn	1	1 (1.92)	0	0 (0.00)
Investigations				
- Total	43	22 (42.31)	16	12 (23.08)
Neutrophil count decreased	11	7 (13.46)	8	6 (11.54)
White blood cell count decreased	6	4 (7.69)	3	2 (3.85)
Weight decreased	4	4 (7.69)	0	0 (0.00)
Aspartate aminotransferase increased	3	3 (5.77)	2	2 (3.85)
Platelet count decreased	3	2 (3.85)	0	0 (0.00)
Alanine aminotransferase increased	2	2 (3.85)	2	2 (3.85)
Blood urea increased	2	1 (1.92)	0	0 (0.00)
Haemoglobin decreased	2	2 (3.85)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Weight increased	2	2 (3.85)	0	0 (0.00)
Blood bilirubin increased	1	1 (1.92)	1	1 (1.92)
Blood creatinine increased	1	1 (1.92)	0	0 (0.00)
Blood magnesium decreased	1	1 (1.92)	0	0 (0.00)
Blood uric acid increased	1	1 (1.92)	0	0 (0.00)
Lymphocyte count decreased	1	1 (1.92)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.92)	0	0 (0.00)
Serum ferritin increased	1	1 (1.92)	0	0 (0.00)
Transaminases increased	1	1 (1.92)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	14	9 (17.31)	6	4 (7.69)
Decreased appetite	2	2 (3.85)	0	0 (0.00)
Hyperalbuminaemia	2	1 (1.92)	0	0 (0.00)
Hypokalaemia	2	2 (3.85)	1	1 (1.92)
Dehydration	1	1 (1.92)	1	1 (1.92)
Hypercalcaemia	1	1 (1.92)	0	0 (0.00)
Hyperglycaemia	1	1 (1.92)	1	1 (1.92)
Hyperphosphataemia	1	1 (1.92)	0	0 (0.00)
Hypophosphataemia	1	1 (1.92)	1	1 (1.92)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Iron overload	1	1 (1.92)	1	1 (1.92)
Tumour lysis syndrome	1	1 (1.92)	1	1 (1.92)
Vitamin D deficiency	1	1 (1.92)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	20	15 (28.85)	0	0 (0.00)
Pain in extremity	7	7 (13.46)	0	0 (0.00)
Arthralgia	2	2 (3.85)	0	0 (0.00)
Joint range of motion decreased	2	2 (3.85)	0	0 (0.00)
Muscular weakness	2	2 (3.85)	0	0 (0.00)
Back pain	1	1 (1.92)	0	0 (0.00)
Flank pain	1	1 (1.92)	0	0 (0.00)
Muscle spasms	1	1 (1.92)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.92)	0	0 (0.00)
Osteonecrosis	1	1 (1.92)	0	0 (0.00)
Pain in jaw	1	1 (1.92)	0	0 (0.00)
Toe walking	1	1 (1.92)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (1.92)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Myelodysplastic syndrome	1	1 (1.92)	0	0 (0.00)
Nervous system disorders				
- Total	12	8 (15.38)	0	0 (0.00)
Headache	7	5 (9.62)	0	0 (0.00)
Dizziness	3	3 (5.77)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.85)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (3.85)	0	0 (0.00)
Depression	2	2 (3.85)	0	0 (0.00)
Anxiety	1	1 (1.92)	0	0 (0.00)
Sleep disorder	1	1 (1.92)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	3 (5.77)	3	2 (3.85)
Acute kidney injury	1	1 (1.92)	1	1 (1.92)
Calculus urinary	1	1 (1.92)	0	0 (0.00)
Haematuria	1	1 (1.92)	1	1 (1.92)
Nephrolithiasis	1	1 (1.92)	1	1 (1.92)
Urinary incontinence	1	1 (1.92)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Reproductive system and breast disorders				
- Total	2	2 (3.85)	1	1 (1.92)
Scrotal pain	1	1 (1.92)	0	0 (0.00)
Vaginal haemorrhage	1	1 (1.92)	1	1 (1.92)
Respiratory, thoracic and mediastinal disorders				
- Total	27	16 (30.77)	4	3 (5.77)
Cough	8	6 (11.54)	0	0 (0.00)
Nasal congestion	3	3 (5.77)	0	0 (0.00)
Oropharyngeal pain	3	3 (5.77)	0	0 (0.00)
Rhinitis allergic	3	3 (5.77)	0	0 (0.00)
Rhinorrhoea	3	3 (5.77)	0	0 (0.00)
Epistaxis	2	2 (3.85)	1	1 (1.92)
Acute respiratory failure	1	1 (1.92)	1	1 (1.92)
Dysphonia	1	1 (1.92)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.92)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.92)	1	1 (1.92)
Pulmonary oedema	1	1 (1.92)	1	1 (1.92)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	24	15 (28.85)	1	1 (1.92)
Rash	5	4 (7.69)	0	0 (0.00)
Erythema	2	2 (3.85)	0	0 (0.00)
Rash erythematous	2	1 (1.92)	0	0 (0.00)
Alopecia	1	1 (1.92)	0	0 (0.00)
Dermatitis	1	1 (1.92)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.92)	1	1 (1.92)
Dermatitis atopic	1	1 (1.92)	0	0 (0.00)
Dry skin	1	1 (1.92)	0	0 (0.00)
Eczema	1	1 (1.92)	0	0 (0.00)
Hyperhidrosis	1	1 (1.92)	0	0 (0.00)
Ingrowing nail	1	1 (1.92)	0	0 (0.00)
Keloid scar	1	1 (1.92)	0	0 (0.00)
Macule	1	1 (1.92)	0	0 (0.00)
Papule	1	1 (1.92)	0	0 (0.00)
Petechiae	1	1 (1.92)	0	0 (0.00)
Pruritus	1	1 (1.92)	0	0 (0.00)
Rash maculo-papular	1	1 (1.92)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=52 n (%)[1]	Grade >= 3 Total events	All patients N=52 n (%)[2]
Rash pruritic	1	1 (1.92)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (3.85)	0	0 (0.00)
Hypertension	2	2 (3.85)	0	0 (0.00)
Hot flush	1	1 (1.92)	0	0 (0.00)

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Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Total number of AE per patient	2	1 (33.33)	0	0 (0.00)
Investigations				
- Total	2	1 (33.33)	0	0 (0.00)
Lymphocyte count decreased	1	1 (33.33)	0	0 (0.00)
Neutrophil count decreased	1	1 (33.33)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Total number of AE per patient	88	21 (67.74)	23	12 (38.71)
Blood and lymphatic system disorders				
- Total	2	2 (6.45)	1	1 (3.23)
Febrile neutropenia	1	1 (3.23)	1	1 (3.23)
Thrombocytopenia	1	1 (3.23)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Tympanic membrane perforation	1	1 (3.23)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	3 (9.68)	0	0 (0.00)
Diarrhoea	2	2 (6.45)	0	0 (0.00)
Abdominal pain	1	1 (3.23)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Nausea	1	1 (3.23)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	2 (6.45)	1	1 (3.23)
Pyrexia	2	1 (3.23)	0	0 (0.00)
Chills	1	1 (3.23)	0	0 (0.00)
Cyst	1	1 (3.23)	1	1 (3.23)
Immune system disorders				
- Total	2	2 (6.45)	0	0 (0.00)
Chronic graft versus host disease	1	1 (3.23)	0	0 (0.00)
Immunodeficiency	1	1 (3.23)	0	0 (0.00)
Infections and infestations				
- Total	32	11 (35.48)	7	4 (12.90)
Otitis media	5	3 (9.68)	1	1 (3.23)
Otitis media acute	4	2 (6.45)	0	0 (0.00)
Upper respiratory tract infection	4	2 (6.45)	0	0 (0.00)
Sinusitis	3	3 (9.68)	0	0 (0.00)
Urinary tract infection	3	2 (6.45)	1	1 (3.23)
Pneumonia	2	2 (6.45)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Campylobacter infection	1	1 (3.23)	1	1 (3.23)
Cellulitis of male external genital organ	1	1 (3.23)	1	1 (3.23)
Clostridium difficile infection	1	1 (3.23)	1	1 (3.23)
Gingivitis	1	1 (3.23)	0	0 (0.00)
Haemophilus infection	1	1 (3.23)	0	0 (0.00)
Meningitis aseptic	1	1 (3.23)	0	0 (0.00)
Respiratory tract infection	1	1 (3.23)	1	1 (3.23)
Respiratory tract infection viral	1	1 (3.23)	1	1 (3.23)
Skin infection	1	1 (3.23)	0	0 (0.00)
Viral infection	1	1 (3.23)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (3.23)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (3.23)	1	1 (3.23)
Procedural pain	1	1 (3.23)	1	1 (3.23)
Investigations				
- Total	20	7 (22.58)	8	5 (16.13)
White blood cell count decreased	5	4 (12.90)	3	3 (9.68)
Lymphocyte count decreased	4	2 (6.45)	1	1 (3.23)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Alanine aminotransferase increased	3	3 (9.68)	2	2 (6.45)
Aspartate aminotransferase increased	2	2 (6.45)	1	1 (3.23)
Neutrophil count decreased	2	1 (3.23)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (3.23)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (3.23)	0	0 (0.00)
C-reactive protein increased	1	1 (3.23)	0	0 (0.00)
Platelet count decreased	1	1 (3.23)	1	1 (3.23)
Metabolism and nutrition disorders				
- Total	2	2 (6.45)	1	1 (3.23)
Hypokalaemia	1	1 (3.23)	1	1 (3.23)
Vitamin D deficiency	1	1 (3.23)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Neck pain	1	1 (3.23)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
- Total	1	1 (3.23)	1	1 (3.23)
Glioblastoma multiforme	1	1 (3.23)	1	1 (3.23)
Nervous system disorders				
- Total	4	3 (9.68)	1	1 (3.23)
Disturbance in attention	1	1 (3.23)	0	0 (0.00)
Dizziness	1	1 (3.23)	0	0 (0.00)
Headache	1	1 (3.23)	0	0 (0.00)
Seizure	1	1 (3.23)	1	1 (3.23)
Renal and urinary disorders				
- Total	3	2 (6.45)	1	1 (3.23)
Acute kidney injury	2	1 (3.23)	1	1 (3.23)
Haematuria	1	1 (3.23)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.23)	1	1 (3.23)
Ovarian failure	1	1 (3.23)	1	1 (3.23)
Respiratory, thoracic and mediastinal disorders				
- Total	7	4 (12.90)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Cough	3	2 (6.45)	0	0 (0.00)
Epistaxis	1	1 (3.23)	0	0 (0.00)
Oropharyngeal pain	1	1 (3.23)	0	0 (0.00)
Rhinitis allergic	1	1 (3.23)	0	0 (0.00)
Rhinorrhoea	1	1 (3.23)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (9.68)	0	0 (0.00)
Acne	1	1 (3.23)	0	0 (0.00)
Papule	1	1 (3.23)	0	0 (0.00)
Pruritus	1	1 (3.23)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Total number of AE per patient	65	4 (100.00)	14	3 (75.00)
Blood and lymphatic system disorders				
- Total	6	3 (75.00)	3	3 (75.00)
Anaemia	3	2 (50.00)	0	0 (0.00)
Febrile neutropenia	2	2 (50.00)	2	2 (50.00)
Neutropenia	1	1 (25.00)	1	1 (25.00)
Eye disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Ocular hyperaemia	1	1 (25.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	6	3 (75.00)	1	1 (25.00)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Vomiting	3	2 (50.00)	0	0 (0.00)
Constipation	1	1 (25.00)	0	0 (0.00)
Enterocolitis	1	1 (25.00)	1	1 (25.00)
Nausea	1	1 (25.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	2 (50.00)	1	1 (25.00)
Fatigue	1	1 (25.00)	0	0 (0.00)
Influenza like illness	1	1 (25.00)	0	0 (0.00)
Pyrexia	1	1 (25.00)	1	1 (25.00)
Immune system disorders				
- Total	4	3 (75.00)	0	0 (0.00)
Cytokine release syndrome	3	3 (75.00)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (25.00)	0	0 (0.00)
Infections and infestations				
- Total	5	3 (75.00)	2	1 (25.00)
Corona virus infection	1	1 (25.00)	1	1 (25.00)
Fungal skin infection	1	1 (25.00)	0	0 (0.00)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Rash pustular	1	1 (25.00)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (25.00)	1	1 (25.00)
Viral infection	1	1 (25.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (25.00)	0	0 (0.00)
Skin laceration	1	1 (25.00)	0	0 (0.00)
Investigations				
- Total	24	3 (75.00)	6	2 (50.00)
White blood cell count decreased	6	2 (50.00)	2	1 (25.00)
Neutrophil count decreased	5	2 (50.00)	3	1 (25.00)
Lymphocyte count decreased	4	3 (75.00)	1	1 (25.00)
Platelet count decreased	3	1 (25.00)	0	0 (0.00)
Blood creatinine increased	2	1 (25.00)	0	0 (0.00)
Blood bilirubin increased	1	1 (25.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (25.00)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (25.00)	0	0 (0.00)
Fibrin D dimer increased	1	1 (25.00)	0	0 (0.00)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Metabolism and nutrition disorders				
- Total	3	1 (25.00)	0	0 (0.00)
Hyperphosphataemia	2	1 (25.00)	0	0 (0.00)
Decreased appetite	1	1 (25.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Pain in extremity	1	1 (25.00)	0	0 (0.00)
Nervous system disorders				
- Total	2	1 (25.00)	0	0 (0.00)
Headache	1	1 (25.00)	0	0 (0.00)
Tremor	1	1 (25.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	4	2 (50.00)	0	0 (0.00)
Cough	1	1 (25.00)	0	0 (0.00)
Hypoxia	1	1 (25.00)	0	0 (0.00)
Nasal congestion	1	1 (25.00)	0	0 (0.00)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Rhinorrhoea	1	1 (25.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	4	3 (75.00)	0	0 (0.00)
Dermatitis diaper	1	1 (25.00)	0	0 (0.00)
Dry skin	1	1 (25.00)	0	0 (0.00)
Erythema	1	1 (25.00)	0	0 (0.00)
Rash maculo-papular	1	1 (25.00)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (25.00)	1	1 (25.00)
Hypotension	1	1 (25.00)	1	1 (25.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Total number of AE per patient	1685	60 (100.00)	538	56 (93.33)
Blood and lymphatic system disorders				
- Total	136	45 (75.00)	104	40 (66.67)
Anaemia	46	25 (41.67)	32	20 (33.33)
Thrombocytopenia	33	10 (16.67)	24	9 (15.00)
Febrile neutropenia	28	22 (36.67)	28	22 (36.67)
Neutropenia	14	10 (16.67)	13	10 (16.67)
Disseminated intravascular coagulation	5	4 (6.67)	2	2 (3.33)
Lymphopenia	4	4 (6.67)	2	2 (3.33)
Eosinophilia	2	1 (1.67)	1	1 (1.67)
Coagulopathy	1	1 (1.67)	0	0 (0.00)
Leukopenia	1	1 (1.67)	1	1 (1.67)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Lymphadenopathy	1	1 (1.67)	0	0 (0.00)
Pancytopenia	1	1 (1.67)	1	1 (1.67)
Cardiac disorders				
- Total	33	23 (38.33)	3	2 (3.33)
Tachycardia	17	15 (25.00)	2	2 (3.33)
Sinus tachycardia	6	6 (10.00)	0	0 (0.00)
Pericardial effusion	2	2 (3.33)	0	0 (0.00)
Sinus bradycardia	2	1 (1.67)	0	0 (0.00)
Atrioventricular block second degree	1	1 (1.67)	0	0 (0.00)
Bradycardia	1	1 (1.67)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.67)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.67)	1	1 (1.67)
Palpitations	1	1 (1.67)	0	0 (0.00)
Ventricular tachycardia	1	1 (1.67)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	4	4 (6.67)	0	0 (0.00)
Ear pain	2	2 (3.33)	0	0 (0.00)
Hypoacusis	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Tympanic membrane perforation	1	1 (1.67)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (3.33)	0	0 (0.00)
Adrenal insufficiency	2	2 (3.33)	0	0 (0.00)
Eye disorders				
- Total	29	17 (28.33)	0	0 (0.00)
Vision blurred	5	4 (6.67)	0	0 (0.00)
Eye pain	4	3 (5.00)	0	0 (0.00)
Periorbital oedema	4	4 (6.67)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (5.00)	0	0 (0.00)
Photophobia	3	2 (3.33)	0	0 (0.00)
Dry eye	2	2 (3.33)	0	0 (0.00)
Retinal haemorrhage	2	2 (3.33)	0	0 (0.00)
Uveitis	2	2 (3.33)	0	0 (0.00)
Conjunctivitis allergic	1	1 (1.67)	0	0 (0.00)
Ocular hypertension	1	1 (1.67)	0	0 (0.00)
Papilloedema	1	1 (1.67)	0	0 (0.00)
Visual impairment	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Gastrointestinal disorders				
- Total	162	40 (66.67)	22	12 (20.00)
Vomiting	45	25 (41.67)	5	3 (5.00)
Nausea	33	24 (40.00)	5	5 (8.33)
Diarrhoea	28	24 (40.00)	2	2 (3.33)
Abdominal pain	15	11 (18.33)	2	1 (1.67)
Constipation	7	6 (10.00)	0	0 (0.00)
Abdominal pain upper	3	3 (5.00)	0	0 (0.00)
Oral pain	3	2 (3.33)	1	1 (1.67)
Abdominal distension	2	2 (3.33)	0	0 (0.00)
Anal incontinence	2	1 (1.67)	0	0 (0.00)
Dysphagia	2	2 (3.33)	1	1 (1.67)
Haematemesis	2	2 (3.33)	0	0 (0.00)
Mouth haemorrhage	2	1 (1.67)	2	1 (1.67)
Pancreatitis	2	2 (3.33)	1	1 (1.67)
Stomatitis	2	2 (3.33)	0	0 (0.00)
Abdominal discomfort	1	1 (1.67)	0	0 (0.00)
Abdominal pain lower	1	1 (1.67)	0	0 (0.00)
Abdominal tenderness	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Ascites	1	1 (1.67)	1	1 (1.67)
Dyspepsia	1	1 (1.67)	0	0 (0.00)
Flatulence	1	1 (1.67)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.67)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.67)	0	0 (0.00)
Glossodynia	1	1 (1.67)	0	0 (0.00)
Ileus	1	1 (1.67)	1	1 (1.67)
Intestinal obstruction	1	1 (1.67)	1	1 (1.67)
Lip pain	1	1 (1.67)	0	0 (0.00)
Pigmentation lip	1	1 (1.67)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (1.67)	0	0 (0.00)
General disorders and administration site conditions				
- Total	104	40 (66.67)	15	11 (18.33)
Pyrexia	42	24 (40.00)	6	6 (10.00)
Fatigue	15	14 (23.33)	1	1 (1.67)
Chills	11	10 (16.67)	0	0 (0.00)
Catheter site pain	4	4 (6.67)	0	0 (0.00)
Generalised oedema	4	3 (5.00)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Malaise	4	4 (6.67)	0	0 (0.00)
Pain	4	4 (6.67)	2	2 (3.33)
Oedema peripheral	3	3 (5.00)	1	1 (1.67)
Face oedema	2	2 (3.33)	1	1 (1.67)
Acquired gene mutation	1	1 (1.67)	0	0 (0.00)
Asthenia	1	1 (1.67)	0	0 (0.00)
Catheter site extravasation	1	1 (1.67)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.67)	0	0 (0.00)
Crying	1	1 (1.67)	0	0 (0.00)
Cyst	1	1 (1.67)	1	1 (1.67)
Facial pain	1	1 (1.67)	0	0 (0.00)
Influenza like illness	1	1 (1.67)	0	0 (0.00)
Injection site haematoma	1	1 (1.67)	0	0 (0.00)
Localised oedema	1	1 (1.67)	1	1 (1.67)
Mucosal haemorrhage	1	1 (1.67)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.67)	1	1 (1.67)
Non-cardiac chest pain	1	1 (1.67)	0	0 (0.00)
Peripheral swelling	1	1 (1.67)	0	0 (0.00)
Physical deconditioning	1	1 (1.67)	1	1 (1.67)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Hepatobiliary disorders				
- Total	9	7 (11.67)	2	2 (3.33)
Hyperbilirubinaemia	4	3 (5.00)	2	2 (3.33)
Hepatomegaly	3	3 (5.00)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.67)	0	0 (0.00)
Hepatosplenomegaly	1	1 (1.67)	0	0 (0.00)
Immune system disorders				
- Total	131	55 (91.67)	34	22 (36.67)
Cytokine release syndrome	83	47 (78.33)	29	19 (31.67)
Hypogammaglobulinaemia	35	32 (53.33)	5	5 (8.33)
Graft versus host disease	3	2 (3.33)	0	0 (0.00)
Immunodeficiency common variable	2	2 (3.33)	0	0 (0.00)
Seasonal allergy	2	2 (3.33)	0	0 (0.00)
Chronic graft versus host disease	1	1 (1.67)	0	0 (0.00)
Drug hypersensitivity	1	1 (1.67)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (1.67)	0	0 (0.00)
Graft versus host disease in skin	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Haemophagocytic lymphohistiocytosis	1	1 (1.67)	0	0 (0.00)
Immunodeficiency	1	1 (1.67)	0	0 (0.00)
Infections and infestations				
- Total	129	43 (71.67)	29	17 (28.33)
Upper respiratory tract infection	12	9 (15.00)	1	1 (1.67)
Urinary tract infection	8	5 (8.33)	3	2 (3.33)
Otitis media	7	4 (6.67)	1	1 (1.67)
Rhinovirus infection	7	5 (8.33)	0	0 (0.00)
Cellulitis of male external genital organ	6	1 (1.67)	3	1 (1.67)
Clostridium difficile infection	5	5 (8.33)	1	1 (1.67)
Gastroenteritis	5	5 (8.33)	1	1 (1.67)
Otitis media acute	5	2 (3.33)	0	0 (0.00)
Sinusitis	5	4 (6.67)	0	0 (0.00)
Clostridium difficile colitis	4	4 (6.67)	1	1 (1.67)
Influenza	4	4 (6.67)	0	0 (0.00)
Pneumonia	4	4 (6.67)	1	1 (1.67)
Viral upper respiratory tract infection	3	3 (5.00)	1	1 (1.67)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Cytomegalovirus infection	2	2 (3.33)	0	0 (0.00)
Ear infection	2	2 (3.33)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (1.67)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (3.33)	1	1 (1.67)
Skin infection	2	2 (3.33)	0	0 (0.00)
Staphylococcal infection	2	2 (3.33)	1	1 (1.67)
Viral infection	2	2 (3.33)	0	0 (0.00)
Vulvovaginal candidiasis	2	2 (3.33)	0	0 (0.00)
Acute sinusitis	1	1 (1.67)	0	0 (0.00)
Bacterial sepsis	1	1 (1.67)	1	1 (1.67)
Body tinea	1	1 (1.67)	0	0 (0.00)
Campylobacter infection	1	1 (1.67)	1	1 (1.67)
Catheter site cellulitis	1	1 (1.67)	0	0 (0.00)
Catheter site infection	1	1 (1.67)	1	1 (1.67)
Cholecystitis infective	1	1 (1.67)	1	1 (1.67)
Enterococcal infection	1	1 (1.67)	0	0 (0.00)
Enterovirus infection	1	1 (1.67)	1	1 (1.67)
Escherichia urinary tract infection	1	1 (1.67)	1	1 (1.67)
Folliculitis	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Gastroenteritis viral	1	1 (1.67)	0	0 (0.00)
Gingivitis	1	1 (1.67)	0	0 (0.00)
Haemophilus infection	1	1 (1.67)	0	0 (0.00)
Herpes simplex	1	1 (1.67)	0	0 (0.00)
Herpes zoster	1	1 (1.67)	1	1 (1.67)
Human herpesvirus 6 infection	1	1 (1.67)	0	0 (0.00)
Hypopyon	1	1 (1.67)	0	0 (0.00)
Meningitis aseptic	1	1 (1.67)	0	0 (0.00)
Molluscum contagiosum	1	1 (1.67)	0	0 (0.00)
Oral candidiasis	1	1 (1.67)	0	0 (0.00)
Oral herpes	1	1 (1.67)	0	0 (0.00)
Orchitis	1	1 (1.67)	0	0 (0.00)
Otitis externa	1	1 (1.67)	0	0 (0.00)
Paronychia	1	1 (1.67)	0	0 (0.00)
Pharyngitis	1	1 (1.67)	0	0 (0.00)
Respiratory tract infection	1	1 (1.67)	1	1 (1.67)
Respiratory tract infection viral	1	1 (1.67)	1	1 (1.67)
Rhinitis	1	1 (1.67)	0	0 (0.00)
Rotavirus infection	1	1 (1.67)	1	1 (1.67)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Sepsis	1	1 (1.67)	1	1 (1.67)
Septic embolus	1	1 (1.67)	1	1 (1.67)
Streptococcal infection	1	1 (1.67)	0	0 (0.00)
Subcutaneous abscess	1	1 (1.67)	0	0 (0.00)
Tinea capitis	1	1 (1.67)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (1.67)	1	1 (1.67)
Vascular device infection	1	1 (1.67)	1	1 (1.67)
Vulvovaginal mycotic infection	1	1 (1.67)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	38	21 (35.00)	3	3 (5.00)
Procedural pain	6	5 (8.33)	1	1 (1.67)
Infusion related reaction	4	4 (6.67)	0	0 (0.00)
Transfusion reaction	4	3 (5.00)	0	0 (0.00)
Contusion	3	3 (5.00)	0	0 (0.00)
Skin abrasion	2	2 (3.33)	0	0 (0.00)
Tracheal haemorrhage	2	1 (1.67)	1	1 (1.67)
Arthropod bite	1	1 (1.67)	0	0 (0.00)
Foot fracture	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Incision site pain	1	1 (1.67)	0	0 (0.00)
Limb injury	1	1 (1.67)	0	0 (0.00)
Mouth injury	1	1 (1.67)	0	0 (0.00)
Post procedural haemorrhage	1	1 (1.67)	0	0 (0.00)
Procedural complication	1	1 (1.67)	0	0 (0.00)
Procedural headache	1	1 (1.67)	0	0 (0.00)
Procedural nausea	1	1 (1.67)	0	0 (0.00)
Procedural site reaction	1	1 (1.67)	0	0 (0.00)
Radius fracture	1	1 (1.67)	0	0 (0.00)
Stoma site irritation	1	1 (1.67)	0	0 (0.00)
Subdural haemorrhage	1	1 (1.67)	0	0 (0.00)
Sunburn	1	1 (1.67)	0	0 (0.00)
Tibia fracture	1	1 (1.67)	0	0 (0.00)
Tongue injury	1	1 (1.67)	0	0 (0.00)
Transfusion related complication	1	1 (1.67)	1	1 (1.67)
Investigations				
- Total	378	53 (88.33)	196	47 (78.33)
White blood cell count decreased	61	33 (55.00)	41	29 (48.33)
Neutrophil count decreased	57	26 (43.33)	49	24 (40.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Platelet count decreased	46	19 (31.67)	38	15 (25.00)
Aspartate aminotransferase increased	37	20 (33.33)	19	12 (20.00)
Alanine aminotransferase increased	33	21 (35.00)	18	14 (23.33)
Lymphocyte count decreased	19	13 (21.67)	12	11 (18.33)
Prothrombin time prolonged	17	9 (15.00)	1	1 (1.67)
Blood fibrinogen decreased	15	4 (6.67)	4	3 (5.00)
Blood bilirubin increased	13	7 (11.67)	3	3 (5.00)
International normalised ratio increased	11	9 (15.00)	1	1 (1.67)
Blood creatinine increased	10	8 (13.33)	2	2 (3.33)
Activated partial thromboplastin time prolonged	8	5 (8.33)	0	0 (0.00)
Blood urea increased	5	3 (5.00)	1	1 (1.67)
Weight decreased	4	4 (6.67)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (5.00)	0	0 (0.00)
Blood phosphorus increased	3	2 (3.33)	0	0 (0.00)
Blood uric acid increased	3	2 (3.33)	0	0 (0.00)
Haemoglobin decreased	3	3 (5.00)	1	1 (1.67)
Transaminases increased	3	3 (5.00)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Blood immunoglobulin A decreased	2	2 (3.33)	0	0 (0.00)
Blood magnesium decreased	2	2 (3.33)	1	1 (1.67)
Blood sodium increased	2	1 (1.67)	0	0 (0.00)
C-reactive protein increased	2	2 (3.33)	1	1 (1.67)
Lipase increased	2	2 (3.33)	2	2 (3.33)
Serum ferritin increased	2	2 (3.33)	0	0 (0.00)
Weight increased	2	2 (3.33)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (1.67)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.67)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.67)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (1.67)	0	0 (0.00)
Blood lactic acid increased	1	1 (1.67)	1	1 (1.67)
Blood phosphorus decreased	1	1 (1.67)	0	0 (0.00)
Cardiac murmur	1	1 (1.67)	0	0 (0.00)
Culture stool positive	1	1 (1.67)	0	0 (0.00)
Hepatic enzyme increased	1	1 (1.67)	0	0 (0.00)
Norovirus test positive	1	1 (1.67)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Protein total decreased	1	1 (1.67)	1	1 (1.67)
Pulmonary function test decreased	1	1 (1.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	130	42 (70.00)	50	27 (45.00)
Decreased appetite	25	21 (35.00)	13	12 (20.00)
Hypokalaemia	23	19 (31.67)	9	9 (15.00)
Hypophosphataemia	14	10 (16.67)	10	8 (13.33)
Hyperphosphataemia	10	7 (11.67)	0	0 (0.00)
Hypernatraemia	7	4 (6.67)	1	1 (1.67)
Hypoalbuminaemia	6	5 (8.33)	1	1 (1.67)
Hyperglycaemia	5	3 (5.00)	2	2 (3.33)
Dehydration	4	4 (6.67)	3	3 (5.00)
Hyperuricaemia	4	3 (5.00)	1	1 (1.67)
Hypocalcaemia	4	3 (5.00)	1	1 (1.67)
Fluid overload	3	3 (5.00)	0	0 (0.00)
Hyperalbuminaemia	3	1 (1.67)	0	0 (0.00)
Hypercalcaemia	3	1 (1.67)	0	0 (0.00)
Hypertriglyceridaemia	3	2 (3.33)	1	1 (1.67)
Hyponatraemia	3	2 (3.33)	3	2 (3.33)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Acidosis	2	2 (3.33)	1	1 (1.67)
Tumour lysis syndrome	2	2 (3.33)	2	2 (3.33)
Vitamin D deficiency	2	2 (3.33)	0	0 (0.00)
Hyperchloraemia	1	1 (1.67)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.67)	0	0 (0.00)
Hypomagnesaemia	1	1 (1.67)	0	0 (0.00)
Iron overload	1	1 (1.67)	1	1 (1.67)
Malnutrition	1	1 (1.67)	1	1 (1.67)
Metabolic acidosis	1	1 (1.67)	0	0 (0.00)
Metabolic alkalosis	1	1 (1.67)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	44	24 (40.00)	1	1 (1.67)
Pain in extremity	11	10 (16.67)	0	0 (0.00)
Arthralgia	6	5 (8.33)	1	1 (1.67)
Myalgia	5	5 (8.33)	0	0 (0.00)
Musculoskeletal pain	4	3 (5.00)	0	0 (0.00)
Muscular weakness	3	3 (5.00)	0	0 (0.00)
Joint range of motion decreased	2	2 (3.33)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Muscle spasms	2	2 (3.33)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (3.33)	0	0 (0.00)
Back pain	1	1 (1.67)	0	0 (0.00)
Coccydynia	1	1 (1.67)	0	0 (0.00)
Flank pain	1	1 (1.67)	0	0 (0.00)
Limb discomfort	1	1 (1.67)	0	0 (0.00)
Neck pain	1	1 (1.67)	0	0 (0.00)
Osteonecrosis	1	1 (1.67)	0	0 (0.00)
Osteopenia	1	1 (1.67)	0	0 (0.00)
Pain in jaw	1	1 (1.67)	0	0 (0.00)
Toe walking	1	1 (1.67)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (5.00)	1	1 (1.67)
Glioblastoma multiforme	1	1 (1.67)	1	1 (1.67)
Myelodysplastic syndrome	1	1 (1.67)	0	0 (0.00)
Skin papilloma	1	1 (1.67)	0	0 (0.00)
Nervous system disorders				
- Total	72	34 (56.67)	7	6 (10.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Headache	38	23 (38.33)	2	2 (3.33)
Dizziness	8	6 (10.00)	0	0 (0.00)
Encephalopathy	6	4 (6.67)	2	2 (3.33)
Seizure	4	4 (6.67)	2	2 (3.33)
Dysarthria	2	2 (3.33)	0	0 (0.00)
Peroneal nerve palsy	2	2 (3.33)	0	0 (0.00)
Asterixis	1	1 (1.67)	0	0 (0.00)
Ataxia	1	1 (1.67)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.67)	0	0 (0.00)
Disturbance in attention	1	1 (1.67)	0	0 (0.00)
Embolic stroke	1	1 (1.67)	1	1 (1.67)
Idiopathic intracranial hypertension	1	1 (1.67)	0	0 (0.00)
Migraine	1	1 (1.67)	0	0 (0.00)
Myoclonus	1	1 (1.67)	0	0 (0.00)
Neuropathy peripheral	1	1 (1.67)	0	0 (0.00)
Pleocytosis	1	1 (1.67)	0	0 (0.00)
Somnolence	1	1 (1.67)	0	0 (0.00)
Tremor	1	1 (1.67)	0	0 (0.00)

Product issues

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
- Total	1	1 (1.67)	0	0 (0.00)
Device occlusion	1	1 (1.67)	0	0 (0.00)
Psychiatric disorders				
- Total	34	17 (28.33)	1	1 (1.67)
Anxiety	7	7 (11.67)	1	1 (1.67)
Confusional state	6	6 (10.00)	0	0 (0.00)
Delirium	4	4 (6.67)	0	0 (0.00)
Agitation	3	2 (3.33)	0	0 (0.00)
Hallucination	3	2 (3.33)	0	0 (0.00)
Depression	2	2 (3.33)	0	0 (0.00)
Irritability	2	2 (3.33)	0	0 (0.00)
Adjustment disorder	1	1 (1.67)	0	0 (0.00)
Insomnia	1	1 (1.67)	0	0 (0.00)
Listless	1	1 (1.67)	0	0 (0.00)
Mental status changes	1	1 (1.67)	0	0 (0.00)
Panic attack	1	1 (1.67)	0	0 (0.00)
Sleep disorder	1	1 (1.67)	0	0 (0.00)
Suicidal ideation	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Renal and urinary disorders				
- Total	26	15 (25.00)	15	10 (16.67)
Acute kidney injury	10	9 (15.00)	7	7 (11.67)
Haematuria	6	5 (8.33)	3	3 (5.00)
Dysuria	2	2 (3.33)	0	0 (0.00)
Oliguria	2	2 (3.33)	2	2 (3.33)
Calculus urinary	1	1 (1.67)	0	0 (0.00)
Nephrolithiasis	1	1 (1.67)	1	1 (1.67)
Pollakiuria	1	1 (1.67)	0	0 (0.00)
Renal failure	1	1 (1.67)	1	1 (1.67)
Renal impairment	1	1 (1.67)	1	1 (1.67)
Urinary incontinence	1	1 (1.67)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	7	6 (10.00)	2	2 (3.33)
Oedema genital	2	1 (1.67)	0	0 (0.00)
Vulvovaginal adhesion	2	2 (3.33)	0	0 (0.00)
Ovarian failure	1	1 (1.67)	1	1 (1.67)
Scrotal pain	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Vaginal haemorrhage	1	1 (1.67)	1	1 (1.67)
Respiratory, thoracic and mediastinal disorders				
- Total	106	36 (60.00)	32	15 (25.00)
Cough	19	13 (21.67)	0	0 (0.00)
Epistaxis	14	10 (16.67)	5	5 (8.33)
Hypoxia	12	9 (15.00)	8	7 (11.67)
Pleural effusion	8	8 (13.33)	2	2 (3.33)
Pulmonary oedema	7	7 (11.67)	6	6 (10.00)
Oropharyngeal pain	6	6 (10.00)	0	0 (0.00)
Tachypnoea	6	5 (8.33)	1	1 (1.67)
Rhinitis allergic	5	4 (6.67)	0	0 (0.00)
Rhinorrhoea	5	5 (8.33)	0	0 (0.00)
Nasal congestion	4	4 (6.67)	0	0 (0.00)
Dyspnoea	3	2 (3.33)	2	2 (3.33)
Haemoptysis	3	2 (3.33)	1	1 (1.67)
Respiratory failure	3	3 (5.00)	3	3 (5.00)
Acute respiratory failure	1	1 (1.67)	1	1 (1.67)
Atelectasis	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Dysphonia	1	1 (1.67)	0	0 (0.00)
Interstitial lung disease	1	1 (1.67)	1	1 (1.67)
Oropharyngeal plaque	1	1 (1.67)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.67)	0	0 (0.00)
Pharyngeal lesion	1	1 (1.67)	1	1 (1.67)
Pharyngeal ulceration	1	1 (1.67)	0	0 (0.00)
Respiratory depression	1	1 (1.67)	0	0 (0.00)
Respiratory distress	1	1 (1.67)	1	1 (1.67)
Wheezing	1	1 (1.67)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	65	27 (45.00)	3	3 (5.00)
Rash	9	8 (13.33)	0	0 (0.00)
Erythema	5	4 (6.67)	0	0 (0.00)
Hyperhidrosis	5	4 (6.67)	0	0 (0.00)
Dry skin	4	4 (6.67)	0	0 (0.00)
Ingrowing nail	4	3 (5.00)	0	0 (0.00)
Petechiae	4	4 (6.67)	0	0 (0.00)
Pruritus	4	4 (6.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Rash maculo-papular	4	4 (6.67)	1	1 (1.67)
Rash erythematous	3	2 (3.33)	0	0 (0.00)
Macule	2	2 (3.33)	0	0 (0.00)
Papule	2	2 (3.33)	0	0 (0.00)
Rash papular	2	2 (3.33)	0	0 (0.00)
Acne	1	1 (1.67)	0	0 (0.00)
Alopecia	1	1 (1.67)	0	0 (0.00)
Dermatitis	1	1 (1.67)	0	0 (0.00)
Dermatitis acneiform	1	1 (1.67)	1	1 (1.67)
Dermatitis atopic	1	1 (1.67)	0	0 (0.00)
Ecchymosis	1	1 (1.67)	1	1 (1.67)
Eczema	1	1 (1.67)	0	0 (0.00)
Keloid scar	1	1 (1.67)	0	0 (0.00)
Livedo reticularis	1	1 (1.67)	0	0 (0.00)
Night sweats	1	1 (1.67)	0	0 (0.00)
Rash follicular	1	1 (1.67)	0	0 (0.00)
Rash macular	1	1 (1.67)	0	0 (0.00)
Rash pruritic	1	1 (1.67)	0	0 (0.00)
Rash vesicular	1	1 (1.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=60 n (%)[1]	Grade >= 3 Total events	All patients N=60 n (%)[2]
Skin exfoliation	1	1 (1.67)	0	0 (0.00)
Skin fissures	1	1 (1.67)	0	0 (0.00)
Skin irritation	1	1 (1.67)	0	0 (0.00)
Vascular disorders				
- Total	42	24 (40.00)	18	15 (25.00)
Hypotension	18	15 (25.00)	15	14 (23.33)
Hypertension	14	12 (20.00)	1	1 (1.67)
Flushing	3	2 (3.33)	0	0 (0.00)
Orthostatic hypotension	2	2 (3.33)	0	0 (0.00)
Capillary leak syndrome	1	1 (1.67)	1	1 (1.67)
Embolism	1	1 (1.67)	1	1 (1.67)
Haematoma	1	1 (1.67)	0	0 (0.00)
Hot flush	1	1 (1.67)	0	0 (0.00)
Secondary hypertension	1	1 (1.67)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Total number of AE per patient	530	32 (100.00)	201	29 (90.63)
Blood and lymphatic system disorders				
- Total	38	20 (62.50)	34	19 (59.38)
Anaemia	17	11 (34.38)	14	9 (28.13)
Febrile neutropenia	13	10 (31.25)	13	10 (31.25)
Disseminated intravascular coagulation	3	2 (6.25)	2	2 (6.25)
Neutropenia	2	2 (6.25)	2	2 (6.25)
Lymphopenia	1	1 (3.13)	1	1 (3.13)
Pancytopenia	1	1 (3.13)	1	1 (3.13)
Thrombocytopenia	1	1 (3.13)	1	1 (3.13)
Cardiac disorders				
- Total	10	8 (25.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Tachycardia	6	5 (15.63)	0	0 (0.00)
Sinus tachycardia	2	2 (6.25)	0	0 (0.00)
Atrioventricular block second degree	1	1 (3.13)	0	0 (0.00)
Cardiac dysfunction	1	1 (3.13)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.13)	0	0 (0.00)
Ear pain	1	1 (3.13)	0	0 (0.00)
Eye disorders				
- Total	10	5 (15.63)	0	0 (0.00)
Eye pain	3	2 (6.25)	0	0 (0.00)
Photophobia	3	2 (6.25)	0	0 (0.00)
Vision blurred	2	2 (6.25)	0	0 (0.00)
Retinal haemorrhage	1	1 (3.13)	0	0 (0.00)
Uveitis	1	1 (3.13)	0	0 (0.00)
Gastrointestinal disorders				
- Total	55	17 (53.13)	8	6 (18.75)
Vomiting	17	11 (34.38)	3	3 (9.38)
Nausea	10	10 (31.25)	1	1 (3.13)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Diarrhoea	8	8 (25.00)	1	1 (3.13)
Abdominal pain	7	6 (18.75)	1	1 (3.13)
Constipation	5	5 (15.63)	0	0 (0.00)
Abdominal distension	1	1 (3.13)	0	0 (0.00)
Abdominal pain upper	1	1 (3.13)	0	0 (0.00)
Abdominal tenderness	1	1 (3.13)	0	0 (0.00)
Dyspepsia	1	1 (3.13)	0	0 (0.00)
Glossodynia	1	1 (3.13)	0	0 (0.00)
Ileus	1	1 (3.13)	1	1 (3.13)
Intestinal obstruction	1	1 (3.13)	1	1 (3.13)
Pancreatitis	1	1 (3.13)	0	0 (0.00)
General disorders and administration site conditions				
- Total	26	13 (40.63)	5	5 (15.63)
Pyrexia	14	9 (28.13)	4	4 (12.50)
Fatigue	3	3 (9.38)	0	0 (0.00)
Catheter site pain	2	2 (6.25)	0	0 (0.00)
Malaise	2	2 (6.25)	0	0 (0.00)
Catheter site haemorrhage	1	1 (3.13)	0	0 (0.00)
Generalised oedema	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Injection site haematoma	1	1 (3.13)	0	0 (0.00)
Oedema peripheral	1	1 (3.13)	0	0 (0.00)
Pain	1	1 (3.13)	1	1 (3.13)
Hepatobiliary disorders				
- Total	1	1 (3.13)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (3.13)	0	0 (0.00)
Immune system disorders				
- Total	60	29 (90.63)	13	10 (31.25)
Cytokine release syndrome	43	25 (78.13)	10	7 (21.88)
Hypogammaglobulinaemia	16	16 (50.00)	3	3 (9.38)
Haemophagocytic lymphohistiocytosis	1	1 (3.13)	0	0 (0.00)
Infections and infestations				
- Total	24	14 (43.75)	5	5 (15.63)
Clostridium difficile infection	4	4 (12.50)	0	0 (0.00)
Rhinovirus infection	2	2 (6.25)	0	0 (0.00)
Catheter site cellulitis	1	1 (3.13)	0	0 (0.00)
Catheter site infection	1	1 (3.13)	1	1 (3.13)
Clostridium difficile colitis	1	1 (3.13)	1	1 (3.13)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Cytomegalovirus infection	1	1 (3.13)	0	0 (0.00)
Enterococcal infection	1	1 (3.13)	0	0 (0.00)
Folliculitis	1	1 (3.13)	0	0 (0.00)
Fungal skin infection	1	1 (3.13)	0	0 (0.00)
Gastroenteritis	1	1 (3.13)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (3.13)	0	0 (0.00)
Influenza	1	1 (3.13)	0	0 (0.00)
Oral candidiasis	1	1 (3.13)	0	0 (0.00)
Orchitis	1	1 (3.13)	0	0 (0.00)
Septic embolus	1	1 (3.13)	1	1 (3.13)
Skin infection	1	1 (3.13)	0	0 (0.00)
Staphylococcal infection	1	1 (3.13)	1	1 (3.13)
Upper respiratory tract infection	1	1 (3.13)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (3.13)	1	1 (3.13)
Vulvovaginal candidiasis	1	1 (3.13)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	8	4 (12.50)	1	1 (3.13)
Transfusion reaction	3	2 (6.25)	0	0 (0.00)
Infusion related reaction	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Procedural pain	1	1 (3.13)	0	0 (0.00)
Procedural site reaction	1	1 (3.13)	0	0 (0.00)
Subdural haemorrhage	1	1 (3.13)	0	0 (0.00)
Transfusion related complication	1	1 (3.13)	1	1 (3.13)
Investigations				
- Total	151	28 (87.50)	103	25 (78.13)
White blood cell count decreased	33	17 (53.13)	23	17 (53.13)
Neutrophil count decreased	30	14 (43.75)	30	14 (43.75)
Platelet count decreased	29	10 (31.25)	27	9 (28.13)
Aspartate aminotransferase increased	13	7 (21.88)	6	5 (15.63)
Alanine aminotransferase increased	10	7 (21.88)	6	4 (12.50)
Blood bilirubin increased	6	3 (9.38)	1	1 (3.13)
Lymphocyte count decreased	6	6 (18.75)	6	6 (18.75)
Prothrombin time prolonged	5	3 (9.38)	0	0 (0.00)
Blood creatinine increased	4	3 (9.38)	0	0 (0.00)
Activated partial thromboplastin time prolonged	3	2 (6.25)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (6.25)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Blood lactic acid increased	1	1 (3.13)	1	1 (3.13)
C-reactive protein increased	1	1 (3.13)	1	1 (3.13)
Cardiac murmur	1	1 (3.13)	0	0 (0.00)
Haemoglobin decreased	1	1 (3.13)	1	1 (3.13)
Hepatic enzyme increased	1	1 (3.13)	0	0 (0.00)
Lipase increased	1	1 (3.13)	1	1 (3.13)
Pulmonary function test decreased	1	1 (3.13)	0	0 (0.00)
Serum ferritin increased	1	1 (3.13)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	45	17 (53.13)	17	9 (28.13)
Decreased appetite	9	7 (21.88)	4	3 (9.38)
Hypokalaemia	8	7 (21.88)	4	4 (12.50)
Hypophosphataemia	5	4 (12.50)	3	3 (9.38)
Hyperphosphataemia	4	3 (9.38)	0	0 (0.00)
Hyperglycaemia	3	2 (6.25)	0	0 (0.00)
Hypernatraemia	3	1 (3.13)	1	1 (3.13)
Hyperuricaemia	3	2 (6.25)	1	1 (3.13)
Hypocalcaemia	3	2 (6.25)	0	0 (0.00)
Dehydration	2	2 (6.25)	1	1 (3.13)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Hypertriglyceridaemia	2	1 (3.13)	1	1 (3.13)
Hyponatraemia	2	1 (3.13)	2	1 (3.13)
Fluid overload	1	1 (3.13)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	7	6 (18.75)	1	1 (3.13)
Pain in extremity	3	3 (9.38)	0	0 (0.00)
Arthralgia	2	2 (6.25)	1	1 (3.13)
Coccydynia	1	1 (3.13)	0	0 (0.00)
Muscular weakness	1	1 (3.13)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.13)	0	0 (0.00)
Skin papilloma	1	1 (3.13)	0	0 (0.00)
Nervous system disorders				
- Total	26	17 (53.13)	4	4 (12.50)
Headache	16	13 (40.63)	1	1 (3.13)
Encephalopathy	3	1 (3.13)	1	1 (3.13)
Dizziness	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Dysarthria	1	1 (3.13)	0	0 (0.00)
Embolic stroke	1	1 (3.13)	1	1 (3.13)
Migraine	1	1 (3.13)	0	0 (0.00)
Seizure	1	1 (3.13)	1	1 (3.13)
Somnolence	1	1 (3.13)	0	0 (0.00)
Tremor	1	1 (3.13)	0	0 (0.00)
Product issues				
- Total	1	1 (3.13)	0	0 (0.00)
Device occlusion	1	1 (3.13)	0	0 (0.00)
Psychiatric disorders				
- Total	8	7 (21.88)	0	0 (0.00)
Anxiety	2	2 (6.25)	0	0 (0.00)
Confusional state	2	2 (6.25)	0	0 (0.00)
Delirium	1	1 (3.13)	0	0 (0.00)
Hallucination	1	1 (3.13)	0	0 (0.00)
Mental status changes	1	1 (3.13)	0	0 (0.00)
Panic attack	1	1 (3.13)	0	0 (0.00)
Renal and urinary disorders				

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
- Total	2	2 (6.25)	0	0 (0.00)
Acute kidney injury	2	2 (6.25)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.13)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (3.13)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	25	13 (40.63)	4	3 (9.38)
Epistaxis	7	3 (9.38)	2	2 (6.25)
Hypoxia	5	4 (12.50)	2	2 (6.25)
Cough	3	3 (9.38)	0	0 (0.00)
Tachypnoea	3	2 (6.25)	0	0 (0.00)
Nasal congestion	1	1 (3.13)	0	0 (0.00)
Oropharyngeal plaque	1	1 (3.13)	0	0 (0.00)
Pharyngeal ulceration	1	1 (3.13)	0	0 (0.00)
Pleural effusion	1	1 (3.13)	0	0 (0.00)
Pulmonary oedema	1	1 (3.13)	0	0 (0.00)
Respiratory depression	1	1 (3.13)	0	0 (0.00)
Wheezing	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	15	9 (28.13)	0	0 (0.00)
Dry skin	3	3 (9.38)	0	0 (0.00)
Erythema	3	2 (6.25)	0	0 (0.00)
Pruritus	2	2 (6.25)	0	0 (0.00)
Hyperhidrosis	1	1 (3.13)	0	0 (0.00)
Ingrowing nail	1	1 (3.13)	0	0 (0.00)
Livedo reticularis	1	1 (3.13)	0	0 (0.00)
Rash	1	1 (3.13)	0	0 (0.00)
Rash follicular	1	1 (3.13)	0	0 (0.00)
Rash papular	1	1 (3.13)	0	0 (0.00)
Rash vesicular	1	1 (3.13)	0	0 (0.00)
Vascular disorders				
- Total	15	9 (28.13)	6	5 (15.63)
Hypotension	8	5 (15.63)	5	4 (12.50)
Hypertension	4	4 (12.50)	0	0 (0.00)
Embolism	1	1 (3.13)	1	1 (3.13)
Flushing	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Orthostatic hypotension	1	1 (3.13)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Total number of AE per patient	784	31 (96.88)	257	25 (78.13)
Blood and lymphatic system disorders				
- Total	84	23 (71.88)	59	19 (59.38)
Anaemia	30	16 (50.00)	17	10 (31.25)
Thrombocytopenia	29	7 (21.88)	22	7 (21.88)
Febrile neutropenia	13	12 (37.50)	13	12 (37.50)
Neutropenia	7	6 (18.75)	6	6 (18.75)
Disseminated intravascular coagulation	2	2 (6.25)	0	0 (0.00)
Lymphopenia	2	2 (6.25)	1	1 (3.13)
Coagulopathy	1	1 (3.13)	0	0 (0.00)
Cardiac disorders				
- Total	22	14 (43.75)	3	2 (6.25)
Tachycardia	11	10 (31.25)	2	2 (6.25)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Sinus tachycardia	3	3 (9.38)	0	0 (0.00)
Pericardial effusion	2	2 (6.25)	0	0 (0.00)
Sinus bradycardia	2	1 (3.13)	0	0 (0.00)
Bradycardia	1	1 (3.13)	0	0 (0.00)
Left ventricular dysfunction	1	1 (3.13)	1	1 (3.13)
Palpitations	1	1 (3.13)	0	0 (0.00)
Ventricular tachycardia	1	1 (3.13)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (6.25)	0	0 (0.00)
Ear pain	1	1 (3.13)	0	0 (0.00)
Hypoacusis	1	1 (3.13)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (3.13)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.13)	0	0 (0.00)
Eye disorders				
- Total	15	8 (25.00)	0	0 (0.00)
Periorbital oedema	4	4 (12.50)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (9.38)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Vision blurred	2	1 (3.13)	0	0 (0.00)
Eye pain	1	1 (3.13)	0	0 (0.00)
Ocular hypertension	1	1 (3.13)	0	0 (0.00)
Papilloedema	1	1 (3.13)	0	0 (0.00)
Retinal haemorrhage	1	1 (3.13)	0	0 (0.00)
Uveitis	1	1 (3.13)	0	0 (0.00)
Visual impairment	1	1 (3.13)	0	0 (0.00)
Gastrointestinal disorders				
- Total	71	19 (59.38)	7	5 (15.63)
Vomiting	18	11 (34.38)	0	0 (0.00)
Nausea	16	11 (34.38)	2	2 (6.25)
Diarrhoea	10	10 (31.25)	0	0 (0.00)
Abdominal pain	3	3 (9.38)	0	0 (0.00)
Constipation	3	2 (6.25)	0	0 (0.00)
Anal incontinence	2	1 (3.13)	0	0 (0.00)
Dysphagia	2	2 (6.25)	1	1 (3.13)
Haematemesis	2	2 (6.25)	0	0 (0.00)
Mouth haemorrhage	2	1 (3.13)	2	1 (3.13)
Stomatitis	2	2 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Abdominal discomfort	1	1 (3.13)	0	0 (0.00)
Abdominal distension	1	1 (3.13)	0	0 (0.00)
Abdominal pain lower	1	1 (3.13)	0	0 (0.00)
Abdominal pain upper	1	1 (3.13)	0	0 (0.00)
Ascites	1	1 (3.13)	1	1 (3.13)
Flatulence	1	1 (3.13)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (3.13)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (3.13)	0	0 (0.00)
Lip pain	1	1 (3.13)	0	0 (0.00)
Pancreatitis	1	1 (3.13)	1	1 (3.13)
Tooth socket haemorrhage	1	1 (3.13)	0	0 (0.00)
General disorders and administration site conditions				
- Total	51	19 (59.38)	9	5 (15.63)
Pyrexia	13	7 (21.88)	2	2 (6.25)
Fatigue	11	10 (31.25)	1	1 (3.13)
Chills	9	8 (25.00)	0	0 (0.00)
Face oedema	2	2 (6.25)	1	1 (3.13)
Generalised oedema	2	1 (3.13)	0	0 (0.00)
Pain	2	2 (6.25)	1	1 (3.13)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Asthenia	1	1 (3.13)	0	0 (0.00)
Catheter site extravasation	1	1 (3.13)	0	0 (0.00)
Catheter site pain	1	1 (3.13)	0	0 (0.00)
Facial pain	1	1 (3.13)	0	0 (0.00)
Localised oedema	1	1 (3.13)	1	1 (3.13)
Malaise	1	1 (3.13)	0	0 (0.00)
Mucosal haemorrhage	1	1 (3.13)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (3.13)	1	1 (3.13)
Non-cardiac chest pain	1	1 (3.13)	0	0 (0.00)
Oedema peripheral	1	1 (3.13)	1	1 (3.13)
Peripheral swelling	1	1 (3.13)	0	0 (0.00)
Physical deconditioning	1	1 (3.13)	1	1 (3.13)
Hepatobiliary disorders				
- Total	8	6 (18.75)	2	2 (6.25)
Hepatomegaly	3	3 (9.38)	0	0 (0.00)
Hyperbilirubinaemia	3	2 (6.25)	2	2 (6.25)
Gallbladder enlargement	1	1 (3.13)	0	0 (0.00)
Hepatosplenomegaly	1	1 (3.13)	0	0 (0.00)
Immune system disorders				

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
- Total	56	28 (87.50)	20	12 (37.50)
Cytokine release syndrome	43	25 (78.13)	19	12 (37.50)
Hypogammaglobulinaemia	11	10 (31.25)	1	1 (3.13)
Drug hypersensitivity	1	1 (3.13)	0	0 (0.00)
Graft versus host disease in skin	1	1 (3.13)	0	0 (0.00)
Infections and infestations				
- Total	17	12 (37.50)	2	2 (6.25)
Clostridium difficile colitis	3	3 (9.38)	0	0 (0.00)
Pneumonia	2	2 (6.25)	1	1 (3.13)
Acute sinusitis	1	1 (3.13)	0	0 (0.00)
Body tinea	1	1 (3.13)	0	0 (0.00)
Gastroenteritis	1	1 (3.13)	1	1 (3.13)
Herpes simplex	1	1 (3.13)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (3.13)	0	0 (0.00)
Hypopyon	1	1 (3.13)	0	0 (0.00)
Pharyngitis	1	1 (3.13)	0	0 (0.00)
Rhinovirus infection	1	1 (3.13)	0	0 (0.00)
Staphylococcal infection	1	1 (3.13)	0	0 (0.00)
Streptococcal infection	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Viral infection	1	1 (3.13)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (3.13)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	17	11 (34.38)	1	1 (3.13)
Procedural pain	2	2 (6.25)	0	0 (0.00)
Tracheal haemorrhage	2	1 (3.13)	1	1 (3.13)
Contusion	1	1 (3.13)	0	0 (0.00)
Incision site pain	1	1 (3.13)	0	0 (0.00)
Infusion related reaction	1	1 (3.13)	0	0 (0.00)
Limb injury	1	1 (3.13)	0	0 (0.00)
Mouth injury	1	1 (3.13)	0	0 (0.00)
Post procedural haemorrhage	1	1 (3.13)	0	0 (0.00)
Procedural complication	1	1 (3.13)	0	0 (0.00)
Procedural headache	1	1 (3.13)	0	0 (0.00)
Skin abrasion	1	1 (3.13)	0	0 (0.00)
Stoma site irritation	1	1 (3.13)	0	0 (0.00)
Tibia fracture	1	1 (3.13)	0	0 (0.00)
Tongue injury	1	1 (3.13)	0	0 (0.00)
Transfusion reaction	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Investigations				
- Total	181	24 (75.00)	75	19 (59.38)
White blood cell count decreased	22	13 (40.63)	14	9 (28.13)
Aspartate aminotransferase increased	19	11 (34.38)	10	6 (18.75)
Alanine aminotransferase increased	18	12 (37.50)	8	7 (21.88)
Neutrophil count decreased	17	11 (34.38)	14	9 (28.13)
Blood fibrinogen decreased	15	4 (12.50)	4	3 (9.38)
Platelet count decreased	14	9 (28.13)	10	5 (15.63)
Prothrombin time prolonged	12	6 (18.75)	1	1 (3.13)
International normalised ratio increased	11	9 (28.13)	1	1 (3.13)
Lymphocyte count decreased	10	8 (25.00)	6	5 (15.63)
Blood bilirubin increased	7	4 (12.50)	1	1 (3.13)
Blood creatinine increased	7	6 (18.75)	2	2 (6.25)
Activated partial thromboplastin time prolonged	5	3 (9.38)	0	0 (0.00)
Blood phosphorus increased	3	2 (6.25)	0	0 (0.00)
Blood urea increased	3	3 (9.38)	1	1 (3.13)
Blood immunoglobulin M decreased	2	2 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Blood sodium increased	2	1 (3.13)	0	0 (0.00)
Blood uric acid increased	2	1 (3.13)	0	0 (0.00)
Transaminases increased	2	2 (6.25)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (3.13)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (3.13)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (3.13)	0	0 (0.00)
Blood magnesium decreased	1	1 (3.13)	1	1 (3.13)
Blood phosphorus decreased	1	1 (3.13)	0	0 (0.00)
Culture stool positive	1	1 (3.13)	0	0 (0.00)
Fibrin D dimer increased	1	1 (3.13)	0	0 (0.00)
Lipase increased	1	1 (3.13)	1	1 (3.13)
Norovirus test positive	1	1 (3.13)	0	0 (0.00)
Protein total decreased	1	1 (3.13)	1	1 (3.13)
Metabolism and nutrition disorders				
- Total	71	22 (68.75)	26	15 (46.88)
Decreased appetite	15	13 (40.63)	9	9 (28.13)
Hypokalaemia	12	9 (28.13)	3	3 (9.38)
Hypophosphataemia	8	5 (15.63)	6	4 (12.50)
Hyperphosphataemia	6	5 (15.63)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Hypoalbuminaemia	6	5 (15.63)	1	1 (3.13)
Hypernatraemia	4	3 (9.38)	0	0 (0.00)
Acidosis	2	2 (6.25)	1	1 (3.13)
Fluid overload	2	2 (6.25)	0	0 (0.00)
Hypercalcaemia	2	1 (3.13)	0	0 (0.00)
Dehydration	1	1 (3.13)	1	1 (3.13)
Hyperalbuminaemia	1	1 (3.13)	0	0 (0.00)
Hyperchloraemia	1	1 (3.13)	0	0 (0.00)
Hyperglycaemia	1	1 (3.13)	1	1 (3.13)
Hypermagnesaemia	1	1 (3.13)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (3.13)	0	0 (0.00)
Hyperuricaemia	1	1 (3.13)	0	0 (0.00)
Hypocalcaemia	1	1 (3.13)	1	1 (3.13)
Hypomagnesaemia	1	1 (3.13)	0	0 (0.00)
Hyponatraemia	1	1 (3.13)	1	1 (3.13)
Malnutrition	1	1 (3.13)	1	1 (3.13)
Metabolic acidosis	1	1 (3.13)	0	0 (0.00)
Metabolic alkalosis	1	1 (3.13)	0	0 (0.00)
Tumour lysis syndrome	1	1 (3.13)	1	1 (3.13)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	16	9 (28.13)	0	0 (0.00)
Myalgia	5	5 (15.63)	0	0 (0.00)
Musculoskeletal pain	4	3 (9.38)	0	0 (0.00)
Arthralgia	2	2 (6.25)	0	0 (0.00)
Limb discomfort	1	1 (3.13)	0	0 (0.00)
Muscle spasms	1	1 (3.13)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.13)	0	0 (0.00)
Osteopenia	1	1 (3.13)	0	0 (0.00)
Pain in extremity	1	1 (3.13)	0	0 (0.00)
Nervous system disorders				
- Total	32	16 (50.00)	2	1 (3.13)
Headache	15	11 (34.38)	1	1 (3.13)
Dizziness	3	3 (9.38)	0	0 (0.00)
Encephalopathy	3	3 (9.38)	1	1 (3.13)
Seizure	2	2 (6.25)	0	0 (0.00)
Asterixis	1	1 (3.13)	0	0 (0.00)
Ataxia	1	1 (3.13)	0	0 (0.00)
Depressed level of consciousness	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Dysarthria	1	1 (3.13)	0	0 (0.00)
Idiopathic intracranial hypertension	1	1 (3.13)	0	0 (0.00)
Myoclonus	1	1 (3.13)	0	0 (0.00)
Neuropathy peripheral	1	1 (3.13)	0	0 (0.00)
Pleocytosis	1	1 (3.13)	0	0 (0.00)
Tremor	1	1 (3.13)	0	0 (0.00)
Psychiatric disorders				
- Total	22	9 (28.13)	1	1 (3.13)
Anxiety	4	4 (12.50)	1	1 (3.13)
Confusional state	4	4 (12.50)	0	0 (0.00)
Agitation	3	2 (6.25)	0	0 (0.00)
Delirium	3	3 (9.38)	0	0 (0.00)
Hallucination	2	1 (3.13)	0	0 (0.00)
Irritability	2	2 (6.25)	0	0 (0.00)
Adjustment disorder	1	1 (3.13)	0	0 (0.00)
Insomnia	1	1 (3.13)	0	0 (0.00)
Listless	1	1 (3.13)	0	0 (0.00)
Suicidal ideation	1	1 (3.13)	0	0 (0.00)
Renal and urinary disorders				

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
- Total	16	9 (28.13)	11	7 (21.88)
Acute kidney injury	5	5 (15.63)	5	5 (15.63)
Haematuria	4	4 (12.50)	2	2 (6.25)
Dysuria	2	2 (6.25)	0	0 (0.00)
Oliguria	2	2 (6.25)	2	2 (6.25)
Pollakiuria	1	1 (3.13)	0	0 (0.00)
Renal failure	1	1 (3.13)	1	1 (3.13)
Renal impairment	1	1 (3.13)	1	1 (3.13)
Reproductive system and breast disorders				
- Total	3	2 (6.25)	0	0 (0.00)
Oedema genital	2	1 (3.13)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (3.13)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	48	15 (46.88)	24	9 (28.13)
Hypoxia	8	6 (18.75)	6	5 (15.63)
Pleural effusion	7	7 (21.88)	2	2 (6.25)
Cough	5	5 (15.63)	0	0 (0.00)
Pulmonary oedema	5	5 (15.63)	5	5 (15.63)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Epistaxis	4	4 (12.50)	2	2 (6.25)
Dyspnoea	3	2 (6.25)	2	2 (6.25)
Haemoptysis	3	2 (6.25)	1	1 (3.13)
Respiratory failure	3	3 (9.38)	3	3 (9.38)
Tachypnoea	3	3 (9.38)	1	1 (3.13)
Oropharyngeal pain	2	2 (6.25)	0	0 (0.00)
Atelectasis	1	1 (3.13)	0	0 (0.00)
Interstitial lung disease	1	1 (3.13)	1	1 (3.13)
Respiratory distress	1	1 (3.13)	1	1 (3.13)
Rhinitis allergic	1	1 (3.13)	0	0 (0.00)
Rhinorrhoea	1	1 (3.13)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	26	12 (37.50)	2	2 (6.25)
Hyperhidrosis	3	2 (6.25)	0	0 (0.00)
Petechiae	3	3 (9.38)	0	0 (0.00)
Rash	3	3 (9.38)	0	0 (0.00)
Rash maculo-papular	3	3 (9.38)	1	1 (3.13)
Ingrowing nail	2	1 (3.13)	0	0 (0.00)
Dermatitis diaper	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Dry skin	1	1 (3.13)	0	0 (0.00)
Ecchymosis	1	1 (3.13)	1	1 (3.13)
Erythema	1	1 (3.13)	0	0 (0.00)
Macule	1	1 (3.13)	0	0 (0.00)
Night sweats	1	1 (3.13)	0	0 (0.00)
Rash erythematous	1	1 (3.13)	0	0 (0.00)
Rash macular	1	1 (3.13)	0	0 (0.00)
Rash papular	1	1 (3.13)	0	0 (0.00)
Skin exfoliation	1	1 (3.13)	0	0 (0.00)
Skin fissures	1	1 (3.13)	0	0 (0.00)
Skin irritation	1	1 (3.13)	0	0 (0.00)
Vascular disorders				
- Total	25	15 (46.88)	13	11 (34.38)
Hypotension	11	11 (34.38)	11	11 (34.38)
Hypertension	8	6 (18.75)	1	1 (3.13)
Flushing	2	1 (3.13)	0	0 (0.00)
Capillary leak syndrome	1	1 (3.13)	1	1 (3.13)
Haematoma	1	1 (3.13)	0	0 (0.00)
Orthostatic hypotension	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Secondary hypertension	1	1 (3.13)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Total number of AE per patient	211	25 (86.21)	38	13 (44.83)
Blood and lymphatic system disorders				
- Total	6	5 (17.24)	3	2 (6.90)
Anaemia	2	2 (6.90)	1	1 (3.45)
Febrile neutropenia	1	1 (3.45)	1	1 (3.45)
Lymphadenopathy	1	1 (3.45)	0	0 (0.00)
Neutropenia	1	1 (3.45)	1	1 (3.45)
Thrombocytopenia	1	1 (3.45)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (3.45)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.45)	0	0 (0.00)
Eye disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=29** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=29** **n (%)[2]**
- Total	5	5 (17.24)	0	0 (0.00)
Dry eye	2	2 (6.90)	0	0 (0.00)
Conjunctivitis allergic	1	1 (3.45)	0	0 (0.00)
Ocular hyperaemia	1	1 (3.45)	0	0 (0.00)
Vision blurred	1	1 (3.45)	0	0 (0.00)
Gastrointestinal disorders				
- Total	28	11 (37.93)	7	3 (10.34)
Vomiting	9	6 (20.69)	2	2 (6.90)
Diarrhoea	7	7 (24.14)	1	1 (3.45)
Nausea	5	4 (13.79)	2	2 (6.90)
Abdominal pain	4	4 (13.79)	1	1 (3.45)
Oral pain	3	2 (6.90)	1	1 (3.45)
General disorders and administration site conditions				
- Total	15	12 (41.38)	1	1 (3.45)
Pyrexia	7	7 (24.14)	1	1 (3.45)
Fatigue	2	2 (6.90)	0	0 (0.00)
Catheter site pain	1	1 (3.45)	0	0 (0.00)
Crying	1	1 (3.45)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Generalised oedema	1	1 (3.45)	0	0 (0.00)
Influenza like illness	1	1 (3.45)	0	0 (0.00)
Malaise	1	1 (3.45)	0	0 (0.00)
Oedema peripheral	1	1 (3.45)	0	0 (0.00)
Immune system disorders				
- Total	11	8 (27.59)	0	0 (0.00)
Hypogammaglobulinaemia	5	4 (13.79)	0	0 (0.00)
Graft versus host disease	2	1 (3.45)	0	0 (0.00)
Seasonal allergy	2	2 (6.90)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (3.45)	0	0 (0.00)
Immunodeficiency common variable	1	1 (3.45)	0	0 (0.00)
Infections and infestations				
- Total	36	19 (65.52)	8	6 (20.69)
Rhinovirus infection	4	2 (6.90)	0	0 (0.00)
Upper respiratory tract infection	4	4 (13.79)	0	0 (0.00)
Ear infection	2	2 (6.90)	0	0 (0.00)
Gastroenteritis	2	2 (6.90)	0	0 (0.00)
Influenza	2	2 (6.90)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Sinusitis	2	2 (6.90)	0	0 (0.00)
Urinary tract infection	2	2 (6.90)	1	1 (3.45)
Viral upper respiratory tract infection	2	2 (6.90)	1	1 (3.45)
Bacterial sepsis	1	1 (3.45)	1	1 (3.45)
Cytomegalovirus infection	1	1 (3.45)	0	0 (0.00)
Enterovirus infection	1	1 (3.45)	1	1 (3.45)
Escherichia urinary tract infection	1	1 (3.45)	1	1 (3.45)
Gastroenteritis norovirus	1	1 (3.45)	0	0 (0.00)
Gastroenteritis viral	1	1 (3.45)	0	0 (0.00)
Molluscum contagiosum	1	1 (3.45)	0	0 (0.00)
Oral herpes	1	1 (3.45)	0	0 (0.00)
Otitis media acute	1	1 (3.45)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (3.45)	1	1 (3.45)
Rhinitis	1	1 (3.45)	0	0 (0.00)
Rotavirus infection	1	1 (3.45)	1	1 (3.45)
Sepsis	1	1 (3.45)	1	1 (3.45)
Subcutaneous abscess	1	1 (3.45)	0	0 (0.00)
Tinea capitis	1	1 (3.45)	0	0 (0.00)
Viral infection	1	1 (3.45)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Injury, poisoning and procedural complications				
- Total	11	6 (20.69)	0	0 (0.00)
Contusion	2	2 (6.90)	0	0 (0.00)
Infusion related reaction	2	2 (6.90)	0	0 (0.00)
Procedural pain	2	2 (6.90)	0	0 (0.00)
Arthropod bite	1	1 (3.45)	0	0 (0.00)
Procedural nausea	1	1 (3.45)	0	0 (0.00)
Skin abrasion	1	1 (3.45)	0	0 (0.00)
Skin laceration	1	1 (3.45)	0	0 (0.00)
Sunburn	1	1 (3.45)	0	0 (0.00)
Investigations				
- Total	22	11 (37.93)	7	6 (20.69)
Neutrophil count decreased	5	3 (10.34)	2	2 (6.90)
White blood cell count decreased	5	3 (10.34)	3	2 (6.90)
Platelet count decreased	2	1 (3.45)	0	0 (0.00)
Weight increased	2	2 (6.90)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (3.45)	1	1 (3.45)
Blood bilirubin increased	1	1 (3.45)	1	1 (3.45)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Blood creatinine increased	1	1 (3.45)	0	0 (0.00)
Blood magnesium decreased	1	1 (3.45)	0	0 (0.00)
Lymphocyte count decreased	1	1 (3.45)	0	0 (0.00)
Oxygen saturation decreased	1	1 (3.45)	0	0 (0.00)
Serum ferritin increased	1	1 (3.45)	0	0 (0.00)
Weight decreased	1	1 (3.45)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	10	7 (24.14)	5	3 (10.34)
Decreased appetite	2	2 (6.90)	0	0 (0.00)
Hyperphosphataemia	2	2 (6.90)	0	0 (0.00)
Hypokalaemia	2	2 (6.90)	1	1 (3.45)
Dehydration	1	1 (3.45)	1	1 (3.45)
Hyperglycaemia	1	1 (3.45)	1	1 (3.45)
Hypophosphataemia	1	1 (3.45)	1	1 (3.45)
Iron overload	1	1 (3.45)	1	1 (3.45)
Musculoskeletal and connective tissue disorders				
- Total	13	10 (34.48)	0	0 (0.00)
Pain in extremity	5	5 (17.24)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Arthralgia	2	2 (6.90)	0	0 (0.00)
Muscular weakness	2	2 (6.90)	0	0 (0.00)
Flank pain	1	1 (3.45)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.45)	0	0 (0.00)
Pain in jaw	1	1 (3.45)	0	0 (0.00)
Toe walking	1	1 (3.45)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.45)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (3.45)	0	0 (0.00)
Nervous system disorders				
- Total	6	5 (17.24)	0	0 (0.00)
Headache	3	3 (10.34)	0	0 (0.00)
Dizziness	2	2 (6.90)	0	0 (0.00)
Peroneal nerve palsy	1	1 (3.45)	0	0 (0.00)
Psychiatric disorders				
- Total	4	2 (6.90)	0	0 (0.00)
Depression	2	2 (6.90)	0	0 (0.00)
Anxiety	1	1 (3.45)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Sleep disorder	1	1 (3.45)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	3 (10.34)	3	2 (6.90)
Acute kidney injury	1	1 (3.45)	1	1 (3.45)
Calculus urinary	1	1 (3.45)	0	0 (0.00)
Haematuria	1	1 (3.45)	1	1 (3.45)
Nephrolithiasis	1	1 (3.45)	1	1 (3.45)
Urinary incontinence	1	1 (3.45)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.45)	1	1 (3.45)
Vaginal haemorrhage	1	1 (3.45)	1	1 (3.45)
Respiratory, thoracic and mediastinal disorders				
- Total	18	11 (37.93)	3	2 (6.90)
Cough	5	5 (17.24)	0	0 (0.00)
Epistaxis	2	2 (6.90)	1	1 (3.45)
Nasal congestion	2	2 (6.90)	0	0 (0.00)
Oropharyngeal pain	2	2 (6.90)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Rhinorrhoea	2	2 (6.90)	0	0 (0.00)
Acute respiratory failure	1	1 (3.45)	1	1 (3.45)
Dysphonia	1	1 (3.45)	0	0 (0.00)
Pharyngeal erythema	1	1 (3.45)	0	0 (0.00)
Pharyngeal lesion	1	1 (3.45)	1	1 (3.45)
Rhinitis allergic	1	1 (3.45)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	15	8 (27.59)	0	0 (0.00)
Rash	4	3 (10.34)	0	0 (0.00)
Rash erythematous	2	1 (3.45)	0	0 (0.00)
Alopecia	1	1 (3.45)	0	0 (0.00)
Dermatitis	1	1 (3.45)	0	0 (0.00)
Dry skin	1	1 (3.45)	0	0 (0.00)
Erythema	1	1 (3.45)	0	0 (0.00)
Keloid scar	1	1 (3.45)	0	0 (0.00)
Petechiae	1	1 (3.45)	0	0 (0.00)
Pruritus	1	1 (3.45)	0	0 (0.00)
Rash maculo-papular	1	1 (3.45)	0	0 (0.00)
Rash pruritic	1	1 (3.45)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Vascular disorders				
- Total	3	2 (6.90)	0	0 (0.00)
Hypertension	2	2 (6.90)	0	0 (0.00)
Hot flush	1	1 (3.45)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Total number of AE per patient	135	21 (77.78)	33	13 (48.15)
Blood and lymphatic system disorders				
- Total	12	6 (22.22)	10	5 (18.52)
Neutropenia	5	3 (11.11)	5	3 (11.11)
Eosinophilia	2	1 (3.70)	1	1 (3.70)
Febrile neutropenia	2	2 (7.41)	2	2 (7.41)
Leukopenia	1	1 (3.70)	1	1 (3.70)
Lymphopenia	1	1 (3.70)	0	0 (0.00)
Thrombocytopenia	1	1 (3.70)	1	1 (3.70)
Cardiac disorders				
- Total	1	1 (3.70)	0	0 (0.00)
Sinus tachycardia	1	1 (3.70)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Gastrointestinal disorders				
- Total	10	5 (18.52)	1	1 (3.70)
Vomiting	4	3 (11.11)	0	0 (0.00)
Nausea	2	2 (7.41)	0	0 (0.00)
Abdominal pain upper	1	1 (3.70)	0	0 (0.00)
Diarrhoea	1	1 (3.70)	0	0 (0.00)
Enterocolitis	1	1 (3.70)	1	1 (3.70)
Pigmentation lip	1	1 (3.70)	0	0 (0.00)
General disorders and administration site conditions				
- Total	11	5 (18.52)	0	0 (0.00)
Pyrexia	7	3 (11.11)	0	0 (0.00)
Acquired gene mutation	1	1 (3.70)	0	0 (0.00)
Chills	1	1 (3.70)	0	0 (0.00)
Influenza like illness	1	1 (3.70)	0	0 (0.00)
Pain	1	1 (3.70)	0	0 (0.00)
Immune system disorders				
- Total	6	6 (22.22)	1	1 (3.70)
Hypogammaglobulinaemia	4	4 (14.81)	1	1 (3.70)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Graft versus host disease	1	1 (3.70)	0	0 (0.00)
Immunodeficiency common variable	1	1 (3.70)	0	0 (0.00)
Infections and infestations				
- Total	25	14 (51.85)	9	6 (22.22)
Cellulitis of male external genital organ	5	1 (3.70)	2	1 (3.70)
Upper respiratory tract infection	3	3 (11.11)	1	1 (3.70)
Urinary tract infection	3	2 (7.41)	1	1 (3.70)
Otitis media	2	1 (3.70)	0	0 (0.00)
Cholecystitis infective	1	1 (3.70)	1	1 (3.70)
Corona virus infection	1	1 (3.70)	1	1 (3.70)
Gastroenteritis	1	1 (3.70)	0	0 (0.00)
Herpes zoster	1	1 (3.70)	1	1 (3.70)
Influenza	1	1 (3.70)	0	0 (0.00)
Otitis externa	1	1 (3.70)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (3.70)	0	0 (0.00)
Paronychia	1	1 (3.70)	0	0 (0.00)
Rash pustular	1	1 (3.70)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (3.70)	1	1 (3.70)
Vascular device infection	1	1 (3.70)	1	1 (3.70)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Vulvovaginal mycotic infection	1	1 (3.70)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	2 (7.41)	0	0 (0.00)
Foot fracture	1	1 (3.70)	0	0 (0.00)
Radius fracture	1	1 (3.70)	0	0 (0.00)
Investigations				
- Total	26	12 (44.44)	9	6 (22.22)
Neutrophil count decreased	7	5 (18.52)	6	4 (14.81)
Platelet count decreased	3	2 (7.41)	0	0 (0.00)
Weight decreased	3	3 (11.11)	0	0 (0.00)
Alanine aminotransferase increased	2	2 (7.41)	2	2 (7.41)
Aspartate aminotransferase increased	2	2 (7.41)	1	1 (3.70)
Blood urea increased	2	1 (3.70)	0	0 (0.00)
Haemoglobin decreased	2	2 (7.41)	0	0 (0.00)
White blood cell count decreased	2	2 (7.41)	0	0 (0.00)
Blood uric acid increased	1	1 (3.70)	0	0 (0.00)
Lymphocyte count decreased	1	1 (3.70)	0	0 (0.00)
Transaminases increased	1	1 (3.70)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Metabolism and nutrition disorders				
- Total	5	3 (11.11)	1	1 (3.70)
Hyperalbuminaemia	2	1 (3.70)	0	0 (0.00)
Hypercalcaemia	1	1 (3.70)	0	0 (0.00)
Tumour lysis syndrome	1	1 (3.70)	1	1 (3.70)
Vitamin D deficiency	1	1 (3.70)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	8	6 (22.22)	0	0 (0.00)
Pain in extremity	3	3 (11.11)	0	0 (0.00)
Joint range of motion decreased	2	2 (7.41)	0	0 (0.00)
Back pain	1	1 (3.70)	0	0 (0.00)
Muscle spasms	1	1 (3.70)	0	0 (0.00)
Osteonecrosis	1	1 (3.70)	0	0 (0.00)
Nervous system disorders				
- Total	6	3 (11.11)	0	0 (0.00)
Headache	4	2 (7.41)	0	0 (0.00)
Dizziness	1	1 (3.70)	0	0 (0.00)
Peroneal nerve palsy	1	1 (3.70)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Reproductive system and breast disorders				
- Total	1	1 (3.70)	0	0 (0.00)
Scrotal pain	1	1 (3.70)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	12	7 (25.93)	1	1 (3.70)
Cough	4	2 (7.41)	0	0 (0.00)
Nasal congestion	2	2 (7.41)	0	0 (0.00)
Rhinitis allergic	2	2 (7.41)	0	0 (0.00)
Rhinorrhoea	2	2 (7.41)	0	0 (0.00)
Oropharyngeal pain	1	1 (3.70)	0	0 (0.00)
Pulmonary oedema	1	1 (3.70)	1	1 (3.70)
Skin and subcutaneous tissue disorders				
- Total	10	8 (29.63)	1	1 (3.70)
Dermatitis acneiform	1	1 (3.70)	1	1 (3.70)
Dermatitis atopic	1	1 (3.70)	0	0 (0.00)
Eczema	1	1 (3.70)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Erythema	1	1 (3.70)	0	0 (0.00)
Hyperhidrosis	1	1 (3.70)	0	0 (0.00)
Ingrowing nail	1	1 (3.70)	0	0 (0.00)
Macule	1	1 (3.70)	0	0 (0.00)
Papule	1	1 (3.70)	0	0 (0.00)
Rash	1	1 (3.70)	0	0 (0.00)
Rash maculo-papular	1	1 (3.70)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Total number of AE per patient	49	13 (72.22)	15	8 (44.44)
Blood and lymphatic system disorders				
- Total	1	1 (5.56)	1	1 (5.56)
Febrile neutropenia	1	1 (5.56)	1	1 (5.56)
Gastrointestinal disorders				
- Total	3	2 (11.11)	0	0 (0.00)
Abdominal pain	1	1 (5.56)	0	0 (0.00)
Diarrhoea	1	1 (5.56)	0	0 (0.00)
Nausea	1	1 (5.56)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	2 (11.11)	1	1 (5.56)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Pyrexia	2	1 (5.56)	0	0 (0.00)
Chills	1	1 (5.56)	0	0 (0.00)
Cyst	1	1 (5.56)	1	1 (5.56)
Immune system disorders				
- Total	2	2 (11.11)	0	0 (0.00)
Chronic graft versus host disease	1	1 (5.56)	0	0 (0.00)
Immunodeficiency	1	1 (5.56)	0	0 (0.00)
Infections and infestations				
- Total	10	5 (27.78)	4	2 (11.11)
Campylobacter infection	1	1 (5.56)	1	1 (5.56)
Clostridium difficile infection	1	1 (5.56)	1	1 (5.56)
Otitis media acute	1	1 (5.56)	0	0 (0.00)
Pneumonia	1	1 (5.56)	0	0 (0.00)
Respiratory tract infection	1	1 (5.56)	1	1 (5.56)
Respiratory tract infection viral	1	1 (5.56)	1	1 (5.56)
Sinusitis	1	1 (5.56)	0	0 (0.00)
Skin infection	1	1 (5.56)	0	0 (0.00)
Urinary tract infection	1	1 (5.56)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (5.56)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Injury, poisoning and procedural complications				
- Total	1	1 (5.56)	1	1 (5.56)
Procedural pain	1	1 (5.56)	1	1 (5.56)
Investigations				
- Total	12	4 (22.22)	5	3 (16.67)
Lymphocyte count decreased	3	2 (11.11)	1	1 (5.56)
White blood cell count decreased	2	2 (11.11)	2	2 (11.11)
Alanine aminotransferase increased	1	1 (5.56)	1	1 (5.56)
Aspartate aminotransferase increased	1	1 (5.56)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (5.56)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (5.56)	0	0 (0.00)
C-reactive protein increased	1	1 (5.56)	0	0 (0.00)
Neutrophil count decreased	1	1 (5.56)	0	0 (0.00)
Platelet count decreased	1	1 (5.56)	1	1 (5.56)
Metabolism and nutrition disorders				
- Total	2	2 (11.11)	1	1 (5.56)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Hypokalaemia	1	1 (5.56)	1	1 (5.56)
Vitamin D deficiency	1	1 (5.56)	0	0 (0.00)
Nervous system disorders				
- Total	3	2 (11.11)	0	0 (0.00)
Disturbance in attention	1	1 (5.56)	0	0 (0.00)
Dizziness	1	1 (5.56)	0	0 (0.00)
Headache	1	1 (5.56)	0	0 (0.00)
Renal and urinary disorders				
- Total	3	2 (11.11)	1	1 (5.56)
Acute kidney injury	2	1 (5.56)	1	1 (5.56)
Haematuria	1	1 (5.56)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (5.56)	1	1 (5.56)
Ovarian failure	1	1 (5.56)	1	1 (5.56)
Respiratory, thoracic and mediastinal disorders				
- Total	4	3 (16.67)	0	0 (0.00)
Cough	1	1 (5.56)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Epistaxis	1	1 (5.56)	0	0 (0.00)
Oropharyngeal pain	1	1 (5.56)	0	0 (0.00)
Rhinorrhoea	1	1 (5.56)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (16.67)	0	0 (0.00)
Acne	1	1 (5.56)	0	0 (0.00)
Papule	1	1 (5.56)	0	0 (0.00)
Pruritus	1	1 (5.56)	0	0 (0.00)

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Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Total number of AE per patient	41	9 (56.25)	8	4 (25.00)
Blood and lymphatic system disorders				
- Total	1	1 (6.25)	0	0 (0.00)
Thrombocytopenia	1	1 (6.25)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (6.25)	0	0 (0.00)
Tympanic membrane perforation	1	1 (6.25)	0	0 (0.00)
Gastrointestinal disorders				
- Total	1	1 (6.25)	0	0 (0.00)
Diarrhoea	1	1 (6.25)	0	0 (0.00)
Infections and infestations				
- Total	22	6 (37.50)	3	2 (12.50)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Otitis media	5	3 (18.75)	1	1 (6.25)
Upper respiratory tract infection	4	2 (12.50)	0	0 (0.00)
Otitis media acute	3	1 (6.25)	0	0 (0.00)
Sinusitis	2	2 (12.50)	0	0 (0.00)
Urinary tract infection	2	1 (6.25)	1	1 (6.25)
Cellulitis of male external genital organ	1	1 (6.25)	1	1 (6.25)
Gingivitis	1	1 (6.25)	0	0 (0.00)
Haemophilus infection	1	1 (6.25)	0	0 (0.00)
Meningitis aseptic	1	1 (6.25)	0	0 (0.00)
Pneumonia	1	1 (6.25)	0	0 (0.00)
Viral infection	1	1 (6.25)	0	0 (0.00)
Investigations				
- Total	10	4 (25.00)	3	2 (12.50)
White blood cell count decreased	3	2 (12.50)	1	1 (6.25)
Alanine aminotransferase increased	2	2 (12.50)	1	1 (6.25)
Lymphocyte count decreased	2	1 (6.25)	0	0 (0.00)
Neutrophil count decreased	2	1 (6.25)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (6.25)	1	1 (6.25)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	1	1 (6.25)	0	0 (0.00)
Neck pain	1	1 (6.25)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (6.25)	1	1 (6.25)
Glioblastoma multiforme	1	1 (6.25)	1	1 (6.25)
Nervous system disorders				
- Total	1	1 (6.25)	1	1 (6.25)
Seizure	1	1 (6.25)	1	1 (6.25)
Respiratory, thoracic and mediastinal disorders				
- Total	3	1 (6.25)	0	0 (0.00)
Cough	2	1 (6.25)	0	0 (0.00)
Rhinitis allergic	1	1 (6.25)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.

1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Total number of AE per patient	790	32 (100.00)	254	31 (96.88)
Blood and lymphatic system disorders				
- Total	45	22 (68.75)	38	21 (65.63)
Anaemia	19	11 (34.38)	15	10 (31.25)
Febrile neutropenia	15	12 (37.50)	15	12 (37.50)
Disseminated intravascular coagulation	3	2 (6.25)	2	2 (6.25)
Neutropenia	3	3 (9.38)	3	3 (9.38)
Thrombocytopenia	2	2 (6.25)	1	1 (3.13)
Lymphadenopathy	1	1 (3.13)	0	0 (0.00)
Lymphopenia	1	1 (3.13)	1	1 (3.13)
Pancytopenia	1	1 (3.13)	1	1 (3.13)
Cardiac disorders				

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
- Total	10	8 (25.00)	0	0 (0.00)
Tachycardia	6	5 (15.63)	0	0 (0.00)
Sinus tachycardia	2	2 (6.25)	0	0 (0.00)
Atrioventricular block second degree	1	1 (3.13)	0	0 (0.00)
Cardiac dysfunction	1	1 (3.13)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.13)	0	0 (0.00)
Ear pain	1	1 (3.13)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (3.13)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.13)	0	0 (0.00)
Eye disorders				
- Total	15	10 (31.25)	0	0 (0.00)
Eye pain	3	2 (6.25)	0	0 (0.00)
Photophobia	3	2 (6.25)	0	0 (0.00)
Vision blurred	3	3 (9.38)	0	0 (0.00)
Dry eye	2	2 (6.25)	0	0 (0.00)
Conjunctivitis allergic	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Ocular hyperaemia	1	1 (3.13)	0	0 (0.00)
Retinal haemorrhage	1	1 (3.13)	0	0 (0.00)
Uveitis	1	1 (3.13)	0	0 (0.00)
Gastrointestinal disorders				
- Total	86	21 (65.63)	15	7 (21.88)
Vomiting	26	14 (43.75)	5	3 (9.38)
Diarrhoea	16	12 (37.50)	2	2 (6.25)
Nausea	16	13 (40.63)	3	3 (9.38)
Abdominal pain	12	8 (25.00)	2	1 (3.13)
Constipation	5	5 (15.63)	0	0 (0.00)
Oral pain	3	2 (6.25)	1	1 (3.13)
Abdominal distension	1	1 (3.13)	0	0 (0.00)
Abdominal pain upper	1	1 (3.13)	0	0 (0.00)
Abdominal tenderness	1	1 (3.13)	0	0 (0.00)
Dyspepsia	1	1 (3.13)	0	0 (0.00)
Glossodynia	1	1 (3.13)	0	0 (0.00)
Ileus	1	1 (3.13)	1	1 (3.13)
Intestinal obstruction	1	1 (3.13)	1	1 (3.13)
Pancreatitis	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
General disorders and administration site conditions				
- Total	45	20 (62.50)	7	7 (21.88)
Pyrexia	23	15 (46.88)	5	5 (15.63)
Fatigue	5	5 (15.63)	0	0 (0.00)
Catheter site pain	3	3 (9.38)	0	0 (0.00)
Malaise	3	3 (9.38)	0	0 (0.00)
Generalised oedema	2	2 (6.25)	0	0 (0.00)
Oedema peripheral	2	2 (6.25)	0	0 (0.00)
Catheter site haemorrhage	1	1 (3.13)	0	0 (0.00)
Chills	1	1 (3.13)	0	0 (0.00)
Crying	1	1 (3.13)	0	0 (0.00)
Cyst	1	1 (3.13)	1	1 (3.13)
Influenza like illness	1	1 (3.13)	0	0 (0.00)
Injection site haematoma	1	1 (3.13)	0	0 (0.00)
Pain	1	1 (3.13)	1	1 (3.13)
Hepatobiliary disorders				
- Total	1	1 (3.13)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Immune system disorders				
- Total	73	29 (90.63)	13	10 (31.25)
Cytokine release syndrome	43	25 (78.13)	10	7 (21.88)
Hypogammaglobulinaemia	21	20 (62.50)	3	3 (9.38)
Graft versus host disease	2	1 (3.13)	0	0 (0.00)
Seasonal allergy	2	2 (6.25)	0	0 (0.00)
Chronic graft versus host disease	1	1 (3.13)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (3.13)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (3.13)	0	0 (0.00)
Immunodeficiency	1	1 (3.13)	0	0 (0.00)
Immunodeficiency common variable	1	1 (3.13)	0	0 (0.00)
Infections and infestations				
- Total	70	24 (75.00)	17	10 (31.25)
Rhinovirus infection	6	4 (12.50)	0	0 (0.00)
Clostridium difficile infection	5	5 (15.63)	1	1 (3.13)
Upper respiratory tract infection	5	4 (12.50)	0	0 (0.00)
Gastroenteritis	3	3 (9.38)	0	0 (0.00)
Influenza	3	3 (9.38)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Sinusitis	3	2 (6.25)	0	0 (0.00)
Urinary tract infection	3	3 (9.38)	1	1 (3.13)
Cytomegalovirus infection	2	2 (6.25)	0	0 (0.00)
Ear infection	2	2 (6.25)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (3.13)	0	0 (0.00)
Otitis media acute	2	1 (3.13)	0	0 (0.00)
Skin infection	2	2 (6.25)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (6.25)	1	1 (3.13)
Vulvovaginal candidiasis	2	2 (6.25)	0	0 (0.00)
Bacterial sepsis	1	1 (3.13)	1	1 (3.13)
Campylobacter infection	1	1 (3.13)	1	1 (3.13)
Catheter site cellulitis	1	1 (3.13)	0	0 (0.00)
Catheter site infection	1	1 (3.13)	1	1 (3.13)
Clostridium difficile colitis	1	1 (3.13)	1	1 (3.13)
Enterococcal infection	1	1 (3.13)	0	0 (0.00)
Enterovirus infection	1	1 (3.13)	1	1 (3.13)
Escherichia urinary tract infection	1	1 (3.13)	1	1 (3.13)
Folliculitis	1	1 (3.13)	0	0 (0.00)
Fungal skin infection	1	1 (3.13)	0	0 (0.00)
Gastroenteritis viral	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Molluscum contagiosum	1	1 (3.13)	0	0 (0.00)
Oral candidiasis	1	1 (3.13)	0	0 (0.00)
Oral herpes	1	1 (3.13)	0	0 (0.00)
Orchitis	1	1 (3.13)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (3.13)	1	1 (3.13)
Pneumonia	1	1 (3.13)	0	0 (0.00)
Respiratory tract infection	1	1 (3.13)	1	1 (3.13)
Respiratory tract infection viral	1	1 (3.13)	1	1 (3.13)
Rhinitis	1	1 (3.13)	0	0 (0.00)
Rotavirus infection	1	1 (3.13)	1	1 (3.13)
Sepsis	1	1 (3.13)	1	1 (3.13)
Septic embolus	1	1 (3.13)	1	1 (3.13)
Staphylococcal infection	1	1 (3.13)	1	1 (3.13)
Subcutaneous abscess	1	1 (3.13)	0	0 (0.00)
Tinea capitis	1	1 (3.13)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (3.13)	1	1 (3.13)
Viral infection	1	1 (3.13)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	20	10 (31.25)	2	2 (6.25)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Procedural pain	4	3 (9.38)	1	1 (3.13)
Infusion related reaction	3	3 (9.38)	0	0 (0.00)
Transfusion reaction	3	2 (6.25)	0	0 (0.00)
Contusion	2	2 (6.25)	0	0 (0.00)
Arthropod bite	1	1 (3.13)	0	0 (0.00)
Procedural nausea	1	1 (3.13)	0	0 (0.00)
Procedural site reaction	1	1 (3.13)	0	0 (0.00)
Skin abrasion	1	1 (3.13)	0	0 (0.00)
Skin laceration	1	1 (3.13)	0	0 (0.00)
Subdural haemorrhage	1	1 (3.13)	0	0 (0.00)
Sunburn	1	1 (3.13)	0	0 (0.00)
Transfusion related complication	1	1 (3.13)	1	1 (3.13)
Investigations				
- Total	185	30 (93.75)	115	28 (87.50)
White blood cell count decreased	40	21 (65.63)	28	20 (62.50)
Neutrophil count decreased	36	15 (46.88)	32	14 (43.75)
Platelet count decreased	32	11 (34.38)	28	10 (31.25)
Aspartate aminotransferase increased	15	8 (25.00)	7	5 (15.63)
Alanine aminotransferase increased	11	8 (25.00)	7	5 (15.63)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Lymphocyte count decreased	10	8 (25.00)	7	7 (21.88)
Blood bilirubin increased	7	4 (12.50)	2	2 (6.25)
Blood creatinine increased	5	3 (9.38)	0	0 (0.00)
Prothrombin time prolonged	5	3 (9.38)	0	0 (0.00)
Activated partial thromboplastin time prolonged	3	2 (6.25)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (6.25)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (6.25)	0	0 (0.00)
C-reactive protein increased	2	2 (6.25)	1	1 (3.13)
Serum ferritin increased	2	2 (6.25)	0	0 (0.00)
Weight increased	2	2 (6.25)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (3.13)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (3.13)	0	0 (0.00)
Blood lactic acid increased	1	1 (3.13)	1	1 (3.13)
Blood magnesium decreased	1	1 (3.13)	0	0 (0.00)
Cardiac murmur	1	1 (3.13)	0	0 (0.00)
Haemoglobin decreased	1	1 (3.13)	1	1 (3.13)
Hepatic enzyme increased	1	1 (3.13)	0	0 (0.00)
Lipase increased	1	1 (3.13)	1	1 (3.13)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Oxygen saturation decreased	1	1 (3.13)	0	0 (0.00)
Pulmonary function test decreased	1	1 (3.13)	0	0 (0.00)
Weight decreased	1	1 (3.13)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	57	20 (62.50)	23	12 (37.50)
Decreased appetite	11	9 (28.13)	4	3 (9.38)
Hypokalaemia	11	10 (31.25)	6	6 (18.75)
Hyperphosphataemia	6	3 (9.38)	0	0 (0.00)
Hypophosphataemia	6	5 (15.63)	4	4 (12.50)
Hyperglycaemia	4	2 (6.25)	1	1 (3.13)
Dehydration	3	3 (9.38)	2	2 (6.25)
Hypernatraemia	3	1 (3.13)	1	1 (3.13)
Hyperuricaemia	3	2 (6.25)	1	1 (3.13)
Hypocalcaemia	3	2 (6.25)	0	0 (0.00)
Hypertriglyceridaemia	2	1 (3.13)	1	1 (3.13)
Hyponatraemia	2	1 (3.13)	2	1 (3.13)
Fluid overload	1	1 (3.13)	0	0 (0.00)
Iron overload	1	1 (3.13)	1	1 (3.13)
Vitamin D deficiency	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	20	12 (37.50)	1	1 (3.13)
Pain in extremity	8	7 (21.88)	0	0 (0.00)
Arthralgia	4	3 (9.38)	1	1 (3.13)
Muscular weakness	3	3 (9.38)	0	0 (0.00)
Coccydynia	1	1 (3.13)	0	0 (0.00)
Flank pain	1	1 (3.13)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.13)	0	0 (0.00)
Pain in jaw	1	1 (3.13)	0	0 (0.00)
Toe walking	1	1 (3.13)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	2 (6.25)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (3.13)	0	0 (0.00)
Skin papilloma	1	1 (3.13)	0	0 (0.00)
Nervous system disorders				
- Total	35	17 (53.13)	4	4 (12.50)
Headache	20	13 (40.63)	1	1 (3.13)
Dizziness	4	2 (6.25)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Encephalopathy	3	1 (3.13)	1	1 (3.13)
Disturbance in attention	1	1 (3.13)	0	0 (0.00)
Dysarthria	1	1 (3.13)	0	0 (0.00)
Embolic stroke	1	1 (3.13)	1	1 (3.13)
Migraine	1	1 (3.13)	0	0 (0.00)
Peroneal nerve palsy	1	1 (3.13)	0	0 (0.00)
Seizure	1	1 (3.13)	1	1 (3.13)
Somnolence	1	1 (3.13)	0	0 (0.00)
Tremor	1	1 (3.13)	0	0 (0.00)
Product issues				
- Total	1	1 (3.13)	0	0 (0.00)
Device occlusion	1	1 (3.13)	0	0 (0.00)
Psychiatric disorders				
- Total	12	8 (25.00)	0	0 (0.00)
Anxiety	3	3 (9.38)	0	0 (0.00)
Confusional state	2	2 (6.25)	0	0 (0.00)
Depression	2	2 (6.25)	0	0 (0.00)
Delirium	1	1 (3.13)	0	0 (0.00)
Hallucination	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Mental status changes	1	1 (3.13)	0	0 (0.00)
Panic attack	1	1 (3.13)	0	0 (0.00)
Sleep disorder	1	1 (3.13)	0	0 (0.00)
Renal and urinary disorders				
- Total	10	6 (18.75)	4	3 (9.38)
Acute kidney injury	5	4 (12.50)	2	2 (6.25)
Haematuria	2	1 (3.13)	1	1 (3.13)
Calculus urinary	1	1 (3.13)	0	0 (0.00)
Nephrolithiasis	1	1 (3.13)	1	1 (3.13)
Urinary incontinence	1	1 (3.13)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	3	3 (9.38)	2	2 (6.25)
Ovarian failure	1	1 (3.13)	1	1 (3.13)
Vaginal haemorrhage	1	1 (3.13)	1	1 (3.13)
Vulvovaginal adhesion	1	1 (3.13)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	47	19 (59.38)	7	5 (15.63)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Epistaxis	10	6 (18.75)	3	3 (9.38)
Cough	9	7 (21.88)	0	0 (0.00)
Hypoxia	5	4 (12.50)	2	2 (6.25)
Nasal congestion	3	3 (9.38)	0	0 (0.00)
Oropharyngeal pain	3	3 (9.38)	0	0 (0.00)
Rhinorrhoea	3	3 (9.38)	0	0 (0.00)
Tachypnoea	3	2 (6.25)	0	0 (0.00)
Acute respiratory failure	1	1 (3.13)	1	1 (3.13)
Dysphonia	1	1 (3.13)	0	0 (0.00)
Oropharyngeal plaque	1	1 (3.13)	0	0 (0.00)
Pharyngeal erythema	1	1 (3.13)	0	0 (0.00)
Pharyngeal lesion	1	1 (3.13)	1	1 (3.13)
Pharyngeal ulceration	1	1 (3.13)	0	0 (0.00)
Pleural effusion	1	1 (3.13)	0	0 (0.00)
Pulmonary oedema	1	1 (3.13)	0	0 (0.00)
Respiratory depression	1	1 (3.13)	0	0 (0.00)
Rhinitis allergic	1	1 (3.13)	0	0 (0.00)
Wheezing	1	1 (3.13)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
- Total	33	14 (43.75)	0	0 (0.00)
Rash	5	4 (12.50)	0	0 (0.00)
Dry skin	4	4 (12.50)	0	0 (0.00)
Erythema	4	3 (9.38)	0	0 (0.00)
Pruritus	4	4 (12.50)	0	0 (0.00)
Rash erythematous	2	1 (3.13)	0	0 (0.00)
Acne	1	1 (3.13)	0	0 (0.00)
Alopecia	1	1 (3.13)	0	0 (0.00)
Dermatitis	1	1 (3.13)	0	0 (0.00)
Hyperhidrosis	1	1 (3.13)	0	0 (0.00)
Ingrowing nail	1	1 (3.13)	0	0 (0.00)
Keloid scar	1	1 (3.13)	0	0 (0.00)
Livedo reticularis	1	1 (3.13)	0	0 (0.00)
Papule	1	1 (3.13)	0	0 (0.00)
Petechiae	1	1 (3.13)	0	0 (0.00)
Rash follicular	1	1 (3.13)	0	0 (0.00)
Rash maculo-papular	1	1 (3.13)	0	0 (0.00)
Rash papular	1	1 (3.13)	0	0 (0.00)
Rash pruritic	1	1 (3.13)	0	0 (0.00)
Rash vesicular	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Vascular disorders				
- Total	18	10 (31.25)	6	5 (15.63)
Hypotension	8	5 (15.63)	5	4 (12.50)
Hypertension	6	6 (18.75)	0	0 (0.00)
Embolism	1	1 (3.13)	1	1 (3.13)
Flushing	1	1 (3.13)	0	0 (0.00)
Hot flush	1	1 (3.13)	0	0 (0.00)
Orthostatic hypotension	1	1 (3.13)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Total number of AE per patient	960	32 (100.00)	298	28 (87.50)
Blood and lymphatic system disorders				
- Total	97	26 (81.25)	69	22 (68.75)
Thrombocytopenia	31	8 (25.00)	23	8 (25.00)
Anaemia	30	16 (50.00)	17	10 (31.25)
Febrile neutropenia	15	12 (37.50)	15	12 (37.50)
Neutropenia	12	8 (25.00)	11	8 (25.00)
Lymphopenia	3	3 (9.38)	1	1 (3.13)
Disseminated intravascular coagulation	2	2 (6.25)	0	0 (0.00)
Eosinophilia	2	1 (3.13)	1	1 (3.13)
Coagulopathy	1	1 (3.13)	0	0 (0.00)
Leukopenia	1	1 (3.13)	1	1 (3.13)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Cardiac disorders				
- Total	23	15 (46.88)	3	2 (6.25)
Tachycardia	11	10 (31.25)	2	2 (6.25)
Sinus tachycardia	4	4 (12.50)	0	0 (0.00)
Pericardial effusion	2	2 (6.25)	0	0 (0.00)
Sinus bradycardia	2	1 (3.13)	0	0 (0.00)
Bradycardia	1	1 (3.13)	0	0 (0.00)
Left ventricular dysfunction	1	1 (3.13)	1	1 (3.13)
Palpitations	1	1 (3.13)	0	0 (0.00)
Ventricular tachycardia	1	1 (3.13)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (9.38)	0	0 (0.00)
Ear pain	1	1 (3.13)	0	0 (0.00)
Hypoacusis	1	1 (3.13)	0	0 (0.00)
Tympanic membrane perforation	1	1 (3.13)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (3.13)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Eye disorders				
- Total	15	8 (25.00)	0	0 (0.00)
Periorbital oedema	4	4 (12.50)	0	0 (0.00)
Conjunctival haemorrhage	3	3 (9.38)	0	0 (0.00)
Vision blurred	2	1 (3.13)	0	0 (0.00)
Eye pain	1	1 (3.13)	0	0 (0.00)
Ocular hypertension	1	1 (3.13)	0	0 (0.00)
Papilloedema	1	1 (3.13)	0	0 (0.00)
Retinal haemorrhage	1	1 (3.13)	0	0 (0.00)
Uveitis	1	1 (3.13)	0	0 (0.00)
Visual impairment	1	1 (3.13)	0	0 (0.00)
Gastrointestinal disorders				
- Total	82	22 (68.75)	8	6 (18.75)
Vomiting	22	13 (40.63)	0	0 (0.00)
Nausea	18	12 (37.50)	2	2 (6.25)
Diarrhoea	12	12 (37.50)	0	0 (0.00)
Abdominal pain	3	3 (9.38)	0	0 (0.00)
Constipation	3	2 (6.25)	0	0 (0.00)
Abdominal pain upper	2	2 (6.25)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Anal incontinence	2	1 (3.13)	0	0 (0.00)
Dysphagia	2	2 (6.25)	1	1 (3.13)
Haematemesis	2	2 (6.25)	0	0 (0.00)
Mouth haemorrhage	2	1 (3.13)	2	1 (3.13)
Stomatitis	2	2 (6.25)	0	0 (0.00)
Abdominal discomfort	1	1 (3.13)	0	0 (0.00)
Abdominal distension	1	1 (3.13)	0	0 (0.00)
Abdominal pain lower	1	1 (3.13)	0	0 (0.00)
Ascites	1	1 (3.13)	1	1 (3.13)
Enterocolitis	1	1 (3.13)	1	1 (3.13)
Flatulence	1	1 (3.13)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (3.13)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (3.13)	0	0 (0.00)
Lip pain	1	1 (3.13)	0	0 (0.00)
Pancreatitis	1	1 (3.13)	1	1 (3.13)
Pigmentation lip	1	1 (3.13)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (3.13)	0	0 (0.00)
General disorders and administration site conditions				
- Total	62	22 (68.75)	9	5 (15.63)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Pyrexia	20	10 (31.25)	2	2 (6.25)
Fatigue	11	10 (31.25)	1	1 (3.13)
Chills	10	9 (28.13)	0	0 (0.00)
Pain	3	3 (9.38)	1	1 (3.13)
Face oedema	2	2 (6.25)	1	1 (3.13)
Generalised oedema	2	1 (3.13)	0	0 (0.00)
Acquired gene mutation	1	1 (3.13)	0	0 (0.00)
Asthenia	1	1 (3.13)	0	0 (0.00)
Catheter site extravasation	1	1 (3.13)	0	0 (0.00)
Catheter site pain	1	1 (3.13)	0	0 (0.00)
Facial pain	1	1 (3.13)	0	0 (0.00)
Influenza like illness	1	1 (3.13)	0	0 (0.00)
Localised oedema	1	1 (3.13)	1	1 (3.13)
Malaise	1	1 (3.13)	0	0 (0.00)
Mucosal haemorrhage	1	1 (3.13)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (3.13)	1	1 (3.13)
Non-cardiac chest pain	1	1 (3.13)	0	0 (0.00)
Oedema peripheral	1	1 (3.13)	1	1 (3.13)
Peripheral swelling	1	1 (3.13)	0	0 (0.00)
Physical deconditioning	1	1 (3.13)	1	1 (3.13)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Hepatobiliary disorders				
- Total	8	6 (18.75)	2	2 (6.25)
Hepatomegaly	3	3 (9.38)	0	0 (0.00)
Hyperbilirubinaemia	3	2 (6.25)	2	2 (6.25)
Gallbladder enlargement	1	1 (3.13)	0	0 (0.00)
Hepatosplenomegaly	1	1 (3.13)	0	0 (0.00)
Immune system disorders				
- Total	62	29 (90.63)	21	12 (37.50)
Cytokine release syndrome	43	25 (78.13)	19	12 (37.50)
Hypogammaglobulinaemia	15	13 (40.63)	2	2 (6.25)
Drug hypersensitivity	1	1 (3.13)	0	0 (0.00)
Graft versus host disease	1	1 (3.13)	0	0 (0.00)
Graft versus host disease in skin	1	1 (3.13)	0	0 (0.00)
Immunodeficiency common variable	1	1 (3.13)	0	0 (0.00)
Infections and infestations				
- Total	64	22 (68.75)	14	8 (25.00)
Otitis media	7	4 (12.50)	1	1 (3.13)
Upper respiratory tract infection	7	5 (15.63)	1	1 (3.13)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Cellulitis of male external genital organ	6	1 (3.13)	3	1 (3.13)
Urinary tract infection	5	2 (6.25)	2	1 (3.13)
Clostridium difficile colitis	3	3 (9.38)	0	0 (0.00)
Otitis media acute	3	1 (3.13)	0	0 (0.00)
Pneumonia	3	3 (9.38)	1	1 (3.13)
Gastroenteritis	2	2 (6.25)	1	1 (3.13)
Sinusitis	2	2 (6.25)	0	0 (0.00)
Viral infection	2	2 (6.25)	0	0 (0.00)
Acute sinusitis	1	1 (3.13)	0	0 (0.00)
Body tinea	1	1 (3.13)	0	0 (0.00)
Cholecystitis infective	1	1 (3.13)	1	1 (3.13)
Corona virus infection	1	1 (3.13)	1	1 (3.13)
Gingivitis	1	1 (3.13)	0	0 (0.00)
Haemophilus infection	1	1 (3.13)	0	0 (0.00)
Herpes simplex	1	1 (3.13)	0	0 (0.00)
Herpes zoster	1	1 (3.13)	1	1 (3.13)
Human herpesvirus 6 infection	1	1 (3.13)	0	0 (0.00)
Hypopyon	1	1 (3.13)	0	0 (0.00)
Influenza	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Meningitis aseptic	1	1 (3.13)	0	0 (0.00)
Otitis externa	1	1 (3.13)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (3.13)	0	0 (0.00)
Paronychia	1	1 (3.13)	0	0 (0.00)
Pharyngitis	1	1 (3.13)	0	0 (0.00)
Rash pustular	1	1 (3.13)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (3.13)	1	1 (3.13)
Rhinovirus infection	1	1 (3.13)	0	0 (0.00)
Staphylococcal infection	1	1 (3.13)	0	0 (0.00)
Streptococcal infection	1	1 (3.13)	0	0 (0.00)
Vascular device infection	1	1 (3.13)	1	1 (3.13)
Viral upper respiratory tract infection	1	1 (3.13)	0	0 (0.00)
Vulvovaginal mycotic infection	1	1 (3.13)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	19	12 (37.50)	1	1 (3.13)
Procedural pain	2	2 (6.25)	0	0 (0.00)
Tracheal haemorrhage	2	1 (3.13)	1	1 (3.13)
Contusion	1	1 (3.13)	0	0 (0.00)
Foot fracture	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Incision site pain	1	1 (3.13)	0	0 (0.00)
Infusion related reaction	1	1 (3.13)	0	0 (0.00)
Limb injury	1	1 (3.13)	0	0 (0.00)
Mouth injury	1	1 (3.13)	0	0 (0.00)
Post procedural haemorrhage	1	1 (3.13)	0	0 (0.00)
Procedural complication	1	1 (3.13)	0	0 (0.00)
Procedural headache	1	1 (3.13)	0	0 (0.00)
Radius fracture	1	1 (3.13)	0	0 (0.00)
Skin abrasion	1	1 (3.13)	0	0 (0.00)
Stoma site irritation	1	1 (3.13)	0	0 (0.00)
Tibia fracture	1	1 (3.13)	0	0 (0.00)
Tongue injury	1	1 (3.13)	0	0 (0.00)
Transfusion reaction	1	1 (3.13)	0	0 (0.00)
Investigations				
- Total	217	26 (81.25)	87	21 (65.63)
White blood cell count decreased	27	14 (43.75)	15	10 (31.25)
Neutrophil count decreased	26	13 (40.63)	20	11 (34.38)
Alanine aminotransferase increased	22	13 (40.63)	11	9 (28.13)
Aspartate aminotransferase increased	22	12 (37.50)	12	7 (21.88)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Platelet count decreased	17	9 (28.13)	10	5 (15.63)
Blood fibrinogen decreased	15	4 (12.50)	4	3 (9.38)
Lymphocyte count decreased	13	8 (25.00)	6	5 (15.63)
Prothrombin time prolonged	12	6 (18.75)	1	1 (3.13)
International normalised ratio increased	11	9 (28.13)	1	1 (3.13)
Blood bilirubin increased	7	4 (12.50)	1	1 (3.13)
Blood creatinine increased	7	6 (18.75)	2	2 (6.25)
Activated partial thromboplastin time prolonged	5	3 (9.38)	0	0 (0.00)
Blood urea increased	5	3 (9.38)	1	1 (3.13)
Blood phosphorus increased	3	2 (6.25)	0	0 (0.00)
Blood uric acid increased	3	2 (6.25)	0	0 (0.00)
Transaminases increased	3	3 (9.38)	0	0 (0.00)
Weight decreased	3	3 (9.38)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (6.25)	0	0 (0.00)
Blood sodium increased	2	1 (3.13)	0	0 (0.00)
Haemoglobin decreased	2	2 (6.25)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (3.13)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Blood immunoglobulin G decreased	1	1 (3.13)	0	0 (0.00)
Blood magnesium decreased	1	1 (3.13)	1	1 (3.13)
Blood phosphorus decreased	1	1 (3.13)	0	0 (0.00)
Culture stool positive	1	1 (3.13)	0	0 (0.00)
Fibrin D dimer increased	1	1 (3.13)	0	0 (0.00)
Lipase increased	1	1 (3.13)	1	1 (3.13)
Norovirus test positive	1	1 (3.13)	0	0 (0.00)
Protein total decreased	1	1 (3.13)	1	1 (3.13)
Metabolism and nutrition disorders				
- Total	76	23 (71.88)	27	15 (46.88)
Decreased appetite	15	13 (40.63)	9	9 (28.13)
Hypokalaemia	12	9 (28.13)	3	3 (9.38)
Hypophosphataemia	8	5 (15.63)	6	4 (12.50)
Hyperphosphataemia	6	5 (15.63)	0	0 (0.00)
Hypoalbuminaemia	6	5 (15.63)	1	1 (3.13)
Hypernatraemia	4	3 (9.38)	0	0 (0.00)
Hyperalbuminaemia	3	1 (3.13)	0	0 (0.00)
Hypercalcaemia	3	1 (3.13)	0	0 (0.00)
Acidosis	2	2 (6.25)	1	1 (3.13)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Fluid overload	2	2 (6.25)	0	0 (0.00)
Tumour lysis syndrome	2	2 (6.25)	2	2 (6.25)
Dehydration	1	1 (3.13)	1	1 (3.13)
Hyperchloraemia	1	1 (3.13)	0	0 (0.00)
Hyperglycaemia	1	1 (3.13)	1	1 (3.13)
Hypermagnesaemia	1	1 (3.13)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (3.13)	0	0 (0.00)
Hyperuricaemia	1	1 (3.13)	0	0 (0.00)
Hypocalcaemia	1	1 (3.13)	1	1 (3.13)
Hypomagnesaemia	1	1 (3.13)	0	0 (0.00)
Hyponatraemia	1	1 (3.13)	1	1 (3.13)
Malnutrition	1	1 (3.13)	1	1 (3.13)
Metabolic acidosis	1	1 (3.13)	0	0 (0.00)
Metabolic alkalosis	1	1 (3.13)	0	0 (0.00)
Vitamin D deficiency	1	1 (3.13)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	25	13 (40.63)	0	0 (0.00)
Myalgia	5	5 (15.63)	0	0 (0.00)
Musculoskeletal pain	4	3 (9.38)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Pain in extremity	4	4 (12.50)	0	0 (0.00)
Arthralgia	2	2 (6.25)	0	0 (0.00)
Joint range of motion decreased	2	2 (6.25)	0	0 (0.00)
Muscle spasms	2	2 (6.25)	0	0 (0.00)
Back pain	1	1 (3.13)	0	0 (0.00)
Limb discomfort	1	1 (3.13)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.13)	0	0 (0.00)
Neck pain	1	1 (3.13)	0	0 (0.00)
Osteonecrosis	1	1 (3.13)	0	0 (0.00)
Osteopenia	1	1 (3.13)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.13)	1	1 (3.13)
Glioblastoma multiforme	1	1 (3.13)	1	1 (3.13)
Nervous system disorders				
- Total	39	18 (56.25)	3	2 (6.25)
Headache	19	11 (34.38)	1	1 (3.13)
Dizziness	4	4 (12.50)	0	0 (0.00)
Encephalopathy	3	3 (9.38)	1	1 (3.13)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Seizure	3	3 (9.38)	1	1 (3.13)
Asterixis	1	1 (3.13)	0	0 (0.00)
Ataxia	1	1 (3.13)	0	0 (0.00)
Depressed level of consciousness	1	1 (3.13)	0	0 (0.00)
Dysarthria	1	1 (3.13)	0	0 (0.00)
Idiopathic intracranial hypertension	1	1 (3.13)	0	0 (0.00)
Myoclonus	1	1 (3.13)	0	0 (0.00)
Neuropathy peripheral	1	1 (3.13)	0	0 (0.00)
Peroneal nerve palsy	1	1 (3.13)	0	0 (0.00)
Pleocytosis	1	1 (3.13)	0	0 (0.00)
Tremor	1	1 (3.13)	0	0 (0.00)
Psychiatric disorders				
- Total	22	9 (28.13)	1	1 (3.13)
Anxiety	4	4 (12.50)	1	1 (3.13)
Confusional state	4	4 (12.50)	0	0 (0.00)
Agitation	3	2 (6.25)	0	0 (0.00)
Delirium	3	3 (9.38)	0	0 (0.00)
Hallucination	2	1 (3.13)	0	0 (0.00)
Irritability	2	2 (6.25)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Adjustment disorder	1	1 (3.13)	0	0 (0.00)
Insomnia	1	1 (3.13)	0	0 (0.00)
Listless	1	1 (3.13)	0	0 (0.00)
Suicidal ideation	1	1 (3.13)	0	0 (0.00)
Renal and urinary disorders				
- Total	16	9 (28.13)	11	7 (21.88)
Acute kidney injury	5	5 (15.63)	5	5 (15.63)
Haematuria	4	4 (12.50)	2	2 (6.25)
Dysuria	2	2 (6.25)	0	0 (0.00)
Oliguria	2	2 (6.25)	2	2 (6.25)
Pollakiuria	1	1 (3.13)	0	0 (0.00)
Renal failure	1	1 (3.13)	1	1 (3.13)
Renal impairment	1	1 (3.13)	1	1 (3.13)
Reproductive system and breast disorders				
- Total	4	3 (9.38)	0	0 (0.00)
Oedema genital	2	1 (3.13)	0	0 (0.00)
Scrotal pain	1	1 (3.13)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	63	19 (59.38)	25	10 (31.25)
Cough	11	7 (21.88)	0	0 (0.00)
Hypoxia	8	6 (18.75)	6	5 (15.63)
Pleural effusion	7	7 (21.88)	2	2 (6.25)
Pulmonary oedema	6	6 (18.75)	6	6 (18.75)
Epistaxis	4	4 (12.50)	2	2 (6.25)
Rhinitis allergic	4	3 (9.38)	0	0 (0.00)
Dyspnoea	3	2 (6.25)	2	2 (6.25)
Haemoptysis	3	2 (6.25)	1	1 (3.13)
Oropharyngeal pain	3	3 (9.38)	0	0 (0.00)
Respiratory failure	3	3 (9.38)	3	3 (9.38)
Rhinorrhoea	3	3 (9.38)	0	0 (0.00)
Tachypnoea	3	3 (9.38)	1	1 (3.13)
Nasal congestion	2	2 (6.25)	0	0 (0.00)
Atelectasis	1	1 (3.13)	0	0 (0.00)
Interstitial lung disease	1	1 (3.13)	1	1 (3.13)
Respiratory distress	1	1 (3.13)	1	1 (3.13)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	36	16 (50.00)	3	3 (9.38)
Hyperhidrosis	4	3 (9.38)	0	0 (0.00)
Rash	4	4 (12.50)	0	0 (0.00)
Rash maculo-papular	4	4 (12.50)	1	1 (3.13)
Ingrowing nail	3	2 (6.25)	0	0 (0.00)
Petechiae	3	3 (9.38)	0	0 (0.00)
Erythema	2	2 (6.25)	0	0 (0.00)
Macule	2	2 (6.25)	0	0 (0.00)
Dermatitis acneiform	1	1 (3.13)	1	1 (3.13)
Dermatitis atopic	1	1 (3.13)	0	0 (0.00)
Dermatitis diaper	1	1 (3.13)	0	0 (0.00)
Dry skin	1	1 (3.13)	0	0 (0.00)
Ecchymosis	1	1 (3.13)	1	1 (3.13)
Eczema	1	1 (3.13)	0	0 (0.00)
Night sweats	1	1 (3.13)	0	0 (0.00)
Papule	1	1 (3.13)	0	0 (0.00)
Rash erythematous	1	1 (3.13)	0	0 (0.00)
Rash macular	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Rash papular	1	1 (3.13)	0	0 (0.00)
Skin exfoliation	1	1 (3.13)	0	0 (0.00)
Skin fissures	1	1 (3.13)	0	0 (0.00)
Skin irritation	1	1 (3.13)	0	0 (0.00)
Vascular disorders				
- Total	25	15 (46.88)	13	11 (34.38)
Hypotension	11	11 (34.38)	11	11 (34.38)
Hypertension	8	6 (18.75)	1	1 (3.13)
Flushing	2	1 (3.13)	0	0 (0.00)
Capillary leak syndrome	1	1 (3.13)	1	1 (3.13)
Haematoma	1	1 (3.13)	0	0 (0.00)
Orthostatic hypotension	1	1 (3.13)	0	0 (0.00)
Secondary hypertension	1	1 (3.13)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Total number of AE per patient	140	7 (100.00)	58	6 (85.71)
Blood and lymphatic system disorders				
- Total	11	5 (71.43)	9	4 (57.14)
Anaemia	5	4 (57.14)	3	2 (28.57)
Febrile neutropenia	2	2 (28.57)	2	2 (28.57)
Neutropenia	2	2 (28.57)	2	2 (28.57)
Thrombocytopenia	2	2 (28.57)	2	2 (28.57)
Cardiac disorders				
- Total	5	3 (42.86)	2	1 (14.29)
Tachycardia	2	2 (28.57)	1	1 (14.29)
Left ventricular dysfunction	1	1 (14.29)	1	1 (14.29)
Palpitations	1	1 (14.29)	0	0 (0.00)
Pericardial effusion	1	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Eye disorders				
- Total	2	1 (14.29)	0	0 (0.00)
Eye pain	2	1 (14.29)	0	0 (0.00)
Gastrointestinal disorders				
- Total	13	4 (57.14)	1	1 (14.29)
Nausea	5	3 (42.86)	1	1 (14.29)
Vomiting	4	3 (42.86)	0	0 (0.00)
Diarrhoea	3	3 (42.86)	0	0 (0.00)
Constipation	1	1 (14.29)	0	0 (0.00)
General disorders and administration site conditions				
- Total	8	3 (42.86)	3	3 (42.86)
Pyrexia	5	3 (42.86)	2	2 (28.57)
Asthenia	1	1 (14.29)	0	0 (0.00)
Chills	1	1 (14.29)	0	0 (0.00)
Pain	1	1 (14.29)	1	1 (14.29)
Hepatobiliary disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Hepatomegaly	1	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Immune system disorders				
- Total	15	7 (100.00)	6	3 (42.86)
Cytokine release syndrome	11	5 (71.43)	6	3 (42.86)
Hypogammaglobulinaemia	4	4 (57.14)	0	0 (0.00)
Infections and infestations				
- Total	2	2 (28.57)	0	0 (0.00)
Gastroenteritis	1	1 (14.29)	0	0 (0.00)
Viral infection	1	1 (14.29)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	1 (14.29)	1	1 (14.29)
Tracheal haemorrhage	2	1 (14.29)	1	1 (14.29)
Investigations				
- Total	35	7 (100.00)	15	5 (71.43)
White blood cell count decreased	10	4 (57.14)	6	3 (42.86)
Neutrophil count decreased	9	4 (57.14)	7	3 (42.86)
Blood uric acid increased	2	1 (14.29)	0	0 (0.00)
International normalised ratio increased	2	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Lymphocyte count decreased	2	2 (28.57)	0	0 (0.00)
Activated partial thromboplastin time prolonged	1	1 (14.29)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (14.29)	1	1 (14.29)
Blood creatinine increased	1	1 (14.29)	0	0 (0.00)
Blood fibrinogen decreased	1	1 (14.29)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (14.29)	0	0 (0.00)
Blood magnesium decreased	1	1 (14.29)	1	1 (14.29)
Blood phosphorus increased	1	1 (14.29)	0	0 (0.00)
Cardiac murmur	1	1 (14.29)	0	0 (0.00)
Fibrin D dimer increased	1	1 (14.29)	0	0 (0.00)
Prothrombin time prolonged	1	1 (14.29)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	9	4 (57.14)	2	1 (14.29)
Decreased appetite	3	3 (42.86)	1	1 (14.29)
Hypokalaemia	3	2 (28.57)	0	0 (0.00)
Hypernatraemia	1	1 (14.29)	0	0 (0.00)
Hypoalbuminaemia	1	1 (14.29)	0	0 (0.00)
Hypophosphataemia	1	1 (14.29)	1	1 (14.29)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	1	1 (14.29)	1	1 (14.29)
Arthralgia	1	1 (14.29)	1	1 (14.29)
Nervous system disorders				
- Total	4	4 (57.14)	0	0 (0.00)
Headache	3	3 (42.86)	0	0 (0.00)
Dizziness	1	1 (14.29)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (42.86)	0	0 (0.00)
Confusional state	2	2 (28.57)	0	0 (0.00)
Delirium	1	1 (14.29)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	2 (28.57)	5	2 (28.57)
Haematuria	2	2 (28.57)	2	2 (28.57)
Acute kidney injury	1	1 (14.29)	1	1 (14.29)
Oliguria	1	1 (14.29)	1	1 (14.29)
Renal failure	1	1 (14.29)	1	1 (14.29)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	13	3 (42.86)	9	2 (28.57)
Hypoxia	4	2 (28.57)	3	2 (28.57)
Cough	2	2 (28.57)	0	0 (0.00)
Dyspnoea	1	1 (14.29)	1	1 (14.29)
Epistaxis	1	1 (14.29)	1	1 (14.29)
Haemoptysis	1	1 (14.29)	1	1 (14.29)
Interstitial lung disease	1	1 (14.29)	1	1 (14.29)
Pleural effusion	1	1 (14.29)	0	0 (0.00)
Pulmonary oedema	1	1 (14.29)	1	1 (14.29)
Respiratory failure	1	1 (14.29)	1	1 (14.29)
Skin and subcutaneous tissue disorders				
- Total	5	4 (57.14)	0	0 (0.00)
Dermatitis diaper	1	1 (14.29)	0	0 (0.00)
Dry skin	1	1 (14.29)	0	0 (0.00)
Erythema	1	1 (14.29)	0	0 (0.00)
Livedo reticularis	1	1 (14.29)	0	0 (0.00)
Rash maculo-papular	1	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Vascular disorders				
- Total	6	4 (57.14)	4	4 (57.14)
Hypotension	4	4 (57.14)	4	4 (57.14)
Haematoma	1	1 (14.29)	0	0 (0.00)
Hypertension	1	1 (14.29)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	446	19 (95.00)	147	17 (85.00)
Blood and lymphatic system disorders				
- Total	29	14 (70.00)	24	12 (60.00)
Anaemia	12	8 (40.00)	9	6 (30.00)
Febrile neutropenia	10	9 (45.00)	10	9 (45.00)
Disseminated intravascular coagulation	4	3 (15.00)	2	2 (10.00)
Neutropenia	2	2 (10.00)	2	2 (10.00)
Lymphopenia	1	1 (5.00)	1	1 (5.00)
Cardiac disorders				
- Total	9	6 (30.00)	0	0 (0.00)
Tachycardia	4	3 (15.00)	0	0 (0.00)
Sinus tachycardia	2	2 (10.00)	0	0 (0.00)
Bradycardia	1	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Pericardial effusion	1	1 (5.00)	0	0 (0.00)
Ventricular tachycardia	1	1 (5.00)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Adrenal insufficiency	1	1 (5.00)	0	0 (0.00)
Eye disorders				
- Total	8	4 (20.00)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (10.00)	0	0 (0.00)
Periorbital oedema	2	2 (10.00)	0	0 (0.00)
Vision blurred	2	1 (5.00)	0	0 (0.00)
Retinal haemorrhage	1	1 (5.00)	0	0 (0.00)
Uveitis	1	1 (5.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	46	13 (65.00)	5	5 (25.00)
Vomiting	15	7 (35.00)	1	1 (5.00)
Nausea	7	5 (25.00)	1	1 (5.00)
Constipation	6	5 (25.00)	0	0 (0.00)
Diarrhoea	6	6 (30.00)	1	1 (5.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Abdominal pain	2	2 (10.00)	0	0 (0.00)
Dysphagia	2	2 (10.00)	1	1 (5.00)
Abdominal pain upper	1	1 (5.00)	0	0 (0.00)
Flatulence	1	1 (5.00)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (5.00)	0	0 (0.00)
Glossodynia	1	1 (5.00)	0	0 (0.00)
Haematemesis	1	1 (5.00)	0	0 (0.00)
Ileus	1	1 (5.00)	1	1 (5.00)
Pancreatitis	1	1 (5.00)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (5.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	25	12 (60.00)	8	5 (25.00)
Pyrexia	8	5 (25.00)	3	3 (15.00)
Fatigue	5	5 (25.00)	0	0 (0.00)
Catheter site haemorrhage	1	1 (5.00)	0	0 (0.00)
Catheter site pain	1	1 (5.00)	0	0 (0.00)
Chills	1	1 (5.00)	0	0 (0.00)
Face oedema	1	1 (5.00)	1	1 (5.00)
Generalised oedema	1	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Injection site haematoma	1	1 (5.00)	0	0 (0.00)
Localised oedema	1	1 (5.00)	1	1 (5.00)
Mucosal haemorrhage	1	1 (5.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (5.00)	1	1 (5.00)
Oedema peripheral	1	1 (5.00)	1	1 (5.00)
Pain	1	1 (5.00)	0	0 (0.00)
Physical deconditioning	1	1 (5.00)	1	1 (5.00)
Hepatobiliary disorders				
- Total	3	3 (15.00)	1	1 (5.00)
Gallbladder enlargement	1	1 (5.00)	0	0 (0.00)
Hepatosplenomegaly	1	1 (5.00)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (5.00)	1	1 (5.00)
Immune system disorders				
- Total	37	16 (80.00)	12	8 (40.00)
Cytokine release syndrome	31	16 (80.00)	11	7 (35.00)
Hypogammaglobulinaemia	6	6 (30.00)	1	1 (5.00)
Infections and infestations				
- Total	14	7 (35.00)	4	4 (20.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Clostridium difficile infection	2	2 (10.00)	0	0 (0.00)
Staphylococcal infection	2	2 (10.00)	1	1 (5.00)
Catheter site cellulitis	1	1 (5.00)	0	0 (0.00)
Clostridium difficile colitis	1	1 (5.00)	1	1 (5.00)
Cytomegalovirus infection	1	1 (5.00)	0	0 (0.00)
Enterococcal infection	1	1 (5.00)	0	0 (0.00)
Gastroenteritis	1	1 (5.00)	1	1 (5.00)
Gastroenteritis norovirus	1	1 (5.00)	0	0 (0.00)
Influenza	1	1 (5.00)	0	0 (0.00)
Pharyngitis	1	1 (5.00)	0	0 (0.00)
Pneumonia	1	1 (5.00)	1	1 (5.00)
Streptococcal infection	1	1 (5.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	6	5 (25.00)	1	1 (5.00)
Contusion	1	1 (5.00)	0	0 (0.00)
Post procedural haemorrhage	1	1 (5.00)	0	0 (0.00)
Procedural complication	1	1 (5.00)	0	0 (0.00)
Subdural haemorrhage	1	1 (5.00)	0	0 (0.00)
Transfusion reaction	1	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Transfusion related complication	1	1 (5.00)	1	1 (5.00)
Investigations				
- Total	112	15 (75.00)	60	15 (75.00)
Platelet count decreased	16	9 (45.00)	13	7 (35.00)
Aspartate aminotransferase increased	15	7 (35.00)	6	4 (20.00)
Neutrophil count decreased	14	8 (40.00)	14	8 (40.00)
White blood cell count decreased	14	10 (50.00)	9	8 (40.00)
Alanine aminotransferase increased	10	7 (35.00)	6	4 (20.00)
Prothrombin time prolonged	7	3 (15.00)	0	0 (0.00)
Activated partial thromboplastin time prolonged	6	3 (15.00)	0	0 (0.00)
Lymphocyte count decreased	6	6 (30.00)	6	6 (30.00)
Blood creatinine increased	5	4 (20.00)	1	1 (5.00)
Blood bilirubin increased	4	2 (10.00)	0	0 (0.00)
International normalised ratio increased	4	3 (15.00)	0	0 (0.00)
Blood phosphorus increased	2	1 (5.00)	0	0 (0.00)
Blood fibrinogen decreased	1	1 (5.00)	1	1 (5.00)
Blood immunoglobulin A decreased	1	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Blood immunoglobulin M decreased	1	1 (5.00)	0	0 (0.00)
Blood phosphorus decreased	1	1 (5.00)	0	0 (0.00)
Blood urea increased	1	1 (5.00)	1	1 (5.00)
Haemoglobin decreased	1	1 (5.00)	1	1 (5.00)
Hepatic enzyme increased	1	1 (5.00)	0	0 (0.00)
Lipase increased	1	1 (5.00)	1	1 (5.00)
Protein total decreased	1	1 (5.00)	1	1 (5.00)
Metabolism and nutrition disorders				
- Total	44	11 (55.00)	13	9 (45.00)
Decreased appetite	6	4 (20.00)	3	3 (15.00)
Hypernatraemia	6	3 (15.00)	1	1 (5.00)
Hyperphosphataemia	5	4 (20.00)	0	0 (0.00)
Hypokalaemia	4	3 (15.00)	3	3 (15.00)
Hyperglycaemia	3	2 (10.00)	0	0 (0.00)
Hyperuricaemia	3	2 (10.00)	1	1 (5.00)
Acidosis	2	2 (10.00)	1	1 (5.00)
Dehydration	2	2 (10.00)	1	1 (5.00)
Hypercalcaemia	2	1 (5.00)	0	0 (0.00)
Hypertriglyceridaemia	2	1 (5.00)	1	1 (5.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Hypophosphataemia	2	2 (10.00)	1	1 (5.00)
Hyperalbuminaemia	1	1 (5.00)	0	0 (0.00)
Hyperchloraemia	1	1 (5.00)	0	0 (0.00)
Hypermagnesaemia	1	1 (5.00)	0	0 (0.00)
Hypoalbuminaemia	1	1 (5.00)	0	0 (0.00)
Hypocalcaemia	1	1 (5.00)	0	0 (0.00)
Metabolic alkalosis	1	1 (5.00)	0	0 (0.00)
Tumour lysis syndrome	1	1 (5.00)	1	1 (5.00)
Musculoskeletal and connective tissue disorders				
- Total	6	3 (15.00)	0	0 (0.00)
Arthralgia	2	2 (10.00)	0	0 (0.00)
Coccydynia	1	1 (5.00)	0	0 (0.00)
Muscular weakness	1	1 (5.00)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (5.00)	0	0 (0.00)
Musculoskeletal pain	1	1 (5.00)	0	0 (0.00)
Nervous system disorders				
- Total	28	12 (60.00)	1	1 (5.00)
Headache	12	9 (45.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Encephalopathy	4	2 (10.00)	1	1 (5.00)
Dysarthria	2	2 (10.00)	0	0 (0.00)
Tremor	2	2 (10.00)	0	0 (0.00)
Asterixis	1	1 (5.00)	0	0 (0.00)
Ataxia	1	1 (5.00)	0	0 (0.00)
Depressed level of consciousness	1	1 (5.00)	0	0 (0.00)
Dizziness	1	1 (5.00)	0	0 (0.00)
Neuropathy peripheral	1	1 (5.00)	0	0 (0.00)
Pleocytosis	1	1 (5.00)	0	0 (0.00)
Seizure	1	1 (5.00)	0	0 (0.00)
Somnolence	1	1 (5.00)	0	0 (0.00)
Product issues				
- Total	1	1 (5.00)	0	0 (0.00)
Device occlusion	1	1 (5.00)	0	0 (0.00)
Psychiatric disorders				
- Total	10	4 (20.00)	0	0 (0.00)
Delirium	2	2 (10.00)	0	0 (0.00)
Adjustment disorder	1	1 (5.00)	0	0 (0.00)
Agitation	1	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Anxiety	1	1 (5.00)	0	0 (0.00)
Confusional state	1	1 (5.00)	0	0 (0.00)
Hallucination	1	1 (5.00)	0	0 (0.00)
Insomnia	1	1 (5.00)	0	0 (0.00)
Irritability	1	1 (5.00)	0	0 (0.00)
Suicidal ideation	1	1 (5.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	4	4 (20.00)	2	2 (10.00)
Acute kidney injury	3	3 (15.00)	1	1 (5.00)
Renal impairment	1	1 (5.00)	1	1 (5.00)
Reproductive system and breast disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (5.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	28	9 (45.00)	9	5 (25.00)
Epistaxis	7	3 (15.00)	2	2 (10.00)
Tachypnoea	4	3 (15.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Pleural effusion	3	3 (15.00)	1	1 (5.00)
Pulmonary oedema	3	3 (15.00)	2	2 (10.00)
Haemoptysis	2	1 (5.00)	0	0 (0.00)
Hypoxia	2	2 (10.00)	2	2 (10.00)
Cough	1	1 (5.00)	0	0 (0.00)
Nasal congestion	1	1 (5.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (5.00)	0	0 (0.00)
Oropharyngeal plaque	1	1 (5.00)	0	0 (0.00)
Respiratory distress	1	1 (5.00)	1	1 (5.00)
Respiratory failure	1	1 (5.00)	1	1 (5.00)
Rhinorrhoea	1	1 (5.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	22	8 (40.00)	1	1 (5.00)
Hyperhidrosis	4	3 (15.00)	0	0 (0.00)
Dry skin	3	3 (15.00)	0	0 (0.00)
Erythema	2	1 (5.00)	0	0 (0.00)
Petechiae	2	2 (10.00)	0	0 (0.00)
Ecchymosis	1	1 (5.00)	1	1 (5.00)
Ingrowing nail	1	1 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Macule	1	1 (5.00)	0	0 (0.00)
Pruritus	1	1 (5.00)	0	0 (0.00)
Rash	1	1 (5.00)	0	0 (0.00)
Rash erythematous	1	1 (5.00)	0	0 (0.00)
Rash macular	1	1 (5.00)	0	0 (0.00)
Rash papular	1	1 (5.00)	0	0 (0.00)
Rash vesicular	1	1 (5.00)	0	0 (0.00)
Skin exfoliation	1	1 (5.00)	0	0 (0.00)
Skin fissures	1	1 (5.00)	0	0 (0.00)
Vascular disorders				
- Total	12	6 (30.00)	6	4 (20.00)
Hypotension	5	4 (20.00)	5	4 (20.00)
Flushing	2	1 (5.00)	0	0 (0.00)
Hypertension	2	2 (10.00)	0	0 (0.00)
Capillary leak syndrome	1	1 (5.00)	1	1 (5.00)
Orthostatic hypotension	1	1 (5.00)	0	0 (0.00)
Secondary hypertension	1	1 (5.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Total number of AE per patient	388	21 (100.00)	149	20 (95.24)
Blood and lymphatic system disorders				
- Total	54	15 (71.43)	41	14 (66.67)
Thrombocytopenia	20	4 (19.05)	17	4 (19.05)
Anaemia	14	7 (33.33)	8	5 (23.81)
Febrile neutropenia	11	8 (38.10)	11	8 (38.10)
Neutropenia	4	3 (14.29)	3	3 (14.29)
Lymphopenia	2	2 (9.52)	1	1 (4.76)
Coagulopathy	1	1 (4.76)	0	0 (0.00)
Disseminated intravascular coagulation	1	1 (4.76)	0	0 (0.00)
Pancytopenia	1	1 (4.76)	1	1 (4.76)
Cardiac disorders				

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
- Total	9	7 (33.33)	0	0 (0.00)
Tachycardia	5	5 (23.81)	0	0 (0.00)
Sinus bradycardia	2	1 (4.76)	0	0 (0.00)
Atrioventricular block second degree	1	1 (4.76)	0	0 (0.00)
Sinus tachycardia	1	1 (4.76)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (4.76)	0	0 (0.00)
Hypoacusis	1	1 (4.76)	0	0 (0.00)
Eye disorders				
- Total	10	5 (23.81)	0	0 (0.00)
Photophobia	3	2 (9.52)	0	0 (0.00)
Eye pain	2	2 (9.52)	0	0 (0.00)
Vision blurred	2	2 (9.52)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (4.76)	0	0 (0.00)
Periorbital oedema	1	1 (4.76)	0	0 (0.00)
Retinal haemorrhage	1	1 (4.76)	0	0 (0.00)
Gastrointestinal disorders				
- Total	34	10 (47.62)	7	4 (19.05)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Vomiting	9	7 (33.33)	2	2 (9.52)
Nausea	8	7 (33.33)	1	1 (4.76)
Diarrhoea	4	4 (19.05)	0	0 (0.00)
Abdominal pain	2	2 (9.52)	1	1 (4.76)
Anal incontinence	2	1 (4.76)	0	0 (0.00)
Abdominal discomfort	1	1 (4.76)	0	0 (0.00)
Abdominal pain upper	1	1 (4.76)	0	0 (0.00)
Ascites	1	1 (4.76)	1	1 (4.76)
Constipation	1	1 (4.76)	0	0 (0.00)
Dyspepsia	1	1 (4.76)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (4.76)	0	0 (0.00)
Intestinal obstruction	1	1 (4.76)	1	1 (4.76)
Pancreatitis	1	1 (4.76)	1	1 (4.76)
Stomatitis	1	1 (4.76)	0	0 (0.00)
General disorders and administration site conditions				
- Total	21	9 (42.86)	0	0 (0.00)
Pyrexia	8	5 (23.81)	0	0 (0.00)
Chills	6	5 (23.81)	0	0 (0.00)
Fatigue	3	3 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Malaise	2	2 (9.52)	0	0 (0.00)
Catheter site pain	1	1 (4.76)	0	0 (0.00)
Non-cardiac chest pain	1	1 (4.76)	0	0 (0.00)
Hepatobiliary disorders				
- Total	2	2 (9.52)	0	0 (0.00)
Hepatomegaly	1	1 (4.76)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (4.76)	0	0 (0.00)
Immune system disorders				
- Total	39	20 (95.24)	9	7 (33.33)
Cytokine release syndrome	26	18 (85.71)	6	5 (23.81)
Hypogammaglobulinaemia	12	11 (52.38)	3	3 (14.29)
Drug hypersensitivity	1	1 (4.76)	0	0 (0.00)
Infections and infestations				
- Total	15	9 (42.86)	3	3 (14.29)
Rhinovirus infection	3	3 (14.29)	0	0 (0.00)
Clostridium difficile colitis	2	2 (9.52)	0	0 (0.00)
Acute sinusitis	1	1 (4.76)	0	0 (0.00)
Catheter site infection	1	1 (4.76)	1	1 (4.76)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Clostridium difficile infection	1	1 (4.76)	0	0 (0.00)
Folliculitis	1	1 (4.76)	0	0 (0.00)
Orchitis	1	1 (4.76)	0	0 (0.00)
Pneumonia	1	1 (4.76)	0	0 (0.00)
Septic embolus	1	1 (4.76)	1	1 (4.76)
Upper respiratory tract infection	1	1 (4.76)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (4.76)	1	1 (4.76)
Viral upper respiratory tract infection	1	1 (4.76)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	6	4 (19.05)	0	0 (0.00)
Transfusion reaction	2	1 (4.76)	0	0 (0.00)
Incision site pain	1	1 (4.76)	0	0 (0.00)
Procedural pain	1	1 (4.76)	0	0 (0.00)
Stoma site irritation	1	1 (4.76)	0	0 (0.00)
Tibia fracture	1	1 (4.76)	0	0 (0.00)
Investigations				
- Total	93	17 (80.95)	51	16 (76.19)
White blood cell count decreased	20	10 (47.62)	15	10 (47.62)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Blood fibrinogen decreased	13	2 (9.52)	3	2 (9.52)
Neutrophil count decreased	10	7 (33.33)	10	7 (33.33)
Alanine aminotransferase increased	8	7 (33.33)	5	5 (23.81)
Platelet count decreased	8	5 (23.81)	6	3 (14.29)
Prothrombin time prolonged	8	4 (19.05)	1	1 (4.76)
Blood bilirubin increased	6	2 (9.52)	1	1 (4.76)
Aspartate aminotransferase increased	5	4 (19.05)	4	3 (14.29)
Lymphocyte count decreased	3	3 (14.29)	3	3 (14.29)
Blood sodium increased	2	1 (4.76)	0	0 (0.00)
International normalised ratio increased	2	2 (9.52)	1	1 (4.76)
Transaminases increased	2	2 (9.52)	0	0 (0.00)
Blood creatinine increased	1	1 (4.76)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (4.76)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (4.76)	0	0 (0.00)
Blood urea increased	1	1 (4.76)	0	0 (0.00)
C-reactive protein increased	1	1 (4.76)	1	1 (4.76)
Lipase increased	1	1 (4.76)	1	1 (4.76)
Metabolism and nutrition disorders				

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
- Total	37	14 (66.67)	22	10 (47.62)
Decreased appetite	10	9 (42.86)	7	6 (28.57)
Hypokalaemia	6	5 (23.81)	2	2 (9.52)
Hypophosphataemia	6	4 (19.05)	6	4 (19.05)
Hyperphosphataemia	3	2 (9.52)	0	0 (0.00)
Hyponatraemia	3	2 (9.52)	3	2 (9.52)
Hypoalbuminaemia	2	1 (4.76)	1	1 (4.76)
Dehydration	1	1 (4.76)	1	1 (4.76)
Fluid overload	1	1 (4.76)	0	0 (0.00)
Hyperglycaemia	1	1 (4.76)	1	1 (4.76)
Hypertriglyceridaemia	1	1 (4.76)	0	0 (0.00)
Hypomagnesaemia	1	1 (4.76)	0	0 (0.00)
Malnutrition	1	1 (4.76)	1	1 (4.76)
Metabolic acidosis	1	1 (4.76)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	6	4 (19.05)	0	0 (0.00)
Musculoskeletal pain	2	1 (4.76)	0	0 (0.00)
Limb discomfort	1	1 (4.76)	0	0 (0.00)
Myalgia	1	1 (4.76)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Osteopenia	1	1 (4.76)	0	0 (0.00)
Pain in extremity	1	1 (4.76)	0	0 (0.00)
Nervous system disorders				
- Total	14	9 (42.86)	4	3 (14.29)
Headache	10	6 (28.57)	2	2 (9.52)
Embolic stroke	1	1 (4.76)	1	1 (4.76)
Encephalopathy	1	1 (4.76)	1	1 (4.76)
Migraine	1	1 (4.76)	0	0 (0.00)
Seizure	1	1 (4.76)	0	0 (0.00)
Psychiatric disorders				
- Total	7	6 (28.57)	0	0 (0.00)
Anxiety	2	2 (9.52)	0	0 (0.00)
Confusional state	2	2 (9.52)	0	0 (0.00)
Delirium	1	1 (4.76)	0	0 (0.00)
Mental status changes	1	1 (4.76)	0	0 (0.00)
Panic attack	1	1 (4.76)	0	0 (0.00)
Renal and urinary disorders				
- Total	6	4 (19.05)	2	2 (9.52)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Acute kidney injury	2	2 (9.52)	2	2 (9.52)
Dysuria	2	2 (9.52)	0	0 (0.00)
Haematuria	1	1 (4.76)	0	0 (0.00)
Pollakiuria	1	1 (4.76)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	17	7 (33.33)	5	3 (14.29)
Hypoxia	4	3 (14.29)	2	2 (9.52)
Cough	3	3 (14.29)	0	0 (0.00)
Pleural effusion	2	2 (9.52)	1	1 (4.76)
Atelectasis	1	1 (4.76)	0	0 (0.00)
Epistaxis	1	1 (4.76)	0	0 (0.00)
Pharyngeal ulceration	1	1 (4.76)	0	0 (0.00)
Pulmonary oedema	1	1 (4.76)	1	1 (4.76)
Respiratory depression	1	1 (4.76)	0	0 (0.00)
Respiratory failure	1	1 (4.76)	1	1 (4.76)
Rhinitis allergic	1	1 (4.76)	0	0 (0.00)
Tachypnoea	1	1 (4.76)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
- Total	7	5 (23.81)	1	1 (4.76)
Ingrowing nail	2	1 (4.76)	0	0 (0.00)
Rash maculo-papular	2	2 (9.52)	1	1 (4.76)
Erythema	1	1 (4.76)	0	0 (0.00)
Pruritus	1	1 (4.76)	0	0 (0.00)
Rash	1	1 (4.76)	0	0 (0.00)
Vascular disorders				
- Total	10	8 (38.10)	4	4 (19.05)
Hypertension	5	4 (19.05)	0	0 (0.00)
Hypotension	4	4 (19.05)	4	4 (19.05)
Orthostatic hypotension	1	1 (4.76)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Total number of AE per patient	340	16 (100.00)	104	11 (68.75)
Blood and lymphatic system disorders				
- Total	28	9 (56.25)	19	8 (50.00)
Anaemia	16	8 (50.00)	11	6 (37.50)
Thrombocytopenia	8	2 (12.50)	4	2 (12.50)
Febrile neutropenia	3	3 (18.75)	3	3 (18.75)
Neutropenia	1	1 (6.25)	1	1 (6.25)
Cardiac disorders				
- Total	9	6 (37.50)	1	1 (6.25)
Tachycardia	6	5 (31.25)	1	1 (6.25)
Sinus tachycardia	2	2 (12.50)	0	0 (0.00)
Cardiac dysfunction	1	1 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Ear and labyrinth disorders				
- Total	2	2 (12.50)	0	0 (0.00)
Ear pain	2	2 (12.50)	0	0 (0.00)
Eye disorders				
- Total	5	3 (18.75)	0	0 (0.00)
Ocular hypertension	1	1 (6.25)	0	0 (0.00)
Papilloedema	1	1 (6.25)	0	0 (0.00)
Periorbital oedema	1	1 (6.25)	0	0 (0.00)
Uveitis	1	1 (6.25)	0	0 (0.00)
Visual impairment	1	1 (6.25)	0	0 (0.00)
Gastrointestinal disorders				
- Total	33	9 (56.25)	2	1 (6.25)
Vomiting	7	5 (31.25)	0	0 (0.00)
Abdominal pain	6	5 (31.25)	0	0 (0.00)
Nausea	6	6 (37.50)	0	0 (0.00)
Diarrhoea	5	5 (31.25)	0	0 (0.00)
Abdominal distension	2	2 (12.50)	0	0 (0.00)
Mouth haemorrhage	2	1 (6.25)	2	1 (6.25)
Abdominal pain lower	1	1 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Abdominal tenderness	1	1 (6.25)	0	0 (0.00)
Haematemesis	1	1 (6.25)	0	0 (0.00)
Lip pain	1	1 (6.25)	0	0 (0.00)
Stomatitis	1	1 (6.25)	0	0 (0.00)
General disorders and administration site conditions				
- Total	23	8 (50.00)	3	2 (12.50)
Fatigue	6	5 (31.25)	1	1 (6.25)
Pyrexia	6	3 (18.75)	1	1 (6.25)
Generalised oedema	2	1 (6.25)	0	0 (0.00)
Catheter site extravasation	1	1 (6.25)	0	0 (0.00)
Catheter site pain	1	1 (6.25)	0	0 (0.00)
Chills	1	1 (6.25)	0	0 (0.00)
Face oedema	1	1 (6.25)	0	0 (0.00)
Facial pain	1	1 (6.25)	0	0 (0.00)
Malaise	1	1 (6.25)	0	0 (0.00)
Oedema peripheral	1	1 (6.25)	0	0 (0.00)
Pain	1	1 (6.25)	1	1 (6.25)
Peripheral swelling	1	1 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Hepatobiliary disorders				
- Total	3	1 (6.25)	1	1 (6.25)
Hyperbilirubinaemia	2	1 (6.25)	1	1 (6.25)
Hepatomegaly	1	1 (6.25)	0	0 (0.00)
Immune system disorders				
- Total	25	14 (87.50)	6	4 (25.00)
Cytokine release syndrome	18	11 (68.75)	6	4 (25.00)
Hypogammaglobulinaemia	5	5 (31.25)	0	0 (0.00)
Graft versus host disease in skin	1	1 (6.25)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (6.25)	0	0 (0.00)
Infections and infestations				
- Total	10	8 (50.00)	0	0 (0.00)
Body tinea	1	1 (6.25)	0	0 (0.00)
Clostridium difficile colitis	1	1 (6.25)	0	0 (0.00)
Clostridium difficile infection	1	1 (6.25)	0	0 (0.00)
Fungal skin infection	1	1 (6.25)	0	0 (0.00)
Herpes simplex	1	1 (6.25)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Hypopyon	1	1 (6.25)	0	0 (0.00)
Oral candidiasis	1	1 (6.25)	0	0 (0.00)
Skin infection	1	1 (6.25)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (6.25)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	11	5 (31.25)	0	0 (0.00)
Infusion related reaction	2	2 (12.50)	0	0 (0.00)
Procedural pain	2	2 (12.50)	0	0 (0.00)
Limb injury	1	1 (6.25)	0	0 (0.00)
Mouth injury	1	1 (6.25)	0	0 (0.00)
Procedural headache	1	1 (6.25)	0	0 (0.00)
Procedural site reaction	1	1 (6.25)	0	0 (0.00)
Skin abrasion	1	1 (6.25)	0	0 (0.00)
Tongue injury	1	1 (6.25)	0	0 (0.00)
Transfusion reaction	1	1 (6.25)	0	0 (0.00)
Investigations				
- Total	92	13 (81.25)	52	8 (50.00)
Platelet count decreased	19	5 (31.25)	18	4 (25.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Neutrophil count decreased	14	6 (37.50)	13	5 (31.25)
Aspartate aminotransferase increased	11	6 (37.50)	5	3 (18.75)
White blood cell count decreased	11	6 (37.50)	7	5 (31.25)
Alanine aminotransferase increased	10	5 (31.25)	3	2 (12.50)
Lymphocyte count decreased	5	3 (18.75)	3	2 (12.50)
Blood creatinine increased	4	3 (18.75)	1	1 (6.25)
Blood bilirubin increased	3	3 (18.75)	1	1 (6.25)
International normalised ratio increased	3	3 (18.75)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (12.50)	0	0 (0.00)
Activated partial thromboplastin time prolonged	1	1 (6.25)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (6.25)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (6.25)	0	0 (0.00)
Blood lactic acid increased	1	1 (6.25)	1	1 (6.25)
Blood urea increased	1	1 (6.25)	0	0 (0.00)
Culture stool positive	1	1 (6.25)	0	0 (0.00)
Norovirus test positive	1	1 (6.25)	0	0 (0.00)
Prothrombin time prolonged	1	1 (6.25)	0	0 (0.00)
Pulmonary function test decreased	1	1 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Serum ferritin increased	1	1 (6.25)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	26	10 (62.50)	6	4 (25.00)
Hypokalaemia	7	6 (37.50)	2	2 (12.50)
Decreased appetite	5	4 (25.00)	2	2 (12.50)
Hypophosphataemia	4	2 (12.50)	1	1 (6.25)
Hypocalcaemia	3	2 (12.50)	1	1 (6.25)
Fluid overload	2	2 (12.50)	0	0 (0.00)
Hyperphosphataemia	2	2 (12.50)	0	0 (0.00)
Hypoalbuminaemia	2	2 (12.50)	0	0 (0.00)
Hyperuricaemia	1	1 (6.25)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	10	7 (43.75)	0	0 (0.00)
Myalgia	4	4 (25.00)	0	0 (0.00)
Pain in extremity	3	3 (18.75)	0	0 (0.00)
Arthralgia	1	1 (6.25)	0	0 (0.00)
Muscle spasms	1	1 (6.25)	0	0 (0.00)
Musculoskeletal pain	1	1 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (6.25)	0	0 (0.00)
Skin papilloma	1	1 (6.25)	0	0 (0.00)
Nervous system disorders				
- Total	12	8 (50.00)	1	1 (6.25)
Headache	6	6 (37.50)	0	0 (0.00)
Dizziness	2	2 (12.50)	0	0 (0.00)
Encephalopathy	1	1 (6.25)	0	0 (0.00)
Idiopathic intracranial hypertension	1	1 (6.25)	0	0 (0.00)
Myoclonus	1	1 (6.25)	0	0 (0.00)
Seizure	1	1 (6.25)	1	1 (6.25)
Psychiatric disorders				
- Total	10	3 (18.75)	1	1 (6.25)
Anxiety	3	3 (18.75)	1	1 (6.25)
Agitation	2	1 (6.25)	0	0 (0.00)
Hallucination	2	1 (6.25)	0	0 (0.00)
Confusional state	1	1 (6.25)	0	0 (0.00)
Irritability	1	1 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Listless	1	1 (6.25)	0	0 (0.00)
Renal and urinary disorders				
- Total	3	1 (6.25)	2	1 (6.25)
Acute kidney injury	1	1 (6.25)	1	1 (6.25)
Haematuria	1	1 (6.25)	0	0 (0.00)
Oliguria	1	1 (6.25)	1	1 (6.25)
Reproductive system and breast disorders				
- Total	3	2 (12.50)	0	0 (0.00)
Oedema genital	2	1 (6.25)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (6.25)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	15	9 (56.25)	5	2 (12.50)
Hypoxia	3	3 (18.75)	1	1 (6.25)
Cough	2	2 (12.50)	0	0 (0.00)
Dyspnoea	2	1 (6.25)	1	1 (6.25)
Epistaxis	2	2 (12.50)	1	1 (6.25)
Pleural effusion	2	2 (12.50)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Oropharyngeal pain	1	1 (6.25)	0	0 (0.00)
Pulmonary oedema	1	1 (6.25)	1	1 (6.25)
Tachypnoea	1	1 (6.25)	1	1 (6.25)
Wheezing	1	1 (6.25)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	7	4 (25.00)	0	0 (0.00)
Rash	2	2 (12.50)	0	0 (0.00)
Night sweats	1	1 (6.25)	0	0 (0.00)
Petechiae	1	1 (6.25)	0	0 (0.00)
Rash follicular	1	1 (6.25)	0	0 (0.00)
Rash papular	1	1 (6.25)	0	0 (0.00)
Skin irritation	1	1 (6.25)	0	0 (0.00)
Vascular disorders				
- Total	12	6 (37.50)	5	4 (25.00)
Hypotension	6	4 (25.00)	3	3 (18.75)
Hypertension	4	3 (18.75)	1	1 (6.25)
Embolism	1	1 (6.25)	1	1 (6.25)
Flushing	1	1 (6.25)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	59	4 (80.00)	7	2 (40.00)
Endocrine disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Adrenal insufficiency	1	1 (20.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	11	4 (80.00)	2	2 (40.00)
Oral pain	3	2 (40.00)	1	1 (20.00)
Vomiting	3	2 (40.00)	0	0 (0.00)
Diarrhoea	2	2 (40.00)	0	0 (0.00)
Abdominal pain	1	1 (20.00)	0	0 (0.00)
Enterocolitis	1	1 (20.00)	1	1 (20.00)
Nausea	1	1 (20.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
General disorders and administration site conditions				
- Total	3	3 (60.00)	0	0 (0.00)
Catheter site pain	1	1 (20.00)	0	0 (0.00)
Fatigue	1	1 (20.00)	0	0 (0.00)
Pyrexia	1	1 (20.00)	0	0 (0.00)
Immune system disorders				
- Total	2	1 (20.00)	0	0 (0.00)
Graft versus host disease	2	1 (20.00)	0	0 (0.00)
Infections and infestations				
- Total	10	4 (80.00)	2	1 (20.00)
Rhinovirus infection	3	1 (20.00)	0	0 (0.00)
Upper respiratory tract infection	2	2 (40.00)	0	0 (0.00)
Corona virus infection	1	1 (20.00)	1	1 (20.00)
Ear infection	1	1 (20.00)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (20.00)	1	1 (20.00)
Tinea capitis	1	1 (20.00)	0	0 (0.00)
Viral infection	1	1 (20.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Injury, poisoning and procedural complications				
- Total	4	1 (20.00)	0	0 (0.00)
Contusion	1	1 (20.00)	0	0 (0.00)
Infusion related reaction	1	1 (20.00)	0	0 (0.00)
Procedural nausea	1	1 (20.00)	0	0 (0.00)
Sunburn	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	3	2 (40.00)	1	1 (20.00)
Blood bilirubin increased	1	1 (20.00)	1	1 (20.00)
Blood magnesium decreased	1	1 (20.00)	0	0 (0.00)
Weight decreased	1	1 (20.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	5	3 (60.00)	0	0 (0.00)
Pain in extremity	2	2 (40.00)	0	0 (0.00)
Arthralgia	1	1 (20.00)	0	0 (0.00)
Muscular weakness	1	1 (20.00)	0	0 (0.00)
Pain in jaw	1	1 (20.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Nervous system disorders				
- Total	2	2 (40.00)	0	0 (0.00)
Headache	1	1 (20.00)	0	0 (0.00)
Peroneal nerve palsy	1	1 (20.00)	0	0 (0.00)
Psychiatric disorders				
- Total	3	1 (20.00)	0	0 (0.00)
Anxiety	1	1 (20.00)	0	0 (0.00)
Depression	1	1 (20.00)	0	0 (0.00)
Sleep disorder	1	1 (20.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	8	4 (80.00)	2	1 (20.00)
Rhinorrhoea	2	2 (40.00)	0	0 (0.00)
Cough	1	1 (20.00)	0	0 (0.00)
Epistaxis	1	1 (20.00)	1	1 (20.00)
Nasal congestion	1	1 (20.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (20.00)	0	0 (0.00)
Pharyngeal erythema	1	1 (20.00)	0	0 (0.00)
Pharyngeal lesion	1	1 (20.00)	1	1 (20.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	4	1 (20.00)	0	0 (0.00)
Rash erythematous	2	1 (20.00)	0	0 (0.00)
Alopecia	1	1 (20.00)	0	0 (0.00)
Erythema	1	1 (20.00)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (40.00)	0	0 (0.00)
Hypertension	2	2 (40.00)	0	0 (0.00)
Hot flush	1	1 (20.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Total number of AE per patient	101	17 (89.47)	31	10 (52.63)
Blood and lymphatic system disorders				
- Total	7	3 (15.79)	7	3 (15.79)
Neutropenia	3	1 (5.26)	3	1 (5.26)
Febrile neutropenia	2	2 (10.53)	2	2 (10.53)
Anaemia	1	1 (5.26)	1	1 (5.26)
Leukopenia	1	1 (5.26)	1	1 (5.26)
Eye disorders				
- Total	2	2 (10.53)	0	0 (0.00)
Dry eye	1	1 (5.26)	0	0 (0.00)
Vision blurred	1	1 (5.26)	0	0 (0.00)
Gastrointestinal disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
- Total	9	3 (15.79)	2	1 (5.26)
Nausea	3	2 (10.53)	1	1 (5.26)
Vomiting	3	1 (5.26)	1	1 (5.26)
Diarrhoea	2	2 (10.53)	0	0 (0.00)
Abdominal pain	1	1 (5.26)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	3 (15.79)	1	1 (5.26)
Acquired gene mutation	1	1 (5.26)	0	0 (0.00)
Generalised oedema	1	1 (5.26)	0	0 (0.00)
Oedema peripheral	1	1 (5.26)	0	0 (0.00)
Pyrexia	1	1 (5.26)	1	1 (5.26)
Immune system disorders				
- Total	8	6 (31.58)	1	1 (5.26)
Hypogammaglobulinaemia	4	3 (15.79)	1	1 (5.26)
Immunodeficiency common variable	2	2 (10.53)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (5.26)	0	0 (0.00)
Seasonal allergy	1	1 (5.26)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Infections and infestations				
- Total	19	14 (73.68)	5	4 (21.05)
Gastroenteritis	2	2 (10.53)	0	0 (0.00)
Influenza	2	2 (10.53)	0	0 (0.00)
Urinary tract infection	2	2 (10.53)	1	1 (5.26)
Escherichia urinary tract infection	1	1 (5.26)	1	1 (5.26)
Gastroenteritis norovirus	1	1 (5.26)	0	0 (0.00)
Herpes zoster	1	1 (5.26)	1	1 (5.26)
Oral herpes	1	1 (5.26)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (5.26)	0	0 (0.00)
Rash pustular	1	1 (5.26)	0	0 (0.00)
Rhinitis	1	1 (5.26)	0	0 (0.00)
Rhinovirus infection	1	1 (5.26)	0	0 (0.00)
Sepsis	1	1 (5.26)	1	1 (5.26)
Subcutaneous abscess	1	1 (5.26)	0	0 (0.00)
Upper respiratory tract infection	1	1 (5.26)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (5.26)	1	1 (5.26)
Vulvovaginal mycotic infection	1	1 (5.26)	0	0 (0.00)
Investigations				

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
- Total	16	8 (42.11)	6	4 (21.05)
Neutrophil count decreased	6	3 (15.79)	4	3 (15.79)
Aspartate aminotransferase increased	2	2 (10.53)	2	2 (10.53)
Blood urea increased	2	1 (5.26)	0	0 (0.00)
White blood cell count decreased	2	2 (10.53)	0	0 (0.00)
Blood creatinine increased	1	1 (5.26)	0	0 (0.00)
Platelet count decreased	1	1 (5.26)	0	0 (0.00)
Serum ferritin increased	1	1 (5.26)	0	0 (0.00)
Weight increased	1	1 (5.26)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	10	5 (26.32)	4	2 (10.53)
Hyperalbuminaemia	2	1 (5.26)	0	0 (0.00)
Hypokalaemia	2	2 (10.53)	1	1 (5.26)
Decreased appetite	1	1 (5.26)	0	0 (0.00)
Hypercalcaemia	1	1 (5.26)	0	0 (0.00)
Hyperglycaemia	1	1 (5.26)	1	1 (5.26)
Hyperphosphataemia	1	1 (5.26)	0	0 (0.00)
Hypophosphataemia	1	1 (5.26)	1	1 (5.26)
Iron overload	1	1 (5.26)	1	1 (5.26)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	6	5 (26.32)	0	0 (0.00)
Pain in extremity	2	2 (10.53)	0	0 (0.00)
Flank pain	1	1 (5.26)	0	0 (0.00)
Muscular weakness	1	1 (5.26)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (5.26)	0	0 (0.00)
Osteonecrosis	1	1 (5.26)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (5.26)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (5.26)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (5.26)	0	0 (0.00)
Depression	1	1 (5.26)	0	0 (0.00)
Renal and urinary disorders				
- Total	4	2 (10.53)	3	2 (10.53)
Acute kidney injury	1	1 (5.26)	1	1 (5.26)
Calculus urinary	1	1 (5.26)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Haematuria	1	1 (5.26)	1	1 (5.26)
Nephrolithiasis	1	1 (5.26)	1	1 (5.26)
Respiratory, thoracic and mediastinal disorders				
- Total	6	5 (26.32)	2	2 (10.53)
Acute respiratory failure	1	1 (5.26)	1	1 (5.26)
Cough	1	1 (5.26)	0	0 (0.00)
Epistaxis	1	1 (5.26)	0	0 (0.00)
Nasal congestion	1	1 (5.26)	0	0 (0.00)
Oropharyngeal pain	1	1 (5.26)	0	0 (0.00)
Pulmonary oedema	1	1 (5.26)	1	1 (5.26)
Skin and subcutaneous tissue disorders				
- Total	8	7 (36.84)	0	0 (0.00)
Rash	2	2 (10.53)	0	0 (0.00)
Dry skin	1	1 (5.26)	0	0 (0.00)
Eczema	1	1 (5.26)	0	0 (0.00)
Keloid scar	1	1 (5.26)	0	0 (0.00)
Papule	1	1 (5.26)	0	0 (0.00)
Petechiae	1	1 (5.26)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=19 n (%)[1]	Grade >= 3 Total events	All patients N=19 n (%)[2]
Rash pruritic	1	1 (5.26)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Total number of AE per patient	87	14 (77.78)	19	9 (50.00)
Blood and lymphatic system disorders				
- Total	5	4 (22.22)	3	2 (11.11)
Neutropenia	2	2 (11.11)	2	2 (11.11)
Febrile neutropenia	1	1 (5.56)	1	1 (5.56)
Lymphadenopathy	1	1 (5.56)	0	0 (0.00)
Thrombocytopenia	1	1 (5.56)	0	0 (0.00)
Eye disorders				
- Total	1	1 (5.56)	0	0 (0.00)
Conjunctivitis allergic	1	1 (5.56)	0	0 (0.00)
Gastrointestinal disorders				
- Total	9	4 (22.22)	4	1 (5.56)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Diarrhoea	3	3 (16.67)	1	1 (5.56)
Vomiting	3	3 (16.67)	1	1 (5.56)
Nausea	2	2 (11.11)	1	1 (5.56)
Abdominal pain	1	1 (5.56)	1	1 (5.56)
General disorders and administration site conditions				
- Total	5	5 (27.78)	0	0 (0.00)
Pyrexia	3	3 (16.67)	0	0 (0.00)
Influenza like illness	1	1 (5.56)	0	0 (0.00)
Malaise	1	1 (5.56)	0	0 (0.00)
Immune system disorders				
- Total	4	4 (22.22)	0	0 (0.00)
Hypogammaglobulinaemia	3	3 (16.67)	0	0 (0.00)
Seasonal allergy	1	1 (5.56)	0	0 (0.00)
Infections and infestations				
- Total	13	9 (50.00)	3	3 (16.67)
Bacterial sepsis	1	1 (5.56)	1	1 (5.56)
Cholecystitis infective	1	1 (5.56)	1	1 (5.56)
Gastroenteritis	1	1 (5.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Gastroenteritis viral	1	1 (5.56)	0	0 (0.00)
Influenza	1	1 (5.56)	0	0 (0.00)
Molluscum contagiosum	1	1 (5.56)	0	0 (0.00)
Otitis externa	1	1 (5.56)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (5.56)	1	1 (5.56)
Paronychia	1	1 (5.56)	0	0 (0.00)
Sinusitis	1	1 (5.56)	0	0 (0.00)
Upper respiratory tract infection	1	1 (5.56)	0	0 (0.00)
Urinary tract infection	1	1 (5.56)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (5.56)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	7	5 (27.78)	0	0 (0.00)
Procedural pain	2	2 (11.11)	0	0 (0.00)
Arthropod bite	1	1 (5.56)	0	0 (0.00)
Foot fracture	1	1 (5.56)	0	0 (0.00)
Infusion related reaction	1	1 (5.56)	0	0 (0.00)
Radius fracture	1	1 (5.56)	0	0 (0.00)
Skin abrasion	1	1 (5.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Investigations				
- Total	16	8 (44.44)	6	5 (27.78)
White blood cell count decreased	4	2 (11.11)	3	2 (11.11)
Weight decreased	3	3 (16.67)	0	0 (0.00)
Neutrophil count decreased	2	2 (11.11)	2	2 (11.11)
Platelet count decreased	2	1 (5.56)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (5.56)	1	1 (5.56)
Aspartate aminotransferase increased	1	1 (5.56)	0	0 (0.00)
Haemoglobin decreased	1	1 (5.56)	0	0 (0.00)
Oxygen saturation decreased	1	1 (5.56)	0	0 (0.00)
Transaminases increased	1	1 (5.56)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	1	1 (5.56)	1	1 (5.56)
Tumour lysis syndrome	1	1 (5.56)	1	1 (5.56)
Musculoskeletal and connective tissue disorders				
- Total	4	4 (22.22)	0	0 (0.00)
Pain in extremity	2	2 (11.11)	0	0 (0.00)
Arthralgia	1	1 (5.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Toe walking	1	1 (5.56)	0	0 (0.00)
Nervous system disorders				
- Total	5	4 (22.22)	0	0 (0.00)
Dizziness	2	2 (11.11)	0	0 (0.00)
Headache	2	2 (11.11)	0	0 (0.00)
Peroneal nerve palsy	1	1 (5.56)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (5.56)	1	1 (5.56)
Vaginal haemorrhage	1	1 (5.56)	1	1 (5.56)
Respiratory, thoracic and mediastinal disorders				
- Total	10	6 (33.33)	0	0 (0.00)
Cough	3	2 (11.11)	0	0 (0.00)
Rhinitis allergic	2	2 (11.11)	0	0 (0.00)
Rhinorrhoea	2	2 (11.11)	0	0 (0.00)
Dysphonia	1	1 (5.56)	0	0 (0.00)
Nasal congestion	1	1 (5.56)	0	0 (0.00)
Oropharyngeal pain	1	1 (5.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=18 n (%)[1]	Grade >= 3 Total events	All patients N=18 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	6	4 (22.22)	1	1 (5.56)
Dermatitis	1	1 (5.56)	0	0 (0.00)
Dermatitis acneiform	1	1 (5.56)	1	1 (5.56)
Erythema	1	1 (5.56)	0	0 (0.00)
Hyperhidrosis	1	1 (5.56)	0	0 (0.00)
Ingrowing nail	1	1 (5.56)	0	0 (0.00)
Rash	1	1 (5.56)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Total number of AE per patient	99	11 (78.57)	14	5 (35.71)
Blood and lymphatic system disorders				
- Total	6	4 (28.57)	3	2 (14.29)
Eosinophilia	2	1 (7.14)	1	1 (7.14)
Anaemia	1	1 (7.14)	0	0 (0.00)
Lymphopenia	1	1 (7.14)	0	0 (0.00)
Neutropenia	1	1 (7.14)	1	1 (7.14)
Thrombocytopenia	1	1 (7.14)	1	1 (7.14)
Cardiac disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Sinus tachycardia	1	1 (7.14)	0	0 (0.00)
Eye disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
- Total	2	2 (14.29)	0	0 (0.00)
Dry eye	1	1 (7.14)	0	0 (0.00)
Ocular hyperaemia	1	1 (7.14)	0	0 (0.00)
Gastrointestinal disorders				
- Total	9	5 (35.71)	0	0 (0.00)
Vomiting	4	3 (21.43)	0	0 (0.00)
Abdominal pain	1	1 (7.14)	0	0 (0.00)
Abdominal pain upper	1	1 (7.14)	0	0 (0.00)
Diarrhoea	1	1 (7.14)	0	0 (0.00)
Nausea	1	1 (7.14)	0	0 (0.00)
Pigmentation lip	1	1 (7.14)	0	0 (0.00)
General disorders and administration site conditions				
- Total	14	6 (42.86)	0	0 (0.00)
Pyrexia	9	5 (35.71)	0	0 (0.00)
Chills	1	1 (7.14)	0	0 (0.00)
Crying	1	1 (7.14)	0	0 (0.00)
Fatigue	1	1 (7.14)	0	0 (0.00)
Influenza like illness	1	1 (7.14)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Pain	1	1 (7.14)	0	0 (0.00)
Immune system disorders				
- Total	3	3 (21.43)	0	0 (0.00)
Hypogammaglobulinaemia	2	2 (14.29)	0	0 (0.00)
Graft versus host disease	1	1 (7.14)	0	0 (0.00)
Infections and infestations				
- Total	19	6 (42.86)	7	4 (28.57)
Cellulitis of male external genital organ	5	1 (7.14)	2	1 (7.14)
Upper respiratory tract infection	3	3 (21.43)	1	1 (7.14)
Otitis media	2	1 (7.14)	0	0 (0.00)
Urinary tract infection	2	1 (7.14)	1	1 (7.14)
Cytomegalovirus infection	1	1 (7.14)	0	0 (0.00)
Ear infection	1	1 (7.14)	0	0 (0.00)
Enterovirus infection	1	1 (7.14)	1	1 (7.14)
Otitis media acute	1	1 (7.14)	0	0 (0.00)
Rotavirus infection	1	1 (7.14)	1	1 (7.14)
Sinusitis	1	1 (7.14)	0	0 (0.00)
Vascular device infection	1	1 (7.14)	1	1 (7.14)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Injury, poisoning and procedural complications				
- Total	2	2 (14.29)	0	0 (0.00)
Contusion	1	1 (7.14)	0	0 (0.00)
Skin laceration	1	1 (7.14)	0	0 (0.00)
Investigations				
- Total	13	5 (35.71)	3	2 (14.29)
Neutrophil count decreased	4	3 (21.43)	2	1 (7.14)
Lymphocyte count decreased	2	2 (14.29)	0	0 (0.00)
Platelet count decreased	2	1 (7.14)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (7.14)	1	1 (7.14)
Blood uric acid increased	1	1 (7.14)	0	0 (0.00)
Haemoglobin decreased	1	1 (7.14)	0	0 (0.00)
Weight increased	1	1 (7.14)	0	0 (0.00)
White blood cell count decreased	1	1 (7.14)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	4	4 (28.57)	1	1 (7.14)
Decreased appetite	1	1 (7.14)	0	0 (0.00)
Dehydration	1	1 (7.14)	1	1 (7.14)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Hyperphosphataemia	1	1 (7.14)	0	0 (0.00)
Vitamin D deficiency	1	1 (7.14)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	6	4 (28.57)	0	0 (0.00)
Joint range of motion decreased	2	2 (14.29)	0	0 (0.00)
Pain in extremity	2	2 (14.29)	0	0 (0.00)
Back pain	1	1 (7.14)	0	0 (0.00)
Muscle spasms	1	1 (7.14)	0	0 (0.00)
Nervous system disorders				
- Total	5	2 (14.29)	0	0 (0.00)
Headache	4	2 (14.29)	0	0 (0.00)
Dizziness	1	1 (7.14)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Urinary incontinence	1	1 (7.14)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (7.14)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Scrotal pain	1	1 (7.14)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	6	3 (21.43)	0	0 (0.00)
Cough	4	3 (21.43)	0	0 (0.00)
Nasal congestion	1	1 (7.14)	0	0 (0.00)
Rhinitis allergic	1	1 (7.14)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	7	4 (28.57)	0	0 (0.00)
Rash	2	1 (7.14)	0	0 (0.00)
Rash maculo-papular	2	2 (14.29)	0	0 (0.00)
Dermatitis atopic	1	1 (7.14)	0	0 (0.00)
Macule	1	1 (7.14)	0	0 (0.00)
Pruritus	1	1 (7.14)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	2	2 (40.00)	1	1 (20.00)
Infections and infestations				
- Total	1	1 (20.00)	0	0 (0.00)
Skin infection	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	1	1 (20.00)	1	1 (20.00)
White blood cell count decreased	1	1 (20.00)	1	1 (20.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Total number of AE per patient	23	7 (63.64)	5	3 (27.27)
Ear and labyrinth disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Tympanic membrane perforation	1	1 (9.09)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Chronic graft versus host disease	1	1 (9.09)	0	0 (0.00)
Infections and infestations				
- Total	13	3 (27.27)	1	1 (9.09)
Otitis media	4	2 (18.18)	1	1 (9.09)
Otitis media acute	3	1 (9.09)	0	0 (0.00)
Gingivitis	1	1 (9.09)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Haemophilus infection	1	1 (9.09)	0	0 (0.00)
Meningitis aseptic	1	1 (9.09)	0	0 (0.00)
Pneumonia	1	1 (9.09)	0	0 (0.00)
Sinusitis	1	1 (9.09)	0	0 (0.00)
Viral infection	1	1 (9.09)	0	0 (0.00)
Investigations				
- Total	1	1 (9.09)	1	1 (9.09)
White blood cell count decreased	1	1 (9.09)	1	1 (9.09)
Metabolism and nutrition disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Vitamin D deficiency	1	1 (9.09)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (9.09)	1	1 (9.09)
Glioblastoma multiforme	1	1 (9.09)	1	1 (9.09)
Nervous system disorders				
- Total	1	1 (9.09)	1	1 (9.09)
Seizure	1	1 (9.09)	1	1 (9.09)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Renal and urinary disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Haematuria	1	1 (9.09)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (9.09)	1	1 (9.09)
Ovarian failure	1	1 (9.09)	1	1 (9.09)
Respiratory, thoracic and mediastinal disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Epistaxis	1	1 (9.09)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Papule	1	1 (9.09)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Total number of AE per patient	33	6 (60.00)	11	5 (50.00)
Blood and lymphatic system disorders				
- Total	1	1 (10.00)	1	1 (10.00)
Febrile neutropenia	1	1 (10.00)	1	1 (10.00)
Gastrointestinal disorders				
- Total	1	1 (10.00)	0	0 (0.00)
Nausea	1	1 (10.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	1 (10.00)	0	0 (0.00)
Pyrexia	2	1 (10.00)	0	0 (0.00)
Chills	1	1 (10.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Immune system disorders				
- Total	1	1 (10.00)	0	0 (0.00)
Immunodeficiency	1	1 (10.00)	0	0 (0.00)
Infections and infestations				
- Total	7	3 (30.00)	1	1 (10.00)
Upper respiratory tract infection	3	1 (10.00)	0	0 (0.00)
Sinusitis	2	2 (20.00)	0	0 (0.00)
Pneumonia	1	1 (10.00)	0	0 (0.00)
Respiratory tract infection	1	1 (10.00)	1	1 (10.00)
Injury, poisoning and procedural complications				
- Total	1	1 (10.00)	1	1 (10.00)
Procedural pain	1	1 (10.00)	1	1 (10.00)
Investigations				
- Total	12	4 (40.00)	6	3 (30.00)
Alanine aminotransferase increased	3	3 (30.00)	2	2 (20.00)
Aspartate aminotransferase increased	2	2 (20.00)	1	1 (10.00)
Lymphocyte count decreased	2	1 (10.00)	1	1 (10.00)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Blood alkaline phosphatase increased	1	1 (10.00)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (10.00)	0	0 (0.00)
C-reactive protein increased	1	1 (10.00)	0	0 (0.00)
Platelet count decreased	1	1 (10.00)	1	1 (10.00)
White blood cell count decreased	1	1 (10.00)	1	1 (10.00)
Metabolism and nutrition disorders				
- Total	1	1 (10.00)	1	1 (10.00)
Hypokalaemia	1	1 (10.00)	1	1 (10.00)
Nervous system disorders				
- Total	1	1 (10.00)	0	0 (0.00)
Disturbance in attention	1	1 (10.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	2	1 (10.00)	1	1 (10.00)
Acute kidney injury	2	1 (10.00)	1	1 (10.00)
Respiratory, thoracic and mediastinal disorders				
- Total	1	1 (10.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Cough	1	1 (10.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	2 (20.00)	0	0 (0.00)
Acne	1	1 (10.00)	0	0 (0.00)
Pruritus	1	1 (10.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=8 n (%)[1]	Grade >= 3 Total events	All patients N=8 n (%)[2]
Total number of AE per patient	32	7 (87.50)	6	3 (37.50)
Blood and lymphatic system disorders				
- Total	1	1 (12.50)	0	0 (0.00)
Thrombocytopenia	1	1 (12.50)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	2 (25.00)	0	0 (0.00)
Diarrhoea	2	2 (25.00)	0	0 (0.00)
Abdominal pain	1	1 (12.50)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (12.50)	1	1 (12.50)
Cyst	1	1 (12.50)	1	1 (12.50)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=8 n (%)[1]	Grade >= 3 Total events	All patients N=8 n (%)[2]
Infections and infestations				
- Total	11	4 (50.00)	5	2 (25.00)
Urinary tract infection	3	2 (25.00)	1	1 (12.50)
Campylobacter infection	1	1 (12.50)	1	1 (12.50)
Cellulitis of male external genital organ	1	1 (12.50)	1	1 (12.50)
Clostridium difficile infection	1	1 (12.50)	1	1 (12.50)
Otitis media	1	1 (12.50)	0	0 (0.00)
Otitis media acute	1	1 (12.50)	0	0 (0.00)
Respiratory tract infection viral	1	1 (12.50)	1	1 (12.50)
Upper respiratory tract infection	1	1 (12.50)	0	0 (0.00)
Vulvovaginal candidiasis	1	1 (12.50)	0	0 (0.00)
Investigations				
- Total	8	2 (25.00)	0	0 (0.00)
Lymphocyte count decreased	3	2 (25.00)	0	0 (0.00)
Neutrophil count decreased	3	2 (25.00)	0	0 (0.00)
White blood cell count decreased	2	1 (12.50)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (12.50)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=8 n (%)[1]	Grade >= 3 Total events	All patients N=8 n (%)[2]
Neck pain	1	1 (12.50)	0	0 (0.00)
Nervous system disorders				
- Total	2	1 (12.50)	0	0 (0.00)
Dizziness	1	1 (12.50)	0	0 (0.00)
Headache	1	1 (12.50)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	5	2 (25.00)	0	0 (0.00)
Cough	2	1 (12.50)	0	0 (0.00)
Oropharyngeal pain	1	1 (12.50)	0	0 (0.00)
Rhinitis allergic	1	1 (12.50)	0	0 (0.00)
Rhinorrhoea	1	1 (12.50)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Total number of AE per patient	201	7 (100.00)	66	6 (85.71)
Blood and lymphatic system disorders				
- Total	11	5 (71.43)	9	4 (57.14)
Anaemia	5	4 (57.14)	3	2 (28.57)
Febrile neutropenia	2	2 (28.57)	2	2 (28.57)
Neutropenia	2	2 (28.57)	2	2 (28.57)
Thrombocytopenia	2	2 (28.57)	2	2 (28.57)
Cardiac disorders				
- Total	5	3 (42.86)	2	1 (14.29)
Tachycardia	2	2 (28.57)	1	1 (14.29)
Left ventricular dysfunction	1	1 (14.29)	1	1 (14.29)
Palpitations	1	1 (14.29)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Pericardial effusion	1	1 (14.29)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Adrenal insufficiency	1	1 (14.29)	0	0 (0.00)
Eye disorders				
- Total	2	1 (14.29)	0	0 (0.00)
Eye pain	2	1 (14.29)	0	0 (0.00)
Gastrointestinal disorders				
- Total	24	6 (85.71)	3	3 (42.86)
Vomiting	7	5 (71.43)	0	0 (0.00)
Nausea	6	4 (57.14)	1	1 (14.29)
Diarrhoea	5	4 (57.14)	0	0 (0.00)
Oral pain	3	2 (28.57)	1	1 (14.29)
Abdominal pain	1	1 (14.29)	0	0 (0.00)
Constipation	1	1 (14.29)	0	0 (0.00)
Enterocolitis	1	1 (14.29)	1	1 (14.29)
General disorders and administration site conditions				

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
- Total	11	5 (71.43)	3	3 (42.86)
Pyrexia	6	4 (57.14)	2	2 (28.57)
Asthenia	1	1 (14.29)	0	0 (0.00)
Catheter site pain	1	1 (14.29)	0	0 (0.00)
Chills	1	1 (14.29)	0	0 (0.00)
Fatigue	1	1 (14.29)	0	0 (0.00)
Pain	1	1 (14.29)	1	1 (14.29)
Hepatobiliary disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Hepatomegaly	1	1 (14.29)	0	0 (0.00)
Immune system disorders				
- Total	17	7 (100.00)	6	3 (42.86)
Cytokine release syndrome	11	5 (71.43)	6	3 (42.86)
Hypogammaglobulinaemia	4	4 (57.14)	0	0 (0.00)
Graft versus host disease	2	1 (14.29)	0	0 (0.00)
Infections and infestations				
- Total	13	4 (57.14)	2	1 (14.29)
Rhinovirus infection	3	1 (14.29)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Upper respiratory tract infection	2	2 (28.57)	0	0 (0.00)
Viral infection	2	2 (28.57)	0	0 (0.00)
Corona virus infection	1	1 (14.29)	1	1 (14.29)
Ear infection	1	1 (14.29)	0	0 (0.00)
Gastroenteritis	1	1 (14.29)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (14.29)	1	1 (14.29)
Skin infection	1	1 (14.29)	0	0 (0.00)
Tinea capitis	1	1 (14.29)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	6	2 (28.57)	1	1 (14.29)
Tracheal haemorrhage	2	1 (14.29)	1	1 (14.29)
Contusion	1	1 (14.29)	0	0 (0.00)
Infusion related reaction	1	1 (14.29)	0	0 (0.00)
Procedural nausea	1	1 (14.29)	0	0 (0.00)
Sunburn	1	1 (14.29)	0	0 (0.00)
Investigations				
- Total	39	7 (100.00)	17	6 (85.71)
White blood cell count decreased	11	4 (57.14)	7	3 (42.86)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Neutrophil count decreased	9	4 (57.14)	7	3 (42.86)
Blood magnesium decreased	2	2 (28.57)	1	1 (14.29)
Blood uric acid increased	2	1 (14.29)	0	0 (0.00)
International normalised ratio increased	2	1 (14.29)	0	0 (0.00)
Lymphocyte count decreased	2	2 (28.57)	0	0 (0.00)
Activated partial thromboplastin time prolonged	1	1 (14.29)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (14.29)	1	1 (14.29)
Blood bilirubin increased	1	1 (14.29)	1	1 (14.29)
Blood creatinine increased	1	1 (14.29)	0	0 (0.00)
Blood fibrinogen decreased	1	1 (14.29)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (14.29)	0	0 (0.00)
Blood phosphorus increased	1	1 (14.29)	0	0 (0.00)
Cardiac murmur	1	1 (14.29)	0	0 (0.00)
Fibrin D dimer increased	1	1 (14.29)	0	0 (0.00)
Prothrombin time prolonged	1	1 (14.29)	0	0 (0.00)
Weight decreased	1	1 (14.29)	0	0 (0.00)
Metabolism and nutrition disorders				

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
- Total	9	4 (57.14)	2	1 (14.29)
Decreased appetite	3	3 (42.86)	1	1 (14.29)
Hypokalaemia	3	2 (28.57)	0	0 (0.00)
Hypernatraemia	1	1 (14.29)	0	0 (0.00)
Hypoalbuminaemia	1	1 (14.29)	0	0 (0.00)
Hypophosphataemia	1	1 (14.29)	1	1 (14.29)
Musculoskeletal and connective tissue disorders				
- Total	6	3 (42.86)	1	1 (14.29)
Arthralgia	2	1 (14.29)	1	1 (14.29)
Pain in extremity	2	2 (28.57)	0	0 (0.00)
Muscular weakness	1	1 (14.29)	0	0 (0.00)
Pain in jaw	1	1 (14.29)	0	0 (0.00)
Nervous system disorders				
- Total	6	4 (57.14)	0	0 (0.00)
Headache	4	3 (42.86)	0	0 (0.00)
Dizziness	1	1 (14.29)	0	0 (0.00)
Peroneal nerve palsy	1	1 (14.29)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Psychiatric disorders				
- Total	6	3 (42.86)	0	0 (0.00)
Confusional state	2	2 (28.57)	0	0 (0.00)
Anxiety	1	1 (14.29)	0	0 (0.00)
Delirium	1	1 (14.29)	0	0 (0.00)
Depression	1	1 (14.29)	0	0 (0.00)
Sleep disorder	1	1 (14.29)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	2 (28.57)	5	2 (28.57)
Haematuria	2	2 (28.57)	2	2 (28.57)
Acute kidney injury	1	1 (14.29)	1	1 (14.29)
Oliguria	1	1 (14.29)	1	1 (14.29)
Renal failure	1	1 (14.29)	1	1 (14.29)
Respiratory, thoracic and mediastinal disorders				
- Total	21	6 (85.71)	11	3 (42.86)
Hypoxia	4	2 (28.57)	3	2 (28.57)
Cough	3	3 (42.86)	0	0 (0.00)
Epistaxis	2	2 (28.57)	2	2 (28.57)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Rhinorrhoea	2	2 (28.57)	0	0 (0.00)
Dyspnoea	1	1 (14.29)	1	1 (14.29)
Haemoptysis	1	1 (14.29)	1	1 (14.29)
Interstitial lung disease	1	1 (14.29)	1	1 (14.29)
Nasal congestion	1	1 (14.29)	0	0 (0.00)
Oropharyngeal pain	1	1 (14.29)	0	0 (0.00)
Pharyngeal erythema	1	1 (14.29)	0	0 (0.00)
Pharyngeal lesion	1	1 (14.29)	1	1 (14.29)
Pleural effusion	1	1 (14.29)	0	0 (0.00)
Pulmonary oedema	1	1 (14.29)	1	1 (14.29)
Respiratory failure	1	1 (14.29)	1	1 (14.29)
Skin and subcutaneous tissue disorders				
- Total	9	4 (57.14)	0	0 (0.00)
Erythema	2	2 (28.57)	0	0 (0.00)
Rash erythematous	2	1 (14.29)	0	0 (0.00)
Alopecia	1	1 (14.29)	0	0 (0.00)
Dermatitis diaper	1	1 (14.29)	0	0 (0.00)
Dry skin	1	1 (14.29)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Livedo reticularis	1	1 (14.29)	0	0 (0.00)
Rash maculo-papular	1	1 (14.29)	0	0 (0.00)
Vascular disorders				
- Total	9	5 (71.43)	4	4 (57.14)
Hypotension	4	4 (57.14)	4	4 (57.14)
Hypertension	3	3 (42.86)	0	0 (0.00)
Haematoma	1	1 (14.29)	0	0 (0.00)
Hot flush	1	1 (14.29)	0	0 (0.00)

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Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	570	20 (100.00)	183	18 (90.00)
Blood and lymphatic system disorders				
- Total	36	15 (75.00)	31	14 (70.00)
Anaemia	13	8 (40.00)	10	7 (35.00)
Febrile neutropenia	12	10 (50.00)	12	10 (50.00)
Neutropenia	5	3 (15.00)	5	3 (15.00)
Disseminated intravascular coagulation	4	3 (15.00)	2	2 (10.00)
Leukopenia	1	1 (5.00)	1	1 (5.00)
Lymphopenia	1	1 (5.00)	1	1 (5.00)
Cardiac disorders				
- Total	9	6 (30.00)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Tachycardia	4	3 (15.00)	0	0 (0.00)
Sinus tachycardia	2	2 (10.00)	0	0 (0.00)
Bradycardia	1	1 (5.00)	0	0 (0.00)
Pericardial effusion	1	1 (5.00)	0	0 (0.00)
Ventricular tachycardia	1	1 (5.00)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Tympanic membrane perforation	1	1 (5.00)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Adrenal insufficiency	1	1 (5.00)	0	0 (0.00)
Eye disorders				
- Total	10	6 (30.00)	0	0 (0.00)
Vision blurred	3	2 (10.00)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (10.00)	0	0 (0.00)
Periorbital oedema	2	2 (10.00)	0	0 (0.00)
Dry eye	1	1 (5.00)	0	0 (0.00)
Retinal haemorrhage	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Uveitis	1	1 (5.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	55	13 (65.00)	7	5 (25.00)
Vomiting	18	7 (35.00)	2	1 (5.00)
Nausea	10	7 (35.00)	2	2 (10.00)
Diarrhoea	8	7 (35.00)	1	1 (5.00)
Constipation	6	5 (25.00)	0	0 (0.00)
Abdominal pain	3	3 (15.00)	0	0 (0.00)
Dysphagia	2	2 (10.00)	1	1 (5.00)
Abdominal pain upper	1	1 (5.00)	0	0 (0.00)
Flatulence	1	1 (5.00)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (5.00)	0	0 (0.00)
Glossodynia	1	1 (5.00)	0	0 (0.00)
Haematemesis	1	1 (5.00)	0	0 (0.00)
Ileus	1	1 (5.00)	1	1 (5.00)
Pancreatitis	1	1 (5.00)	0	0 (0.00)
Tooth socket haemorrhage	1	1 (5.00)	0	0 (0.00)
General disorders and administration site conditions				

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	29	13 (65.00)	9	6 (30.00)
Pyrexia	9	6 (30.00)	4	4 (20.00)
Fatigue	5	5 (25.00)	0	0 (0.00)
Generalised oedema	2	2 (10.00)	0	0 (0.00)
Oedema peripheral	2	2 (10.00)	1	1 (5.00)
Acquired gene mutation	1	1 (5.00)	0	0 (0.00)
Catheter site haemorrhage	1	1 (5.00)	0	0 (0.00)
Catheter site pain	1	1 (5.00)	0	0 (0.00)
Chills	1	1 (5.00)	0	0 (0.00)
Face oedema	1	1 (5.00)	1	1 (5.00)
Injection site haematoma	1	1 (5.00)	0	0 (0.00)
Localised oedema	1	1 (5.00)	1	1 (5.00)
Mucosal haemorrhage	1	1 (5.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (5.00)	1	1 (5.00)
Pain	1	1 (5.00)	0	0 (0.00)
Physical deconditioning	1	1 (5.00)	1	1 (5.00)
Hepatobiliary disorders				
- Total	3	3 (15.00)	1	1 (5.00)
Gallbladder enlargement	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Hepatosplenomegaly	1	1 (5.00)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (5.00)	1	1 (5.00)
Immune system disorders				
- Total	46	16 (80.00)	13	8 (40.00)
Cytokine release syndrome	31	16 (80.00)	11	7 (35.00)
Hypogammaglobulinaemia	10	9 (45.00)	2	2 (10.00)
Immunodeficiency common variable	2	2 (10.00)	0	0 (0.00)
Chronic graft versus host disease	1	1 (5.00)	0	0 (0.00)
Graft versus host disease in gastrointestinal tract	1	1 (5.00)	0	0 (0.00)
Seasonal allergy	1	1 (5.00)	0	0 (0.00)
Infections and infestations				
- Total	46	17 (85.00)	10	8 (40.00)
Otitis media	4	2 (10.00)	1	1 (5.00)
Gastroenteritis	3	3 (15.00)	1	1 (5.00)
Influenza	3	3 (15.00)	0	0 (0.00)
Otitis media acute	3	1 (5.00)	0	0 (0.00)
Clostridium difficile infection	2	2 (10.00)	0	0 (0.00)
Gastroenteritis norovirus	2	1 (5.00)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Pneumonia	2	2 (10.00)	1	1 (5.00)
Staphylococcal infection	2	2 (10.00)	1	1 (5.00)
Urinary tract infection	2	2 (10.00)	1	1 (5.00)
Catheter site cellulitis	1	1 (5.00)	0	0 (0.00)
Clostridium difficile colitis	1	1 (5.00)	1	1 (5.00)
Cytomegalovirus infection	1	1 (5.00)	0	0 (0.00)
Enterococcal infection	1	1 (5.00)	0	0 (0.00)
Escherichia urinary tract infection	1	1 (5.00)	1	1 (5.00)
Gingivitis	1	1 (5.00)	0	0 (0.00)
Haemophilus infection	1	1 (5.00)	0	0 (0.00)
Herpes zoster	1	1 (5.00)	1	1 (5.00)
Meningitis aseptic	1	1 (5.00)	0	0 (0.00)
Oral herpes	1	1 (5.00)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (5.00)	0	0 (0.00)
Pharyngitis	1	1 (5.00)	0	0 (0.00)
Rash pustular	1	1 (5.00)	0	0 (0.00)
Rhinitis	1	1 (5.00)	0	0 (0.00)
Rhinovirus infection	1	1 (5.00)	0	0 (0.00)
Sepsis	1	1 (5.00)	1	1 (5.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Sinusitis	1	1 (5.00)	0	0 (0.00)
Streptococcal infection	1	1 (5.00)	0	0 (0.00)
Subcutaneous abscess	1	1 (5.00)	0	0 (0.00)
Upper respiratory tract infection	1	1 (5.00)	0	0 (0.00)
Viral infection	1	1 (5.00)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (5.00)	1	1 (5.00)
Vulvovaginal mycotic infection	1	1 (5.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	6	5 (25.00)	1	1 (5.00)
Contusion	1	1 (5.00)	0	0 (0.00)
Post procedural haemorrhage	1	1 (5.00)	0	0 (0.00)
Procedural complication	1	1 (5.00)	0	0 (0.00)
Subdural haemorrhage	1	1 (5.00)	0	0 (0.00)
Transfusion reaction	1	1 (5.00)	0	0 (0.00)
Transfusion related complication	1	1 (5.00)	1	1 (5.00)
Investigations				
- Total	129	16 (80.00)	67	16 (80.00)
Neutrophil count decreased	20	9 (45.00)	18	9 (45.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Aspartate aminotransferase increased	17	7 (35.00)	8	4 (20.00)
Platelet count decreased	17	9 (45.00)	13	7 (35.00)
White blood cell count decreased	17	11 (55.00)	10	9 (45.00)
Alanine aminotransferase increased	10	7 (35.00)	6	4 (20.00)
Prothrombin time prolonged	7	3 (15.00)	0	0 (0.00)
Activated partial thromboplastin time prolonged	6	3 (15.00)	0	0 (0.00)
Blood creatinine increased	6	4 (20.00)	1	1 (5.00)
Lymphocyte count decreased	6	6 (30.00)	6	6 (30.00)
Blood bilirubin increased	4	2 (10.00)	0	0 (0.00)
International normalised ratio increased	4	3 (15.00)	0	0 (0.00)
Blood urea increased	3	1 (5.00)	1	1 (5.00)
Blood phosphorus increased	2	1 (5.00)	0	0 (0.00)
Blood fibrinogen decreased	1	1 (5.00)	1	1 (5.00)
Blood immunoglobulin A decreased	1	1 (5.00)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (5.00)	0	0 (0.00)
Blood phosphorus decreased	1	1 (5.00)	0	0 (0.00)
Haemoglobin decreased	1	1 (5.00)	1	1 (5.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Hepatic enzyme increased	1	1 (5.00)	0	0 (0.00)
Lipase increased	1	1 (5.00)	1	1 (5.00)
Protein total decreased	1	1 (5.00)	1	1 (5.00)
Serum ferritin increased	1	1 (5.00)	0	0 (0.00)
Weight increased	1	1 (5.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	55	13 (65.00)	17	10 (50.00)
Decreased appetite	7	5 (25.00)	3	3 (15.00)
Hypernatraemia	6	3 (15.00)	1	1 (5.00)
Hyperphosphataemia	6	4 (20.00)	0	0 (0.00)
Hypokalaemia	6	5 (25.00)	4	4 (20.00)
Hyperglycaemia	4	2 (10.00)	1	1 (5.00)
Hyperalbuminaemia	3	1 (5.00)	0	0 (0.00)
Hypercalcaemia	3	1 (5.00)	0	0 (0.00)
Hyperuricaemia	3	2 (10.00)	1	1 (5.00)
Hypophosphataemia	3	3 (15.00)	2	2 (10.00)
Acidosis	2	2 (10.00)	1	1 (5.00)
Dehydration	2	2 (10.00)	1	1 (5.00)
Hypertriglyceridaemia	2	1 (5.00)	1	1 (5.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Hyperchloraemia	1	1 (5.00)	0	0 (0.00)
Hypermagnesaemia	1	1 (5.00)	0	0 (0.00)
Hypoalbuminaemia	1	1 (5.00)	0	0 (0.00)
Hypocalcaemia	1	1 (5.00)	0	0 (0.00)
Iron overload	1	1 (5.00)	1	1 (5.00)
Metabolic alkalosis	1	1 (5.00)	0	0 (0.00)
Tumour lysis syndrome	1	1 (5.00)	1	1 (5.00)
Vitamin D deficiency	1	1 (5.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	12	7 (35.00)	0	0 (0.00)
Arthralgia	2	2 (10.00)	0	0 (0.00)
Muscular weakness	2	2 (10.00)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (10.00)	0	0 (0.00)
Pain in extremity	2	2 (10.00)	0	0 (0.00)
Coccydynia	1	1 (5.00)	0	0 (0.00)
Flank pain	1	1 (5.00)	0	0 (0.00)
Musculoskeletal pain	1	1 (5.00)	0	0 (0.00)
Osteonecrosis	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	2 (10.00)	1	1 (5.00)
Glioblastoma multiforme	1	1 (5.00)	1	1 (5.00)
Myelodysplastic syndrome	1	1 (5.00)	0	0 (0.00)
Nervous system disorders				
- Total	29	13 (65.00)	2	2 (10.00)
Headache	12	9 (45.00)	0	0 (0.00)
Encephalopathy	4	2 (10.00)	1	1 (5.00)
Dysarthria	2	2 (10.00)	0	0 (0.00)
Seizure	2	2 (10.00)	1	1 (5.00)
Tremor	2	2 (10.00)	0	0 (0.00)
Asterixis	1	1 (5.00)	0	0 (0.00)
Ataxia	1	1 (5.00)	0	0 (0.00)
Depressed level of consciousness	1	1 (5.00)	0	0 (0.00)
Dizziness	1	1 (5.00)	0	0 (0.00)
Neuropathy peripheral	1	1 (5.00)	0	0 (0.00)
Pleocytosis	1	1 (5.00)	0	0 (0.00)
Somnolence	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Product issues				
- Total	1	1 (5.00)	0	0 (0.00)
Device occlusion	1	1 (5.00)	0	0 (0.00)
Psychiatric disorders				
- Total	11	5 (25.00)	0	0 (0.00)
Delirium	2	2 (10.00)	0	0 (0.00)
Adjustment disorder	1	1 (5.00)	0	0 (0.00)
Agitation	1	1 (5.00)	0	0 (0.00)
Anxiety	1	1 (5.00)	0	0 (0.00)
Confusional state	1	1 (5.00)	0	0 (0.00)
Depression	1	1 (5.00)	0	0 (0.00)
Hallucination	1	1 (5.00)	0	0 (0.00)
Insomnia	1	1 (5.00)	0	0 (0.00)
Irritability	1	1 (5.00)	0	0 (0.00)
Suicidal ideation	1	1 (5.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	9	6 (30.00)	5	4 (20.00)
Acute kidney injury	4	4 (20.00)	2	2 (10.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Haematuria	2	1 (5.00)	1	1 (5.00)
Calculus urinary	1	1 (5.00)	0	0 (0.00)
Nephrolithiasis	1	1 (5.00)	1	1 (5.00)
Renal impairment	1	1 (5.00)	1	1 (5.00)
Reproductive system and breast disorders				
- Total	2	2 (10.00)	1	1 (5.00)
Ovarian failure	1	1 (5.00)	1	1 (5.00)
Vulvovaginal adhesion	1	1 (5.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	35	12 (60.00)	11	7 (35.00)
Epistaxis	9	5 (25.00)	2	2 (10.00)
Pulmonary oedema	4	4 (20.00)	3	3 (15.00)
Tachypnoea	4	3 (15.00)	0	0 (0.00)
Pleural effusion	3	3 (15.00)	1	1 (5.00)
Cough	2	2 (10.00)	0	0 (0.00)
Haemoptysis	2	1 (5.00)	0	0 (0.00)
Hypoxia	2	2 (10.00)	2	2 (10.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Nasal congestion	2	2 (10.00)	0	0 (0.00)
Oropharyngeal pain	2	2 (10.00)	0	0 (0.00)
Acute respiratory failure	1	1 (5.00)	1	1 (5.00)
Oropharyngeal plaque	1	1 (5.00)	0	0 (0.00)
Respiratory distress	1	1 (5.00)	1	1 (5.00)
Respiratory failure	1	1 (5.00)	1	1 (5.00)
Rhinorrhoea	1	1 (5.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	31	11 (55.00)	1	1 (5.00)
Dry skin	4	4 (20.00)	0	0 (0.00)
Hyperhidrosis	4	3 (15.00)	0	0 (0.00)
Petechiae	3	3 (15.00)	0	0 (0.00)
Rash	3	3 (15.00)	0	0 (0.00)
Erythema	2	1 (5.00)	0	0 (0.00)
Papule	2	2 (10.00)	0	0 (0.00)
Ecchymosis	1	1 (5.00)	1	1 (5.00)
Eczema	1	1 (5.00)	0	0 (0.00)
Ingrowing nail	1	1 (5.00)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Keloid scar	1	1 (5.00)	0	0 (0.00)
Macule	1	1 (5.00)	0	0 (0.00)
Pruritus	1	1 (5.00)	0	0 (0.00)
Rash erythematous	1	1 (5.00)	0	0 (0.00)
Rash macular	1	1 (5.00)	0	0 (0.00)
Rash papular	1	1 (5.00)	0	0 (0.00)
Rash pruritic	1	1 (5.00)	0	0 (0.00)
Rash vesicular	1	1 (5.00)	0	0 (0.00)
Skin exfoliation	1	1 (5.00)	0	0 (0.00)
Skin fissures	1	1 (5.00)	0	0 (0.00)
Vascular disorders				
- Total	12	6 (30.00)	6	4 (20.00)
Hypotension	5	4 (20.00)	5	4 (20.00)
Flushing	2	1 (5.00)	0	0 (0.00)
Hypertension	2	2 (10.00)	0	0 (0.00)
Capillary leak syndrome	1	1 (5.00)	1	1 (5.00)
Orthostatic hypotension	1	1 (5.00)	0	0 (0.00)
Secondary hypertension	1	1 (5.00)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Total number of AE per patient	508	21 (100.00)	179	21 (100.00)
Blood and lymphatic system disorders				
- Total	60	17 (80.95)	45	15 (71.43)
Thrombocytopenia	21	5 (23.81)	17	4 (19.05)
Anaemia	14	7 (33.33)	8	5 (23.81)
Febrile neutropenia	13	9 (42.86)	13	9 (42.86)
Neutropenia	6	4 (19.05)	5	4 (19.05)
Lymphopenia	2	2 (9.52)	1	1 (4.76)
Coagulopathy	1	1 (4.76)	0	0 (0.00)
Disseminated intravascular coagulation	1	1 (4.76)	0	0 (0.00)
Lymphadenopathy	1	1 (4.76)	0	0 (0.00)
Pancytopenia	1	1 (4.76)	1	1 (4.76)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Cardiac disorders				
- Total	9	7 (33.33)	0	0 (0.00)
Tachycardia	5	5 (23.81)	0	0 (0.00)
Sinus bradycardia	2	1 (4.76)	0	0 (0.00)
Atrioventricular block second degree	1	1 (4.76)	0	0 (0.00)
Sinus tachycardia	1	1 (4.76)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (4.76)	0	0 (0.00)
Hypoacusis	1	1 (4.76)	0	0 (0.00)
Eye disorders				
- Total	11	6 (28.57)	0	0 (0.00)
Photophobia	3	2 (9.52)	0	0 (0.00)
Eye pain	2	2 (9.52)	0	0 (0.00)
Vision blurred	2	2 (9.52)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (4.76)	0	0 (0.00)
Conjunctivitis allergic	1	1 (4.76)	0	0 (0.00)
Periorbital oedema	1	1 (4.76)	0	0 (0.00)
Retinal haemorrhage	1	1 (4.76)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Gastrointestinal disorders				
- Total	44	12 (57.14)	11	4 (19.05)
Vomiting	12	8 (38.10)	3	2 (9.52)
Nausea	11	8 (38.10)	2	2 (9.52)
Diarrhoea	7	7 (33.33)	1	1 (4.76)
Abdominal pain	3	2 (9.52)	2	1 (4.76)
Anal incontinence	2	1 (4.76)	0	0 (0.00)
Abdominal discomfort	1	1 (4.76)	0	0 (0.00)
Abdominal pain upper	1	1 (4.76)	0	0 (0.00)
Ascites	1	1 (4.76)	1	1 (4.76)
Constipation	1	1 (4.76)	0	0 (0.00)
Dyspepsia	1	1 (4.76)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (4.76)	0	0 (0.00)
Intestinal obstruction	1	1 (4.76)	1	1 (4.76)
Pancreatitis	1	1 (4.76)	1	1 (4.76)
Stomatitis	1	1 (4.76)	0	0 (0.00)
General disorders and administration site conditions				
- Total	29	12 (57.14)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Pyrexia	13	8 (38.10)	0	0 (0.00)
Chills	7	6 (28.57)	0	0 (0.00)
Fatigue	3	3 (14.29)	0	0 (0.00)
Malaise	3	3 (14.29)	0	0 (0.00)
Catheter site pain	1	1 (4.76)	0	0 (0.00)
Influenza like illness	1	1 (4.76)	0	0 (0.00)
Non-cardiac chest pain	1	1 (4.76)	0	0 (0.00)
Hepatobiliary disorders				
- Total	2	2 (9.52)	0	0 (0.00)
Hepatomegaly	1	1 (4.76)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (4.76)	0	0 (0.00)
Immune system disorders				
- Total	44	20 (95.24)	9	7 (33.33)
Cytokine release syndrome	26	18 (85.71)	6	5 (23.81)
Hypogammaglobulinaemia	15	13 (61.90)	3	3 (14.29)
Drug hypersensitivity	1	1 (4.76)	0	0 (0.00)
Immunodeficiency	1	1 (4.76)	0	0 (0.00)
Seasonal allergy	1	1 (4.76)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Infections and infestations				
- Total	35	14 (66.67)	7	5 (23.81)
Upper respiratory tract infection	5	2 (9.52)	0	0 (0.00)
Rhinovirus infection	3	3 (14.29)	0	0 (0.00)
Sinusitis	3	2 (9.52)	0	0 (0.00)
Clostridium difficile colitis	2	2 (9.52)	0	0 (0.00)
Pneumonia	2	2 (9.52)	0	0 (0.00)
Viral upper respiratory tract infection	2	2 (9.52)	0	0 (0.00)
Acute sinusitis	1	1 (4.76)	0	0 (0.00)
Bacterial sepsis	1	1 (4.76)	1	1 (4.76)
Catheter site infection	1	1 (4.76)	1	1 (4.76)
Cholecystitis infective	1	1 (4.76)	1	1 (4.76)
Clostridium difficile infection	1	1 (4.76)	0	0 (0.00)
Folliculitis	1	1 (4.76)	0	0 (0.00)
Gastroenteritis	1	1 (4.76)	0	0 (0.00)
Gastroenteritis viral	1	1 (4.76)	0	0 (0.00)
Influenza	1	1 (4.76)	0	0 (0.00)
Molluscum contagiosum	1	1 (4.76)	0	0 (0.00)
Orchitis	1	1 (4.76)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Otitis externa	1	1 (4.76)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (4.76)	1	1 (4.76)
Paronychia	1	1 (4.76)	0	0 (0.00)
Respiratory tract infection	1	1 (4.76)	1	1 (4.76)
Septic embolus	1	1 (4.76)	1	1 (4.76)
Urinary tract infection	1	1 (4.76)	0	0 (0.00)
Urinary tract infection enterococcal	1	1 (4.76)	1	1 (4.76)
Injury, poisoning and procedural complications				
- Total	14	8 (38.10)	1	1 (4.76)
Procedural pain	4	3 (14.29)	1	1 (4.76)
Transfusion reaction	2	1 (4.76)	0	0 (0.00)
Arthropod bite	1	1 (4.76)	0	0 (0.00)
Foot fracture	1	1 (4.76)	0	0 (0.00)
Incision site pain	1	1 (4.76)	0	0 (0.00)
Infusion related reaction	1	1 (4.76)	0	0 (0.00)
Radius fracture	1	1 (4.76)	0	0 (0.00)
Skin abrasion	1	1 (4.76)	0	0 (0.00)
Stoma site irritation	1	1 (4.76)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Tibia fracture	1	1 (4.76)	0	0 (0.00)
Investigations				
- Total	121	20 (95.24)	63	19 (90.48)
White blood cell count decreased	25	13 (61.90)	19	13 (61.90)
Blood fibrinogen decreased	13	2 (9.52)	3	2 (9.52)
Alanine aminotransferase increased	12	9 (42.86)	8	7 (33.33)
Neutrophil count decreased	12	8 (38.10)	12	8 (38.10)
Platelet count decreased	11	6 (28.57)	7	4 (19.05)
Aspartate aminotransferase increased	8	6 (28.57)	5	4 (19.05)
Prothrombin time prolonged	8	4 (19.05)	1	1 (4.76)
Blood bilirubin increased	6	2 (9.52)	1	1 (4.76)
Lymphocyte count decreased	5	4 (19.05)	4	4 (19.05)
Transaminases increased	3	3 (14.29)	0	0 (0.00)
Weight decreased	3	3 (14.29)	0	0 (0.00)
Blood sodium increased	2	1 (4.76)	0	0 (0.00)
C-reactive protein increased	2	2 (9.52)	1	1 (4.76)
International normalised ratio increased	2	2 (9.52)	1	1 (4.76)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Blood alkaline phosphatase increased	1	1 (4.76)	0	0 (0.00)
Blood creatinine increased	1	1 (4.76)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (4.76)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (4.76)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (4.76)	0	0 (0.00)
Blood urea increased	1	1 (4.76)	0	0 (0.00)
Haemoglobin decreased	1	1 (4.76)	0	0 (0.00)
Lipase increased	1	1 (4.76)	1	1 (4.76)
Oxygen saturation decreased	1	1 (4.76)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	39	15 (71.43)	24	11 (52.38)
Decreased appetite	10	9 (42.86)	7	6 (28.57)
Hypokalaemia	7	6 (28.57)	3	3 (14.29)
Hypophosphataemia	6	4 (19.05)	6	4 (19.05)
Hyperphosphataemia	3	2 (9.52)	0	0 (0.00)
Hyponatraemia	3	2 (9.52)	3	2 (9.52)
Hypoalbuminaemia	2	1 (4.76)	1	1 (4.76)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Dehydration	1	1 (4.76)	1	1 (4.76)
Fluid overload	1	1 (4.76)	0	0 (0.00)
Hyperglycaemia	1	1 (4.76)	1	1 (4.76)
Hypertriglyceridaemia	1	1 (4.76)	0	0 (0.00)
Hypomagnesaemia	1	1 (4.76)	0	0 (0.00)
Malnutrition	1	1 (4.76)	1	1 (4.76)
Metabolic acidosis	1	1 (4.76)	0	0 (0.00)
Tumour lysis syndrome	1	1 (4.76)	1	1 (4.76)
Musculoskeletal and connective tissue disorders				
- Total	10	7 (33.33)	0	0 (0.00)
Pain in extremity	3	3 (14.29)	0	0 (0.00)
Musculoskeletal pain	2	1 (4.76)	0	0 (0.00)
Arthralgia	1	1 (4.76)	0	0 (0.00)
Limb discomfort	1	1 (4.76)	0	0 (0.00)
Myalgia	1	1 (4.76)	0	0 (0.00)
Osteopenia	1	1 (4.76)	0	0 (0.00)
Toe walking	1	1 (4.76)	0	0 (0.00)
Nervous system disorders				

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
- Total	20	10 (47.62)	4	3 (14.29)
Headache	12	6 (28.57)	2	2 (9.52)
Dizziness	2	2 (9.52)	0	0 (0.00)
Disturbance in attention	1	1 (4.76)	0	0 (0.00)
Embolic stroke	1	1 (4.76)	1	1 (4.76)
Encephalopathy	1	1 (4.76)	1	1 (4.76)
Migraine	1	1 (4.76)	0	0 (0.00)
Peroneal nerve palsy	1	1 (4.76)	0	0 (0.00)
Seizure	1	1 (4.76)	0	0 (0.00)
Psychiatric disorders				
- Total	7	6 (28.57)	0	0 (0.00)
Anxiety	2	2 (9.52)	0	0 (0.00)
Confusional state	2	2 (9.52)	0	0 (0.00)
Delirium	1	1 (4.76)	0	0 (0.00)
Mental status changes	1	1 (4.76)	0	0 (0.00)
Panic attack	1	1 (4.76)	0	0 (0.00)
Renal and urinary disorders				
- Total	8	5 (23.81)	3	3 (14.29)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Acute kidney injury	4	3 (14.29)	3	3 (14.29)
Dysuria	2	2 (9.52)	0	0 (0.00)
Haematuria	1	1 (4.76)	0	0 (0.00)
Pollakiuria	1	1 (4.76)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (4.76)	1	1 (4.76)
Vaginal haemorrhage	1	1 (4.76)	1	1 (4.76)
Respiratory, thoracic and mediastinal disorders				
- Total	28	10 (47.62)	5	3 (14.29)
Cough	7	5 (23.81)	0	0 (0.00)
Hypoxia	4	3 (14.29)	2	2 (9.52)
Rhinitis allergic	3	3 (14.29)	0	0 (0.00)
Pleural effusion	2	2 (9.52)	1	1 (4.76)
Rhinorrhoea	2	2 (9.52)	0	0 (0.00)
Atelectasis	1	1 (4.76)	0	0 (0.00)
Dysphonia	1	1 (4.76)	0	0 (0.00)
Epistaxis	1	1 (4.76)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Nasal congestion	1	1 (4.76)	0	0 (0.00)
Oropharyngeal pain	1	1 (4.76)	0	0 (0.00)
Pharyngeal ulceration	1	1 (4.76)	0	0 (0.00)
Pulmonary oedema	1	1 (4.76)	1	1 (4.76)
Respiratory depression	1	1 (4.76)	0	0 (0.00)
Respiratory failure	1	1 (4.76)	1	1 (4.76)
Tachypnoea	1	1 (4.76)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	15	8 (38.10)	2	2 (9.52)
Ingrowing nail	3	2 (9.52)	0	0 (0.00)
Erythema	2	2 (9.52)	0	0 (0.00)
Pruritus	2	2 (9.52)	0	0 (0.00)
Rash	2	2 (9.52)	0	0 (0.00)
Rash maculo-papular	2	2 (9.52)	1	1 (4.76)
Acne	1	1 (4.76)	0	0 (0.00)
Dermatitis	1	1 (4.76)	0	0 (0.00)
Dermatitis acneiform	1	1 (4.76)	1	1 (4.76)
Hyperhidrosis	1	1 (4.76)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Vascular disorders				
- Total	10	8 (38.10)	4	4 (19.05)
Hypertension	5	4 (19.05)	0	0 (0.00)
Hypotension	4	4 (19.05)	4	4 (19.05)
Orthostatic hypotension	1	1 (4.76)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 220r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Total number of AE per patient	471	16 (100.00)	124	14 (87.50)
Blood and lymphatic system disorders				
- Total	35	11 (68.75)	22	10 (62.50)
Anaemia	17	8 (50.00)	11	6 (37.50)
Thrombocytopenia	10	3 (18.75)	5	3 (18.75)
Febrile neutropenia	3	3 (18.75)	3	3 (18.75)
Eosinophilia	2	1 (6.25)	1	1 (6.25)
Neutropenia	2	2 (12.50)	2	2 (12.50)
Lymphopenia	1	1 (6.25)	0	0 (0.00)
Cardiac disorders				
- Total	10	7 (43.75)	1	1 (6.25)
Tachycardia	6	5 (31.25)	1	1 (6.25)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Sinus tachycardia	3	3 (18.75)	0	0 (0.00)
Cardiac dysfunction	1	1 (6.25)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (12.50)	0	0 (0.00)
Ear pain	2	2 (12.50)	0	0 (0.00)
Eye disorders				
- Total	7	5 (31.25)	0	0 (0.00)
Dry eye	1	1 (6.25)	0	0 (0.00)
Ocular hyperaemia	1	1 (6.25)	0	0 (0.00)
Ocular hypertension	1	1 (6.25)	0	0 (0.00)
Papilloedema	1	1 (6.25)	0	0 (0.00)
Periorbital oedema	1	1 (6.25)	0	0 (0.00)
Uveitis	1	1 (6.25)	0	0 (0.00)
Visual impairment	1	1 (6.25)	0	0 (0.00)
Gastrointestinal disorders				
- Total	45	12 (75.00)	2	1 (6.25)
Vomiting	11	7 (43.75)	0	0 (0.00)
Abdominal pain	8	5 (31.25)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Diarrhoea	8	6 (37.50)	0	0 (0.00)
Nausea	7	6 (37.50)	0	0 (0.00)
Abdominal distension	2	2 (12.50)	0	0 (0.00)
Mouth haemorrhage	2	1 (6.25)	2	1 (6.25)
Abdominal pain lower	1	1 (6.25)	0	0 (0.00)
Abdominal pain upper	1	1 (6.25)	0	0 (0.00)
Abdominal tenderness	1	1 (6.25)	0	0 (0.00)
Haematemesis	1	1 (6.25)	0	0 (0.00)
Lip pain	1	1 (6.25)	0	0 (0.00)
Pigmentation lip	1	1 (6.25)	0	0 (0.00)
Stomatitis	1	1 (6.25)	0	0 (0.00)
General disorders and administration site conditions				
- Total	38	12 (75.00)	4	3 (18.75)
Pyrexia	15	7 (43.75)	1	1 (6.25)
Fatigue	7	6 (37.50)	1	1 (6.25)
Chills	2	2 (12.50)	0	0 (0.00)
Generalised oedema	2	1 (6.25)	0	0 (0.00)
Pain	2	2 (12.50)	1	1 (6.25)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Catheter site extravasation	1	1 (6.25)	0	0 (0.00)
Catheter site pain	1	1 (6.25)	0	0 (0.00)
Crying	1	1 (6.25)	0	0 (0.00)
Cyst	1	1 (6.25)	1	1 (6.25)
Face oedema	1	1 (6.25)	0	0 (0.00)
Facial pain	1	1 (6.25)	0	0 (0.00)
Influenza like illness	1	1 (6.25)	0	0 (0.00)
Malaise	1	1 (6.25)	0	0 (0.00)
Oedema peripheral	1	1 (6.25)	0	0 (0.00)
Peripheral swelling	1	1 (6.25)	0	0 (0.00)
Hepatobiliary disorders				
- Total	3	1 (6.25)	1	1 (6.25)
Hyperbilirubinaemia	2	1 (6.25)	1	1 (6.25)
Hepatomegaly	1	1 (6.25)	0	0 (0.00)
Immune system disorders				
- Total	28	15 (93.75)	6	4 (25.00)
Cytokine release syndrome	18	11 (68.75)	6	4 (25.00)
Hypogammaglobulinaemia	7	7 (43.75)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Graft versus host disease	1	1 (6.25)	0	0 (0.00)
Graft versus host disease in skin	1	1 (6.25)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (6.25)	0	0 (0.00)
Infections and infestations				
- Total	40	11 (68.75)	12	4 (25.00)
Cellulitis of male external genital organ	6	1 (6.25)	3	1 (6.25)
Urinary tract infection	5	2 (12.50)	2	1 (6.25)
Upper respiratory tract infection	4	4 (25.00)	1	1 (6.25)
Otitis media	3	2 (12.50)	0	0 (0.00)
Clostridium difficile infection	2	2 (12.50)	1	1 (6.25)
Otitis media acute	2	1 (6.25)	0	0 (0.00)
Vulvovaginal candidiasis	2	2 (12.50)	0	0 (0.00)
Body tinea	1	1 (6.25)	0	0 (0.00)
Campylobacter infection	1	1 (6.25)	1	1 (6.25)
Clostridium difficile colitis	1	1 (6.25)	0	0 (0.00)
Cytomegalovirus infection	1	1 (6.25)	0	0 (0.00)
Ear infection	1	1 (6.25)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Enterovirus infection	1	1 (6.25)	1	1 (6.25)
Fungal skin infection	1	1 (6.25)	0	0 (0.00)
Herpes simplex	1	1 (6.25)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (6.25)	0	0 (0.00)
Hypopyon	1	1 (6.25)	0	0 (0.00)
Oral candidiasis	1	1 (6.25)	0	0 (0.00)
Respiratory tract infection viral	1	1 (6.25)	1	1 (6.25)
Rotavirus infection	1	1 (6.25)	1	1 (6.25)
Sinusitis	1	1 (6.25)	0	0 (0.00)
Skin infection	1	1 (6.25)	0	0 (0.00)
Vascular device infection	1	1 (6.25)	1	1 (6.25)
Injury, poisoning and procedural complications				
- Total	13	7 (43.75)	0	0 (0.00)
Infusion related reaction	2	2 (12.50)	0	0 (0.00)
Procedural pain	2	2 (12.50)	0	0 (0.00)
Contusion	1	1 (6.25)	0	0 (0.00)
Limb injury	1	1 (6.25)	0	0 (0.00)
Mouth injury	1	1 (6.25)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Procedural headache	1	1 (6.25)	0	0 (0.00)
Procedural site reaction	1	1 (6.25)	0	0 (0.00)
Skin abrasion	1	1 (6.25)	0	0 (0.00)
Skin laceration	1	1 (6.25)	0	0 (0.00)
Tongue injury	1	1 (6.25)	0	0 (0.00)
Transfusion reaction	1	1 (6.25)	0	0 (0.00)
Investigations				
- Total	113	13 (81.25)	55	8 (50.00)
Neutrophil count decreased	21	7 (43.75)	15	5 (31.25)
Platelet count decreased	21	5 (31.25)	18	4 (25.00)
White blood cell count decreased	14	7 (43.75)	7	5 (31.25)
Alanine aminotransferase increased	11	5 (31.25)	4	3 (18.75)
Aspartate aminotransferase increased	11	6 (37.50)	5	3 (18.75)
Lymphocyte count decreased	10	4 (25.00)	3	2 (12.50)
Blood creatinine increased	4	3 (18.75)	1	1 (6.25)
Blood bilirubin increased	3	3 (18.75)	1	1 (6.25)
International normalised ratio increased	3	3 (18.75)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Blood immunoglobulin A decreased	2	2 (12.50)	0	0 (0.00)
Activated partial thromboplastin time prolonged	1	1 (6.25)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (6.25)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (6.25)	0	0 (0.00)
Blood lactic acid increased	1	1 (6.25)	1	1 (6.25)
Blood urea increased	1	1 (6.25)	0	0 (0.00)
Blood uric acid increased	1	1 (6.25)	0	0 (0.00)
Culture stool positive	1	1 (6.25)	0	0 (0.00)
Haemoglobin decreased	1	1 (6.25)	0	0 (0.00)
Norovirus test positive	1	1 (6.25)	0	0 (0.00)
Prothrombin time prolonged	1	1 (6.25)	0	0 (0.00)
Pulmonary function test decreased	1	1 (6.25)	0	0 (0.00)
Serum ferritin increased	1	1 (6.25)	0	0 (0.00)
Weight increased	1	1 (6.25)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	30	11 (68.75)	7	5 (31.25)
Hypokalaemia	7	6 (37.50)	2	2 (12.50)
Decreased appetite	6	5 (31.25)	2	2 (12.50)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Hypophosphataemia	4	2 (12.50)	1	1 (6.25)
Hyperphosphataemia	3	2 (12.50)	0	0 (0.00)
Hypocalcaemia	3	2 (12.50)	1	1 (6.25)
Fluid overload	2	2 (12.50)	0	0 (0.00)
Hypoalbuminaemia	2	2 (12.50)	0	0 (0.00)
Dehydration	1	1 (6.25)	1	1 (6.25)
Hyperuricaemia	1	1 (6.25)	0	0 (0.00)
Vitamin D deficiency	1	1 (6.25)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	17	8 (50.00)	0	0 (0.00)
Pain in extremity	5	4 (25.00)	0	0 (0.00)
Myalgia	4	4 (25.00)	0	0 (0.00)
Joint range of motion decreased	2	2 (12.50)	0	0 (0.00)
Muscle spasms	2	2 (12.50)	0	0 (0.00)
Arthralgia	1	1 (6.25)	0	0 (0.00)
Back pain	1	1 (6.25)	0	0 (0.00)
Musculoskeletal pain	1	1 (6.25)	0	0 (0.00)
Neck pain	1	1 (6.25)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (6.25)	0	0 (0.00)
Skin papilloma	1	1 (6.25)	0	0 (0.00)
Nervous system disorders				
- Total	19	8 (50.00)	1	1 (6.25)
Headache	11	6 (37.50)	0	0 (0.00)
Dizziness	4	2 (12.50)	0	0 (0.00)
Encephalopathy	1	1 (6.25)	0	0 (0.00)
Idiopathic intracranial hypertension	1	1 (6.25)	0	0 (0.00)
Myoclonus	1	1 (6.25)	0	0 (0.00)
Seizure	1	1 (6.25)	1	1 (6.25)
Psychiatric disorders				
- Total	10	3 (18.75)	1	1 (6.25)
Anxiety	3	3 (18.75)	1	1 (6.25)
Agitation	2	1 (6.25)	0	0 (0.00)
Hallucination	2	1 (6.25)	0	0 (0.00)
Confusional state	1	1 (6.25)	0	0 (0.00)
Irritability	1	1 (6.25)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Listless	1	1 (6.25)	0	0 (0.00)
Renal and urinary disorders				
- Total	4	2 (12.50)	2	1 (6.25)
Acute kidney injury	1	1 (6.25)	1	1 (6.25)
Haematuria	1	1 (6.25)	0	0 (0.00)
Oliguria	1	1 (6.25)	1	1 (6.25)
Urinary incontinence	1	1 (6.25)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	4	3 (18.75)	0	0 (0.00)
Oedema genital	2	1 (6.25)	0	0 (0.00)
Scrotal pain	1	1 (6.25)	0	0 (0.00)
Vulvovaginal adhesion	1	1 (6.25)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	26	10 (62.50)	5	2 (12.50)
Cough	8	4 (25.00)	0	0 (0.00)
Hypoxia	3	3 (18.75)	1	1 (6.25)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Dyspnoea	2	1 (6.25)	1	1 (6.25)
Epistaxis	2	2 (12.50)	1	1 (6.25)
Oropharyngeal pain	2	2 (12.50)	0	0 (0.00)
Pleural effusion	2	2 (12.50)	0	0 (0.00)
Rhinitis allergic	2	1 (6.25)	0	0 (0.00)
Nasal congestion	1	1 (6.25)	0	0 (0.00)
Pulmonary oedema	1	1 (6.25)	1	1 (6.25)
Rhinorrhoea	1	1 (6.25)	0	0 (0.00)
Tachypnoea	1	1 (6.25)	1	1 (6.25)
Wheezing	1	1 (6.25)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	14	7 (43.75)	0	0 (0.00)
Rash	4	3 (18.75)	0	0 (0.00)
Rash maculo-papular	2	2 (12.50)	0	0 (0.00)
Dermatitis atopic	1	1 (6.25)	0	0 (0.00)
Macule	1	1 (6.25)	0	0 (0.00)
Night sweats	1	1 (6.25)	0	0 (0.00)
Petechiae	1	1 (6.25)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Pruritus	1	1 (6.25)	0	0 (0.00)
Rash follicular	1	1 (6.25)	0	0 (0.00)
Rash papular	1	1 (6.25)	0	0 (0.00)
Skin irritation	1	1 (6.25)	0	0 (0.00)
Vascular disorders				
- Total	12	6 (37.50)	5	4 (25.00)
Hypotension	6	4 (25.00)	3	3 (18.75)
Hypertension	4	3 (18.75)	1	1 (6.25)
Embolism	1	1 (6.25)	1	1 (6.25)
Flushing	1	1 (6.25)	0	0 (0.00)

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
Percentages are calculated out of number of patients in safety set.
1 number of patients with any AE (irrespective of grade)
2 number of patients with Grade 3 or more AE

Table 221a
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Age
Safety Set

Subgroup: Age: <10 years

	All patients N=20
Cytokine Release Syndrome (CRS) - n (%)	
No	4 (20.0)
Yes	16 (80.0)
Maximum CRS grade - n(%)	
Grade 1	2 (10.0)
Grade 2	8 (40.0)
Grade 3	3 (15.0)
Grade 4	3 (15.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	16
Mean (SD)	4.8 (3.02)
Median	4.0
Min - Max	1 - 10

	All patients N=20
Time to grade 3/4 CRS (days)	
n	6
Mean (SD)	4.7 (3.08)
Median	4.0
Min - Max	2 - 10
Concurrent infections - n(%)	4 (20.0)
Blood	1 (5.0)
GI	1 (5.0)
Lung	1 (5.0)
Other	1 (5.0)
Sinus	1 (5.0)
High fevers during CRS - n (%)	16 (80.0)
Time to high fever onset (days)	
n	16
Mean (SD)	5.3 (3.82)
Median	5.0
Min - Max	1 - 16
Duration (days)	
n	16
Mean (SD)	7.1 (5.87)
Median	6.0

	All patients N=20
Min - Max	1 - 19
Admitted to ICU - n (%)	8 (40.0)
Time to ICU Admission (days)	
n	8
Mean (SD)	6.5 (3.74)
Median	6.0
Min - Max	2 - 15
Duration of ICU stay (days)	
n	8
Mean (SD)	8.3 (5.09)
Median	9.5
Min - Max	1 - 15
Hypotension that required intervention - n (%)	5 (25.0)
High dose vasopressors used - n (%)	3 (15.0)
Oxygen supplementation given - n (%)	7 (35.0)
Patient intubated - n (%)	2 (10.0)
Duration (days)	
n	2
Mean (SD)	6.5 (3.54)
Median	6.5
Min - Max	4 - 9

	All patients N=20
Patient dialyzed - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	8 (40.0)
Duration (days)	
n	8
Mean (SD)	13.3 (5.65)
Median	11.0
Min - Max	7 - 22
Pulmonary abnormalities - n (%)	2 (10.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	1 (5.0)
Bleeding observed - n (%)	4 (20.0)
Blood product support given for bleeding - n (%)	4 (20.0)
Systemic anti-cytokine therapy given - n (%)	6 (30.0)
Tocilizumab	5 (25.0)
1 dose	4 (20.0)
2 doses	0
3 doses	1 (5.0)

	All patients N=20
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	3 (15.0)
Other	1 (5.0)

Only the first CRS episode is summarized for each patient.

Table 221a
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Age
Safety Set

Subgroup: Age: >=10 years to <18 years

	All patients N=34
Cytokine Release Syndrome (CRS) - n (%)	
No	8 (23.5)
Yes	26 (76.5)
Maximum CRS grade - n(%)	
Grade 1	4 (11.8)
Grade 2	12 (35.3)
Grade 3	5 (14.7)
Grade 4	5 (14.7)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	26
Mean (SD)	4.3 (3.51)
Median	3.5
Min - Max	1 - 16
Time to grade 3/4 CRS (days)	

	All patients N=34
n	10
Mean (SD)	5.3 (3.23)
Median	4.0
Min - Max	2 - 13
Concurrent infections - n(%)	4 (11.8)
Blood	1 (2.9)
GI	3 (8.8)
Other	1 (2.9)
High fevers during CRS - n (%)	25 (73.5)
Time to high fever onset (days)	
n	25
Mean (SD)	4.3 (3.58)
Median	3.0
Min - Max	1 - 16
Duration (days)	
n	25
Mean (SD)	5.5 (2.62)
Median	6.0
Min - Max	1 - 11
Admitted to ICU - n (%)	10 (29.4)
Time to ICU Admission (days)	

	All patients N=34
n	10
Mean (SD)	6.0 (3.46)
Median	5.5
Min - Max	2 - 12
Duration of ICU stay (days)	
n	10
Mean (SD)	7.8 (5.22)
Median	6.0
Min - Max	2 - 17
Hypotension that required intervention - n (%)	12 (35.3)
High dose vasopressors used - n (%)	6 (17.6)
Oxygen supplementation given - n (%)	9 (26.5)
Patient intubated - n (%)	2 (5.9)
Duration (days)	
n	2
Mean (SD)	7.5 (0.71)
Median	7.5
Min - Max	7 - 8
Patient dialyzed - n (%)	2 (5.9)
Duration (days)	
n	2

	All patients N=34
Mean (SD)	29.0 (38.18)
Median	29.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	12 (35.3)
Duration (days)	
n	12
Mean (SD)	15.3 (20.96)
Median	8.0
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	5 (14.7)
Disseminated intravascular coagulation (DIC) observed - n (%)	4 (11.8)
Bleeding observed - n (%)	5 (14.7)
Blood product support given for bleeding - n (%)	4 (11.8)
Systemic anti-cytokine therapy given - n (%)	5 (14.7)
Tocilizumab	5 (14.7)
1 dose	1 (2.9)
2 doses	4 (11.8)
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0

	All patients N=34
Corticosteroids	4 (11.8)
Other	2 (5.9)

Only the first CRS episode is summarized for each patient.

Table 221a
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Age
Safety Set

Subgroup: Age: >=18

	All patients N=10
Cytokine Release Syndrome (CRS) - n (%)	
No	2 (20.0)
Yes	8 (80.0)
Maximum CRS grade - n(%)	
Grade 2	5 (50.0)
Grade 4	3 (30.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	8
Mean (SD)	7.6 (5.97)
Median	6.5
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	
n	3

	All patients N=10
Mean (SD)	7.0 (3.61)
Median	8.0
Min - Max	3 - 10
Concurrent infections - n(%)	1 (10.0)
Blood	1 (10.0)
High fevers during CRS - n (%)	8 (80.0)
Time to high fever onset (days)	
n	8
Mean (SD)	7.6 (5.97)
Median	6.5
Min - Max	1 - 20
Duration (days)	
n	8
Mean (SD)	8.8 (8.45)
Median	4.0
Min - Max	3 - 27
Admitted to ICU - n (%)	2 (20.0)
Time to ICU Admission (days)	
n	2
Mean (SD)	5.5 (6.36)
Median	5.5

	All patients N=10
Min - Max	1 - 10
Duration of ICU stay (days)	
n	2
Mean (SD)	27.0 (0.00)
Median	27.0
Min - Max	27 - 27
Hypotension that required intervention - n (%)	3 (30.0)
High dose vasopressors used - n (%)	3 (30.0)
Oxygen supplementation given - n (%)	3 (30.0)
Patient intubated - n (%)	2 (20.0)
Duration (days)	
n	2
Mean (SD)	17.5 (12.02)
Median	17.5
Min - Max	9 - 26
Patient dialyzed - n (%)	2 (20.0)
Duration (days)	
n	2
Mean (SD)	37.0 (14.14)
Median	37.0
Min - Max	27 - 47

	All patients N=10
Total Parenteral Nutrition (TPN) used - n (%)	3 (30.0)
Duration (days)	
n	3
Mean (SD)	14.3 (13.05)
Median	10.0
Min - Max	4 - 29
Pulmonary abnormalities - n (%)	2 (20.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	2 (20.0)
Blood product support given for bleeding - n (%)	2 (20.0)
Systemic anti-cytokine therapy given - n (%)	2 (20.0)
Tocilizumab	2 (20.0)
1 dose	0
2 doses	0
3 doses	2 (20.0)
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	2 (20.0)
Other	2 (20.0)

Only the first CRS episode is summarized for each patient.

Table 221b
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Gender
Safety Set

Subgroup: Gender: Male

	All patients N=30
Cytokine Release Syndrome (CRS) - n (%)	
No	7 (23.3)
Yes	23 (76.7)
Maximum CRS grade - n(%)	
Grade 1	4 (13.3)
Grade 2	10 (33.3)
Grade 3	3 (10.0)
Grade 4	6 (20.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	23
Mean (SD)	5.2 (4.24)
Median	5.0
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=30
n	9
Mean (SD)	6.8 (3.11)
Median	6.0
Min - Max	3 - 13
Concurrent infections - n(%)	1 (3.3)
Other	1 (3.3)
High fevers during CRS - n (%)	22 (73.3)
Time to high fever onset (days)	
n	22
Mean (SD)	5.4 (4.25)
Median	5.0
Min - Max	1 - 20
Duration (days)	
n	22
Mean (SD)	5.8 (5.25)
Median	4.5
Min - Max	1 - 27
Admitted to ICU - n (%)	10 (33.3)
Time to ICU Admission (days)	
n	10
Mean (SD)	6.5 (2.59)

	All patients N=30
Median	6.0
Min - Max	3 - 12
Duration of ICU stay (days)	
n	10
Mean (SD)	8.8 (8.24)
Median	6.0
Min - Max	1 - 27
Hypotension that required intervention - n (%)	11 (36.7)
High dose vasopressors used - n (%)	7 (23.3)
Oxygen supplementation given - n (%)	10 (33.3)
Patient intubated - n (%)	3 (10.0)
Duration (days)	
n	3
Mean (SD)	14.3 (10.12)
Median	9.0
Min - Max	8 - 26
Patient dialyzed - n (%)	2 (6.7)
Duration (days)	
n	2
Mean (SD)	41.5 (20.51)
Median	41.5

	All patients N=30
Min - Max	27 - 56
Total Parenteral Nutrition (TPN) used - n (%)	8 (26.7)
Duration (days)	
n	8
Mean (SD)	23.5 (23.99)
Median	13.5
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	4 (13.3)
Disseminated intravascular coagulation (DIC) observed - n (%)	3 (10.0)
Bleeding observed - n (%)	6 (20.0)
Blood product support given for bleeding - n (%)	5 (16.7)
Systemic anti-cytokine therapy given - n (%)	5 (16.7)
Tocilizumab	5 (16.7)
1 dose	2 (6.7)
2 doses	2 (6.7)
3 doses	1 (3.3)
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	4 (13.3)
Other	2 (6.7)

Only the first CRS episode is summarized for each patient.

Table 221b
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Gender
Safety Set

Subgroup: Gender: Female

	All patients N=34
Cytokine Release Syndrome (CRS) - n (%)	
No	7 (20.6)
Yes	27 (79.4)
Maximum CRS grade - n(%)	
Grade 1	2 (5.9)
Grade 2	15 (44.1)
Grade 3	5 (14.7)
Grade 4	5 (14.7)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	27
Mean (SD)	4.8 (3.75)
Median	3.0
Min - Max	1 - 16
Time to grade 3/4 CRS (days)	

	All patients N=34
n	10
Mean (SD)	4.1 (2.73)
Median	3.0
Min - Max	2 - 10
Concurrent infections - n(%)	8 (23.5)
Blood	3 (8.8)
GI	4 (11.8)
Lung	1 (2.9)
Other	1 (2.9)
Sinus	1 (2.9)
High fevers during CRS - n (%)	27 (79.4)
Time to high fever onset (days)	
n	27
Mean (SD)	4.9 (4.21)
Median	4.0
Min - Max	1 - 16
Duration (days)	
n	27
Mean (SD)	7.1 (5.01)
Median	6.0
Min - Max	1 - 19

	All patients N=34
Admitted to ICU - n (%)	10 (29.4)
Time to ICU Admission (days)	
n	10
Mean (SD)	5.8 (4.54)
Median	5.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	10
Mean (SD)	11.0 (7.01)
Median	9.5
Min - Max	3 - 27
Hypotension that required intervention - n (%)	9 (26.5)
High dose vasopressors used - n (%)	5 (14.7)
Oxygen supplementation given - n (%)	9 (26.5)
Patient intubated - n (%)	3 (8.8)
Duration (days)	
n	3
Mean (SD)	6.7 (2.52)
Median	7.0
Min - Max	4 - 9
Patient dialyzed - n (%)	2 (5.9)

	All patients N=34
Duration (days)	
n	2
Mean (SD)	24.5 (31.82)
Median	24.5
Min - Max	2 - 47
Total Parenteral Nutrition (TPN) used - n (%)	15 (44.1)
Duration (days)	
n	15
Mean (SD)	9.7 (5.27)
Median	9.0
Min - Max	4 - 22
Pulmonary abnormalities - n (%)	5 (14.7)
Disseminated intravascular coagulation (DIC) observed - n (%)	2 (5.9)
Bleeding observed - n (%)	5 (14.7)
Blood product support given for bleeding - n (%)	5 (14.7)
Systemic anti-cytokine therapy given - n (%)	8 (23.5)
Tocilizumab	7 (20.6)
1 dose	3 (8.8)
2 doses	2 (5.9)
3 doses	2 (5.9)
4 doses	0

	All patients N=34
>4 doses	0
Siltuximab	0
Corticosteroids	5 (14.7)
Other	3 (8.8)

Only the first CRS episode is summarized for each patient.

Table 221c
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Race
Safety Set

Subgroup: Race: White

	All patients N=52
Cytokine Release Syndrome (CRS) - n (%)	
No	12 (23.1)
Yes	40 (76.9)
Maximum CRS grade - n(%)	
Grade 1	4 (7.7)
Grade 2	19 (36.5)
Grade 3	7 (13.5)
Grade 4	10 (19.2)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	40
Mean (SD)	4.9 (4.26)
Median	3.0
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=52
n	17
Mean (SD)	5.7 (3.16)
Median	5.0
Min - Max	2 - 13
Concurrent infections - n(%)	6 (11.5)
Blood	2 (3.8)
GI	2 (3.8)
Lung	1 (1.9)
Other	1 (1.9)
Sinus	1 (1.9)
High fevers during CRS - n (%)	40 (76.9)
Time to high fever onset (days)	
n	40
Mean (SD)	5.1 (4.23)
Median	4.5
Min - Max	1 - 20
Duration (days)	
n	40
Mean (SD)	6.4 (5.18)
Median	6.0
Min - Max	1 - 27

	All patients N=52
Admitted to ICU - n (%)	18 (34.6)
Time to ICU Admission (days)	
n	18
Mean (SD)	6.2 (3.81)
Median	6.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	18
Mean (SD)	9.8 (7.73)
Median	9.0
Min - Max	1 - 27
Hypotension that required intervention - n (%)	17 (32.7)
High dose vasopressors used - n (%)	11 (21.2)
Oxygen supplementation given - n (%)	18 (34.6)
Patient intubated - n (%)	6 (11.5)
Duration (days)	
n	6
Mean (SD)	10.5 (7.82)
Median	8.5
Min - Max	4 - 26
Patient dialyzed - n (%)	4 (7.7)

	All patients N=52
Duration (days)	
n	4
Mean (SD)	33.0 (23.96)
Median	37.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	19 (36.5)
Duration (days)	
n	19
Mean (SD)	15.9 (16.94)
Median	10.0
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	8 (15.4)
Disseminated intravascular coagulation (DIC) observed - n (%)	4 (7.7)
Bleeding observed - n (%)	10 (19.2)
Blood product support given for bleeding - n (%)	9 (17.3)
Systemic anti-cytokine therapy given - n (%)	11 (21.2)
Tocilizumab	11 (21.2)
1 dose	5 (9.6)
2 doses	3 (5.8)
3 doses	3 (5.8)
4 doses	0

	All patients N=52
>4 doses	0
Siltuximab	0
Corticosteroids	7 (13.5)
Other	5 (9.6)

Only the first CRS episode is summarized for each patient.

Table 221c
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Race
Safety Set

Subgroup: Race: Asian

	All patients N=5
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (20.0)
Yes	4 (80.0)
Maximum CRS grade - n(%)	
Grade 2	4 (80.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	4
Mean (SD)	6.8 (2.50)
Median	6.5
Min - Max	4 - 10
Time to grade 3/4 CRS (days)	
n	-
Mean (SD)	-

	All patients N=5
Median	-
Min - Max	-
Concurrent infections - n(%)	1 (20.0)
Other	1 (20.0)
High fevers during CRS - n (%)	4 (80.0)
Time to high fever onset (days)	
n	4
Mean (SD)	7.3 (5.97)
Median	5.0
Min - Max	3 - 16
Duration (days)	
n	4
Mean (SD)	10.3 (5.85)
Median	7.5
Min - Max	7 - 19
Admitted to ICU - n (%)	0
Time to ICU Admission (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-

	All patients N=5
Duration of ICU stay (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Hypotension that required intervention - n (%)	0
High dose vasopressors used - n (%)	0
Oxygen supplementation given - n (%)	0
Patient intubated - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Patient dialyzed - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	1 (20.0)

	All patients N=5
Duration (days)	
n	1
Mean (SD)	7.0
Median	7.0
Min - Max	7 - 7
Pulmonary abnormalities - n (%)	0
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	1 (20.0)
Blood product support given for bleeding - n (%)	1 (20.0)
Systemic anti-cytokine therapy given - n (%)	1 (20.0)
Tocilizumab	0
1 dose	0
2 doses	0
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	1 (20.0)
Other	0

Only the first CRS episode is summarized for each patient.

Table 221c
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Race
Safety Set

Subgroup: Race: Other

	All patients N=7
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (14.3)
Yes	6 (85.7)
Maximum CRS grade - n(%)	
Grade 1	2 (28.6)
Grade 2	2 (28.6)
Grade 3	1 (14.3)
Grade 4	1 (14.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	6
Mean (SD)	4.7 (2.16)
Median	5.5
Min - Max	2 - 7

	All patients N=7
Time to grade 3/4 CRS (days)	
n	2
Mean (SD)	2.5 (0.71)
Median	2.5
Min - Max	2 - 3
Concurrent infections - n(%)	2 (28.6)
Blood	1 (14.3)
GI	2 (28.6)
High fevers during CRS - n (%)	5 (71.4)
Time to high fever onset (days)	
n	5
Mean (SD)	4.2 (2.05)
Median	5.0
Min - Max	2 - 6
Duration (days)	
n	5
Mean (SD)	4.4 (2.51)
Median	3.0
Min - Max	2 - 8
Admitted to ICU - n (%)	2 (28.6)
Time to ICU Admission (days)	

	All patients N=7
n	2
Mean (SD)	5.5 (0.71)
Median	5.5
Min - Max	5 - 6
Duration of ICU stay (days)	
n	2
Mean (SD)	10.5 (7.78)
Median	10.5
Min - Max	5 - 16
Hypotension that required intervention - n (%)	3 (42.9)
High dose vasopressors used - n (%)	1 (14.3)
Oxygen supplementation given - n (%)	1 (14.3)
Patient intubated - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Patient dialyzed - n (%)	0
Duration (days)	
n	-

	All patients N=7
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	3 (42.9)
Duration (days)	
n	3
Mean (SD)	8.0 (4.00)
Median	8.0
Min - Max	4 - 12
Pulmonary abnormalities - n (%)	1 (14.3)
Disseminated intravascular coagulation (DIC) observed - n (%)	1 (14.3)
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	1 (14.3)
Tocilizumab	1 (14.3)
1 dose	0
2 doses	1 (14.3)
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0

	All patients N=7
Corticosteroids	1 (14.3)
Other	0

Only the first CRS episode is summarized for each patient.

Table 221d
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Ethnicity
Safety Set

Subgroup: Ethnicity: Hispanic or Latino

	All patients N=25
Cytokine Release Syndrome (CRS) - n (%)	
No	5 (20.0)
Yes	20 (80.0)
Maximum CRS grade - n(%)	
Grade 1	2 (8.0)
Grade 2	12 (48.0)
Grade 3	3 (12.0)
Grade 4	3 (12.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	20
Mean (SD)	5.7 (4.27)
Median	5.0
Min - Max	1 - 20

	All patients N=25
Time to grade 3/4 CRS (days)	
n	6
Mean (SD)	6.3 (4.13)
Median	6.0
Min - Max	2 - 13
Concurrent infections - n(%)	3 (12.0)
Blood	1 (4.0)
GI	2 (8.0)
Other	1 (4.0)
High fevers during CRS - n (%)	19 (76.0)
Time to high fever onset (days)	
n	19
Mean (SD)	5.8 (4.34)
Median	5.0
Min - Max	1 - 20
Duration (days)	
n	19
Mean (SD)	4.3 (2.10)
Median	4.0
Min - Max	1 - 9
Admitted to ICU - n (%)	6 (24.0)

	All patients N=25
Time to ICU Admission (days)	
n	6
Mean (SD)	7.2 (3.87)
Median	5.5
Min - Max	3 - 12
Duration of ICU stay (days)	
n	6
Mean (SD)	7.5 (5.28)
Median	8.0
Min - Max	1 - 16
Hypotension that required intervention - n (%)	8 (32.0)
High dose vasopressors used - n (%)	4 (16.0)
Oxygen supplementation given - n (%)	6 (24.0)
Patient intubated - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Patient dialyzed - n (%)	0
Duration (days)	

	All patients N=25
n	-
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	6 (24.0)
Duration (days)	
n	6
Mean (SD)	8.8 (5.91)
Median	8.0
Min - Max	3 - 20
Pulmonary abnormalities - n (%)	2 (8.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	2 (8.0)
Bleeding observed - n (%)	2 (8.0)
Blood product support given for bleeding - n (%)	2 (8.0)
Systemic anti-cytokine therapy given - n (%)	3 (12.0)
Tocilizumab	3 (12.0)
1 dose	2 (8.0)
2 doses	1 (4.0)
3 doses	0
4 doses	0
>4 doses	0

	All patients N=25
Siltuximab	0
Corticosteroids	1 (4.0)
Other	0

Only the first CRS episode is summarized for each patient.

Table 221d
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Ethnicity
Safety Set

Subgroup: Ethnicity: Other

	All patients N=39
Cytokine Release Syndrome (CRS) - n (%)	
No	9 (23.1)
Yes	30 (76.9)
Maximum CRS grade - n(%)	
Grade 1	4 (10.3)
Grade 2	13 (33.3)
Grade 3	5 (12.8)
Grade 4	8 (20.5)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	30
Mean (SD)	4.5 (3.72)
Median	2.5
Min - Max	1 - 16
Time to grade 3/4 CRS (days)	

	All patients N=39
n	13
Mean (SD)	4.9 (2.66)
Median	4.0
Min - Max	2 - 10
Concurrent infections - n(%)	6 (15.4)
Blood	2 (5.1)
GI	2 (5.1)
Lung	1 (2.6)
Other	1 (2.6)
Sinus	1 (2.6)
High fevers during CRS - n (%)	30 (76.9)
Time to high fever onset (days)	
n	30
Mean (SD)	4.7 (4.12)
Median	3.5
Min - Max	1 - 16
Duration (days)	
n	30
Mean (SD)	8.0 (5.91)
Median	7.0
Min - Max	1 - 27

	All patients N=39
Admitted to ICU - n (%)	14 (35.9)
Time to ICU Admission (days)	
n	14
Mean (SD)	5.7 (3.56)
Median	6.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	14
Mean (SD)	10.9 (8.27)
Median	10.0
Min - Max	2 - 27
Hypotension that required intervention - n (%)	12 (30.8)
High dose vasopressors used - n (%)	8 (20.5)
Oxygen supplementation given - n (%)	13 (33.3)
Patient intubated - n (%)	6 (15.4)
Duration (days)	
n	6
Mean (SD)	10.5 (7.82)
Median	8.5
Min - Max	4 - 26
Patient dialyzed - n (%)	4 (10.3)

	All patients N=39
Duration (days)	
n	4
Mean (SD)	33.0 (23.96)
Median	37.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	17 (43.6)
Duration (days)	
n	17
Mean (SD)	16.5 (17.65)
Median	10.0
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	7 (17.9)
Disseminated intravascular coagulation (DIC) observed - n (%)	3 (7.7)
Bleeding observed - n (%)	9 (23.1)
Blood product support given for bleeding - n (%)	8 (20.5)
Systemic anti-cytokine therapy given - n (%)	10 (25.6)
Tocilizumab	9 (23.1)
1 dose	3 (7.7)
2 doses	3 (7.7)
3 doses	3 (7.7)
4 doses	0

	All patients N=39
>4 doses	0
Siltuximab	0
Corticosteroids	8 (20.5)
Other	5 (12.8)

Only the first CRS episode is summarized for each patient.

Table 221e
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Response status at study entry
Safety Set
Subgroup: Response status at study entry: Primary refractory

	All patients N=7
Cytokine Release Syndrome (CRS) - n (%)	
No	2 (28.6)
Yes	5 (71.4)
Maximum CRS grade - n(%)	
Grade 2	2 (28.6)
Grade 4	3 (42.9)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	5
Mean (SD)	4.6 (3.44)
Median	3.0
Min - Max	2 - 10
Time to grade 3/4 CRS (days)	
n	3
Mean (SD)	6.0 (3.46)

	All patients N=7
Median	4.0
Min - Max	4 - 10
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	5 (71.4)
Time to high fever onset (days)	
n	5
Mean (SD)	4.8 (3.56)
Median	5.0
Min - Max	1 - 10
Duration (days)	
n	5
Mean (SD)	9.4 (10.50)
Median	5.0
Min - Max	2 - 27
Admitted to ICU - n (%)	4 (57.1)
Time to ICU Admission (days)	
n	4
Mean (SD)	5.8 (3.30)
Median	5.5
Min - Max	2 - 10
Duration of ICU stay (days)	

	All patients N=7
n	4
Mean (SD)	10.5 (11.62)
Median	7.0
Min - Max	1 - 27
Hypotension that required intervention - n (%)	4 (57.1)
High dose vasopressors used - n (%)	3 (42.9)
Oxygen supplementation given - n (%)	3 (42.9)
Patient intubated - n (%)	2 (28.6)
Duration (days)	
n	2
Mean (SD)	16.5 (13.44)
Median	16.5
Min - Max	7 - 26
Patient dialyzed - n (%)	2 (28.6)
Duration (days)	
n	2
Mean (SD)	14.5 (17.68)
Median	14.5
Min - Max	2 - 27
Total Parenteral Nutrition (TPN) used - n (%)	3 (42.9)
Duration (days)	

	All patients N=7
n	3
Mean (SD)	13.3 (14.01)
Median	9.0
Min - Max	2 - 29
Pulmonary abnormalities - n (%)	2 (28.6)
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	2 (28.6)
Blood product support given for bleeding - n (%)	2 (28.6)
Systemic anti-cytokine therapy given - n (%)	2 (28.6)
Tocilizumab	2 (28.6)
1 dose	0
2 doses	1 (14.3)
3 doses	1 (14.3)
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	2 (28.6)
Other	2 (28.6)

Only the first CRS episode is summarized for each patient.

Table 221e
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Response status at study entry
Safety Set
Subgroup: Response status at study entry: Relapsed disease

	All patients N=57
Cytokine Release Syndrome (CRS) - n (%)	
No	12 (21.1)
Yes	45 (78.9)
Maximum CRS grade - n(%)	
Grade 1	6 (10.5)
Grade 2	23 (40.4)
Grade 3	8 (14.0)
Grade 4	8 (14.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	45
Mean (SD)	5.0 (4.03)
Median	5.0
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=57
n	16
Mean (SD)	5.3 (3.19)
Median	4.5
Min - Max	2 - 13
Concurrent infections - n(%)	9 (15.8)
Blood	3 (5.3)
GI	4 (7.0)
Lung	1 (1.8)
Other	2 (3.5)
Sinus	1 (1.8)
High fevers during CRS - n (%)	44 (77.2)
Time to high fever onset (days)	
n	44
Mean (SD)	5.2 (4.29)
Median	4.5
Min - Max	1 - 20
Duration (days)	
n	44
Mean (SD)	6.2 (4.22)
Median	6.0
Min - Max	1 - 19

	All patients N=57
Admitted to ICU - n (%)	16 (28.1)
Time to ICU Admission (days)	
n	16
Mean (SD)	6.3 (3.79)
Median	6.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	16
Mean (SD)	9.8 (6.69)
Median	9.0
Min - Max	2 - 27
Hypotension that required intervention - n (%)	16 (28.1)
High dose vasopressors used - n (%)	9 (15.8)
Oxygen supplementation given - n (%)	16 (28.1)
Patient intubated - n (%)	4 (7.0)
Duration (days)	
n	4
Mean (SD)	7.5 (2.38)
Median	8.5
Min - Max	4 - 9
Patient dialyzed - n (%)	2 (3.5)

	All patients N=57
Duration (days)	
n	2
Mean (SD)	51.5 (6.36)
Median	51.5
Min - Max	47 - 56
Total Parenteral Nutrition (TPN) used - n (%)	20 (35.1)
Duration (days)	
n	20
Mean (SD)	14.7 (16.26)
Median	9.5
Min - Max	3 - 65
Pulmonary abnormalities - n (%)	7 (12.3)
Disseminated intravascular coagulation (DIC) observed - n (%)	5 (8.8)
Bleeding observed - n (%)	9 (15.8)
Blood product support given for bleeding - n (%)	8 (14.0)
Systemic anti-cytokine therapy given - n (%)	11 (19.3)
Tocilizumab	10 (17.5)
1 dose	5 (8.8)
2 doses	3 (5.3)
3 doses	2 (3.5)
4 doses	0

	All patients N=57
>4 doses	0
Siltuximab	0
Corticosteroids	7 (12.3)
Other	3 (5.3)

Only the first CRS episode is summarized for each patient.

Table 221f
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Philadelphia chromosome/BCR-ABL
Safety Set

Subgroup: Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2
Cytokine Release Syndrome (CRS) - n (%)	
No	2 (100)
Maximum CRS grade - n(%)	
Fatal - n(%)	0
Time to onset of CRS (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Time to grade 3/4 CRS (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-

	All patients N=2
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	0
Time to high fever onset (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Admitted to ICU - n (%)	0
Time to ICU Admission (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Duration of ICU stay (days)	
n	-
Mean (SD)	-

	All patients N=2
Median	-
Min - Max	-
Hypotension that required intervention - n (%)	0
High dose vasopressors used - n (%)	0
Oxygen supplementation given - n (%)	0
Patient intubated - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Patient dialyzed - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	0
Duration (days)	
n	-
Mean (SD)	-

	All patients N=2
Median	-
Min - Max	-
Pulmonary abnormalities - n (%)	0
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	0
Tocilizumab	0
1 dose	0
2 doses	0
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	0
Other	0

Only the first CRS episode is summarized for each patient.

Table 221f
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Philadelphia chromosome/BCR-ABL
Safety Set

Subgroup: Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62
Cytokine Release Syndrome (CRS) - n (%)	
No	12 (19.4)
Yes	50 (80.6)
Maximum CRS grade - n(%)	
Grade 1	6 (9.7)
Grade 2	25 (40.3)
Grade 3	8 (12.9)
Grade 4	11 (17.7)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	50
Mean (SD)	5.0 (3.95)
Median	4.5
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=62
n	19
Mean (SD)	5.4 (3.15)
Median	4.0
Min - Max	2 - 13
Concurrent infections - n(%)	9 (14.5)
Blood	3 (4.8)
GI	4 (6.5)
Lung	1 (1.6)
Other	2 (3.2)
Sinus	1 (1.6)
High fevers during CRS - n (%)	49 (79.0)
Time to high fever onset (days)	
n	49
Mean (SD)	5.1 (4.19)
Median	5.0
Min - Max	1 - 20
Duration (days)	
n	49
Mean (SD)	6.5 (5.11)
Median	6.0
Min - Max	1 - 27

	All patients N=62
Admitted to ICU - n (%)	20 (32.3)
Time to ICU Admission (days)	
n	20
Mean (SD)	6.2 (3.62)
Median	6.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	20
Mean (SD)	9.9 (7.53)
Median	9.0
Min - Max	1 - 27
Hypotension that required intervention - n (%)	20 (32.3)
High dose vasopressors used - n (%)	12 (19.4)
Oxygen supplementation given - n (%)	19 (30.6)
Patient intubated - n (%)	6 (9.7)
Duration (days)	
n	6
Mean (SD)	10.5 (7.82)
Median	8.5
Min - Max	4 - 26
Patient dialyzed - n (%)	4 (6.5)

	All patients N=62
Duration (days)	
n	4
Mean (SD)	33.0 (23.96)
Median	37.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	23 (37.1)
Duration (days)	
n	23
Mean (SD)	14.5 (15.69)
Median	9.0
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	9 (14.5)
Disseminated intravascular coagulation (DIC) observed - n (%)	5 (8.1)
Bleeding observed - n (%)	11 (17.7)
Blood product support given for bleeding - n (%)	10 (16.1)
Systemic anti-cytokine therapy given - n (%)	13 (21.0)
Tocilizumab	12 (19.4)
1 dose	5 (8.1)
2 doses	4 (6.5)
3 doses	3 (4.8)
4 doses	0

	All patients N=62
>4 doses	0
Siltuximab	0
Corticosteroids	9 (14.5)
Other	5 (8.1)

Only the first CRS episode is summarized for each patient.

Table 221g
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by MLL rearrangement
Safety Set

Subgroup: Mixed-lineage leukemia rearrangement: Yes

	All patients N=3
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (33.3)
Yes	2 (66.7)
Maximum CRS grade - n(%)	
Grade 4	2 (66.7)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	2
Mean (SD)	6.0 (5.66)
Median	6.0
Min - Max	2 - 10
Time to grade 3/4 CRS (days)	
n	2
Mean (SD)	7.5 (3.54)
Median	7.5

	All patients N=3
Min - Max	5 - 10
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	2 (66.7)
Time to high fever onset (days)	
n	2
Mean (SD)	6.5 (4.95)
Median	6.5
Min - Max	3 - 10
Duration (days)	
n	2
Mean (SD)	17.0 (14.14)
Median	17.0
Min - Max	7 - 27
Admitted to ICU - n (%)	2 (66.7)
Time to ICU Admission (days)	
n	2
Mean (SD)	7.5 (3.54)
Median	7.5
Min - Max	5 - 10
Duration of ICU stay (days)	
n	2

	All patients N=3
Mean (SD)	20.0 (9.90)
Median	20.0
Min - Max	13 - 27
Hypotension that required intervention - n (%)	2 (66.7)
High dose vasopressors used - n (%)	2 (66.7)
Oxygen supplementation given - n (%)	2 (66.7)
Patient intubated - n (%)	2 (66.7)
Duration (days)	
n	2
Mean (SD)	17.5 (12.02)
Median	17.5
Min - Max	9 - 26
Patient dialyzed - n (%)	1 (33.3)
Duration (days)	
n	1
Mean (SD)	27.0
Median	27.0
Min - Max	27 - 27
Total Parenteral Nutrition (TPN) used - n (%)	2 (66.7)
Duration (days)	
n	2

	All patients N=3
Mean (SD)	23.0 (8.49)
Median	23.0
Min - Max	17 - 29
Pulmonary abnormalities - n (%)	1 (33.3)
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	2 (66.7)
Blood product support given for bleeding - n (%)	2 (66.7)
Systemic anti-cytokine therapy given - n (%)	2 (66.7)
Tocilizumab	2 (66.7)
1 dose	1 (33.3)
2 doses	0
3 doses	1 (33.3)
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	1 (33.3)
Other	1 (33.3)

Only the first CRS episode is summarized for each patient.

Table 221g
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by MLL rearrangement
Safety Set

Subgroup: Mixed-lineage leukemia rearrangement: No

	All patients N=61
Cytokine Release Syndrome (CRS) - n (%)	
No	13 (21.3)
Yes	48 (78.7)
Maximum CRS grade - n(%)	
Grade 1	6 (9.8)
Grade 2	25 (41.0)
Grade 3	8 (13.1)
Grade 4	9 (14.8)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	48
Mean (SD)	4.9 (3.94)
Median	4.5
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=61
n	17
Mean (SD)	5.1 (3.12)
Median	4.0
Min - Max	2 - 13
Concurrent infections - n(%)	9 (14.8)
Blood	3 (4.9)
GI	4 (6.6)
Lung	1 (1.6)
Other	2 (3.3)
Sinus	1 (1.6)
High fevers during CRS - n (%)	47 (77.0)
Time to high fever onset (days)	
n	47
Mean (SD)	5.1 (4.21)
Median	5.0
Min - Max	1 - 20
Duration (days)	
n	47
Mean (SD)	6.1 (4.23)
Median	6.0
Min - Max	1 - 19

	All patients N=61
Admitted to ICU - n (%)	18 (29.5)
Time to ICU Admission (days)	
n	18
Mean (SD)	6.0 (3.69)
Median	6.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	18
Mean (SD)	8.8 (6.66)
Median	8.0
Min - Max	1 - 27
Hypotension that required intervention - n (%)	18 (29.5)
High dose vasopressors used - n (%)	10 (16.4)
Oxygen supplementation given - n (%)	17 (27.9)
Patient intubated - n (%)	4 (6.6)
Duration (days)	
n	4
Mean (SD)	7.0 (2.16)
Median	7.5
Min - Max	4 - 9
Patient dialyzed - n (%)	3 (4.9)

	All patients N=61
Duration (days)	
n	3
Mean (SD)	35.0 (28.93)
Median	47.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	21 (34.4)
Duration (days)	
n	21
Mean (SD)	13.7 (16.10)
Median	9.0
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	8 (13.1)
Disseminated intravascular coagulation (DIC) observed - n (%)	5 (8.2)
Bleeding observed - n (%)	9 (14.8)
Blood product support given for bleeding - n (%)	8 (13.1)
Systemic anti-cytokine therapy given - n (%)	11 (18.0)
Tocilizumab	10 (16.4)
1 dose	4 (6.6)
2 doses	4 (6.6)
3 doses	2 (3.3)
4 doses	0

	All patients N=61
>4 doses	0
Siltuximab	0
Corticosteroids	8 (13.1)
Other	4 (6.6)

Only the first CRS episode is summarized for each patient.

Table 221h
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Hypodiploidy
Safety Set

Subgroup: Hypodiploidy: Yes

	All patients N=1
Cytokine Release Syndrome (CRS) - n (%)	
Yes	1 (100)
Maximum CRS grade - n(%)	
Grade 2	1 (100)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	1
Mean (SD)	2.0
Median	2.0
Min - Max	2 - 2
Time to grade 3/4 CRS (days)	
n	-
Mean (SD)	-
Median	-

	All patients N=1
Min - Max	-
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	1 (100.0)
Time to high fever onset (days)	
n	1
Mean (SD)	2.0
Median	2.0
Min - Max	2 - 2
Duration (days)	
n	1
Mean (SD)	9.0
Median	9.0
Min - Max	9 - 9
Admitted to ICU - n (%)	0
Time to ICU Admission (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Duration of ICU stay (days)	
n	-

	All patients N=1
Mean (SD)	-
Median	-
Min - Max	-
Hypotension that required intervention - n (%)	0
High dose vasopressors used - n (%)	0
Oxygen supplementation given - n (%)	0
Patient intubated - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Patient dialyzed - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	1 (100.0)
Duration (days)	
n	1

	All patients N=1
Mean (SD)	65.0
Median	65.0
Min - Max	65 - 65
Pulmonary abnormalities - n (%)	0
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	0
Tocilizumab	0
1 dose	0
2 doses	0
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	0
Other	0

Only the first CRS episode is summarized for each patient.

Table 221h
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Hypodiploidy
Safety Set

Subgroup: Hypodiploidy: No

	All patients N=63
Cytokine Release Syndrome (CRS) - n (%)	
No	14 (22.2)
Yes	49 (77.8)
Maximum CRS grade - n(%)	
Grade 1	6 (9.5)
Grade 2	24 (38.1)
Grade 3	8 (12.7)
Grade 4	11 (17.5)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	49
Mean (SD)	5.0 (3.96)
Median	5.0
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=63
n	19
Mean (SD)	5.4 (3.15)
Median	4.0
Min - Max	2 - 13
Concurrent infections - n(%)	9 (14.3)
Blood	3 (4.8)
GI	4 (6.3)
Lung	1 (1.6)
Other	2 (3.2)
Sinus	1 (1.6)
High fevers during CRS - n (%)	48 (76.2)
Time to high fever onset (days)	
n	48
Mean (SD)	5.2 (4.21)
Median	5.0
Min - Max	1 - 20
Duration (days)	
n	48
Mean (SD)	6.5 (5.15)
Median	6.0
Min - Max	1 - 27

	All patients N=63
Admitted to ICU - n (%)	20 (31.7)
Time to ICU Admission (days)	
n	20
Mean (SD)	6.2 (3.62)
Median	6.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	20
Mean (SD)	9.9 (7.53)
Median	9.0
Min - Max	1 - 27
Hypotension that required intervention - n (%)	20 (31.7)
High dose vasopressors used - n (%)	12 (19.0)
Oxygen supplementation given - n (%)	19 (30.2)
Patient intubated - n (%)	6 (9.5)
Duration (days)	
n	6
Mean (SD)	10.5 (7.82)
Median	8.5
Min - Max	4 - 26
Patient dialyzed - n (%)	4 (6.3)

	All patients N=63
Duration (days)	
n	4
Mean (SD)	33.0 (23.96)
Median	37.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	22 (34.9)
Duration (days)	
n	22
Mean (SD)	12.2 (11.44)
Median	9.0
Min - Max	2 - 54
Pulmonary abnormalities - n (%)	9 (14.3)
Disseminated intravascular coagulation (DIC) observed - n (%)	5 (7.9)
Bleeding observed - n (%)	11 (17.5)
Blood product support given for bleeding - n (%)	10 (15.9)
Systemic anti-cytokine therapy given - n (%)	13 (20.6)
Tocilizumab	12 (19.0)
1 dose	5 (7.9)
2 doses	4 (6.3)
3 doses	3 (4.8)
4 doses	0

	All patients N=63
>4 doses	0
Siltuximab	0
Corticosteroids	9 (14.3)
Other	5 (7.9)

Only the first CRS episode is summarized for each patient.

Table 221i
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by BCR-ABL1-like
Safety Set

Subgroup: BCR-ABL1-like: Yes

	All patients N=4
Cytokine Release Syndrome (CRS) - n (%)	
No	2 (50.0)
Yes	2 (50.0)
Maximum CRS grade - n(%)	
Grade 2	1 (25.0)
Grade 3	1 (25.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	2
Mean (SD)	6.0 (2.83)
Median	6.0
Min - Max	4 - 8
Time to grade 3/4 CRS (days)	
n	1

	All patients N=4
Mean (SD)	8.0
Median	8.0
Min - Max	8 - 8
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	2 (50.0)
Time to high fever onset (days)	
n	2
Mean (SD)	6.0 (2.83)
Median	6.0
Min - Max	4 - 8
Duration (days)	
n	2
Mean (SD)	7.0 (1.41)
Median	7.0
Min - Max	6 - 8
Admitted to ICU - n (%)	1 (25.0)
Time to ICU Admission (days)	
n	1
Mean (SD)	12.0
Median	12.0
Min - Max	12 - 12

	All patients N=4
Duration of ICU stay (days)	
n	1
Mean (SD)	3.0
Median	3.0
Min - Max	3 - 3
Hypotension that required intervention - n (%)	1 (25.0)
High dose vasopressors used - n (%)	0
Oxygen supplementation given - n (%)	0
Patient intubated - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Patient dialyzed - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	1 (25.0)

	All patients N=4
Duration (days)	
n	1
Mean (SD)	5.0
Median	5.0
Min - Max	5 - 5
Pulmonary abnormalities - n (%)	0
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	0
Tocilizumab	0
1 dose	0
2 doses	0
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	0
Other	0

Only the first CRS episode is summarized for each patient.

Table 221i
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by BCR-ABL1-like
Safety Set

Subgroup: BCR-ABL1-like: No

	All patients N=60
Cytokine Release Syndrome (CRS) - n (%)	
No	12 (20.0)
Yes	48 (80.0)
Maximum CRS grade - n(%)	
Grade 1	6 (10.0)
Grade 2	24 (40.0)
Grade 3	7 (11.7)
Grade 4	11 (18.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	48
Mean (SD)	4.9 (4.00)
Median	4.5
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=60
n	18
Mean (SD)	5.2 (3.17)
Median	4.0
Min - Max	2 - 13
Concurrent infections - n(%)	9 (15.0)
Blood	3 (5.0)
GI	4 (6.7)
Lung	1 (1.7)
Other	2 (3.3)
Sinus	1 (1.7)
High fevers during CRS - n (%)	47 (78.3)
Time to high fever onset (days)	
n	47
Mean (SD)	5.1 (4.26)
Median	5.0
Min - Max	1 - 20
Duration (days)	
n	47
Mean (SD)	6.5 (5.21)
Median	6.0
Min - Max	1 - 27

	All patients N=60
Admitted to ICU - n (%)	19 (31.7)
Time to ICU Admission (days)	
n	19
Mean (SD)	5.8 (3.44)
Median	6.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	19
Mean (SD)	10.3 (7.56)
Median	9.0
Min - Max	1 - 27
Hypotension that required intervention - n (%)	19 (31.7)
High dose vasopressors used - n (%)	12 (20.0)
Oxygen supplementation given - n (%)	19 (31.7)
Patient intubated - n (%)	6 (10.0)
Duration (days)	
n	6
Mean (SD)	10.5 (7.82)
Median	8.5
Min - Max	4 - 26
Patient dialyzed - n (%)	4 (6.7)

	All patients N=60
Duration (days)	
n	4
Mean (SD)	33.0 (23.96)
Median	37.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	22 (36.7)
Duration (days)	
n	22
Mean (SD)	14.9 (15.92)
Median	9.5
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	9 (15.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	5 (8.3)
Bleeding observed - n (%)	11 (18.3)
Blood product support given for bleeding - n (%)	10 (16.7)
Systemic anti-cytokine therapy given - n (%)	13 (21.7)
Tocilizumab	12 (20.0)
1 dose	5 (8.3)
2 doses	4 (6.7)
3 doses	3 (5.0)
4 doses	0

	All patients N=60
>4 doses	0
Siltuximab	0
Corticosteroids	9 (15.0)
Other	5 (8.3)

Only the first CRS episode is summarized for each patient.

Table 221j
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Complex Karyotypes
Safety Set
Subgroup: Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (5.3)
Yes	18 (94.7)
Maximum CRS grade - n(%)	
Grade 1	1 (5.3)
Grade 2	9 (47.4)
Grade 3	3 (15.8)
Grade 4	5 (26.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	18
Mean (SD)	4.0 (2.68)
Median	3.0
Min - Max	1 - 10
Time to grade 3/4 CRS (days)	

	All patients N=19
n	8
Mean (SD)	3.5 (1.41)
Median	3.0
Min - Max	2 - 6
Concurrent infections - n(%)	4 (21.1)
GI	2 (10.5)
Other	1 (5.3)
Sinus	1 (5.3)
High fevers during CRS - n (%)	18 (94.7)
Time to high fever onset (days)	
n	18
Mean (SD)	3.9 (2.60)
Median	3.5
Min - Max	1 - 10
Duration (days)	
n	18
Mean (SD)	6.5 (3.54)
Median	7.0
Min - Max	1 - 16
Admitted to ICU - n (%)	8 (42.1)
Time to ICU Admission (days)	

	All patients N=19
n	8
Mean (SD)	4.1 (2.17)
Median	4.0
Min - Max	1 - 7
Duration of ICU stay (days)	
n	8
Mean (SD)	11.1 (8.04)
Median	10.0
Min - Max	2 - 27
Hypotension that required intervention - n (%)	8 (42.1)
High dose vasopressors used - n (%)	5 (26.3)
Oxygen supplementation given - n (%)	9 (47.4)
Patient intubated - n (%)	4 (21.1)
Duration (days)	
n	4
Mean (SD)	7.5 (2.38)
Median	8.5
Min - Max	4 - 9
Patient dialyzed - n (%)	2 (10.5)
Duration (days)	
n	2

	All patients N=19
Mean (SD)	51.5 (6.36)
Median	51.5
Min - Max	47 - 56
Total Parenteral Nutrition (TPN) used - n (%)	11 (57.9)
Duration (days)	
n	11
Mean (SD)	14.2 (14.30)
Median	10.0
Min - Max	4 - 54
Pulmonary abnormalities - n (%)	4 (21.1)
Disseminated intravascular coagulation (DIC) observed - n (%)	2 (10.5)
Bleeding observed - n (%)	5 (26.3)
Blood product support given for bleeding - n (%)	4 (21.1)
Systemic anti-cytokine therapy given - n (%)	5 (26.3)
Tocilizumab	5 (26.3)
1 dose	2 (10.5)
2 doses	1 (5.3)
3 doses	2 (10.5)
4 doses	0
>4 doses	0
Siltuximab	0

	All patients N=19
Corticosteroids	3 (15.8)
Other	3 (15.8)

Only the first CRS episode is summarized for each patient.

Table 221j
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Complex Karyotypes
Safety Set
Subgroup: Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45
Cytokine Release Syndrome (CRS) - n (%)	
No	13 (28.9)
Yes	32 (71.1)
Maximum CRS grade - n(%)	
Grade 1	5 (11.1)
Grade 2	16 (35.6)
Grade 3	5 (11.1)
Grade 4	6 (13.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	32
Mean (SD)	5.5 (4.45)
Median	5.0
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=45
n	11
Mean (SD)	6.7 (3.41)
Median	6.0
Min - Max	2 - 13
Concurrent infections - n(%)	5 (11.1)
Blood	3 (6.7)
GI	2 (4.4)
Lung	1 (2.2)
Other	1 (2.2)
High fevers during CRS - n (%)	31 (68.9)
Time to high fever onset (days)	
n	31
Mean (SD)	5.8 (4.79)
Median	5.0
Min - Max	1 - 20
Duration (days)	
n	31
Mean (SD)	6.5 (5.89)
Median	4.0
Min - Max	1 - 27
Admitted to ICU - n (%)	12 (26.7)

	All patients N=45
Time to ICU Admission (days)	
n	12
Mean (SD)	7.5 (3.83)
Median	6.0
Min - Max	2 - 15
Duration of ICU stay (days)	
n	12
Mean (SD)	9.1 (7.42)
Median	8.0
Min - Max	1 - 27
Hypotension that required intervention - n (%)	12 (26.7)
High dose vasopressors used - n (%)	7 (15.6)
Oxygen supplementation given - n (%)	10 (22.2)
Patient intubated - n (%)	2 (4.4)
Duration (days)	
n	2
Mean (SD)	16.5 (13.44)
Median	16.5
Min - Max	7 - 26
Patient dialyzed - n (%)	2 (4.4)
Duration (days)	

	All patients N=45
n	2
Mean (SD)	14.5 (17.68)
Median	14.5
Min - Max	2 - 27
Total Parenteral Nutrition (TPN) used - n (%)	12 (26.7)
Duration (days)	
n	12
Mean (SD)	14.8 (17.51)
Median	8.5
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	5 (11.1)
Disseminated intravascular coagulation (DIC) observed - n (%)	3 (6.7)
Bleeding observed - n (%)	6 (13.3)
Blood product support given for bleeding - n (%)	6 (13.3)
Systemic anti-cytokine therapy given - n (%)	8 (17.8)
Tocilizumab	7 (15.6)
1 dose	3 (6.7)
2 doses	3 (6.7)
3 doses	1 (2.2)
4 doses	0
>4 doses	0

	All patients N=45
Siltuximab	0
Corticosteroids	6 (13.3)
Other	2 (4.4)

Only the first CRS episode is summarized for each patient.

Table 221k
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Region
Safety Set

Subgroup: Region: US

	All patients N=64
Cytokine Release Syndrome (CRS) - n (%)	
No	14 (21.9)
Yes	50 (78.1)
Maximum CRS grade - n(%)	
Grade 1	6 (9.4)
Grade 2	25 (39.1)
Grade 3	8 (12.5)
Grade 4	11 (17.2)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	50
Mean (SD)	5.0 (3.95)
Median	4.5
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=64
n	19
Mean (SD)	5.4 (3.15)
Median	4.0
Min - Max	2 - 13
Concurrent infections - n(%)	9 (14.1)
Blood	3 (4.7)
GI	4 (6.3)
Lung	1 (1.6)
Other	2 (3.1)
Sinus	1 (1.6)
High fevers during CRS - n (%)	49 (76.6)
Time to high fever onset (days)	
n	49
Mean (SD)	5.1 (4.19)
Median	5.0
Min - Max	1 - 20
Duration (days)	
n	49
Mean (SD)	6.5 (5.11)
Median	6.0
Min - Max	1 - 27

	All patients N=64
Admitted to ICU - n (%)	20 (31.3)
Time to ICU Admission (days)	
n	20
Mean (SD)	6.2 (3.62)
Median	6.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	20
Mean (SD)	9.9 (7.53)
Median	9.0
Min - Max	1 - 27
Hypotension that required intervention - n (%)	20 (31.3)
High dose vasopressors used - n (%)	12 (18.8)
Oxygen supplementation given - n (%)	19 (29.7)
Patient intubated - n (%)	6 (9.4)
Duration (days)	
n	6
Mean (SD)	10.5 (7.82)
Median	8.5
Min - Max	4 - 26
Patient dialyzed - n (%)	4 (6.3)

	All patients N=64
Duration (days)	
n	4
Mean (SD)	33.0 (23.96)
Median	37.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	23 (35.9)
Duration (days)	
n	23
Mean (SD)	14.5 (15.69)
Median	9.0
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	9 (14.1)
Disseminated intravascular coagulation (DIC) observed - n (%)	5 (7.8)
Bleeding observed - n (%)	11 (17.2)
Blood product support given for bleeding - n (%)	10 (15.6)
Systemic anti-cytokine therapy given - n (%)	13 (20.3)
Tocilizumab	12 (18.8)
1 dose	5 (7.8)
2 doses	4 (6.3)
3 doses	3 (4.7)
4 doses	0

	All patients N=64
>4 doses	0
Siltuximab	0
Corticosteroids	9 (14.1)
Other	5 (7.8)

Only the first CRS episode is summarized for each patient.

Table 221l
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Prior SCT therapy
Safety Set

Subgroup: Prior SCT therapy: Yes

	All patients N=28
Cytokine Release Syndrome (CRS) - n (%)	
No	8 (28.6)
Yes	20 (71.4)
Maximum CRS grade - n(%)	
Grade 1	3 (10.7)
Grade 2	11 (39.3)
Grade 3	4 (14.3)
Grade 4	2 (7.1)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	20
Mean (SD)	4.9 (3.73)
Median	5.0
Min - Max	1 - 16
Time to grade 3/4 CRS (days)	

	All patients N=28
n	6
Mean (SD)	6.2 (4.12)
Median	6.0
Min - Max	2 - 13
Concurrent infections - n(%)	6 (21.4)
Blood	2 (7.1)
GI	4 (14.3)
Other	1 (3.6)
High fevers during CRS - n (%)	19 (67.9)
Time to high fever onset (days)	
n	19
Mean (SD)	4.7 (3.93)
Median	5.0
Min - Max	1 - 16
Duration (days)	
n	19
Mean (SD)	5.8 (3.95)
Median	6.0
Min - Max	1 - 16
Admitted to ICU - n (%)	6 (21.4)
Time to ICU Admission (days)	

	All patients N=28
n	6
Mean (SD)	7.3 (3.93)
Median	6.0
Min - Max	2 - 12
Duration of ICU stay (days)	
n	6
Mean (SD)	8.0 (5.18)
Median	6.0
Min - Max	3 - 17
Hypotension that required intervention - n (%)	7 (25.0)
High dose vasopressors used - n (%)	3 (10.7)
Oxygen supplementation given - n (%)	5 (17.9)
Patient intubated - n (%)	2 (7.1)
Duration (days)	
n	2
Mean (SD)	6.0 (2.83)
Median	6.0
Min - Max	4 - 8
Patient dialyzed - n (%)	1 (3.6)
Duration (days)	
n	1

	All patients N=28
Mean (SD)	56.0
Median	56.0
Min - Max	56 - 56
Total Parenteral Nutrition (TPN) used - n (%)	9 (32.1)
Duration (days)	
n	9
Mean (SD)	14.2 (15.90)
Median	8.0
Min - Max	4 - 54
Pulmonary abnormalities - n (%)	4 (14.3)
Disseminated intravascular coagulation (DIC) observed - n (%)	2 (7.1)
Bleeding observed - n (%)	4 (14.3)
Blood product support given for bleeding - n (%)	4 (14.3)
Systemic anti-cytokine therapy given - n (%)	3 (10.7)
Tocilizumab	3 (10.7)
1 dose	0
2 doses	2 (7.1)
3 doses	1 (3.6)
4 doses	0
>4 doses	0
Siltuximab	0

	All patients N=28
Corticosteroids	3 (10.7)
Other	2 (7.1)

Only the first CRS episode is summarized for each patient.

Table 221l
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Prior SCT therapy
Safety Set

Subgroup: Prior SCT therapy: No

	All patients N=36
Cytokine Release Syndrome (CRS) - n (%)	
No	6 (16.7)
Yes	30 (83.3)
Maximum CRS grade - n(%)	
Grade 1	3 (8.3)
Grade 2	14 (38.9)
Grade 3	4 (11.1)
Grade 4	9 (25.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	30
Mean (SD)	5.1 (4.14)
Median	3.5
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=36
n	13
Mean (SD)	5.0 (2.71)
Median	4.0
Min - Max	2 - 10
Concurrent infections - n(%)	3 (8.3)
Blood	1 (2.8)
Lung	1 (2.8)
Other	1 (2.8)
Sinus	1 (2.8)
High fevers during CRS - n (%)	30 (83.3)
Time to high fever onset (days)	
n	30
Mean (SD)	5.4 (4.40)
Median	4.5
Min - Max	1 - 20
Duration (days)	
n	30
Mean (SD)	7.0 (5.74)
Median	6.0
Min - Max	2 - 27
Admitted to ICU - n (%)	14 (38.9)

	All patients N=36
Time to ICU Admission (days)	
n	14
Mean (SD)	5.6 (3.50)
Median	5.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	14
Mean (SD)	10.7 (8.38)
Median	9.5
Min - Max	1 - 27
Hypotension that required intervention - n (%)	13 (36.1)
High dose vasopressors used - n (%)	9 (25.0)
Oxygen supplementation given - n (%)	14 (38.9)
Patient intubated - n (%)	4 (11.1)
Duration (days)	
n	4
Mean (SD)	12.8 (8.88)
Median	9.0
Min - Max	7 - 26
Patient dialyzed - n (%)	3 (8.3)
Duration (days)	

	All patients N=36
n	3
Mean (SD)	25.3 (22.55)
Median	27.0
Min - Max	2 - 47
Total Parenteral Nutrition (TPN) used - n (%)	14 (38.9)
Duration (days)	
n	14
Mean (SD)	14.6 (16.16)
Median	9.5
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	5 (13.9)
Disseminated intravascular coagulation (DIC) observed - n (%)	3 (8.3)
Bleeding observed - n (%)	7 (19.4)
Blood product support given for bleeding - n (%)	6 (16.7)
Systemic anti-cytokine therapy given - n (%)	10 (27.8)
Tocilizumab	9 (25.0)
1 dose	5 (13.9)
2 doses	2 (5.6)
3 doses	2 (5.6)
4 doses	0
>4 doses	0

	All patients N=36
Siltuximab	0
Corticosteroids	6 (16.7)
Other	3 (8.3)

Only the first CRS episode is summarized for each patient.

Table 221m
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Eligibility for SCT
Safety Set

Subgroup: Eligibility for SCT: Yes

	All patients N=14
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (7.1)
Yes	13 (92.9)
Maximum CRS grade - n(%)	
Grade 2	10 (71.4)
Grade 3	2 (14.3)
Grade 4	1 (7.1)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	13
Mean (SD)	7.2 (4.69)
Median	7.0
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=14
n	3
Mean (SD)	6.7 (4.16)
Median	8.0
Min - Max	2 - 10
Concurrent infections - n(%)	3 (21.4)
Blood	2 (14.3)
GI	1 (7.1)
Lung	1 (7.1)
Other	1 (7.1)
High fevers during CRS - n (%)	13 (92.9)
Time to high fever onset (days)	
n	13
Mean (SD)	7.0 (4.74)
Median	6.0
Min - Max	2 - 20
Duration (days)	
n	13
Mean (SD)	5.1 (4.52)
Median	4.0
Min - Max	1 - 19
Admitted to ICU - n (%)	3 (21.4)

	All patients N=14
Time to ICU Admission (days)	
n	3
Mean (SD)	8.7 (5.51)
Median	6.0
Min - Max	5 - 15
Duration of ICU stay (days)	
n	3
Mean (SD)	8.3 (7.02)
Median	9.0
Min - Max	1 - 15
Hypotension that required intervention - n (%)	4 (28.6)
High dose vasopressors used - n (%)	1 (7.1)
Oxygen supplementation given - n (%)	5 (35.7)
Patient intubated - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Patient dialyzed - n (%)	0
Duration (days)	

	All patients N=14
n	-
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	4 (28.6)
Duration (days)	
n	4
Mean (SD)	10.8 (6.80)
Median	9.5
Min - Max	4 - 20
Pulmonary abnormalities - n (%)	2 (14.3)
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	2 (14.3)
Tocilizumab	2 (14.3)
1 dose	2 (14.3)
2 doses	0
3 doses	0
4 doses	0
>4 doses	0

	All patients N=14
Siltuximab	0
Corticosteroids	0
Other	0

Only the first CRS episode is summarized for each patient.

Table 221m
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Eligibility for SCT
Safety Set

Subgroup: Eligibility for SCT: No

	All patients N=50
Cytokine Release Syndrome (CRS) - n (%)	
No	13 (26.0)
Yes	37 (74.0)
Maximum CRS grade - n(%)	
Grade 1	6 (12.0)
Grade 2	15 (30.0)
Grade 3	6 (12.0)
Grade 4	10 (20.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	37
Mean (SD)	4.2 (3.37)
Median	3.0
Min - Max	1 - 16
Time to grade 3/4 CRS (days)	

	All patients N=50
n	16
Mean (SD)	5.1 (3.03)
Median	4.0
Min - Max	2 - 13
Concurrent infections - n(%)	6 (12.0)
Blood	1 (2.0)
GI	3 (6.0)
Other	1 (2.0)
Sinus	1 (2.0)
High fevers during CRS - n (%)	36 (72.0)
Time to high fever onset (days)	
n	36
Mean (SD)	4.5 (3.83)
Median	3.5
Min - Max	1 - 16
Duration (days)	
n	36
Mean (SD)	7.1 (5.26)
Median	6.0
Min - Max	1 - 27
Admitted to ICU - n (%)	17 (34.0)

	All patients N=50
Time to ICU Admission (days)	
n	17
Mean (SD)	5.7 (3.22)
Median	6.0
Min - Max	1 - 12
Duration of ICU stay (days)	
n	17
Mean (SD)	10.2 (7.79)
Median	9.0
Min - Max	2 - 27
Hypotension that required intervention - n (%)	16 (32.0)
High dose vasopressors used - n (%)	11 (22.0)
Oxygen supplementation given - n (%)	14 (28.0)
Patient intubated - n (%)	6 (12.0)
Duration (days)	
n	6
Mean (SD)	10.5 (7.82)
Median	8.5
Min - Max	4 - 26
Patient dialyzed - n (%)	4 (8.0)
Duration (days)	

	All patients N=50
n	4
Mean (SD)	33.0 (23.96)
Median	37.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	19 (38.0)
Duration (days)	
n	19
Mean (SD)	15.3 (17.02)
Median	9.0
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	7 (14.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	5 (10.0)
Bleeding observed - n (%)	11 (22.0)
Blood product support given for bleeding - n (%)	10 (20.0)
Systemic anti-cytokine therapy given - n (%)	11 (22.0)
Tocilizumab	10 (20.0)
1 dose	3 (6.0)
2 doses	4 (8.0)
3 doses	3 (6.0)
4 doses	0
>4 doses	0

	All patients N=50
Siltuximab	0
Corticosteroids	9 (18.0)
Other	5 (10.0)

Only the first CRS episode is summarized for each patient.

Table 221n
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Baseline bone marrow tumor burden
Safety Set

Subgroup: Baseline bone marrow tumor burden: Low

	All patients N=20
Cytokine Release Syndrome (CRS) - n (%)	
No	4 (20.0)
Yes	16 (80.0)
Maximum CRS grade - n(%)	
Grade 2	11 (55.0)
Grade 3	3 (15.0)
Grade 4	2 (10.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	16
Mean (SD)	4.0 (2.50)
Median	3.5
Min - Max	1 - 10
Time to grade 3/4 CRS (days)	
n	5

	All patients N=20
Mean (SD)	4.6 (2.41)
Median	4.0
Min - Max	2 - 8
Concurrent infections - n(%)	2 (10.0)
GI	1 (5.0)
Other	1 (5.0)
High fevers during CRS - n (%)	16 (80.0)
Time to high fever onset (days)	
n	16
Mean (SD)	4.1 (2.50)
Median	4.0
Min - Max	1 - 10
Duration (days)	
n	16
Mean (SD)	4.8 (2.69)
Median	4.0
Min - Max	1 - 9
Admitted to ICU - n (%)	5 (25.0)
Time to ICU Admission (days)	
n	5
Mean (SD)	5.2 (1.30)

	All patients N=20
Median	6.0
Min - Max	3 - 6
Duration of ICU stay (days)	
n	5
Mean (SD)	3.4 (1.82)
Median	4.0
Min - Max	1 - 5
Hypotension that required intervention - n (%)	6 (30.0)
High dose vasopressors used - n (%)	2 (10.0)
Oxygen supplementation given - n (%)	5 (25.0)
Patient intubated - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Patient dialyzed - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-

	All patients N=20
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	7 (35.0)
Duration (days)	
n	7
Mean (SD)	14.4 (22.56)
Median	7.0
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	2 (10.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	1 (5.0)
Bleeding observed - n (%)	2 (10.0)
Blood product support given for bleeding - n (%)	1 (5.0)
Systemic anti-cytokine therapy given - n (%)	1 (5.0)
Tocilizumab	1 (5.0)
1 dose	0
2 doses	1 (5.0)
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	1 (5.0)
Other	0

Only the first CRS episode is summarized for each patient.

Table 221n
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Baseline bone marrow tumor burden
Safety Set

Subgroup: Baseline bone marrow tumor burden: High

	All patients N=44
Cytokine Release Syndrome (CRS) - n (%)	
No	10 (22.7)
Yes	34 (77.3)
Maximum CRS grade - n(%)	
Grade 1	6 (13.6)
Grade 2	14 (31.8)
Grade 3	5 (11.4)
Grade 4	9 (20.5)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	34
Mean (SD)	5.4 (4.43)
Median	5.0
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=44
n	14
Mean (SD)	5.6 (3.41)
Median	4.5
Min - Max	2 - 13
Concurrent infections - n(%)	7 (15.9)
Blood	3 (6.8)
GI	3 (6.8)
Lung	1 (2.3)
Other	1 (2.3)
Sinus	1 (2.3)
High fevers during CRS - n (%)	33 (75.0)
Time to high fever onset (days)	
n	33
Mean (SD)	5.6 (4.76)
Median	5.0
Min - Max	1 - 20
Duration (days)	
n	33
Mean (SD)	7.4 (5.79)
Median	6.0
Min - Max	2 - 27

	All patients N=44
Admitted to ICU - n (%)	15 (34.1)
Time to ICU Admission (days)	
n	15
Mean (SD)	6.5 (4.10)
Median	6.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	15
Mean (SD)	12.1 (7.48)
Median	10.0
Min - Max	2 - 27
Hypotension that required intervention - n (%)	14 (31.8)
High dose vasopressors used - n (%)	10 (22.7)
Oxygen supplementation given - n (%)	14 (31.8)
Patient intubated - n (%)	6 (13.6)
Duration (days)	
n	6
Mean (SD)	10.5 (7.82)
Median	8.5
Min - Max	4 - 26
Patient dialyzed - n (%)	4 (9.1)

	All patients N=44
Duration (days)	
n	4
Mean (SD)	33.0 (23.96)
Median	37.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	16 (36.4)
Duration (days)	
n	16
Mean (SD)	14.5 (12.55)
Median	10.0
Min - Max	4 - 54
Pulmonary abnormalities - n (%)	7 (15.9)
Disseminated intravascular coagulation (DIC) observed - n (%)	4 (9.1)
Bleeding observed - n (%)	9 (20.5)
Blood product support given for bleeding - n (%)	9 (20.5)
Systemic anti-cytokine therapy given - n (%)	12 (27.3)
Tocilizumab	11 (25.0)
1 dose	5 (11.4)
2 doses	3 (6.8)
3 doses	3 (6.8)
4 doses	0

	All patients N=44
>4 doses	0
Siltuximab	0
Corticosteroids	8 (18.2)
Other	5 (11.4)

Only the first CRS episode is summarized for each patient.

Table 221o
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Baseline extramedullary disease presence
Safety Set

Subgroup: Baseline extramedullary disease presence: Yes

	All patients N=5
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (20.0)
Yes	4 (80.0)
Maximum CRS grade - n(%)	
Grade 1	2 (40.0)
Grade 2	1 (20.0)
Grade 4	1 (20.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	4
Mean (SD)	3.8 (2.75)
Median	3.5
Min - Max	1 - 7
Time to grade 3/4 CRS (days)	

	All patients N=5
n	1
Mean (SD)	5.0
Median	5.0
Min - Max	5 - 5
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	3 (60.0)
Time to high fever onset (days)	
n	3
Mean (SD)	3.3 (1.53)
Median	3.0
Min - Max	2 - 5
Duration (days)	
n	3
Mean (SD)	5.0 (2.65)
Median	6.0
Min - Max	2 - 7
Admitted to ICU - n (%)	1 (20.0)
Time to ICU Admission (days)	
n	1
Mean (SD)	5.0
Median	5.0

	All patients N=5
Min - Max	5 - 5
Duration of ICU stay (days)	
n	1
Mean (SD)	13.0
Median	13.0
Min - Max	13 - 13
Hypotension that required intervention - n (%)	1 (20.0)
High dose vasopressors used - n (%)	1 (20.0)
Oxygen supplementation given - n (%)	2 (40.0)
Patient intubated - n (%)	1 (20.0)
Duration (days)	
n	1
Mean (SD)	9.0
Median	9.0
Min - Max	9 - 9
Patient dialyzed - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-

	All patients N=5
Total Parenteral Nutrition (TPN) used - n (%)	1 (20.0)
Duration (days)	
n	1
Mean (SD)	17.0
Median	17.0
Min - Max	17 - 17
Pulmonary abnormalities - n (%)	0
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	1 (20.0)
Blood product support given for bleeding - n (%)	1 (20.0)
Systemic anti-cytokine therapy given - n (%)	1 (20.0)
Tocilizumab	1 (20.0)
1 dose	1 (20.0)
2 doses	0
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	0
Other	0

Only the first CRS episode is summarized for each patient.

Table 221o
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Baseline extramedullary disease presence
Safety Set

Subgroup: Baseline extramedullary disease presence: No

	All patients N=59
Cytokine Release Syndrome (CRS) - n (%)	
No	13 (22.0)
Yes	46 (78.0)
Maximum CRS grade - n(%)	
Grade 1	4 (6.8)
Grade 2	24 (40.7)
Grade 3	8 (13.6)
Grade 4	10 (16.9)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	46
Mean (SD)	5.1 (4.04)
Median	4.5
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=59
n	18
Mean (SD)	5.4 (3.24)
Median	4.0
Min - Max	2 - 13
Concurrent infections - n(%)	9 (15.3)
Blood	3 (5.1)
GI	4 (6.8)
Lung	1 (1.7)
Other	2 (3.4)
Sinus	1 (1.7)
High fevers during CRS - n (%)	46 (78.0)
Time to high fever onset (days)	
n	46
Mean (SD)	5.3 (4.29)
Median	5.0
Min - Max	1 - 20
Duration (days)	
n	46
Mean (SD)	6.6 (5.23)
Median	6.0
Min - Max	1 - 27

	All patients N=59
Admitted to ICU - n (%)	19 (32.2)
Time to ICU Admission (days)	
n	19
Mean (SD)	6.2 (3.71)
Median	6.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	19
Mean (SD)	9.7 (7.70)
Median	9.0
Min - Max	1 - 27
Hypotension that required intervention - n (%)	19 (32.2)
High dose vasopressors used - n (%)	11 (18.6)
Oxygen supplementation given - n (%)	17 (28.8)
Patient intubated - n (%)	5 (8.5)
Duration (days)	
n	5
Mean (SD)	10.8 (8.70)
Median	8.0
Min - Max	4 - 26
Patient dialyzed - n (%)	4 (6.8)

	All patients N=59
Duration (days)	
n	4
Mean (SD)	33.0 (23.96)
Median	37.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	22 (37.3)
Duration (days)	
n	22
Mean (SD)	14.4 (16.05)
Median	9.0
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	9 (15.3)
Disseminated intravascular coagulation (DIC) observed - n (%)	5 (8.5)
Bleeding observed - n (%)	10 (16.9)
Blood product support given for bleeding - n (%)	9 (15.3)
Systemic anti-cytokine therapy given - n (%)	12 (20.3)
Tocilizumab	11 (18.6)
1 dose	4 (6.8)
2 doses	4 (6.8)
3 doses	3 (5.1)
4 doses	0

	All patients N=59
>4 doses	0
Siltuximab	0
Corticosteroids	9 (15.3)
Other	5 (8.5)

Only the first CRS episode is summarized for each patient.

Table 221p
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Down syndrome
Safety Set

Subgroup: Down syndrome: Yes

	All patients N=4
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (25.0)
Yes	3 (75.0)
Maximum CRS grade - n(%)	
Grade 1	1 (25.0)
Grade 2	2 (50.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	3
Mean (SD)	5.0 (1.00)
Median	5.0
Min - Max	4 - 6
Time to grade 3/4 CRS (days)	
n	-

	All patients N=4
Mean (SD)	-
Median	-
Min - Max	-
Concurrent infections - n(%)	1 (25.0)
Other	1 (25.0)
High fevers during CRS - n (%)	3 (75.0)
Time to high fever onset (days)	
n	3
Mean (SD)	5.0 (1.00)
Median	5.0
Min - Max	4 - 6
Duration (days)	
n	3
Mean (SD)	1.7 (0.58)
Median	2.0
Min - Max	1 - 2
Admitted to ICU - n (%)	2 (50.0)
Time to ICU Admission (days)	
n	2
Mean (SD)	6.0 (0.00)
Median	6.0

	All patients N=4
Min - Max	6 - 6
Duration of ICU stay (days)	
n	2
Mean (SD)	1.5 (0.71)
Median	1.5
Min - Max	1 - 2
Hypotension that required intervention - n (%)	1 (25.0)
High dose vasopressors used - n (%)	0
Oxygen supplementation given - n (%)	1 (25.0)
Patient intubated - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Patient dialyzed - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-

	All patients N=4
Total Parenteral Nutrition (TPN) used - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Pulmonary abnormalities - n (%)	1 (25.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	0
Tocilizumab	0
1 dose	0
2 doses	0
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	0
Other	0

Only the first CRS episode is summarized for each patient.

Table 221p
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship by Down syndrome
Safety Set

Subgroup: Down syndrome: No

	All patients N=60
Cytokine Release Syndrome (CRS) - n (%)	
No	13 (21.7)
Yes	47 (78.3)
Maximum CRS grade - n(%)	
Grade 1	5 (8.3)
Grade 2	23 (38.3)
Grade 3	8 (13.3)
Grade 4	11 (18.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	47
Mean (SD)	5.0 (4.07)
Median	4.0
Min - Max	1 - 20
Time to grade 3/4 CRS (days)	

	All patients N=60
n	19
Mean (SD)	5.4 (3.15)
Median	4.0
Min - Max	2 - 13
Concurrent infections - n(%)	8 (13.3)
Blood	3 (5.0)
GI	4 (6.7)
Lung	1 (1.7)
Other	1 (1.7)
Sinus	1 (1.7)
High fevers during CRS - n (%)	46 (76.7)
Time to high fever onset (days)	
n	46
Mean (SD)	5.2 (4.33)
Median	4.5
Min - Max	1 - 20
Duration (days)	
n	46
Mean (SD)	6.8 (5.11)
Median	6.0
Min - Max	1 - 27

	All patients N=60
Admitted to ICU - n (%)	18 (30.0)
Time to ICU Admission (days)	
n	18
Mean (SD)	6.2 (3.82)
Median	5.5
Min - Max	1 - 15
Duration of ICU stay (days)	
n	18
Mean (SD)	10.8 (7.36)
Median	9.5
Min - Max	2 - 27
Hypotension that required intervention - n (%)	19 (31.7)
High dose vasopressors used - n (%)	12 (20.0)
Oxygen supplementation given - n (%)	18 (30.0)
Patient intubated - n (%)	6 (10.0)
Duration (days)	
n	6
Mean (SD)	10.5 (7.82)
Median	8.5
Min - Max	4 - 26
Patient dialyzed - n (%)	4 (6.7)

	All patients N=60
Duration (days)	
n	4
Mean (SD)	33.0 (23.96)
Median	37.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	23 (38.3)
Duration (days)	
n	23
Mean (SD)	14.5 (15.69)
Median	9.0
Min - Max	2 - 65
Pulmonary abnormalities - n (%)	8 (13.3)
Disseminated intravascular coagulation (DIC) observed - n (%)	5 (8.3)
Bleeding observed - n (%)	11 (18.3)
Blood product support given for bleeding - n (%)	10 (16.7)
Systemic anti-cytokine therapy given - n (%)	13 (21.7)
Tocilizumab	12 (20.0)
1 dose	5 (8.3)
2 doses	4 (6.7)
3 doses	3 (5.0)
4 doses	0

	All patients N=60
>4 doses	0
Siltuximab	0
Corticosteroids	9 (15.0)
Other	5 (8.3)

Only the first CRS episode is summarized for each patient.

Table 221q
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Time since enrollment to CTL019 infusion
Safety Set
Subgroup: Time since enrollment to CTL019 infusion: > Median

	All patients N=32
Cytokine Release Syndrome (CRS) - n (%)	
No	7 (21.9)
Yes	25 (78.1)
Maximum CRS grade - n(%)	
Grade 1	3 (9.4)
Grade 2	15 (46.9)
Grade 3	2 (6.3)
Grade 4	5 (15.6)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	25
Mean (SD)	5.3 (4.13)
Median	5.0
Min - Max	1 - 20

	All patients N=32
Time to grade 3/4 CRS (days)	
n	7
Mean (SD)	5.7 (3.77)
Median	4.0
Min - Max	2 - 13
Concurrent infections - n(%)	4 (12.5)
Blood	1 (3.1)
GI	3 (9.4)
Other	1 (3.1)
High fevers during CRS - n (%)	24 (75.0)
Time to high fever onset (days)	
n	24
Mean (SD)	5.3 (4.19)
Median	5.0
Min - Max	1 - 20
Duration (days)	
n	24
Mean (SD)	5.2 (3.16)
Median	5.5
Min - Max	1 - 16
Admitted to ICU - n (%)	6 (18.8)

	All patients N=32
Time to ICU Admission (days)	
n	6
Mean (SD)	5.2 (3.66)
Median	4.0
Min - Max	2 - 12
Duration of ICU stay (days)	
n	6
Mean (SD)	7.2 (3.54)
Median	8.0
Min - Max	2 - 11
Hypotension that required intervention - n (%)	8 (25.0)
High dose vasopressors used - n (%)	6 (18.8)
Oxygen supplementation given - n (%)	9 (28.1)
Patient intubated - n (%)	1 (3.1)
Duration (days)	
n	1
Mean (SD)	4.0
Median	4.0
Min - Max	4 - 4
Patient dialyzed - n (%)	0
Duration (days)	

	All patients N=32
n	-
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	10 (31.3)
Duration (days)	
n	10
Mean (SD)	8.2 (5.65)
Median	7.5
Min - Max	2 - 22
Pulmonary abnormalities - n (%)	2 (6.3)
Disseminated intravascular coagulation (DIC) observed - n (%)	2 (6.3)
Bleeding observed - n (%)	5 (15.6)
Blood product support given for bleeding - n (%)	4 (12.5)
Systemic anti-cytokine therapy given - n (%)	3 (9.4)
Tocilizumab	3 (9.4)
1 dose	2 (6.3)
2 doses	0
3 doses	1 (3.1)
4 doses	0
>4 doses	0

	All patients N=32
Siltuximab	0
Corticosteroids	2 (6.3)
Other	1 (3.1)

Only the first CRS episode is summarized for each patient.

Table 221q
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Time since enrollment to CTL019 infusion
Safety Set
Subgroup: Time since enrollment to CTL019 infusion: <=Median

	All patients N=32
Cytokine Release Syndrome (CRS) - n (%)	
No	7 (21.9)
Yes	25 (78.1)
Maximum CRS grade - n(%)	
Grade 1	3 (9.4)
Grade 2	10 (31.3)
Grade 3	6 (18.8)
Grade 4	6 (18.8)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	25
Mean (SD)	4.7 (3.82)
Median	3.0
Min - Max	1 - 16
Time to grade 3/4 CRS (days)	

	All patients N=32
n	12
Mean (SD)	5.2 (2.89)
Median	4.5
Min - Max	2 - 10
Concurrent infections - n(%)	5 (15.6)
Blood	2 (6.3)
GI	1 (3.1)
Lung	1 (3.1)
Other	1 (3.1)
Sinus	1 (3.1)
High fevers during CRS - n (%)	25 (78.1)
Time to high fever onset (days)	
n	25
Mean (SD)	5.0 (4.28)
Median	4.0
Min - Max	1 - 16
Duration (days)	
n	25
Mean (SD)	7.8 (6.24)
Median	7.0
Min - Max	2 - 27

	All patients N=32
Admitted to ICU - n (%)	14 (43.8)
Time to ICU Admission (days)	
n	14
Mean (SD)	6.6 (3.65)
Median	6.0
Min - Max	1 - 15
Duration of ICU stay (days)	
n	14
Mean (SD)	11.1 (8.55)
Median	9.5
Min - Max	1 - 27
Hypotension that required intervention - n (%)	12 (37.5)
High dose vasopressors used - n (%)	6 (18.8)
Oxygen supplementation given - n (%)	10 (31.3)
Patient intubated - n (%)	5 (15.6)
Duration (days)	
n	5
Mean (SD)	11.8 (7.98)
Median	9.0
Min - Max	7 - 26
Patient dialyzed - n (%)	4 (12.5)

	All patients N=32
Duration (days)	
n	4
Mean (SD)	33.0 (23.96)
Median	37.0
Min - Max	2 - 56
Total Parenteral Nutrition (TPN) used - n (%)	13 (40.6)
Duration (days)	
n	13
Mean (SD)	19.3 (19.22)
Median	11.0
Min - Max	3 - 65
Pulmonary abnormalities - n (%)	7 (21.9)
Disseminated intravascular coagulation (DIC) observed - n (%)	3 (9.4)
Bleeding observed - n (%)	6 (18.8)
Blood product support given for bleeding - n (%)	6 (18.8)
Systemic anti-cytokine therapy given - n (%)	10 (31.3)
Tocilizumab	9 (28.1)
1 dose	3 (9.4)
2 doses	4 (12.5)
3 doses	2 (6.3)
4 doses	0

	All patients N=32
>4 doses	0
Siltuximab	0
Corticosteroids	7 (21.9)
Other	4 (12.5)

Only the first CRS episode is summarized for each patient.

Table 221r
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Number of previous relapses
Safety Set

Subgroup: Number of previous relapses: 0

	All patients N=7
Cytokine Release Syndrome (CRS) - n (%)	
No	2 (28.6)
Yes	5 (71.4)
Maximum CRS grade - n(%)	
Grade 2	2 (28.6)
Grade 4	3 (42.9)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	5
Mean (SD)	4.6 (3.44)
Median	3.0
Min - Max	2 - 10
Time to grade 3/4 CRS (days)	
n	3
Mean (SD)	6.0 (3.46)

	All patients N=7
Median	4.0
Min - Max	4 - 10
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	5 (71.4)
Time to high fever onset (days)	
n	5
Mean (SD)	4.8 (3.56)
Median	5.0
Min - Max	1 - 10
Duration (days)	
n	5
Mean (SD)	9.4 (10.50)
Median	5.0
Min - Max	2 - 27
Admitted to ICU - n (%)	4 (57.1)
Time to ICU Admission (days)	
n	4
Mean (SD)	5.8 (3.30)
Median	5.5
Min - Max	2 - 10
Duration of ICU stay (days)	

	All patients N=7
n	4
Mean (SD)	10.5 (11.62)
Median	7.0
Min - Max	1 - 27
Hypotension that required intervention - n (%)	4 (57.1)
High dose vasopressors used - n (%)	3 (42.9)
Oxygen supplementation given - n (%)	3 (42.9)
Patient intubated - n (%)	2 (28.6)
Duration (days)	
n	2
Mean (SD)	16.5 (13.44)
Median	16.5
Min - Max	7 - 26
Patient dialyzed - n (%)	2 (28.6)
Duration (days)	
n	2
Mean (SD)	14.5 (17.68)
Median	14.5
Min - Max	2 - 27
Total Parenteral Nutrition (TPN) used - n (%)	3 (42.9)
Duration (days)	

	All patients N=7
n	3
Mean (SD)	13.3 (14.01)
Median	9.0
Min - Max	2 - 29
Pulmonary abnormalities - n (%)	2 (28.6)
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	2 (28.6)
Blood product support given for bleeding - n (%)	2 (28.6)
Systemic anti-cytokine therapy given - n (%)	2 (28.6)
Tocilizumab	2 (28.6)
1 dose	0
2 doses	1 (14.3)
3 doses	1 (14.3)
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	2 (28.6)
Other	2 (28.6)

Only the first CRS episode is summarized for each patient.

Table 221r
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Number of previous relapses
Safety Set

Subgroup: Number of previous relapses: 1

	All patients N=20
Cytokine Release Syndrome (CRS) - n (%)	
No	4 (20.0)
Yes	16 (80.0)
Maximum CRS grade - n(%)	
Grade 1	2 (10.0)
Grade 2	7 (35.0)
Grade 3	2 (10.0)
Grade 4	5 (25.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	16
Mean (SD)	4.4 (2.78)
Median	4.5
Min - Max	1 - 10
Time to grade 3/4 CRS (days)	

	All patients N=20
n	7
Mean (SD)	6.3 (2.50)
Median	6.0
Min - Max	3 - 10
Concurrent infections - n(%)	3 (15.0)
Blood	2 (10.0)
GI	2 (10.0)
Lung	1 (5.0)
High fevers during CRS - n (%)	16 (80.0)
Time to high fever onset (days)	
n	16
Mean (SD)	4.7 (2.57)
Median	5.0
Min - Max	1 - 10
Duration (days)	
n	16
Mean (SD)	6.3 (4.08)
Median	6.0
Min - Max	2 - 19
Admitted to ICU - n (%)	7 (35.0)
Time to ICU Admission (days)	

	All patients N=20
n	7
Mean (SD)	7.4 (4.35)
Median	6.0
Min - Max	3 - 15
Duration of ICU stay (days)	
n	7
Mean (SD)	9.7 (5.53)
Median	10.0
Min - Max	2 - 16
Hypotension that required intervention - n (%)	7 (35.0)
High dose vasopressors used - n (%)	5 (25.0)
Oxygen supplementation given - n (%)	7 (35.0)
Patient intubated - n (%)	1 (5.0)
Duration (days)	
n	1
Mean (SD)	9.0
Median	9.0
Min - Max	9 - 9
Patient dialyzed - n (%)	0
Duration (days)	
n	-

	All patients N=20
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	8 (40.0)
Duration (days)	
n	8
Mean (SD)	16.1 (20.15)
Median	9.5
Min - Max	4 - 65
Pulmonary abnormalities - n (%)	2 (10.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	3 (15.0)
Bleeding observed - n (%)	3 (15.0)
Blood product support given for bleeding - n (%)	3 (15.0)
Systemic anti-cytokine therapy given - n (%)	5 (25.0)
Tocilizumab	5 (25.0)
1 dose	4 (20.0)
2 doses	1 (5.0)
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0

	All patients N=20
Corticosteroids	2 (10.0)
Other	0

Only the first CRS episode is summarized for each patient.

Table 221r
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Number of previous relapses
Safety Set

Subgroup: Number of previous relapses: 2

	All patients N=21
Cytokine Release Syndrome (CRS) - n (%)	
No	3 (14.3)
Yes	18 (85.7)
Maximum CRS grade - n(%)	
Grade 1	1 (4.8)
Grade 2	12 (57.1)
Grade 3	4 (19.0)
Grade 4	1 (4.8)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	18
Mean (SD)	5.6 (4.71)
Median	5.0
Min - Max	1 - 20

	All patients N=21
Time to grade 3/4 CRS (days)	
n	5
Mean (SD)	3.4 (1.52)
Median	3.0
Min - Max	2 - 6
Concurrent infections - n(%)	3 (14.3)
GI	1 (4.8)
Other	1 (4.8)
Sinus	1 (4.8)
High fevers during CRS - n (%)	18 (85.7)
Time to high fever onset (days)	
n	18
Mean (SD)	5.8 (5.19)
Median	4.5
Min - Max	1 - 20
Duration (days)	
n	18
Mean (SD)	6.4 (4.68)
Median	5.0
Min - Max	2 - 19
Admitted to ICU - n (%)	5 (23.8)

	All patients N=21
Time to ICU Admission (days)	
n	5
Mean (SD)	4.4 (2.41)
Median	5.0
Min - Max	1 - 7
Duration of ICU stay (days)	
n	5
Mean (SD)	9.6 (10.04)
Median	5.0
Min - Max	2 - 27
Hypotension that required intervention - n (%)	5 (23.8)
High dose vasopressors used - n (%)	1 (4.8)
Oxygen supplementation given - n (%)	6 (28.6)
Patient intubated - n (%)	1 (4.8)
Duration (days)	
n	1
Mean (SD)	9.0
Median	9.0
Min - Max	9 - 9
Patient dialyzed - n (%)	1 (4.8)
Duration (days)	

	All patients N=21
n	1
Mean (SD)	47.0
Median	47.0
Min - Max	47 - 47
Total Parenteral Nutrition (TPN) used - n (%)	8 (38.1)
Duration (days)	
n	8
Mean (SD)	8.6 (5.40)
Median	8.0
Min - Max	3 - 20
Pulmonary abnormalities - n (%)	2 (9.5)
Disseminated intravascular coagulation (DIC) observed - n (%)	1 (4.8)
Bleeding observed - n (%)	2 (9.5)
Blood product support given for bleeding - n (%)	1 (4.8)
Systemic anti-cytokine therapy given - n (%)	4 (19.0)
Tocilizumab	3 (14.3)
1 dose	1 (4.8)
2 doses	1 (4.8)
3 doses	1 (4.8)
4 doses	0
>4 doses	0

	All patients N=21
Siltuximab	0
Corticosteroids	3 (14.3)
Other	1 (4.8)

Only the first CRS episode is summarized for each patient.

Table 221r
Cytokine release syndrome post CTL019 infusion, regardless of study drug relationship
by Number of previous relapses
Safety Set

Subgroup: Number of previous relapses: >=3

	All patients N=16
Cytokine Release Syndrome (CRS) - n (%)	
No	5 (31.3)
Yes	11 (68.8)
Maximum CRS grade - n(%)	
Grade 1	3 (18.8)
Grade 2	4 (25.0)
Grade 3	2 (12.5)
Grade 4	2 (12.5)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	11
Mean (SD)	5.1 (4.59)
Median	4.0
Min - Max	1 - 16

	All patients N=16
Time to grade 3/4 CRS (days)	
n	4
Mean (SD)	5.8 (5.19)
Median	4.0
Min - Max	2 - 13
Concurrent infections - n(%)	3 (18.8)
Blood	1 (6.3)
GI	1 (6.3)
Other	1 (6.3)
High fevers during CRS - n (%)	10 (62.5)
Time to high fever onset (days)	
n	10
Mean (SD)	4.9 (5.00)
Median	3.0
Min - Max	1 - 16
Duration (days)	
n	10
Mean (SD)	5.6 (3.92)
Median	6.0
Min - Max	1 - 14
Admitted to ICU - n (%)	4 (25.0)

	All patients N=16
Time to ICU Admission (days)	
n	4
Mean (SD)	6.5 (4.12)
Median	6.0
Min - Max	2 - 12
Duration of ICU stay (days)	
n	4
Mean (SD)	10.0 (5.29)
Median	9.0
Min - Max	5 - 17
Hypotension that required intervention - n (%)	4 (25.0)
High dose vasopressors used - n (%)	3 (18.8)
Oxygen supplementation given - n (%)	3 (18.8)
Patient intubated - n (%)	2 (12.5)
Duration (days)	
n	2
Mean (SD)	6.0 (2.83)
Median	6.0
Min - Max	4 - 8
Patient dialyzed - n (%)	1 (6.3)
Duration (days)	

	All patients N=16
n	1
Mean (SD)	56.0
Median	56.0
Min - Max	56 - 56
Total Parenteral Nutrition (TPN) used - n (%)	4 (25.0)
Duration (days)	
n	4
Mean (SD)	23.8 (21.11)
Median	17.0
Min - Max	7 - 54
Pulmonary abnormalities - n (%)	3 (18.8)
Disseminated intravascular coagulation (DIC) observed - n (%)	1 (6.3)
Bleeding observed - n (%)	4 (25.0)
Blood product support given for bleeding - n (%)	4 (25.0)
Systemic anti-cytokine therapy given - n (%)	2 (12.5)
Tocilizumab	2 (12.5)
1 dose	0
2 doses	1 (6.3)
3 doses	1 (6.3)
4 doses	0
>4 doses	0

	All patients N=16
Siltuximab	0
Corticosteroids	2 (12.5)
Other	2 (12.5)

Only the first CRS episode is summarized for each patient.

Table 223a
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (22.7)	0	1 (4.5)	4 (18.2)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	5 (22.7)	0	1 (4.5)	4 (18.2)	0
Alpha haemolytic streptococcal infection	1 (4.5)	0	0	1 (4.5)	0
Bronchopulmonary aspergillosis	1 (4.5)	0	0	1 (4.5)	0
Device related infection	1 (4.5)	0	0	1 (4.5)	0
Enterococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Respiratory syncytial virus infection	1 (4.5)	0	1 (4.5)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	1 (4.5)	0	0	1 (4.5)	0
Streptococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223a
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (35.9)	0	1 (2.6)	9 (23.1)	4 (10.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (2.6)	0	0	0	1 (2.6)
Pancytopenia	1 (2.6)	0	0	0	1 (2.6)
Infections					
-Total	12 (30.8)	0	1 (2.6)	8 (20.5)	3 (7.7)
Device related infection	2 (5.1)	0	0	2 (5.1)	0
Staphylococcal bacteraemia	2 (5.1)	0	0	2 (5.1)	0
Bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Candida sepsis	1 (2.6)	0	0	0	1 (2.6)
Cellulitis	1 (2.6)	0	0	1 (2.6)	0

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Escherichia urinary tract infection	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis	1 (2.6)	0	0	1 (2.6)	0
Klebsiella sepsis	1 (2.6)	0	0	0	1 (2.6)
Parainfluenzae virus infection	1 (2.6)	0	1 (2.6)	0	0
Pneumonia	1 (2.6)	0	1 (2.6)	0	0
Pneumonia fungal	1 (2.6)	0	0	1 (2.6)	0
Respiratory syncytial virus bronchitis	1 (2.6)	0	0	1 (2.6)	0
Sepsis	1 (2.6)	0	0	0	1 (2.6)
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Abscess limb	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (2.6)	0	0	1 (2.6)	0
Mental status changes	1 (2.6)	0	0	1 (2.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223a
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (35.7)	0	0	1 (7.1)	4 (28.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	5 (35.7)	0	0	1 (7.1)	4 (28.6)
Abscess limb	1 (7.1)	0	0	1 (7.1)	0
Escherichia sepsis	1 (7.1)	0	0	0	1 (7.1)
Klebsiella sepsis	1 (7.1)	0	0	0	1 (7.1)
Pneumonia	1 (7.1)	0	0	0	1 (7.1)

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	1 (7.1)	0	1 (7.1)	0	0
Serratia infection	1 (7.1)	0	0	1 (7.1)	0
Staphylococcal scalded skin syndrome	1 (7.1)	0	1 (7.1)	0	0
Staphylococcal sepsis	1 (7.1)	0	0	0	1 (7.1)
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Sepsis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223b
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (30.0)	0	1 (2.5)	6 (15.0)	5 (12.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	11 (27.5)	0	1 (2.5)	5 (12.5)	5 (12.5)
Klebsiella sepsis	2 (5.0)	0	0	0	2 (5.0)
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Candida sepsis	1 (2.5)	0	0	0	1 (2.5)
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis	1 (2.5)	0	0	1 (2.5)	0

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (2.5)	0	0	0	1 (2.5)
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	1 (2.5)	0	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Serratia infection	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (2.5)	0	0	1 (2.5)	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223b
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (34.3)	0	1 (2.9)	8 (22.9)	3 (8.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (2.9)	0	0	0	1 (2.9)
Pancytopenia	1 (2.9)	0	0	0	1 (2.9)
Infections					
-Total	11 (31.4)	0	1 (2.9)	8 (22.9)	2 (5.7)
Device related infection	2 (5.7)	0	0	2 (5.7)	0
Abscess limb	1 (2.9)	0	0	1 (2.9)	0
Alpha haemolytic streptococcal infection	1 (2.9)	0	0	1 (2.9)	0
Bronchopulmonary aspergillosis	1 (2.9)	0	0	1 (2.9)	0
Cellulitis	1 (2.9)	0	0	1 (2.9)	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Escherichia bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Escherichia sepsis	1 (2.9)	0	0	0	1 (2.9)
Escherichia urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Parainfluenzae virus infection	1 (2.9)	0	1 (2.9)	0	0
Pneumonia	1 (2.9)	0	1 (2.9)	0	0
Pneumonia fungal	1 (2.9)	0	1 (2.9)	0	0
Respiratory syncytial virus bronchitis	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal infection	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal scalded skin syndrome	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Streptococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Bacteraemia	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223c
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (25.0)	0	2 (3.3)	8 (13.3)	5 (8.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	15 (25.0)	0	2 (3.3)	8 (13.3)	5 (8.3)
Pneumonia	2 (3.3)	0	1 (1.7)	0	1 (1.7)
Staphylococcal bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bronchopulmonary aspergillosis	1 (1.7)	0	0	1 (1.7)	0
Candida sepsis	1 (1.7)	0	0	0	1 (1.7)

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cellulitis	1 (1.7)	0	0	1 (1.7)	0
Device related infection	1 (1.7)	0	0	1 (1.7)	0
Enterococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Escherichia bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Escherichia sepsis	1 (1.7)	0	0	0	1 (1.7)
Klebsiella sepsis	1 (1.7)	0	0	0	1 (1.7)
Parainfluenzae virus infection	1 (1.7)	0	1 (1.7)	0	0
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Respiratory syncytial virus bronchitis	1 (1.7)	0	0	1 (1.7)	0
Respiratory syncytial virus infection	1 (1.7)	0	1 (1.7)	0	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Serratia infection	1 (1.7)	0	0	1 (1.7)	0
Streptococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223c
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (50.0)	0	0	3 (50.0)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	3 (50.0)	0	0	3 (50.0)	0
Device related infection	1 (16.7)	0	0	1 (16.7)	0
Alpha haemolytic streptococcal infection	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis	1 (16.7)	0	0	1 (16.7)	0
Staphylococcal infection	1 (16.7)	0	0	1 (16.7)	0
Pneumonia	0	0	0	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Abscess limb	0	0	0	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia urinary tract infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223c
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (66.7)	0	0	3 (33.3)	3 (33.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (11.1)	0	0	0	1 (11.1)
Pancytopenia	1 (11.1)	0	0	0	1 (11.1)
Infections					
-Total	4 (44.4)	0	0	2 (22.2)	2 (22.2)
Device related infection	1 (11.1)	0	0	1 (11.1)	0
Klebsiella sepsis	1 (11.1)	0	0	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	1 (11.1)	0	0
Abscess limb	1 (11.1)	0	0	1 (11.1)	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia urinary tract infection	1 (11.1)	0	0	1 (11.1)	0
Staphylococcal scalded skin syndrome	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal sepsis	1 (11.1)	0	0	0	1 (11.1)
Pneumonia	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Streptococcal bacteraemia	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (11.1)	0	0	1 (11.1)	0
Mental status changes	1 (11.1)	0	0	1 (11.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223d
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (43.3)	0	1 (3.3)	7 (23.3)	5 (16.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (3.3)	0	0	0	1 (3.3)
Pancytopenia	1 (3.3)	0	0	0	1 (3.3)
Infections					
-Total	11 (36.7)	0	1 (3.3)	6 (20.0)	4 (13.3)
Bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Candida sepsis	1 (3.3)	0	0	0	1 (3.3)
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Enterococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	0	0	1 (3.3)	0

Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia sepsis	1 (3.3)	0	0	0	1 (3.3)
Escherichia urinary tract infection	1 (3.3)	0	0	1 (3.3)	0
Klebsiella sepsis	1 (3.3)	0	0	0	1 (3.3)
Parainfluenzae virus infection	1 (3.3)	0	1 (3.3)	0	0
Pneumonia	1 (3.3)	0	1 (3.3)	0	0
Pneumonia fungal	1 (3.3)	0	0	1 (3.3)	0
Respiratory syncytial virus bronchitis	1 (3.3)	0	0	1 (3.3)	0
Sepsis	1 (3.3)	0	0	0	1 (3.3)
Serratia infection	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Streptococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0

Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.3)	0	0	1 (3.3)	0
Mental status changes	1 (3.3)	0	0	1 (3.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223d
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (24.4)	0	1 (2.2)	7 (15.6)	3 (6.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	11 (24.4)	0	1 (2.2)	7 (15.6)	3 (6.7)
Device related infection	2 (4.4)	0	0	2 (4.4)	0
Klebsiella sepsis	1 (2.2)	0	0	0	1 (2.2)
Pneumonia	1 (2.2)	0	0	0	1 (2.2)
Pneumonia fungal	1 (2.2)	0	1 (2.2)	0	0
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (2.2)	0	0	1 (2.2)	0
Alpha haemolytic streptococcal infection	1 (2.2)	0	0	1 (2.2)	0
Bronchopulmonary aspergillosis	1 (2.2)	0	0	1 (2.2)	0
Cellulitis	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis	1 (2.2)	0	0	1 (2.2)	0
Respiratory syncytial virus infection	1 (2.2)	0	1 (2.2)	0	0
Staphylococcal infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal scalded skin syndrome	1 (2.2)	0	1 (2.2)	0	0
Staphylococcal sepsis	1 (2.2)	0	0	0	1 (2.2)
Bacteraemia	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223e
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0

Response status at study entry: Primary refractory

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

Response status at study entry: Primary refractory

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223e
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	22 (32.8)	0	2 (3.0)	13 (19.4)	7 (10.4)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.5)	0	0	0	1 (1.5)
Pancytopenia	1 (1.5)	0	0	0	1 (1.5)
Infections					
-Total	20 (29.9)	0	2 (3.0)	12 (17.9)	6 (9.0)
Device related infection	3 (4.5)	0	0	3 (4.5)	0
Klebsiella sepsis	2 (3.0)	0	0	0	2 (3.0)
Pneumonia fungal	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Staphylococcal bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Pneumonia	1 (1.5)	0	1 (1.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Alpha haemolytic streptococcal infection	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Candida sepsis	1 (1.5)	0	0	0	1 (1.5)
Enterococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Escherichia bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	0	0	1 (1.5)
Escherichia urinary tract infection	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis	1 (1.5)	0	0	1 (1.5)	0
Parainfluenzae virus infection	1 (1.5)	0	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	1 (1.5)	0	0
Sepsis	1 (1.5)	0	0	0	1 (1.5)
Serratia infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal scalded skin syndrome	1 (1.5)	0	1 (1.5)	0	0

Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Cellulitis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (1.5)	0	0	1 (1.5)	0
Mental status changes	1 (1.5)	0	0	1 (1.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223f
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	0	0	1 (50.0)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Bacteraemia	1 (50.0)	0	0	1 (50.0)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cellulitis	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223f
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (31.5)	0	2 (2.7)	13 (17.8)	8 (11.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.4)	0	0	0	1 (1.4)
Pancytopenia	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	21 (28.8)	0	2 (2.7)	12 (16.4)	7 (9.6)
Device related infection	3 (4.1)	0	0	3 (4.1)	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Pneumonia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0

Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All patients N=73 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (1.4)	0	0	1 (1.4)	0
Mental status changes	1 (1.4)	0	0	1 (1.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223g
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	24 (33.3)	0	2 (2.8)	14 (19.4)	8 (11.1)
Hematopoietic cytopenias not resolved by Day 28					
Pancytopenia	1 (1.4)	0	0	0	1 (1.4)
-Total	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	22 (30.6)	0	2 (2.8)	13 (18.1)	7 (9.7)
Device related infection	3 (4.2)	0	0	3 (4.2)	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Pneumonia	2 (2.8)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0

Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	1 (1.4)	0	0	1 (1.4)	0
Mental status changes	1 (1.4)	0	0	1 (1.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223h
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	24 (32.4)	0	2 (2.7)	14 (18.9)	8 (10.8)
Hematopoietic cytopenias not resolved by Day 28					
Pancytopenia	1 (1.4)	0	0	0	1 (1.4)
-Total	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	22 (29.7)	0	2 (2.7)	13 (17.6)	7 (9.5)
Device related infection	3 (4.1)	0	0	3 (4.1)	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Pneumonia	2 (2.7)	0	1 (1.4)	0	1 (1.4)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	1 (1.4)	0	0	1 (1.4)	0
Mental status changes	1 (1.4)	0	0	1 (1.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223i
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (50.0)	0	0	2 (50.0)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	2 (50.0)	0	0	2 (50.0)	0
Enterococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Streptococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0

BCR-ABL1-like: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Device related infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0

BCR-ABL1-like: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223i
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	22 (31.0)	0	2 (2.8)	12 (16.9)	8 (11.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.4)	0	0	0	1 (1.4)
Pancytopenia	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	20 (28.2)	0	2 (2.8)	11 (15.5)	7 (9.9)
Device related infection	3 (4.2)	0	0	3 (4.2)	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Pneumonia	2 (2.8)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterococcal bacteraemia	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (1.4)	0	0	1 (1.4)	0
Mental status changes	1 (1.4)	0	0	1 (1.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223j
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (31.8)	0	1 (4.5)	4 (18.2)	2 (9.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	7 (31.8)	0	1 (4.5)	4 (18.2)	2 (9.1)
Device related infection	2 (9.1)	0	0	2 (9.1)	0
Alpha haemolytic streptococcal infection	1 (4.5)	0	0	1 (4.5)	0
Bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Candida sepsis	1 (4.5)	0	0	0	1 (4.5)
Gastroenteritis	1 (4.5)	0	0	1 (4.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (4.5)	0	1 (4.5)	0	0
Pneumonia fungal	1 (4.5)	0	0	1 (4.5)	0
Sepsis	1 (4.5)	0	0	0	1 (4.5)
Abscess limb	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223j
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	17 (32.1)	0	1 (1.9)	10 (18.9)	6 (11.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.9)	0	0	0	1 (1.9)
Pancytopenia	1 (1.9)	0	0	0	1 (1.9)
Infections					
-Total	15 (28.3)	0	1 (1.9)	9 (17.0)	5 (9.4)
Klebsiella sepsis	2 (3.8)	0	0	0	2 (3.8)
Pneumonia	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Staphylococcal bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Device related infection	1 (1.9)	0	0	1 (1.9)	0
Pneumonia fungal	1 (1.9)	0	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (1.9)	0	0	1 (1.9)	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Cellulitis	1 (1.9)	0	0	1 (1.9)	0
Enterococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	0	0	1 (1.9)
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Respiratory syncytial virus bronchitis	1 (1.9)	0	0	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	0	1 (1.9)	0	0
Serratia infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Candida sepsis	0	0	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (1.9)	0	0	1 (1.9)	0
Mental status changes	1 (1.9)	0	0	1 (1.9)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223k
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75				
Primary system organ class **Preferred term**	**All grades** **n (%)**	**Grade 1** **n (%)**	**Grade 2** **n (%)**	**Grade 3** **n (%)**	**Grade 4** **n (%)**
Number of patients with at least one event	24 (32.0)	0	2 (2.7)	14 (18.7)	8 (10.7)
Hematopoietic cytopenias not resolved by Day 28					
Pancytopenia	1 (1.3)	0	0	0	1 (1.3)
-Total	1 (1.3)	0	0	0	1 (1.3)
Infections					
-Total	22 (29.3)	0	2 (2.7)	13 (17.3)	7 (9.3)
Device related infection	3 (4.0)	0	0	3 (4.0)	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Pneumonia	2 (2.7)	0	1 (1.3)	0	1 (1.3)

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Abscess limb	1 (1.3)	0	0	1 (1.3)	0
Alpha haemolytic streptococcal infection	1 (1.3)	0	0	1 (1.3)	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Candida sepsis	1 (1.3)	0	0	0	1 (1.3)
Cellulitis	1 (1.3)	0	0	1 (1.3)	0
Enterococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Escherichia bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Escherichia sepsis	1 (1.3)	0	0	0	1 (1.3)
Escherichia urinary tract infection	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis	1 (1.3)	0	0	1 (1.3)	0
Parainfluenzae virus infection	1 (1.3)	0	1 (1.3)	0	0
Respiratory syncytial virus bronchitis	1 (1.3)	0	0	1 (1.3)	0
Respiratory syncytial virus infection	1 (1.3)	0	1 (1.3)	0	0
Sepsis	1 (1.3)	0	0	0	1 (1.3)

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal scalded skin syndrome	1 (1.3)	0	1 (1.3)	0	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Streptococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Serious neurological adverse reactions					
-Total	1 (1.3)	0	0	1 (1.3)	0
Mental status changes	1 (1.3)	0	0	1 (1.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223l
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (37.5)	0	0	7 (21.9)	5 (15.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	11 (34.4)	0	0	6 (18.8)	5 (15.6)
Klebsiella sepsis	2 (6.3)	0	0	0	2 (6.3)
Staphylococcal bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Device related infection	1 (3.1)	0	0	1 (3.1)	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	0	0	1 (3.1)
Escherichia urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Pneumonia	1 (3.1)	0	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	0	0	1 (3.1)	0
Sepsis	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal scalded skin syndrome	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.1)	0	0	1 (3.1)	0
Mental status changes	1 (3.1)	0	0	1 (3.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223l
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (27.9)	0	2 (4.7)	7 (16.3)	3 (7.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (2.3)	0	0	0	1 (2.3)
Pancytopenia	1 (2.3)	0	0	0	1 (2.3)
Infections					
-Total	11 (25.6)	0	2 (4.7)	7 (16.3)	2 (4.7)
Device related infection	2 (4.7)	0	0	2 (4.7)	0
Pneumonia	1 (2.3)	0	0	0	1 (2.3)
Pneumonia fungal	1 (2.3)	0	0	1 (2.3)	0
Alpha haemolytic streptococcal infection	1 (2.3)	0	0	1 (2.3)	0
Bronchopulmonary aspergillosis	1 (2.3)	0	0	1 (2.3)	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Candida sepsis	1 (2.3)	0	0	0	1 (2.3)
Cellulitis	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis	1 (2.3)	0	0	1 (2.3)	0
Parainfluenzae virus infection	1 (2.3)	0	1 (2.3)	0	0
Respiratory syncytial virus infection	1 (2.3)	0	1 (2.3)	0	0
Serratia infection	1 (2.3)	0	0	1 (2.3)	0
Staphylococcal infection	1 (2.3)	0	0	1 (2.3)	0
Klebsiella sepsis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Sepsis	0	0	0	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223m
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (27.8)	0	0	4 (22.2)	1 (5.6)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	5 (27.8)	0	0	4 (22.2)	1 (5.6)
Device related infection	2 (11.1)	0	0	2 (11.1)	0
Alpha haemolytic streptococcal infection	1 (5.6)	0	0	1 (5.6)	0
Bronchopulmonary aspergillosis	1 (5.6)	0	0	1 (5.6)	0
Escherichia urinary tract infection	1 (5.6)	0	0	1 (5.6)	0
Pneumonia	1 (5.6)	0	0	0	1 (5.6)

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223m
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (33.3)	0	2 (3.5)	10 (17.5)	7 (12.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.8)	0	0	0	1 (1.8)
Pancytopenia	1 (1.8)	0	0	0	1 (1.8)
Infections					
-Total	17 (29.8)	0	2 (3.5)	9 (15.8)	6 (10.5)
Klebsiella sepsis	2 (3.5)	0	0	0	2 (3.5)
Pneumonia fungal	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Staphylococcal bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Pneumonia	1 (1.8)	0	1 (1.8)	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (1.8)	0	0	1 (1.8)	0
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Candida sepsis	1 (1.8)	0	0	0	1 (1.8)
Cellulitis	1 (1.8)	0	0	1 (1.8)	0
Enterococcal bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Escherichia bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Escherichia sepsis	1 (1.8)	0	0	0	1 (1.8)
Gastroenteritis	1 (1.8)	0	0	1 (1.8)	0
Parainfluenzae virus infection	1 (1.8)	0	1 (1.8)	0	0
Respiratory syncytial virus bronchitis	1 (1.8)	0	0	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	0	1 (1.8)	0	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Serratia infection	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal scalded skin syndrome	1 (1.8)	0	1 (1.8)	0	0
Staphylococcal sepsis	1 (1.8)	0	0	0	1 (1.8)
Streptococcal bacteraemia	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (1.8)	0	0	1 (1.8)	0
Mental status changes	1 (1.8)	0	0	1 (1.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223n
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (9.1)	0	0	2 (9.1)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	2 (9.1)	0	0	2 (9.1)	0
Gastroenteritis	1 (4.5)	0	0	1 (4.5)	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223n
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	22 (41.5)	0	2 (3.8)	12 (22.6)	8 (15.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.9)	0	0	0	1 (1.9)
Pancytopenia	1 (1.9)	0	0	0	1 (1.9)
Infections					
-Total	20 (37.7)	0	2 (3.8)	11 (20.8)	7 (13.2)
Device related infection	3 (5.7)	0	0	3 (5.7)	0
Klebsiella sepsis	2 (3.8)	0	0	0	2 (3.8)
Pneumonia	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Pneumonia fungal	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Staphylococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0

Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (1.9)	0	0	1 (1.9)	0
Alpha haemolytic streptococcal infection	1 (1.9)	0	0	1 (1.9)	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Candida sepsis	1 (1.9)	0	0	0	1 (1.9)
Cellulitis	1 (1.9)	0	0	1 (1.9)	0
Enterococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	0	0	1 (1.9)
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Parainfluenzae virus infection	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	0	0	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	0	1 (1.9)	0	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Serratia infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (1.9)	0	0	1 (1.9)	0
Mental status changes	1 (1.9)	0	0	1 (1.9)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223o
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (28.6)	0	0	2 (28.6)	0
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	1 (14.3)	0	0	1 (14.3)	0
Device related infection	1 (14.3)	0	0	1 (14.3)	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (14.3)	0	0	1 (14.3)	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223o
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	22 (32.4)	0	2 (2.9)	12 (17.6)	8 (11.8)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (1.5)	0	0	0	1 (1.5)
Pancytopenia	1 (1.5)	0	0	0	1 (1.5)
Infections					
-Total	21 (30.9)	0	2 (2.9)	12 (17.6)	7 (10.3)
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Klebsiella sepsis	2 (2.9)	0	0	0	2 (2.9)
Pneumonia	2 (2.9)	0	1 (1.5)	0	1 (1.5)
Pneumonia fungal	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Alpha haemolytic streptococcal infection	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Candida sepsis	1 (1.5)	0	0	0	1 (1.5)
Cellulitis	1 (1.5)	0	0	1 (1.5)	0
Enterococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Escherichia bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	0	0	1 (1.5)
Escherichia urinary tract infection	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis	1 (1.5)	0	0	1 (1.5)	0
Parainfluenzae virus infection	1 (1.5)	0	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	1 (1.5)	0	0
Sepsis	1 (1.5)	0	0	0	1 (1.5)
Serratia infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal infection	1 (1.5)	0	0	1 (1.5)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	1 (1.5)	0	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223p
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71				
Primary system organ class **Preferred term**	**All grades** **n (%)**	**Grade 1** **n (%)**	**Grade 2** **n (%)**	**Grade 3** **n (%)**	**Grade 4** **n (%)**
Number of patients with at least one event	24 (33.8)	0	2 (2.8)	14 (19.7)	8 (11.3)
Hematopoietic cytopenias not resolved by Day 28					
Pancytopenia	1 (1.4)	0	0	0	1 (1.4)
-Total	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	22 (31.0)	0	2 (2.8)	13 (18.3)	7 (9.9)
Device related infection	3 (4.2)	0	0	3 (4.2)	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Pneumonia	2 (2.8)	0	1 (1.4)	0	1 (1.4)

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	1 (1.4)	0	0	1 (1.4)	0
Mental status changes	1 (1.4)	0	0	1 (1.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223q
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (31.3)	0	2 (6.3)	7 (21.9)	1 (3.1)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	9 (28.1)	0	2 (6.3)	6 (18.8)	1 (3.1)
Device related infection	3 (9.4)	0	0	3 (9.4)	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Alpha haemolytic streptococcal infection	1 (3.1)	0	0	1 (3.1)	0
Enterococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Parainfluenzae virus infection	1 (3.1)	0	1 (3.1)	0	0
Pneumonia	1 (3.1)	0	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	0	0	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal scalded skin syndrome	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Cellulitis	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.1)	0	0	1 (3.1)	0
Mental status changes	1 (3.1)	0	0	1 (3.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223q
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (25.0)	0	0	6 (18.8)	2 (6.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (3.1)	0	0	0	1 (3.1)
Pancytopenia	1 (3.1)	0	0	0	1 (3.1)
Infections					
-Total	7 (21.9)	0	0	6 (18.8)	1 (3.1)
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Bronchopulmonary aspergillosis	1 (3.1)	0	0	1 (3.1)	0
Cellulitis	1 (3.1)	0	0	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	0	0	1 (3.1)
Gastroenteritis	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Device related infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Candida sepsis	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Sepsis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223q
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one event	6 (54.5)	0	0	1 (9.1)	5 (45.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	6 (54.5)	0	0	1 (9.1)	5 (45.5)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Pneumonia fungal	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Device related infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cellulitis	0	0	0	0	0

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223r
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223r
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (47.8)	0	2 (8.7)	7 (30.4)	2 (8.7)
Hematopoietic cytopenias not resolved by Day 28					
-Total	1 (4.3)	0	0	0	1 (4.3)
Pancytopenia	1 (4.3)	0	0	0	1 (4.3)
Infections					
-Total	10 (43.5)	0	2 (8.7)	7 (30.4)	1 (4.3)
Device related infection	2 (8.7)	0	0	2 (8.7)	0
Pneumonia	1 (4.3)	0	1 (4.3)	0	0
Abscess limb	1 (4.3)	0	0	1 (4.3)	0
Bronchopulmonary aspergillosis	1 (4.3)	0	0	1 (4.3)	0
Escherichia bacteraemia	1 (4.3)	0	0	1 (4.3)	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia urinary tract infection	1 (4.3)	0	0	1 (4.3)	0
Gastroenteritis	1 (4.3)	0	0	1 (4.3)	0
Parainfluenzae virus infection	1 (4.3)	0	1 (4.3)	0	0
Pneumonia fungal	1 (4.3)	0	1 (4.3)	0	0
Respiratory syncytial virus bronchitis	1 (4.3)	0	0	1 (4.3)	0
Respiratory syncytial virus infection	1 (4.3)	0	1 (4.3)	0	0
Serratia infection	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal scalded skin syndrome	1 (4.3)	0	1 (4.3)	0	0
Staphylococcal sepsis	1 (4.3)	0	0	0	1 (4.3)
Cellulitis	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223r
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (16.7)	0	0	2 (8.3)	2 (8.3)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	4 (16.7)	0	0	2 (8.3)	2 (8.3)
Alpha haemolytic streptococcal infection	1 (4.2)	0	0	1 (4.2)	0
Candida sepsis	1 (4.2)	0	0	0	1 (4.2)
Device related infection	1 (4.2)	0	0	1 (4.2)	0
Escherichia sepsis	1 (4.2)	0	0	0	1 (4.2)

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	1 (4.2)	0	0	1 (4.2)	0
Staphylococcal infection	1 (4.2)	0	0	1 (4.2)	0
Cellulitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Klebsiella sepsis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia infection	0	0	0	0	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223r
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (35.0)	0	0	4 (20.0)	3 (15.0)
Hematopoietic cytopenias not resolved by Day 28					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	6 (30.0)	0	0	3 (15.0)	3 (15.0)
Klebsiella sepsis	2 (10.0)	0	0	0	2 (10.0)
Bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Enterococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Streptococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Cellulitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Abscess limb	0	0	0	0	0
Alpha haemolytic streptococcal infection	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida sepsis	0	0	0	0	0
Device related infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus bronchitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal scalded skin syndrome	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (5.0)	0	0	1 (5.0)	0
Mental status changes	1 (5.0)	0	0	1 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (95.0)	1 (5.0)	18 (90.0)
Blood and lymphatic system disorders			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Anaemia	2 (10.0)	2 (10.0)	0
Thrombocytopenia	1 (5.0)	0	1 (5.0)
Cardiac disorders			
-Total	5 (25.0)	3 (15.0)	2 (10.0)
Sinus tachycardia	3 (15.0)	2 (10.0)	1 (5.0)
Tachycardia	2 (10.0)	1 (5.0)	1 (5.0)
Eye disorders			
-Total	2 (10.0)	2 (10.0)	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctival haemorrhage	2 (10.0)	2 (10.0)	0
Periorbital oedema	2 (10.0)	2 (10.0)	0
Gastrointestinal disorders			
-Total	10 (50.0)	4 (20.0)	6 (30.0)
Nausea	7 (35.0)	3 (15.0)	4 (20.0)
Vomiting	7 (35.0)	5 (25.0)	2 (10.0)
Diarrhoea	6 (30.0)	4 (20.0)	2 (10.0)
Abdominal pain	4 (20.0)	3 (15.0)	1 (5.0)
Constipation	3 (15.0)	3 (15.0)	0
General disorders and administration site conditions			
-Total	7 (35.0)	2 (10.0)	5 (25.0)
Pyrexia	4 (20.0)	0	4 (20.0)
Fatigue	3 (15.0)	3 (15.0)	0
Catheter site pain	2 (10.0)	0	2 (10.0)
Chills	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	16 (80.0)	1 (5.0)	15 (75.0)
Cytokine release syndrome	13 (65.0)	2 (10.0)	11 (55.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	7 (35.0)	1 (5.0)	6 (30.0)
Infections and infestations			
-Total	8 (40.0)	3 (15.0)	5 (25.0)
Clostridium difficile infection	3 (15.0)	0	3 (15.0)
Rhinovirus infection	3 (15.0)	3 (15.0)	0
Gastroenteritis	1 (5.0)	0	1 (5.0)
Viral upper respiratory tract infection	1 (5.0)	0	1 (5.0)
Vulvovaginal candidiasis	1 (5.0)	1 (5.0)	0
Injury, poisoning and procedural complications			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Procedural pain	2 (10.0)	1 (5.0)	1 (5.0)
Infusion related reaction	1 (5.0)	0	1 (5.0)
Transfusion reaction	1 (5.0)	1 (5.0)	0
Investigations			
-Total	9 (45.0)	2 (10.0)	7 (35.0)
Aspartate aminotransferase increased	4 (20.0)	2 (10.0)	2 (10.0)
White blood cell count decreased	4 (20.0)	2 (10.0)	2 (10.0)

Timing: within 8 weeks post infusion, Age: <10 years

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	3 (15.0)	1 (5.0)	2 (10.0)
Blood bilirubin increased	2 (10.0)	0	2 (10.0)
Lymphocyte count decreased	2 (10.0)	1 (5.0)	1 (5.0)
Prothrombin time prolonged	2 (10.0)	2 (10.0)	0
Activated partial thromboplastin time prolonged	1 (5.0)	1 (5.0)	0
Blood fibrinogen decreased	1 (5.0)	0	1 (5.0)
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0
Blood urea increased	1 (5.0)	1 (5.0)	0
International normalised ratio increased	1 (5.0)	1 (5.0)	0
Neutrophil count decreased	1 (5.0)	0	1 (5.0)
Platelet count decreased	1 (5.0)	0	1 (5.0)
Transaminases increased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	11 (55.0)	4 (20.0)	7 (35.0)
Decreased appetite	4 (20.0)	3 (15.0)	1 (5.0)
Hypokalaemia	3 (15.0)	0	3 (15.0)
Hypertriglyceridaemia	2 (10.0)	1 (5.0)	1 (5.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoalbuminaemia	2 (10.0)	0	2 (10.0)
Hypocalcaemia	2 (10.0)	1 (5.0)	1 (5.0)
Hypophosphataemia	2 (10.0)	2 (10.0)	0
Fluid overload	1 (5.0)	1 (5.0)	0
Hyperphosphataemia	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Pain in extremity	2 (10.0)	1 (5.0)	1 (5.0)
Nervous system disorders			
-Total	7 (35.0)	7 (35.0)	0
Headache	7 (35.0)	7 (35.0)	0
Dizziness	1 (5.0)	1 (5.0)	0
Psychiatric disorders			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Confusional state	2 (10.0)	1 (5.0)	1 (5.0)
Anxiety	1 (5.0)	1 (5.0)	0
Delirium	1 (5.0)	0	1 (5.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Reproductive system and breast disorders			
-Total	2 (10.0)	2 (10.0)	0
Vulvovaginal adhesion	2 (10.0)	2 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (35.0)	3 (15.0)	4 (20.0)
Cough	4 (20.0)	4 (20.0)	0
Hypoxia	2 (10.0)	0	2 (10.0)
Pleural effusion	2 (10.0)	1 (5.0)	1 (5.0)
Epistaxis	1 (5.0)	0	1 (5.0)
Skin and subcutaneous tissue disorders			
-Total	8 (40.0)	7 (35.0)	1 (5.0)
Hyperhidrosis	2 (10.0)	2 (10.0)	0
Rash	2 (10.0)	2 (10.0)	0
Rash maculo-papular	2 (10.0)	1 (5.0)	1 (5.0)
Rash papular	2 (10.0)	2 (10.0)	0
Erythema	1 (5.0)	1 (5.0)	0
Petechiae	1 (5.0)	1 (5.0)	0

Timing: within 8 weeks post infusion, Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Vascular disorders			
-Total	6 (30.0)	3 (15.0)	3 (15.0)
Hypertension	5 (25.0)	2 (10.0)	3 (15.0)
Flushing	2 (10.0)	2 (10.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	33 (97.1)	1 (2.9)	32 (94.1)
Blood and lymphatic system disorders			
-Total	8 (23.5)	2 (5.9)	6 (17.6)
Anaemia	8 (23.5)	2 (5.9)	6 (17.6)
Thrombocytopenia	1 (2.9)	0	1 (2.9)
Cardiac disorders			
-Total	10 (29.4)	6 (17.6)	4 (11.8)
Tachycardia	9 (26.5)	6 (17.6)	3 (8.8)
Sinus tachycardia	2 (5.9)	1 (2.9)	1 (2.9)
Eye disorders			
-Total	3 (8.8)	1 (2.9)	2 (5.9)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Periorbital oedema	2 (5.9)	1 (2.9)	1 (2.9)
Conjunctival haemorrhage	1 (2.9)	1 (2.9)	0
Uveitis	1 (2.9)	0	1 (2.9)
Gastrointestinal disorders			
-Total	17 (50.0)	7 (20.6)	10 (29.4)
Vomiting	11 (32.4)	8 (23.5)	3 (8.8)
Nausea	9 (26.5)	3 (8.8)	6 (17.6)
Diarrhoea	7 (20.6)	5 (14.7)	2 (5.9)
Abdominal pain	4 (11.8)	3 (8.8)	1 (2.9)
Constipation	3 (8.8)	3 (8.8)	0
Abdominal pain upper	1 (2.9)	0	1 (2.9)
General disorders and administration site conditions			
-Total	17 (50.0)	10 (29.4)	7 (20.6)
Fatigue	8 (23.5)	7 (20.6)	1 (2.9)
Pyrexia	7 (20.6)	2 (5.9)	5 (14.7)
Chills	4 (11.8)	4 (11.8)	0
Malaise	2 (5.9)	0	2 (5.9)
Catheter site pain	1 (2.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatobiliary disorders			
-Total	2 (5.9)	1 (2.9)	1 (2.9)
Hepatomegaly	2 (5.9)	1 (2.9)	1 (2.9)
Immune system disorders			
-Total	28 (82.4)	5 (14.7)	23 (67.6)
Cytokine release syndrome	24 (70.6)	5 (14.7)	19 (55.9)
Hypogammaglobulinaemia	11 (32.4)	2 (5.9)	9 (26.5)
Infections and infestations			
-Total	3 (8.8)	1 (2.9)	2 (5.9)
Clostridium difficile infection	1 (2.9)	0	1 (2.9)
Influenza	1 (2.9)	1 (2.9)	0
Upper respiratory tract infection	1 (2.9)	0	1 (2.9)
Injury, poisoning and procedural complications			
-Total	3 (8.8)	1 (2.9)	2 (5.9)
Infusion related reaction	1 (2.9)	0	1 (2.9)
Procedural pain	1 (2.9)	0	1 (2.9)
Transfusion reaction	1 (2.9)	1 (2.9)	0
Investigations			

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	19 (55.9)	4 (11.8)	15 (44.1)
Aspartate aminotransferase increased	7 (20.6)	3 (8.8)	4 (11.8)
Blood creatinine increased	7 (20.6)	5 (14.7)	2 (5.9)
Alanine aminotransferase increased	6 (17.6)	3 (8.8)	3 (8.8)
International normalised ratio increased	6 (17.6)	6 (17.6)	0
White blood cell count decreased	5 (14.7)	1 (2.9)	4 (11.8)
Activated partial thromboplastin time prolonged	4 (11.8)	2 (5.9)	2 (5.9)
Blood bilirubin increased	4 (11.8)	2 (5.9)	2 (5.9)
Prothrombin time prolonged	4 (11.8)	3 (8.8)	1 (2.9)
Platelet count decreased	3 (8.8)	2 (5.9)	1 (2.9)
Blood immunoglobulin m decreased	2 (5.9)	2 (5.9)	0
Lymphocyte count decreased	2 (5.9)	0	2 (5.9)
Blood urea increased	1 (2.9)	0	1 (2.9)
Neutrophil count decreased	1 (2.9)	0	1 (2.9)
Transaminases increased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	14 (41.2)	7 (20.6)	7 (20.6)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	6 (17.6)	4 (11.8)	2 (5.9)
Hyperphosphataemia	6 (17.6)	6 (17.6)	0
Hypokalaemia	4 (11.8)	1 (2.9)	3 (8.8)
Hypoalbuminaemia	3 (8.8)	1 (2.9)	2 (5.9)
Fluid overload	1 (2.9)	0	1 (2.9)
Hypophosphataemia	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders			
-Total	8 (23.5)	6 (17.6)	2 (5.9)
Myalgia	5 (14.7)	4 (11.8)	1 (2.9)
Arthralgia	3 (8.8)	3 (8.8)	0
Musculoskeletal pain	2 (5.9)	1 (2.9)	1 (2.9)
Pain in extremity	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	15 (44.1)	8 (23.5)	7 (20.6)
Headache	15 (44.1)	8 (23.5)	7 (20.6)
Dizziness	1 (2.9)	1 (2.9)	0
Psychiatric disorders			
-Total	7 (20.6)	3 (8.8)	4 (11.8)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Anxiety	4 (11.8)	1 (2.9)	3 (8.8)
Confusional state	3 (8.8)	1 (2.9)	2 (5.9)
Delirium	2 (5.9)	1 (2.9)	1 (2.9)
Renal and urinary disorders			
-Total	1 (2.9)	0	1 (2.9)
Haematuria	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (35.3)	6 (17.6)	6 (17.6)
Cough	3 (8.8)	3 (8.8)	0
Hypoxia	3 (8.8)	0	3 (8.8)
Epistaxis	2 (5.9)	1 (2.9)	1 (2.9)
Oropharyngeal pain	2 (5.9)	1 (2.9)	1 (2.9)
Pleural effusion	2 (5.9)	1 (2.9)	1 (2.9)
Nasal congestion	1 (2.9)	1 (2.9)	0
Rhinitis allergic	1 (2.9)	1 (2.9)	0
Rhinorrhoea	1 (2.9)	1 (2.9)	0
Skin and subcutaneous tissue disorders			

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	8 (23.5)	7 (20.6)	1 (2.9)
Dry skin	4 (11.8)	4 (11.8)	0
Erythema	2 (5.9)	2 (5.9)	0
Hyperhidrosis	1 (2.9)	1 (2.9)	0
Ingrowing nail	1 (2.9)	0	1 (2.9)
Petechiae	1 (2.9)	1 (2.9)	0
Pruritus	1 (2.9)	1 (2.9)	0
Rash	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	2 (5.9)	0	2 (5.9)
Hypertension	1 (2.9)	0	1 (2.9)
Orthostatic hypotension	1 (2.9)	0	1 (2.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (100)	0	10 (100)
Blood and lymphatic system disorders			
-Total	2 (20.0)	0	2 (20.0)
Anaemia	1 (10.0)	0	1 (10.0)
Lymphopenia	1 (10.0)	0	1 (10.0)
Neutropenia	1 (10.0)	1 (10.0)	0
Thrombocytopenia	1 (10.0)	0	1 (10.0)
Cardiac disorders			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Tachycardia	3 (30.0)	1 (10.0)	2 (20.0)

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Ear and labyrinth disorders			
-Total	1 (10.0)	0	1 (10.0)
Hypoacusis	1 (10.0)	0	1 (10.0)
Eye disorders			
-Total	2 (20.0)	0	2 (20.0)
Papilloedema	1 (10.0)	0	1 (10.0)
Uveitis	1 (10.0)	0	1 (10.0)
Visual impairment	1 (10.0)	0	1 (10.0)
Gastrointestinal disorders			
-Total	5 (50.0)	1 (10.0)	4 (40.0)
Diarrhoea	4 (40.0)	2 (20.0)	2 (20.0)
Nausea	4 (40.0)	0	4 (40.0)
Vomiting	2 (20.0)	0	2 (20.0)
Abdominal discomfort	1 (10.0)	1 (10.0)	0
Abdominal pain upper	1 (10.0)	0	1 (10.0)
Constipation	1 (10.0)	0	1 (10.0)
Dyspepsia	1 (10.0)	0	1 (10.0)
General disorders and administration site conditions			

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (40.0)	1 (10.0)	3 (30.0)
Chills	3 (30.0)	3 (30.0)	0
Pyrexia	3 (30.0)	1 (10.0)	2 (20.0)
Fatigue	2 (20.0)	0	2 (20.0)
Asthenia	1 (10.0)	1 (10.0)	0
Facial pain	1 (10.0)	0	1 (10.0)
Malaise	1 (10.0)	0	1 (10.0)
Hepatobiliary disorders			
-Total	1 (10.0)	0	1 (10.0)
Hepatomegaly	1 (10.0)	0	1 (10.0)
Immune system disorders			
-Total	8 (80.0)	0	8 (80.0)
Cytokine release syndrome	8 (80.0)	0	8 (80.0)
Hypogammaglobulinaemia	3 (30.0)	0	3 (30.0)
Infections and infestations			
-Total	3 (30.0)	0	3 (30.0)
Folliculitis	1 (10.0)	0	1 (10.0)
Human herpesvirus 6 infection	1 (10.0)	0	1 (10.0)
Pneumonia	1 (10.0)	0	1 (10.0)

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Incision site pain	1 (10.0)	1 (10.0)	0
Limb injury	1 (10.0)	1 (10.0)	0
Tracheal haemorrhage	1 (10.0)	0	1 (10.0)
Transfusion reaction	1 (10.0)	0	1 (10.0)
Investigations			
-Total	5 (50.0)	0	5 (50.0)
Prothrombin time prolonged	3 (30.0)	0	3 (30.0)
Blood fibrinogen decreased	2 (20.0)	0	2 (20.0)
Platelet count decreased	2 (20.0)	1 (10.0)	1 (10.0)
White blood cell count decreased	2 (20.0)	0	2 (20.0)
Alanine aminotransferase increased	1 (10.0)	1 (10.0)	0
Aspartate aminotransferase increased	1 (10.0)	1 (10.0)	0
Blood immunoglobulin m decreased	1 (10.0)	1 (10.0)	0
Hepatic enzyme increased	1 (10.0)	0	1 (10.0)
International normalised ratio increased	1 (10.0)	1 (10.0)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	5 (50.0)	2 (20.0)	3 (30.0)
Hypokalaemia	3 (30.0)	2 (20.0)	1 (10.0)
Decreased appetite	1 (10.0)	0	1 (10.0)
Fluid overload	1 (10.0)	0	1 (10.0)
Hyperphosphataemia	1 (10.0)	1 (10.0)	0
Metabolic acidosis	1 (10.0)	0	1 (10.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Limb discomfort	1 (10.0)	1 (10.0)	0
Musculoskeletal pain	1 (10.0)	1 (10.0)	0
Pain in extremity	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	4 (40.0)	2 (20.0)	2 (20.0)
Dizziness	2 (20.0)	2 (20.0)	0
Headache	2 (20.0)	1 (10.0)	1 (10.0)
Idiopathic intracranial hypertension	1 (10.0)	0	1 (10.0)
Psychiatric disorders			

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (30.0)	2 (20.0)	1 (10.0)
Confusional state	1 (10.0)	1 (10.0)	0
Delirium	1 (10.0)	1 (10.0)	0
Panic attack	1 (10.0)	0	1 (10.0)
Renal and urinary disorders			
-Total	1 (10.0)	0	1 (10.0)
Haematuria	1 (10.0)	0	1 (10.0)
Reproductive system and breast disorders			
-Total	1 (10.0)	0	1 (10.0)
Oedema genital	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Pleural effusion	2 (20.0)	0	2 (20.0)
Cough	1 (10.0)	1 (10.0)	0
Epistaxis	1 (10.0)	1 (10.0)	0
Skin and subcutaneous tissue disorders			
-Total	3 (30.0)	1 (10.0)	2 (20.0)

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Ingrowing nail	1 (10.0)	0	1 (10.0)
Petechiae	1 (10.0)	0	1 (10.0)
Pruritus	1 (10.0)	1 (10.0)	0
Rash	1 (10.0)	1 (10.0)	0
Vascular disorders			
-Total	4 (40.0)	1 (10.0)	3 (30.0)
Hypertension	3 (30.0)	0	3 (30.0)
Orthostatic hypotension	1 (10.0)	1 (10.0)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (72.2)	3 (16.7)	10 (55.6)
Blood and lymphatic system disorders			
-Total	1 (5.6)	0	1 (5.6)
Thrombocytopenia	1 (5.6)	0	1 (5.6)
Gastrointestinal disorders			
-Total	5 (27.8)	2 (11.1)	3 (16.7)
Vomiting	4 (22.2)	2 (11.1)	2 (11.1)
Diarrhoea	3 (16.7)	3 (16.7)	0
Nausea	2 (11.1)	0	2 (11.1)
Abdominal pain	1 (5.6)	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	6 (33.3)	6 (33.3)	0
Pyrexia	5 (27.8)	5 (27.8)	0
Fatigue	1 (5.6)	1 (5.6)	0
Malaise	1 (5.6)	1 (5.6)	0
Immune system disorders			
-Total	1 (5.6)	0	1 (5.6)
Hypogammaglobulinaemia	1 (5.6)	0	1 (5.6)
Infections and infestations			
-Total	8 (44.4)	3 (16.7)	5 (27.8)
Upper respiratory tract infection	3 (16.7)	2 (11.1)	1 (5.6)
Ear infection	2 (11.1)	1 (5.6)	1 (5.6)
Gastroenteritis	2 (11.1)	1 (5.6)	1 (5.6)
Otitis media acute	1 (5.6)	0	1 (5.6)
Sinusitis	1 (5.6)	0	1 (5.6)
Urinary tract infection	1 (5.6)	0	1 (5.6)
Viral upper respiratory tract infection	1 (5.6)	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Infusion related reaction	1 (5.6)	1 (5.6)	0
Procedural pain	1 (5.6)	1 (5.6)	0
Investigations			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Blood urea increased	1 (5.6)	1 (5.6)	0
Weight decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	1 (5.6)	0	1 (5.6)
Decreased appetite	1 (5.6)	0	1 (5.6)
Musculoskeletal and connective tissue disorders			
-Total	6 (33.3)	4 (22.2)	2 (11.1)
Pain in extremity	6 (33.3)	4 (22.2)	2 (11.1)
Nervous system disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Dizziness	2 (11.1)	2 (11.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	1 (5.6)	0	1 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (27.8)	3 (16.7)	2 (11.1)
Cough	2 (11.1)	2 (11.1)	0
Rhinorrhoea	2 (11.1)	1 (5.6)	1 (5.6)
Nasal congestion	1 (5.6)	1 (5.6)	0
Oropharyngeal pain	1 (5.6)	1 (5.6)	0
Rhinitis allergic	1 (5.6)	0	1 (5.6)
Skin and subcutaneous tissue disorders			
-Total	1 (5.6)	0	1 (5.6)
Pruritus	1 (5.6)	1 (5.6)	0
Rash	1 (5.6)	0	1 (5.6)

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Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	22 (71.0)	4 (12.9)	18 (58.1)
Blood and lymphatic system disorders			
-Total	2 (6.5)	1 (3.2)	1 (3.2)
Anaemia	1 (3.2)	1 (3.2)	0
Lymphopenia	1 (3.2)	0	1 (3.2)
Cardiac disorders			
-Total	1 (3.2)	0	1 (3.2)
Sinus tachycardia	1 (3.2)	0	1 (3.2)
Gastrointestinal disorders			
-Total	8 (25.8)	7 (22.6)	1 (3.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	4 (12.9)	3 (9.7)	1 (3.2)
Vomiting	3 (9.7)	2 (6.5)	1 (3.2)
Abdominal pain	2 (6.5)	1 (3.2)	1 (3.2)
Abdominal pain upper	1 (3.2)	1 (3.2)	0
Nausea	1 (3.2)	1 (3.2)	0
General disorders and administration site conditions			
-Total	5 (16.1)	3 (9.7)	2 (6.5)
Pyrexia	2 (6.5)	1 (3.2)	1 (3.2)
Catheter site pain	1 (3.2)	0	1 (3.2)
Chills	1 (3.2)	1 (3.2)	0
Fatigue	1 (3.2)	1 (3.2)	0
Influenza like illness	1 (3.2)	1 (3.2)	0
Immune system disorders			
-Total	5 (16.1)	0	5 (16.1)
Hypogammaglobulinaemia	5 (16.1)	0	5 (16.1)
Infections and infestations			
-Total	10 (32.3)	3 (9.7)	7 (22.6)
Upper respiratory tract infection	3 (9.7)	1 (3.2)	2 (6.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinovirus infection	2 (6.5)	2 (6.5)	0
Urinary tract infection	2 (6.5)	0	2 (6.5)
Gastroenteritis	1 (3.2)	0	1 (3.2)
Influenza	1 (3.2)	0	1 (3.2)
Sinusitis	1 (3.2)	0	1 (3.2)
Injury, poisoning and procedural complications			
-Total	2 (6.5)	0	2 (6.5)
Infusion related reaction	1 (3.2)	0	1 (3.2)
Procedural pain	1 (3.2)	0	1 (3.2)
Investigations			
-Total	8 (25.8)	4 (12.9)	4 (12.9)
Neutrophil count decreased	3 (9.7)	2 (6.5)	1 (3.2)
White blood cell count decreased	3 (9.7)	1 (3.2)	2 (6.5)
Lymphocyte count decreased	2 (6.5)	1 (3.2)	1 (3.2)
Platelet count decreased	2 (6.5)	2 (6.5)	0
Blood creatinine increased	1 (3.2)	1 (3.2)	0
Haemoglobin decreased	1 (3.2)	1 (3.2)	0
Weight decreased	1 (3.2)	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	4 (12.9)	4 (12.9)	0
Hyperphosphataemia	2 (6.5)	2 (6.5)	0
Decreased appetite	1 (3.2)	1 (3.2)	0
Hypokalaemia	1 (3.2)	1 (3.2)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (9.7)	3 (9.7)	0
Pain in extremity	2 (6.5)	2 (6.5)	0
Arthralgia	1 (3.2)	1 (3.2)	0
Nervous system disorders			
-Total	4 (12.9)	4 (12.9)	0
Headache	3 (9.7)	3 (9.7)	0
Peroneal nerve palsy	1 (3.2)	1 (3.2)	0
Psychiatric disorders			
-Total	1 (3.2)	1 (3.2)	0
Anxiety	1 (3.2)	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	9 (29.0)	6 (19.4)	3 (9.7)
Cough	5 (16.1)	3 (9.7)	2 (6.5)
Nasal congestion	3 (9.7)	3 (9.7)	0
Oropharyngeal pain	2 (6.5)	1 (3.2)	1 (3.2)
Rhinorrhoea	2 (6.5)	2 (6.5)	0
Epistaxis	1 (3.2)	1 (3.2)	0
Rhinitis allergic	1 (3.2)	1 (3.2)	0
Skin and subcutaneous tissue disorders			
-Total	9 (29.0)	7 (22.6)	2 (6.5)
Rash	3 (9.7)	1 (3.2)	2 (6.5)
Rash maculo-papular	2 (6.5)	2 (6.5)	0
Dry skin	1 (3.2)	1 (3.2)	0
Erythema	1 (3.2)	1 (3.2)	0
Ingrowing nail	1 (3.2)	1 (3.2)	0
Petechiae	1 (3.2)	1 (3.2)	0
Vascular disorders			
-Total	2 (6.5)	1 (3.2)	1 (3.2)
Hypertension	2 (6.5)	1 (3.2)	1 (3.2)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (85.7)	1 (14.3)	5 (71.4)
Gastrointestinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Nausea	1 (14.3)	0	1 (14.3)
Vomiting	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Pyrexia	2 (28.6)	1 (14.3)	1 (14.3)
Influenza like illness	1 (14.3)	1 (14.3)	0
Immune system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (14.3)	0	1 (14.3)
Hypogammaglobulinaemia	1 (14.3)	0	1 (14.3)
Infections and infestations			
-Total	2 (28.6)	0	2 (28.6)
Influenza	2 (28.6)	0	2 (28.6)
Injury, poisoning and procedural complications			
-Total	1 (14.3)	0	1 (14.3)
Foot fracture	1 (14.3)	0	1 (14.3)
Investigations			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Weight decreased	2 (28.6)	0	2 (28.6)
Aspartate aminotransferase increased	1 (14.3)	1 (14.3)	0
Haemoglobin decreased	1 (14.3)	1 (14.3)	0
Platelet count decreased	1 (14.3)	1 (14.3)	0
Transaminases increased	1 (14.3)	1 (14.3)	0
White blood cell count decreased	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (14.3)	0	1 (14.3)
Arthralgia	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Dizziness	1 (14.3)	1 (14.3)	0
Headache	1 (14.3)	1 (14.3)	0
Peroneal nerve palsy	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Rhinitis allergic	1 (14.3)	1 (14.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Erythema	1 (14.3)	1 (14.3)	0
Hyperhidrosis	1 (14.3)	1 (14.3)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported

in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (27.3)	0	3 (27.3)
Gastrointestinal disorders			
-Total	1 (9.1)	0	1 (9.1)
Abdominal pain	1 (9.1)	0	1 (9.1)
Diarrhoea	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	3 (27.3)	0	3 (27.3)
Otitis media acute	2 (18.2)	0	2 (18.2)
Pneumonia	1 (9.1)	0	1 (9.1)
Sinusitis	1 (9.1)	0	1 (9.1)

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Urinary tract infection	1 (9.1)	0	1 (9.1)
Vulvovaginal candidiasis	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	0	1 (9.1)
Dizziness	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (9.1)	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0
Rhinorrhoea	1 (9.1)	1 (9.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (45.5)	4 (18.2)	6 (27.3)
Blood and lymphatic system disorders			
-Total	1 (4.5)	1 (4.5)	0
Thrombocytopenia	1 (4.5)	1 (4.5)	0
Gastrointestinal disorders			
-Total	2 (9.1)	0	2 (9.1)
Diarrhoea	1 (4.5)	0	1 (4.5)
Nausea	1 (4.5)	0	1 (4.5)
General disorders and administration site conditions			
-Total	1 (4.5)	0	1 (4.5)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Chills	1 (4.5)	0	1 (4.5)
Pyrexia	1 (4.5)	0	1 (4.5)
Infections and infestations			
-Total	3 (13.6)	1 (4.5)	2 (9.1)
Pneumonia	1 (4.5)	0	1 (4.5)
Sinusitis	1 (4.5)	0	1 (4.5)
Upper respiratory tract infection	1 (4.5)	1 (4.5)	0
Urinary tract infection	1 (4.5)	0	1 (4.5)
Investigations			
-Total	5 (22.7)	2 (9.1)	3 (13.6)
Lymphocyte count decreased	3 (13.6)	2 (9.1)	1 (4.5)
Neutrophil count decreased	2 (9.1)	1 (4.5)	1 (4.5)
Alanine aminotransferase increased	1 (4.5)	0	1 (4.5)
Aspartate aminotransferase increased	1 (4.5)	1 (4.5)	0
White blood cell count decreased	1 (4.5)	1 (4.5)	0
Renal and urinary disorders			
-Total	1 (4.5)	1 (4.5)	0
Haematuria	1 (4.5)	1 (4.5)	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	3 (13.6)	3 (13.6)	0
Cough	2 (9.1)	2 (9.1)	0
Epistaxis	1 (4.5)	1 (4.5)	0
Rhinitis allergic	1 (4.5)	1 (4.5)	0
Skin and subcutaneous tissue disorders			
-Total	1 (4.5)	1 (4.5)	0
Pruritus	1 (4.5)	1 (4.5)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Infections and infestations			
-Total	1 (100)	0	1 (100)
Sinusitis	1 (100)	0	1 (100)
Upper respiratory tract infection	1 (100)	0	1 (100)

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (100)	1 (5.0)	19 (95.0)
Blood and lymphatic system disorders			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Anaemia	2 (10.0)	2 (10.0)	0
Thrombocytopenia	2 (10.0)	0	2 (10.0)
Cardiac disorders			
-Total	5 (25.0)	3 (15.0)	2 (10.0)
Sinus tachycardia	3 (15.0)	2 (10.0)	1 (5.0)
Tachycardia	2 (10.0)	1 (5.0)	1 (5.0)
Eye disorders			

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (10.0)	2 (10.0)	0
Conjunctival haemorrhage	2 (10.0)	2 (10.0)	0
Periorbital oedema	2 (10.0)	2 (10.0)	0
Gastrointestinal disorders			
-Total	11 (55.0)	3 (15.0)	8 (40.0)
Vomiting	9 (45.0)	5 (25.0)	4 (20.0)
Diarrhoea	8 (40.0)	5 (25.0)	3 (15.0)
Nausea	8 (40.0)	2 (10.0)	6 (30.0)
Abdominal pain	4 (20.0)	2 (10.0)	2 (10.0)
Constipation	3 (15.0)	3 (15.0)	0
General disorders and administration site conditions			
-Total	10 (50.0)	5 (25.0)	5 (25.0)
Pyrexia	7 (35.0)	3 (15.0)	4 (20.0)
Fatigue	4 (20.0)	4 (20.0)	0
Catheter site pain	2 (10.0)	0	2 (10.0)
Chills	1 (5.0)	1 (5.0)	0
Malaise	1 (5.0)	1 (5.0)	0
Immune system disorders			

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	16 (80.0)	1 (5.0)	15 (75.0)
Cytokine release syndrome	13 (65.0)	2 (10.0)	11 (55.0)
Hypogammaglobulinaemia	8 (40.0)	1 (5.0)	7 (35.0)
Infections and infestations			
-Total	13 (65.0)	4 (20.0)	9 (45.0)
Clostridium difficile infection	3 (15.0)	0	3 (15.0)
Gastroenteritis	3 (15.0)	1 (5.0)	2 (10.0)
Rhinovirus infection	3 (15.0)	3 (15.0)	0
Upper respiratory tract infection	3 (15.0)	2 (10.0)	1 (5.0)
Ear infection	2 (10.0)	1 (5.0)	1 (5.0)
Otitis media acute	2 (10.0)	0	2 (10.0)
Sinusitis	2 (10.0)	0	2 (10.0)
Urinary tract infection	2 (10.0)	0	2 (10.0)
Viral upper respiratory tract infection	2 (10.0)	1 (5.0)	1 (5.0)
Vulvovaginal candidiasis	2 (10.0)	1 (5.0)	1 (5.0)
Pneumonia	1 (5.0)	0	1 (5.0)
Injury, poisoning and procedural complications			
-Total	4 (20.0)	3 (15.0)	1 (5.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Procedural pain	3 (15.0)	2 (10.0)	1 (5.0)
Infusion related reaction	2 (10.0)	1 (5.0)	1 (5.0)
Transfusion reaction	1 (5.0)	1 (5.0)	0
Investigations			
-Total	9 (45.0)	1 (5.0)	8 (40.0)
Aspartate aminotransferase increased	4 (20.0)	2 (10.0)	2 (10.0)
White blood cell count decreased	4 (20.0)	2 (10.0)	2 (10.0)
Alanine aminotransferase increased	3 (15.0)	1 (5.0)	2 (10.0)
Blood bilirubin increased	2 (10.0)	0	2 (10.0)
Blood urea increased	2 (10.0)	2 (10.0)	0
Lymphocyte count decreased	2 (10.0)	1 (5.0)	1 (5.0)
Prothrombin time prolonged	2 (10.0)	2 (10.0)	0
Activated partial thromboplastin time prolonged	1 (5.0)	1 (5.0)	0
Blood fibrinogen decreased	1 (5.0)	0	1 (5.0)
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0
International normalised ratio increased	1 (5.0)	1 (5.0)	0
Neutrophil count decreased	1 (5.0)	0	1 (5.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Platelet count decreased	1 (5.0)	0	1 (5.0)
Transaminases increased	1 (5.0)	1 (5.0)	0
Weight decreased	1 (5.0)	0	1 (5.0)
Metabolism and nutrition disorders			
-Total	11 (55.0)	4 (20.0)	7 (35.0)
Decreased appetite	5 (25.0)	3 (15.0)	2 (10.0)
Hypokalaemia	3 (15.0)	0	3 (15.0)
Hypertriglyceridaemia	2 (10.0)	1 (5.0)	1 (5.0)
Hypoalbuminaemia	2 (10.0)	0	2 (10.0)
Hypocalcaemia	2 (10.0)	1 (5.0)	1 (5.0)
Hypophosphataemia	2 (10.0)	2 (10.0)	0
Fluid overload	1 (5.0)	1 (5.0)	0
Hyperphosphataemia	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	7 (35.0)	4 (20.0)	3 (15.0)
Pain in extremity	7 (35.0)	4 (20.0)	3 (15.0)
Nervous system disorders			
-Total	8 (40.0)	7 (35.0)	1 (5.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	7 (35.0)	6 (30.0)	1 (5.0)
Dizziness	2 (10.0)	2 (10.0)	0
Psychiatric disorders			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Confusional state	2 (10.0)	1 (5.0)	1 (5.0)
Anxiety	1 (5.0)	1 (5.0)	0
Delirium	1 (5.0)	0	1 (5.0)
Reproductive system and breast disorders			
-Total	2 (10.0)	2 (10.0)	0
Vulvovaginal adhesion	2 (10.0)	2 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	11 (55.0)	5 (25.0)	6 (30.0)
Cough	5 (25.0)	5 (25.0)	0
Rhinorrhoea	3 (15.0)	2 (10.0)	1 (5.0)
Hypoxia	2 (10.0)	0	2 (10.0)
Oropharyngeal pain	2 (10.0)	2 (10.0)	0
Pleural effusion	2 (10.0)	1 (5.0)	1 (5.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	1 (5.0)	0	1 (5.0)
Nasal congestion	1 (5.0)	1 (5.0)	0
Rhinitis allergic	1 (5.0)	0	1 (5.0)
Skin and subcutaneous tissue disorders			
-Total	9 (45.0)	7 (35.0)	2 (10.0)
Rash	3 (15.0)	2 (10.0)	1 (5.0)
Hyperhidrosis	2 (10.0)	2 (10.0)	0
Rash maculo-papular	2 (10.0)	1 (5.0)	1 (5.0)
Rash papular	2 (10.0)	2 (10.0)	0
Erythema	1 (5.0)	1 (5.0)	0
Petechiae	1 (5.0)	1 (5.0)	0
Pruritus	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	6 (30.0)	3 (15.0)	3 (15.0)
Hypertension	5 (25.0)	2 (10.0)	3 (15.0)
Flushing	2 (10.0)	2 (10.0)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	34 (100)	0	34 (100)
Blood and lymphatic system disorders			
-Total	9 (26.5)	3 (8.8)	6 (17.6)
Anaemia	8 (23.5)	2 (5.9)	6 (17.6)
Thrombocytopenia	2 (5.9)	1 (2.9)	1 (2.9)
Lymphopenia	1 (2.9)	0	1 (2.9)
Cardiac disorders			
-Total	11 (32.4)	6 (17.6)	5 (14.7)
Tachycardia	9 (26.5)	6 (17.6)	3 (8.8)
Sinus tachycardia	3 (8.8)	1 (2.9)	2 (5.9)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eye disorders			
-Total	3 (8.8)	1 (2.9)	2 (5.9)
Periorbital oedema	2 (5.9)	1 (2.9)	1 (2.9)
Conjunctival haemorrhage	1 (2.9)	1 (2.9)	0
Uveitis	1 (2.9)	0	1 (2.9)
Gastrointestinal disorders			
-Total	23 (67.6)	11 (32.4)	12 (35.3)
Vomiting	13 (38.2)	10 (29.4)	3 (8.8)
Nausea	11 (32.4)	4 (11.8)	7 (20.6)
Diarrhoea	10 (29.4)	6 (17.6)	4 (11.8)
Abdominal pain	6 (17.6)	4 (11.8)	2 (5.9)
Constipation	3 (8.8)	3 (8.8)	0
Abdominal pain upper	2 (5.9)	1 (2.9)	1 (2.9)
General disorders and administration site conditions			
-Total	21 (61.8)	11 (32.4)	10 (29.4)
Pyrexia	10 (29.4)	3 (8.8)	7 (20.6)
Fatigue	9 (26.5)	8 (23.5)	1 (2.9)
Chills	6 (17.6)	5 (14.7)	1 (2.9)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Catheter site pain	2 (5.9)	1 (2.9)	1 (2.9)
Malaise	2 (5.9)	0	2 (5.9)
Influenza like illness	1 (2.9)	1 (2.9)	0
Hepatobiliary disorders			
-Total	2 (5.9)	1 (2.9)	1 (2.9)
Hepatomegaly	2 (5.9)	1 (2.9)	1 (2.9)
Immune system disorders			
-Total	29 (85.3)	5 (14.7)	24 (70.6)
Cytokine release syndrome	24 (70.6)	5 (14.7)	19 (55.9)
Hypogammaglobulinaemia	16 (47.1)	2 (5.9)	14 (41.2)
Infections and infestations			
-Total	12 (35.3)	5 (14.7)	7 (20.6)
Upper respiratory tract infection	4 (11.8)	2 (5.9)	2 (5.9)
Influenza	2 (5.9)	1 (2.9)	1 (2.9)
Rhinovirus infection	2 (5.9)	2 (5.9)	0
Urinary tract infection	2 (5.9)	0	2 (5.9)
Clostridium difficile infection	1 (2.9)	0	1 (2.9)
Gastroenteritis	1 (2.9)	0	1 (2.9)
Pneumonia	1 (2.9)	0	1 (2.9)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sinusitis	1 (2.9)	0	1 (2.9)
Injury, poisoning and procedural complications			
-Total	5 (14.7)	1 (2.9)	4 (11.8)
Infusion related reaction	2 (5.9)	0	2 (5.9)
Procedural pain	2 (5.9)	0	2 (5.9)
Transfusion reaction	1 (2.9)	1 (2.9)	0
Investigations			
-Total	23 (67.6)	4 (11.8)	19 (55.9)
White blood cell count decreased	9 (26.5)	3 (8.8)	6 (17.6)
Aspartate aminotransferase increased	8 (23.5)	4 (11.8)	4 (11.8)
Alanine aminotransferase increased	7 (20.6)	3 (8.8)	4 (11.8)
Blood creatinine increased	7 (20.6)	5 (14.7)	2 (5.9)
International normalised ratio increased	6 (17.6)	6 (17.6)	0
Lymphocyte count decreased	5 (14.7)	1 (2.9)	4 (11.8)
Activated partial thromboplastin time prolonged	4 (11.8)	2 (5.9)	2 (5.9)
Blood bilirubin increased	4 (11.8)	2 (5.9)	2 (5.9)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Neutrophil count decreased	4 (11.8)	1 (2.9)	3 (8.8)
Prothrombin time prolonged	4 (11.8)	3 (8.8)	1 (2.9)
Platelet count decreased	3 (8.8)	2 (5.9)	1 (2.9)
Blood immunoglobulin m decreased	2 (5.9)	2 (5.9)	0
Blood urea increased	1 (2.9)	0	1 (2.9)
Haemoglobin decreased	1 (2.9)	1 (2.9)	0
Transaminases increased	1 (2.9)	1 (2.9)	0
Weight decreased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	15 (44.1)	8 (23.5)	7 (20.6)
Decreased appetite	7 (20.6)	5 (14.7)	2 (5.9)
Hyperphosphataemia	6 (17.6)	6 (17.6)	0
Hypokalaemia	5 (14.7)	2 (5.9)	3 (8.8)
Hypoalbuminaemia	3 (8.8)	1 (2.9)	2 (5.9)
Fluid overload	1 (2.9)	0	1 (2.9)
Hypophosphataemia	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders			
-Total	10 (29.4)	8 (23.5)	2 (5.9)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Myalgia	5 (14.7)	4 (11.8)	1 (2.9)
Arthralgia	4 (11.8)	4 (11.8)	0
Pain in extremity	3 (8.8)	3 (8.8)	0
Musculoskeletal pain	2 (5.9)	1 (2.9)	1 (2.9)
Nervous system disorders			
-Total	15 (44.1)	8 (23.5)	7 (20.6)
Headache	15 (44.1)	8 (23.5)	7 (20.6)
Dizziness	1 (2.9)	1 (2.9)	0
Peroneal nerve palsy	1 (2.9)	1 (2.9)	0
Psychiatric disorders			
-Total	7 (20.6)	3 (8.8)	4 (11.8)
Anxiety	5 (14.7)	2 (5.9)	3 (8.8)
Confusional state	3 (8.8)	1 (2.9)	2 (5.9)
Delirium	2 (5.9)	1 (2.9)	1 (2.9)
Renal and urinary disorders			
-Total	2 (5.9)	1 (2.9)	1 (2.9)
Haematuria	2 (5.9)	1 (2.9)	1 (2.9)
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	18 (52.9)	10 (29.4)	8 (23.5)
Cough	8 (23.5)	6 (17.6)	2 (5.9)
Epistaxis	4 (11.8)	3 (8.8)	1 (2.9)
Nasal congestion	4 (11.8)	4 (11.8)	0
Oropharyngeal pain	4 (11.8)	2 (5.9)	2 (5.9)
Hypoxia	3 (8.8)	0	3 (8.8)
Rhinorrhoea	3 (8.8)	3 (8.8)	0
Pleural effusion	2 (5.9)	1 (2.9)	1 (2.9)
Rhinitis allergic	2 (5.9)	2 (5.9)	0
Skin and subcutaneous tissue disorders			
-Total	15 (44.1)	12 (35.3)	3 (8.8)
Dry skin	5 (14.7)	5 (14.7)	0
Rash	4 (11.8)	2 (5.9)	2 (5.9)
Erythema	3 (8.8)	3 (8.8)	0
Ingrowing nail	2 (5.9)	1 (2.9)	1 (2.9)
Petechiae	2 (5.9)	2 (5.9)	0
Pruritus	2 (5.9)	2 (5.9)	0
Rash maculo-papular	2 (5.9)	2 (5.9)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperhidrosis	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	4 (11.8)	1 (2.9)	3 (8.8)
Hypertension	3 (8.8)	1 (2.9)	2 (5.9)
Orthostatic hypotension	1 (2.9)	0	1 (2.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (100)	0	10 (100)
Blood and lymphatic system disorders			
-Total	2 (20.0)	0	2 (20.0)
Anaemia	1 (10.0)	0	1 (10.0)
Lymphopenia	1 (10.0)	0	1 (10.0)
Neutropenia	1 (10.0)	1 (10.0)	0
Thrombocytopenia	1 (10.0)	0	1 (10.0)
Cardiac disorders			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Tachycardia	3 (30.0)	1 (10.0)	2 (20.0)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Ear and labyrinth disorders			
-Total	1 (10.0)	0	1 (10.0)
Hypoacusis	1 (10.0)	0	1 (10.0)
Eye disorders			
-Total	2 (20.0)	0	2 (20.0)
Papilloedema	1 (10.0)	0	1 (10.0)
Uveitis	1 (10.0)	0	1 (10.0)
Visual impairment	1 (10.0)	0	1 (10.0)
Gastrointestinal disorders			
-Total	5 (50.0)	1 (10.0)	4 (40.0)
Diarrhoea	4 (40.0)	2 (20.0)	2 (20.0)
Nausea	4 (40.0)	0	4 (40.0)
Vomiting	3 (30.0)	1 (10.0)	2 (20.0)
Abdominal discomfort	1 (10.0)	1 (10.0)	0
Abdominal pain upper	1 (10.0)	0	1 (10.0)
Constipation	1 (10.0)	0	1 (10.0)
Dyspepsia	1 (10.0)	0	1 (10.0)
General disorders and administration site conditions			

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (60.0)	2 (20.0)	4 (40.0)
Pyrexia	5 (50.0)	2 (20.0)	3 (30.0)
Chills	3 (30.0)	3 (30.0)	0
Fatigue	2 (20.0)	0	2 (20.0)
Asthenia	1 (10.0)	1 (10.0)	0
Facial pain	1 (10.0)	0	1 (10.0)
Influenza like illness	1 (10.0)	1 (10.0)	0
Malaise	1 (10.0)	0	1 (10.0)
Hepatobiliary disorders			
-Total	1 (10.0)	0	1 (10.0)
Hepatomegaly	1 (10.0)	0	1 (10.0)
Immune system disorders			
-Total	8 (80.0)	0	8 (80.0)
Cytokine release syndrome	8 (80.0)	0	8 (80.0)
Hypogammaglobulinaemia	3 (30.0)	0	3 (30.0)
Infections and infestations			
-Total	6 (60.0)	0	6 (60.0)
Influenza	2 (20.0)	0	2 (20.0)
Folliculitis	1 (10.0)	0	1 (10.0)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Human herpesvirus 6 infection	1 (10.0)	0	1 (10.0)
Pneumonia	1 (10.0)	0	1 (10.0)
Sinusitis	1 (10.0)	0	1 (10.0)
Upper respiratory tract infection	1 (10.0)	0	1 (10.0)
Injury, poisoning and procedural complications			
-Total	4 (40.0)	1 (10.0)	3 (30.0)
Foot fracture	1 (10.0)	0	1 (10.0)
Incision site pain	1 (10.0)	1 (10.0)	0
Limb injury	1 (10.0)	1 (10.0)	0
Tracheal haemorrhage	1 (10.0)	0	1 (10.0)
Transfusion reaction	1 (10.0)	0	1 (10.0)
Investigations			
-Total	6 (60.0)	1 (10.0)	5 (50.0)
Prothrombin time prolonged	3 (30.0)	0	3 (30.0)
Blood fibrinogen decreased	2 (20.0)	0	2 (20.0)
Platelet count decreased	2 (20.0)	1 (10.0)	1 (10.0)
Weight decreased	2 (20.0)	0	2 (20.0)
White blood cell count decreased	2 (20.0)	0	2 (20.0)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	1 (10.0)	1 (10.0)	0
Aspartate aminotransferase increased	1 (10.0)	1 (10.0)	0
Blood immunoglobulin m decreased	1 (10.0)	1 (10.0)	0
Haemoglobin decreased	1 (10.0)	1 (10.0)	0
Hepatic enzyme increased	1 (10.0)	0	1 (10.0)
International normalised ratio increased	1 (10.0)	1 (10.0)	0
Transaminases increased	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			
-Total	5 (50.0)	2 (20.0)	3 (30.0)
Hypokalaemia	3 (30.0)	2 (20.0)	1 (10.0)
Decreased appetite	1 (10.0)	0	1 (10.0)
Fluid overload	1 (10.0)	0	1 (10.0)
Hyperphosphataemia	1 (10.0)	1 (10.0)	0
Metabolic acidosis	1 (10.0)	0	1 (10.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Arthralgia	1 (10.0)	0	1 (10.0)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Limb discomfort	1 (10.0)	1 (10.0)	0
Musculoskeletal pain	1 (10.0)	1 (10.0)	0
Pain in extremity	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	5 (50.0)	2 (20.0)	3 (30.0)
Dizziness	3 (30.0)	3 (30.0)	0
Headache	2 (20.0)	1 (10.0)	1 (10.0)
Idiopathic intracranial hypertension	1 (10.0)	0	1 (10.0)
Peroneal nerve palsy	1 (10.0)	0	1 (10.0)
Psychiatric disorders			
-Total	3 (30.0)	2 (20.0)	1 (10.0)
Confusional state	1 (10.0)	1 (10.0)	0
Delirium	1 (10.0)	1 (10.0)	0
Panic attack	1 (10.0)	0	1 (10.0)
Renal and urinary disorders			
-Total	1 (10.0)	0	1 (10.0)
Haematuria	1 (10.0)	0	1 (10.0)
Reproductive system and breast disorders			

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (10.0)	0	1 (10.0)
Oedema genital	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (40.0)	2 (20.0)	2 (20.0)
Pleural effusion	2 (20.0)	0	2 (20.0)
Cough	1 (10.0)	1 (10.0)	0
Epistaxis	1 (10.0)	1 (10.0)	0
Rhinitis allergic	1 (10.0)	1 (10.0)	0
Skin and subcutaneous tissue disorders			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Erythema	1 (10.0)	1 (10.0)	0
Hyperhidrosis	1 (10.0)	1 (10.0)	0
Ingrowing nail	1 (10.0)	0	1 (10.0)
Petechiae	1 (10.0)	0	1 (10.0)
Pruritus	1 (10.0)	1 (10.0)	0
Rash	1 (10.0)	1 (10.0)	0
Vascular disorders			

Timing: Any time post CTL019 infusion, Age: >=18

Group term Preferred term	All patients N=10 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
-Total	4 (40.0)	1 (10.0)	3 (30.0)
Hypertension	3 (30.0)	0	3 (30.0)
Orthostatic hypotension	1 (10.0)	1 (10.0)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

		All patients N=30	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	29 (96.7)	2 (6.7)	27 (90.0)
Blood and lymphatic system disorders			
-Total	6 (20.0)	3 (10.0)	3 (10.0)
Anaemia	6 (20.0)	3 (10.0)	3 (10.0)
Cardiac disorders			
-Total	6 (20.0)	3 (10.0)	3 (10.0)
Tachycardia	6 (20.0)	3 (10.0)	3 (10.0)
Gastrointestinal disorders			
-Total	11 (36.7)	5 (16.7)	6 (20.0)
Vomiting	7 (23.3)	5 (16.7)	2 (6.7)
Diarrhoea	6 (20.0)	3 (10.0)	3 (10.0)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	5 (16.7)	2 (6.7)	3 (10.0)
Abdominal pain	2 (6.7)	1 (3.3)	1 (3.3)
Constipation	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	9 (30.0)	3 (10.0)	6 (20.0)
Pyrexia	5 (16.7)	0	5 (16.7)
Chills	4 (13.3)	4 (13.3)	0
Fatigue	3 (10.0)	2 (6.7)	1 (3.3)
Hepatobiliary disorders			
-Total	3 (10.0)	1 (3.3)	2 (6.7)
Hepatomegaly	3 (10.0)	1 (3.3)	2 (6.7)
Immune system disorders			
-Total	25 (83.3)	4 (13.3)	21 (70.0)
Cytokine release syndrome	23 (76.7)	5 (16.7)	18 (60.0)
Hypogammaglobulinaemia	11 (36.7)	1 (3.3)	10 (33.3)
Infections and infestations			
-Total	2 (6.7)	0	2 (6.7)
Upper respiratory tract infection	1 (3.3)	0	1 (3.3)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Viral infection	1 (3.3)	0	1 (3.3)
Investigations			
-Total	14 (46.7)	2 (6.7)	12 (40.0)
Aspartate aminotransferase increased	6 (20.0)	2 (6.7)	4 (13.3)
White blood cell count decreased	6 (20.0)	2 (6.7)	4 (13.3)
International normalised ratio increased	4 (13.3)	4 (13.3)	0
Platelet count decreased	4 (13.3)	2 (6.7)	2 (6.7)
Activated partial thromboplastin time prolonged	3 (10.0)	2 (6.7)	1 (3.3)
Alanine aminotransferase increased	3 (10.0)	2 (6.7)	1 (3.3)
Blood bilirubin increased	3 (10.0)	2 (6.7)	1 (3.3)
Blood creatinine increased	2 (6.7)	2 (6.7)	0
Lymphocyte count decreased	2 (6.7)	1 (3.3)	1 (3.3)
Prothrombin time prolonged	2 (6.7)	1 (3.3)	1 (3.3)
Neutrophil count decreased	1 (3.3)	0	1 (3.3)
Metabolism and nutrition disorders			
-Total	9 (30.0)	6 (20.0)	3 (10.0)
Hypokalaemia	5 (16.7)	3 (10.0)	2 (6.7)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	4 (13.3)	3 (10.0)	1 (3.3)
Hyperphosphataemia	2 (6.7)	2 (6.7)	0
Nervous system disorders			
-Total	12 (40.0)	9 (30.0)	3 (10.0)
Headache	11 (36.7)	8 (26.7)	3 (10.0)
Dizziness	1 (3.3)	1 (3.3)	0
Psychiatric disorders			
-Total	5 (16.7)	3 (10.0)	2 (6.7)
Confusional state	4 (13.3)	3 (10.0)	1 (3.3)
Anxiety	2 (6.7)	0	2 (6.7)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (30.0)	5 (16.7)	4 (13.3)
Cough	4 (13.3)	4 (13.3)	0
Pleural effusion	4 (13.3)	1 (3.3)	3 (10.0)
Epistaxis	2 (6.7)	1 (3.3)	1 (3.3)
Nasal congestion	1 (3.3)	1 (3.3)	0
Skin and subcutaneous tissue disorders			

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (20.0)	6 (20.0)	0
Erythema	2 (6.7)	2 (6.7)	0
Rash	2 (6.7)	2 (6.7)	0
Dry skin	1 (3.3)	1 (3.3)	0
Rash maculo-papular	1 (3.3)	1 (3.3)	0
Vascular disorders			
-Total	5 (16.7)	1 (3.3)	4 (13.3)
Hypertension	5 (16.7)	1 (3.3)	4 (13.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	33 (97.1)	0	33 (97.1)
Blood and lymphatic system disorders			
-Total	5 (14.7)	1 (2.9)	4 (11.8)
Anaemia	5 (14.7)	1 (2.9)	4 (11.8)
Cardiac disorders			
-Total	12 (35.3)	7 (20.6)	5 (14.7)
Tachycardia	8 (23.5)	5 (14.7)	3 (8.8)
Sinus tachycardia	5 (14.7)	3 (8.8)	2 (5.9)
Gastrointestinal disorders			
-Total	21 (61.8)	7 (20.6)	14 (41.2)
Nausea	15 (44.1)	4 (11.8)	11 (32.4)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	13 (38.2)	8 (23.5)	5 (14.7)
Diarrhoea	11 (32.4)	8 (23.5)	3 (8.8)
Abdominal pain	6 (17.6)	5 (14.7)	1 (2.9)
Constipation	6 (17.6)	5 (14.7)	1 (2.9)
General disorders and administration site conditions			
-Total	17 (50.0)	10 (29.4)	7 (20.6)
Fatigue	10 (29.4)	8 (23.5)	2 (5.9)
Pyrexia	9 (26.5)	3 (8.8)	6 (17.6)
Chills	4 (11.8)	4 (11.8)	0
Immune system disorders			
-Total	27 (79.4)	2 (5.9)	25 (73.5)
Cytokine release syndrome	22 (64.7)	2 (5.9)	20 (58.8)
Hypogammaglobulinaemia	10 (29.4)	2 (5.9)	8 (23.5)
Infections and infestations			
-Total	3 (8.8)	3 (8.8)	0
Rhinovirus infection	3 (8.8)	3 (8.8)	0
Injury, poisoning and procedural complications			

Timing: within 8 weeks post infusion, Gender: Female

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (8.8)	1 (2.9)	2 (5.9)
Procedural pain	3 (8.8)	1 (2.9)	2 (5.9)
Investigations			
-Total	17 (50.0)	2 (5.9)	15 (44.1)
Alanine aminotransferase increased	7 (20.6)	3 (8.8)	4 (11.8)
Prothrombin time prolonged	7 (20.6)	4 (11.8)	3 (8.8)
Aspartate aminotransferase increased	6 (17.6)	4 (11.8)	2 (5.9)
Blood creatinine increased	5 (14.7)	3 (8.8)	2 (5.9)
White blood cell count decreased	5 (14.7)	1 (2.9)	4 (11.8)
International normalised ratio increased	4 (11.8)	4 (11.8)	0
Blood bilirubin increased	3 (8.8)	0	3 (8.8)
Activated partial thromboplastin time prolonged	2 (5.9)	1 (2.9)	1 (2.9)
Lymphocyte count decreased	2 (5.9)	0	2 (5.9)
Platelet count decreased	2 (5.9)	1 (2.9)	1 (2.9)
Neutrophil count decreased	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	16 (47.1)	8 (23.5)	8 (23.5)

Timing: within 8 weeks post infusion, Gender: Female

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	7 (20.6)	4 (11.8)	3 (8.8)
Hyperphosphataemia	6 (17.6)	6 (17.6)	0
Hypokalaemia	5 (14.7)	0	5 (14.7)
Musculoskeletal and connective tissue disorders			
-Total	4 (11.8)	2 (5.9)	2 (5.9)
Pain in extremity	4 (11.8)	2 (5.9)	2 (5.9)
Nervous system disorders			
-Total	14 (41.2)	9 (26.5)	5 (14.7)
Headache	13 (38.2)	8 (23.5)	5 (14.7)
Dizziness	3 (8.8)	3 (8.8)	0
Psychiatric disorders			
-Total	5 (14.7)	2 (5.9)	3 (8.8)
Anxiety	3 (8.8)	2 (5.9)	1 (2.9)
Confusional state	2 (5.9)	0	2 (5.9)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (29.4)	7 (20.6)	3 (8.8)
Cough	4 (11.8)	4 (11.8)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	2 (5.9)	1 (2.9)	1 (2.9)
Oropharyngeal pain	2 (5.9)	1 (2.9)	1 (2.9)
Pleural effusion	2 (5.9)	1 (2.9)	1 (2.9)
Rhinorrhoea	1 (2.9)	1 (2.9)	0
Skin and subcutaneous tissue disorders			
-Total	8 (23.5)	6 (17.6)	2 (5.9)
Dry skin	3 (8.8)	3 (8.8)	0
Petechiae	3 (8.8)	2 (5.9)	1 (2.9)
Rash	2 (5.9)	2 (5.9)	0
Erythema	1 (2.9)	1 (2.9)	0
Rash maculo-papular	1 (2.9)	0	1 (2.9)
Vascular disorders			
-Total	4 (11.8)	1 (2.9)	3 (8.8)
Hypertension	4 (11.8)	1 (2.9)	3 (8.8)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (55.6)	3 (11.1)	12 (44.4)
Blood and lymphatic system disorders			
-Total	1 (3.7)	1 (3.7)	0
Anaemia	1 (3.7)	1 (3.7)	0
Cardiac disorders			
-Total	1 (3.7)	0	1 (3.7)
Sinus tachycardia	1 (3.7)	0	1 (3.7)
Gastrointestinal disorders			
-Total	4 (14.8)	3 (11.1)	1 (3.7)
Vomiting	3 (11.1)	3 (11.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Abdominal pain	1 (3.7)	1 (3.7)	0
Diarrhoea	1 (3.7)	1 (3.7)	0
Nausea	1 (3.7)	0	1 (3.7)
General disorders and administration site conditions			
-Total	3 (11.1)	2 (7.4)	1 (3.7)
Pyrexia	2 (7.4)	1 (3.7)	1 (3.7)
Chills	1 (3.7)	1 (3.7)	0
Fatigue	1 (3.7)	1 (3.7)	0
Immune system disorders			
-Total	3 (11.1)	0	3 (11.1)
Hypogammaglobulinaemia	3 (11.1)	0	3 (11.1)
Infections and infestations			
-Total	5 (18.5)	2 (7.4)	3 (11.1)
Upper respiratory tract infection	4 (14.8)	2 (7.4)	2 (7.4)
Otitis media	1 (3.7)	0	1 (3.7)
Rhinovirus infection	1 (3.7)	1 (3.7)	0
Viral infection	1 (3.7)	1 (3.7)	0
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (14.8)	1 (3.7)	3 (11.1)
White blood cell count decreased	3 (11.1)	2 (7.4)	1 (3.7)
Neutrophil count decreased	2 (7.4)	1 (3.7)	1 (3.7)
Lymphocyte count decreased	1 (3.7)	0	1 (3.7)
Platelet count decreased	1 (3.7)	1 (3.7)	0
Metabolism and nutrition disorders			
-Total	1 (3.7)	1 (3.7)	0
Hyperphosphataemia	1 (3.7)	1 (3.7)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Pain in extremity	2 (7.4)	1 (3.7)	1 (3.7)
Nervous system disorders			
-Total	3 (11.1)	3 (11.1)	0
Headache	3 (11.1)	3 (11.1)	0
Psychiatric disorders			
-Total	1 (3.7)	1 (3.7)	0
Anxiety	1 (3.7)	1 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	5 (18.5)	1 (3.7)	4 (14.8)
Cough	2 (7.4)	0	2 (7.4)
Nasal congestion	2 (7.4)	2 (7.4)	0
Rhinorrhoea	2 (7.4)	1 (3.7)	1 (3.7)
Oropharyngeal pain	1 (3.7)	0	1 (3.7)
Skin and subcutaneous tissue disorders			
-Total	5 (18.5)	4 (14.8)	1 (3.7)
Erythema	2 (7.4)	2 (7.4)	0
Rash maculo-papular	2 (7.4)	2 (7.4)	0
Rash	1 (3.7)	0	1 (3.7)
Vascular disorders			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Hypertension	2 (7.4)	1 (3.7)	1 (3.7)

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term in descending frequency of all grades column, as reported in the All patients column.
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Table 225b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

		All patients N=29	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	21 (72.4)	11 (37.9)	10 (34.5)
Gastrointestinal disorders			
-Total	9 (31.0)	5 (17.2)	4 (13.8)
Diarrhoea	6 (20.7)	5 (17.2)	1 (3.4)
Vomiting	5 (17.2)	2 (6.9)	3 (10.3)
Nausea	3 (10.3)	1 (3.4)	2 (6.9)
Abdominal pain	2 (6.9)	1 (3.4)	1 (3.4)
General disorders and administration site conditions			
-Total	7 (24.1)	6 (20.7)	1 (3.4)
Pyrexia	7 (24.1)	6 (20.7)	1 (3.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

		All patients N=29	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fatigue	1 (3.4)	1 (3.4)	0
Immune system disorders			
-Total	4 (13.8)	0	4 (13.8)
Hypogammaglobulinaemia	4 (13.8)	0	4 (13.8)
Infections and infestations			
-Total	3 (10.3)	2 (6.9)	1 (3.4)
Upper respiratory tract infection	2 (6.9)	1 (3.4)	1 (3.4)
Rhinovirus infection	1 (3.4)	1 (3.4)	0
Injury, poisoning and procedural complications			
-Total	2 (6.9)	1 (3.4)	1 (3.4)
Procedural pain	2 (6.9)	1 (3.4)	1 (3.4)
Investigations			
-Total	5 (17.2)	4 (13.8)	1 (3.4)
Platelet count decreased	2 (6.9)	2 (6.9)	0
Aspartate aminotransferase increased	1 (3.4)	1 (3.4)	0
Blood creatinine increased	1 (3.4)	1 (3.4)	0
Lymphocyte count decreased	1 (3.4)	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Neutrophil count decreased	1 (3.4)	1 (3.4)	0
White blood cell count decreased	1 (3.4)	0	1 (3.4)
Metabolism and nutrition disorders			
-Total	4 (13.8)	3 (10.3)	1 (3.4)
Decreased appetite	2 (6.9)	1 (3.4)	1 (3.4)
Hyperphosphataemia	1 (3.4)	1 (3.4)	0
Hypokalaemia	1 (3.4)	1 (3.4)	0
Musculoskeletal and connective tissue disorders			
-Total	6 (20.7)	5 (17.2)	1 (3.4)
Pain in extremity	6 (20.7)	5 (17.2)	1 (3.4)
Nervous system disorders			
-Total	3 (10.3)	2 (6.9)	1 (3.4)
Dizziness	3 (10.3)	3 (10.3)	0
Headache	2 (6.9)	1 (3.4)	1 (3.4)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (27.6)	8 (27.6)	0
Cough	5 (17.2)	5 (17.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasal congestion	2 (6.9)	2 (6.9)	0
Oropharyngeal pain	2 (6.9)	2 (6.9)	0
Rhinorrhoea	2 (6.9)	2 (6.9)	0
Epistaxis	1 (3.4)	1 (3.4)	0
Skin and subcutaneous tissue disorders			
-Total	5 (17.2)	3 (10.3)	2 (6.9)
Rash	3 (10.3)	1 (3.4)	2 (6.9)
Dry skin	1 (3.4)	1 (3.4)	0
Petechiae	1 (3.4)	1 (3.4)	0

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Table 225b
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Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (35.0)	2 (10.0)	5 (25.0)
Gastrointestinal disorders			
-Total	1 (5.0)	0	1 (5.0)
Diarrhoea	1 (5.0)	0	1 (5.0)
Infections and infestations			
-Total	4 (20.0)	1 (5.0)	3 (15.0)
Otitis media	2 (10.0)	0	2 (10.0)
Upper respiratory tract infection	1 (5.0)	0	1 (5.0)
Viral infection	1 (5.0)	1 (5.0)	0
Investigations			

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (15.0)	1 (5.0)	2 (10.0)
Lymphocyte count decreased	2 (10.0)	1 (5.0)	1 (5.0)
Alanine aminotransferase increased	1 (5.0)	0	1 (5.0)
Neutrophil count decreased	1 (5.0)	1 (5.0)	0

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Table 225b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (35.7)	1 (7.1)	4 (28.6)
Gastrointestinal disorders			
-Total	2 (14.3)	0	2 (14.3)
Abdominal pain	1 (7.1)	0	1 (7.1)
Diarrhoea	1 (7.1)	0	1 (7.1)
Nausea	1 (7.1)	0	1 (7.1)
General disorders and administration site conditions			
-Total	1 (7.1)	0	1 (7.1)
Chills	1 (7.1)	0	1 (7.1)
Pyrexia	1 (7.1)	0	1 (7.1)

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Otitis media	1 (7.1)	0	1 (7.1)
Upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Investigations			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Aspartate aminotransferase increased	1 (7.1)	1 (7.1)	0
Lymphocyte count decreased	1 (7.1)	1 (7.1)	0
Neutrophil count decreased	1 (7.1)	0	1 (7.1)
White blood cell count decreased	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	1 (7.1)	0	1 (7.1)
Dizziness	1 (7.1)	1 (7.1)	0
Headache	1 (7.1)	0	1 (7.1)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (28.6)	4 (28.6)	0
Cough	2 (14.3)	2 (14.3)	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	1 (7.1)	1 (7.1)	0
Oropharyngeal pain	1 (7.1)	1 (7.1)	0
Rhinorrhoea	1 (7.1)	1 (7.1)	0

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Table 225b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

		All patients N=30	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	30 (100)	1 (3.3)	29 (96.7)
Blood and lymphatic system disorders			
-Total	6 (20.0)	3 (10.0)	3 (10.0)
Anaemia	6 (20.0)	3 (10.0)	3 (10.0)
Cardiac disorders			
-Total	7 (23.3)	3 (10.0)	4 (13.3)
Tachycardia	6 (20.0)	3 (10.0)	3 (10.0)
Sinus tachycardia	1 (3.3)	0	1 (3.3)
Gastrointestinal disorders			
-Total	15 (50.0)	7 (23.3)	8 (26.7)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	10 (33.3)	8 (26.7)	2 (6.7)
Diarrhoea	7 (23.3)	3 (10.0)	4 (13.3)
Nausea	6 (20.0)	2 (6.7)	4 (13.3)
Abdominal pain	3 (10.0)	2 (6.7)	1 (3.3)
Constipation	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	11 (36.7)	4 (13.3)	7 (23.3)
Pyrexia	7 (23.3)	1 (3.3)	6 (20.0)
Chills	5 (16.7)	5 (16.7)	0
Fatigue	4 (13.3)	3 (10.0)	1 (3.3)
Hepatobiliary disorders			
-Total	3 (10.0)	1 (3.3)	2 (6.7)
Hepatomegaly	3 (10.0)	1 (3.3)	2 (6.7)
Immune system disorders			
-Total	26 (86.7)	4 (13.3)	22 (73.3)
Cytokine release syndrome	23 (76.7)	5 (16.7)	18 (60.0)
Hypogammaglobulinaemia	14 (46.7)	1 (3.3)	13 (43.3)
Infections and infestations			

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	10 (33.3)	3 (10.0)	7 (23.3)
Upper respiratory tract infection	5 (16.7)	2 (6.7)	3 (10.0)
Otitis media	3 (10.0)	0	3 (10.0)
Viral infection	3 (10.0)	2 (6.7)	1 (3.3)
Rhinovirus infection	1 (3.3)	1 (3.3)	0
Investigations			
-Total	16 (53.3)	0	16 (53.3)
White blood cell count decreased	8 (26.7)	3 (10.0)	5 (16.7)
Aspartate aminotransferase increased	6 (20.0)	2 (6.7)	4 (13.3)
Alanine aminotransferase increased	4 (13.3)	2 (6.7)	2 (6.7)
International normalised ratio increased	4 (13.3)	4 (13.3)	0
Lymphocyte count decreased	4 (13.3)	1 (3.3)	3 (10.0)
Platelet count decreased	4 (13.3)	2 (6.7)	2 (6.7)
Activated partial thromboplastin time prolonged	3 (10.0)	2 (6.7)	1 (3.3)
Blood bilirubin increased	3 (10.0)	2 (6.7)	1 (3.3)
Neutrophil count decreased	3 (10.0)	1 (3.3)	2 (6.7)
Blood creatinine increased	2 (6.7)	2 (6.7)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Prothrombin time prolonged	2 (6.7)	1 (3.3)	1 (3.3)
Metabolism and nutrition disorders			
-Total	9 (30.0)	6 (20.0)	3 (10.0)
Hypokalaemia	5 (16.7)	3 (10.0)	2 (6.7)
Decreased appetite	4 (13.3)	3 (10.0)	1 (3.3)
Hyperphosphataemia	2 (6.7)	2 (6.7)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Pain in extremity	2 (6.7)	1 (3.3)	1 (3.3)
Nervous system disorders			
-Total	12 (40.0)	9 (30.0)	3 (10.0)
Headache	11 (36.7)	8 (26.7)	3 (10.0)
Dizziness	1 (3.3)	1 (3.3)	0
Psychiatric disorders			
-Total	6 (20.0)	4 (13.3)	2 (6.7)
Confusional state	4 (13.3)	3 (10.0)	1 (3.3)
Anxiety	3 (10.0)	1 (3.3)	2 (6.7)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	13 (43.3)	5 (16.7)	8 (26.7)
Cough	6 (20.0)	4 (13.3)	2 (6.7)
Pleural effusion	4 (13.3)	1 (3.3)	3 (10.0)
Nasal congestion	3 (10.0)	3 (10.0)	0
Epistaxis	2 (6.7)	1 (3.3)	1 (3.3)
Rhinorrhoea	2 (6.7)	1 (3.3)	1 (3.3)
Oropharyngeal pain	1 (3.3)	0	1 (3.3)
Skin and subcutaneous tissue disorders			
-Total	11 (36.7)	10 (33.3)	1 (3.3)
Erythema	4 (13.3)	4 (13.3)	0
Rash	3 (10.0)	2 (6.7)	1 (3.3)
Rash maculo-papular	3 (10.0)	3 (10.0)	0
Dry skin	1 (3.3)	1 (3.3)	0
Vascular disorders			
-Total	7 (23.3)	2 (6.7)	5 (16.7)
Hypertension	7 (23.3)	2 (6.7)	5 (16.7)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	34 (100)	1 (2.9)	33 (97.1)
Blood and lymphatic system disorders			
-Total	5 (14.7)	1 (2.9)	4 (11.8)
Anaemia	5 (14.7)	1 (2.9)	4 (11.8)
Cardiac disorders			
-Total	12 (35.3)	7 (20.6)	5 (14.7)
Tachycardia	8 (23.5)	5 (14.7)	3 (8.8)
Sinus tachycardia	5 (14.7)	3 (8.8)	2 (5.9)
Gastrointestinal disorders			
-Total	23 (67.6)	7 (20.6)	16 (47.1)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	17 (50.0)	4 (11.8)	13 (38.2)
Diarrhoea	15 (44.1)	10 (29.4)	5 (14.7)
Vomiting	15 (44.1)	8 (23.5)	7 (20.6)
Abdominal pain	7 (20.6)	4 (11.8)	3 (8.8)
Constipation	6 (17.6)	5 (14.7)	1 (2.9)
General disorders and administration site conditions			
-Total	22 (64.7)	13 (38.2)	9 (26.5)
Pyrexia	15 (44.1)	7 (20.6)	8 (23.5)
Fatigue	11 (32.4)	9 (26.5)	2 (5.9)
Chills	5 (14.7)	4 (11.8)	1 (2.9)
Immune system disorders			
-Total	27 (79.4)	2 (5.9)	25 (73.5)
Cytokine release syndrome	22 (64.7)	2 (5.9)	20 (58.8)
Hypogammaglobulinaemia	13 (38.2)	2 (5.9)	11 (32.4)
Infections and infestations			
-Total	8 (23.5)	6 (17.6)	2 (5.9)
Rhinovirus infection	4 (11.8)	4 (11.8)	0
Upper respiratory tract infection	3 (8.8)	2 (5.9)	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Otitis media	1 (2.9)	0	1 (2.9)
Injury, poisoning and procedural complications			
-Total	5 (14.7)	2 (5.9)	3 (8.8)
Procedural pain	5 (14.7)	2 (5.9)	3 (8.8)
Investigations			
-Total	18 (52.9)	3 (8.8)	15 (44.1)
Alanine aminotransferase increased	7 (20.6)	3 (8.8)	4 (11.8)
Aspartate aminotransferase increased	7 (20.6)	5 (14.7)	2 (5.9)
Prothrombin time prolonged	7 (20.6)	4 (11.8)	3 (8.8)
White blood cell count decreased	7 (20.6)	2 (5.9)	5 (14.7)
Blood creatinine increased	5 (14.7)	3 (8.8)	2 (5.9)
International normalised ratio increased	4 (11.8)	4 (11.8)	0
Blood bilirubin increased	3 (8.8)	0	3 (8.8)
Lymphocyte count decreased	3 (8.8)	1 (2.9)	2 (5.9)
Activated partial thromboplastin time prolonged	2 (5.9)	1 (2.9)	1 (2.9)
Neutrophil count decreased	2 (5.9)	0	2 (5.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Platelet count decreased	2 (5.9)	1 (2.9)	1 (2.9)
Metabolism and nutrition disorders			
-Total	17 (50.0)	9 (26.5)	8 (23.5)
Decreased appetite	9 (26.5)	5 (14.7)	4 (11.8)
Hyperphosphataemia	6 (17.6)	6 (17.6)	0
Hypokalaemia	6 (17.6)	1 (2.9)	5 (14.7)
Musculoskeletal and connective tissue disorders			
-Total	9 (26.5)	6 (17.6)	3 (8.8)
Pain in extremity	9 (26.5)	6 (17.6)	3 (8.8)
Nervous system disorders			
-Total	15 (44.1)	9 (26.5)	6 (17.6)
Headache	13 (38.2)	7 (20.6)	6 (17.6)
Dizziness	5 (14.7)	5 (14.7)	0
Psychiatric disorders			
-Total	5 (14.7)	2 (5.9)	3 (8.8)
Anxiety	3 (8.8)	2 (5.9)	1 (2.9)
Confusional state	2 (5.9)	0	2 (5.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	16 (47.1)	13 (38.2)	3 (8.8)
Cough	8 (23.5)	8 (23.5)	0
Oropharyngeal pain	5 (14.7)	4 (11.8)	1 (2.9)
Epistaxis	4 (11.8)	3 (8.8)	1 (2.9)
Rhinorrhoea	4 (11.8)	4 (11.8)	0
Nasal congestion	2 (5.9)	2 (5.9)	0
Pleural effusion	2 (5.9)	1 (2.9)	1 (2.9)
Skin and subcutaneous tissue disorders			
-Total	12 (35.3)	8 (23.5)	4 (11.8)
Rash	5 (14.7)	3 (8.8)	2 (5.9)
Dry skin	4 (11.8)	4 (11.8)	0
Petechiae	4 (11.8)	3 (8.8)	1 (2.9)
Erythema	1 (2.9)	1 (2.9)	0
Rash maculo-papular	1 (2.9)	0	1 (2.9)
Vascular disorders			
-Total	4 (11.8)	1 (2.9)	3 (8.8)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	4 (11.8)	1 (2.9)	3 (8.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	50 (96.2)	3 (5.8)	47 (90.4)
Blood and lymphatic system disorders			
-Total	11 (21.2)	4 (7.7)	7 (13.5)
Anaemia	9 (17.3)	4 (7.7)	5 (9.6)
Disseminated intravascular coagulation	2 (3.8)	0	2 (3.8)
Lymphopenia	1 (1.9)	0	1 (1.9)
Cardiac disorders			
-Total	15 (28.8)	7 (13.5)	8 (15.4)
Tachycardia	11 (21.2)	5 (9.6)	6 (11.5)
Sinus tachycardia	5 (9.6)	3 (5.8)	2 (3.8)

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eye disorders			
-Total	6 (11.5)	3 (5.8)	3 (5.8)
Periorbital oedema	3 (5.8)	2 (3.8)	1 (1.9)
Conjunctival haemorrhage	2 (3.8)	2 (3.8)	0
Vision blurred	2 (3.8)	1 (1.9)	1 (1.9)
Uveitis	1 (1.9)	0	1 (1.9)
Gastrointestinal disorders			
-Total	25 (48.1)	10 (19.2)	15 (28.8)
Diarrhoea	15 (28.8)	11 (21.2)	4 (7.7)
Nausea	15 (28.8)	4 (7.7)	11 (21.2)
Vomiting	15 (28.8)	8 (15.4)	7 (13.5)
Abdominal pain	7 (13.5)	5 (9.6)	2 (3.8)
Constipation	6 (11.5)	5 (9.6)	1 (1.9)
Abdominal pain upper	1 (1.9)	0	1 (1.9)
General disorders and administration site conditions			
-Total	21 (40.4)	8 (15.4)	13 (25.0)
Pyrexia	12 (23.1)	2 (3.8)	10 (19.2)
Fatigue	9 (17.3)	6 (11.5)	3 (5.8)

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Chills	8 (15.4)	8 (15.4)	0
Catheter site pain	2 (3.8)	0	2 (3.8)
Malaise	2 (3.8)	0	2 (3.8)
Immune system disorders			
-Total	41 (78.8)	4 (7.7)	37 (71.2)
Cytokine release syndrome	36 (69.2)	5 (9.6)	31 (59.6)
Hypogammaglobulinaemia	16 (30.8)	1 (1.9)	15 (28.8)
Infections and infestations			
-Total	7 (13.5)	1 (1.9)	6 (11.5)
Clostridium difficile infection	3 (5.8)	0	3 (5.8)
Clostridium difficile colitis	2 (3.8)	1 (1.9)	1 (1.9)
Upper respiratory tract infection	1 (1.9)	0	1 (1.9)
Viral infection	1 (1.9)	0	1 (1.9)
Injury, poisoning and procedural complications			
-Total	4 (7.7)	2 (3.8)	2 (3.8)
Procedural pain	2 (3.8)	1 (1.9)	1 (1.9)
Transfusion reaction	2 (3.8)	1 (1.9)	1 (1.9)
Investigations			

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	26 (50.0)	4 (7.7)	22 (42.3)
Aspartate aminotransferase increased	9 (17.3)	5 (9.6)	4 (7.7)
White blood cell count decreased	9 (17.3)	3 (5.8)	6 (11.5)
Alanine aminotransferase increased	8 (15.4)	4 (7.7)	4 (7.7)
Prothrombin time prolonged	7 (13.5)	4 (7.7)	3 (5.8)
Blood bilirubin increased	6 (11.5)	2 (3.8)	4 (7.7)
International normalised ratio increased	6 (11.5)	6 (11.5)	0
Platelet count decreased	6 (11.5)	3 (5.8)	3 (5.8)
Blood creatinine increased	5 (9.6)	4 (7.7)	1 (1.9)
Activated partial thromboplastin time prolonged	4 (7.7)	2 (3.8)	2 (3.8)
Blood immunoglobulin m decreased	3 (5.8)	3 (5.8)	0
Lymphocyte count decreased	3 (5.8)	1 (1.9)	2 (3.8)
Blood immunoglobulin a decreased	1 (1.9)	1 (1.9)	0
Blood uric acid increased	1 (1.9)	1 (1.9)	0
Neutrophil count decreased	1 (1.9)	0	1 (1.9)
Metabolism and nutrition disorders			
-Total	23 (44.2)	10 (19.2)	13 (25.0)

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	10 (19.2)	3 (5.8)	7 (13.5)
Decreased appetite	9 (17.3)	5 (9.6)	4 (7.7)
Hyperphosphataemia	6 (11.5)	6 (11.5)	0
Hypernatraemia	3 (5.8)	0	3 (5.8)
Hyperuricaemia	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			
-Total	7 (13.5)	4 (7.7)	3 (5.8)
Myalgia	3 (5.8)	2 (3.8)	1 (1.9)
Arthralgia	2 (3.8)	2 (3.8)	0
Pain in extremity	2 (3.8)	1 (1.9)	1 (1.9)
Muscular weakness	1 (1.9)	0	1 (1.9)
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0
Nervous system disorders			
-Total	25 (48.1)	16 (30.8)	9 (17.3)
Headache	19 (36.5)	14 (26.9)	5 (9.6)
Dizziness	4 (7.7)	4 (7.7)	0
Encephalopathy	2 (3.8)	0	2 (3.8)
Dysarthria	1 (1.9)	0	1 (1.9)

Timing: within 8 weeks post infusion, Race: White

		All patients N=52	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Seizure	1 (1.9)	0	1 (1.9)
Tremor	1 (1.9)	1 (1.9)	0
Psychiatric disorders			
-Total	12 (23.1)	7 (13.5)	5 (9.6)
Confusional state	6 (11.5)	3 (5.8)	3 (5.8)
Anxiety	4 (7.7)	2 (3.8)	2 (3.8)
Delirium	3 (5.8)	2 (3.8)	1 (1.9)
Agitation	1 (1.9)	0	1 (1.9)
Renal and urinary disorders			
-Total	2 (3.8)	1 (1.9)	1 (1.9)
Acute kidney injury	1 (1.9)	0	1 (1.9)
Dysuria	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	17 (32.7)	12 (23.1)	5 (9.6)
Cough	8 (15.4)	8 (15.4)	0
Pleural effusion	6 (11.5)	2 (3.8)	4 (7.7)
Epistaxis	3 (5.8)	2 (3.8)	1 (1.9)
Nasal congestion	1 (1.9)	1 (1.9)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oropharyngeal pain	1 (1.9)	1 (1.9)	0
Rhinitis allergic	1 (1.9)	1 (1.9)	0
Rhinorrhoea	1 (1.9)	1 (1.9)	0
Skin and subcutaneous tissue disorders			
-Total	11 (21.2)	11 (21.2)	0
Rash	4 (7.7)	4 (7.7)	0
Dry skin	2 (3.8)	2 (3.8)	0
Erythema	2 (3.8)	2 (3.8)	0
Hyperhidrosis	2 (3.8)	2 (3.8)	0
Pruritus	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	9 (17.3)	3 (5.8)	6 (11.5)
Hypertension	8 (15.4)	2 (3.8)	6 (11.5)
Orthostatic hypotension	1 (1.9)	1 (1.9)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (100)	0	5 (100)
Blood and lymphatic system disorders			
-Total	1 (20.0)	0	1 (20.0)
Anaemia	1 (20.0)	0	1 (20.0)
Cardiac disorders			
-Total	1 (20.0)	1 (20.0)	0
Atrioventricular block second degree	1 (20.0)	1 (20.0)	0
Gastrointestinal disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Diarrhoea	1 (20.0)	0	1 (20.0)
Nausea	1 (20.0)	1 (20.0)	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	4 (80.0)	2 (40.0)	2 (40.0)
Fatigue	3 (60.0)	3 (60.0)	0
Pain	1 (20.0)	0	1 (20.0)
Pyrexia	1 (20.0)	0	1 (20.0)
Immune system disorders			
-Total	5 (100)	0	5 (100)
Cytokine release syndrome	4 (80.0)	0	4 (80.0)
Hypogammaglobulinaemia	3 (60.0)	1 (20.0)	2 (40.0)
Infections and infestations			
-Total	2 (40.0)	0	2 (40.0)
Pharyngitis	1 (20.0)	0	1 (20.0)
Streptococcal infection	1 (20.0)	0	1 (20.0)
Viral upper respiratory tract infection	1 (20.0)	0	1 (20.0)
Investigations			
-Total	1 (20.0)	0	1 (20.0)
Blood immunoglobulin a decreased	1 (20.0)	1 (20.0)	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
International normalised ratio increased	1 (20.0)	1 (20.0)	0
Lymphocyte count decreased	1 (20.0)	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	1 (20.0)
White blood cell count decreased	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	2 (40.0)	2 (40.0)	0
Decreased appetite	1 (20.0)	1 (20.0)	0
Hyperphosphataemia	1 (20.0)	1 (20.0)	0
Hyperuricaemia	1 (20.0)	1 (20.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Pain in extremity	2 (40.0)	1 (20.0)	1 (20.0)
Arthralgia	1 (20.0)	1 (20.0)	0
Myalgia	1 (20.0)	1 (20.0)	0
Nervous system disorders			
-Total	2 (40.0)	2 (40.0)	0
Headache	2 (40.0)	2 (40.0)	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Renal and urinary disorders			
-Total	1 (20.0)	0	1 (20.0)
Dysuria	1 (20.0)	0	1 (20.0)
Pollakiuria	1 (20.0)	1 (20.0)	0
Vascular disorders			
-Total	1 (20.0)	0	1 (20.0)
Hypertension	1 (20.0)	0	1 (20.0)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (100)	0	7 (100)
Blood and lymphatic system disorders			
-Total	2 (28.6)	0	2 (28.6)
Anaemia	1 (14.3)	0	1 (14.3)
Disseminated intravascular coagulation	1 (14.3)	0	1 (14.3)
Cardiac disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Tachycardia	3 (42.9)	3 (42.9)	0
Ventricular tachycardia	1 (14.3)	0	1 (14.3)
Endocrine disorders			

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (14.3)	0	1 (14.3)
Adrenal insufficiency	1 (14.3)	0	1 (14.3)
Eye disorders			
-Total	2 (28.6)	0	2 (28.6)
Conjunctival haemorrhage	1 (14.3)	1 (14.3)	0
Periorbital oedema	1 (14.3)	1 (14.3)	0
Uveitis	1 (14.3)	0	1 (14.3)
Vision blurred	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	5 (71.4)	1 (14.3)	4 (57.1)
Nausea	4 (57.1)	1 (14.3)	3 (42.9)
Vomiting	4 (57.1)	4 (57.1)	0
Abdominal pain	1 (14.3)	1 (14.3)	0
Abdominal pain upper	1 (14.3)	0	1 (14.3)
Constipation	1 (14.3)	1 (14.3)	0
Diarrhoea	1 (14.3)	0	1 (14.3)
Dysphagia	1 (14.3)	0	1 (14.3)
Flatulence	1 (14.3)	1 (14.3)	0
Lip pain	1 (14.3)	0	1 (14.3)

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Catheter site haemorrhage	1 (14.3)	1 (14.3)	0
Catheter site pain	1 (14.3)	1 (14.3)	0
Fatigue	1 (14.3)	1 (14.3)	0
Injection site haematoma	1 (14.3)	1 (14.3)	0
Malaise	1 (14.3)	0	1 (14.3)
Pyrexia	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			
-Total	1 (14.3)	1 (14.3)	0
Gallbladder enlargement	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
Cytokine release syndrome	5 (71.4)	2 (28.6)	3 (42.9)
Hypogammaglobulinaemia	2 (28.6)	1 (14.3)	1 (14.3)
Infections and infestations			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Catheter site cellulitis	1 (14.3)	1 (14.3)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)
Clostridium difficile infection	1 (14.3)	0	1 (14.3)
Cytomegalovirus infection	1 (14.3)	1 (14.3)	0
Herpes simplex	1 (14.3)	1 (14.3)	0
Injury, poisoning and procedural complications			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Post procedural haemorrhage	1 (14.3)	1 (14.3)	0
Procedural pain	1 (14.3)	0	1 (14.3)
Transfusion reaction	1 (14.3)	1 (14.3)	0
Investigations			
-Total	4 (57.1)	0	4 (57.1)
Aspartate aminotransferase increased	3 (42.9)	1 (14.3)	2 (28.6)
Alanine aminotransferase increased	2 (28.6)	1 (14.3)	1 (14.3)
Blood creatinine increased	2 (28.6)	1 (14.3)	1 (14.3)
Prothrombin time prolonged	2 (28.6)	1 (14.3)	1 (14.3)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0
Blood immunoglobulin a decreased	1 (14.3)	1 (14.3)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0
Culture stool positive	1 (14.3)	1 (14.3)	0
Hepatic enzyme increased	1 (14.3)	0	1 (14.3)
International normalised ratio increased	1 (14.3)	1 (14.3)	0
White blood cell count decreased	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	3 (42.9)	3 (42.9)	0
Acidosis	1 (14.3)	1 (14.3)	0
Decreased appetite	1 (14.3)	1 (14.3)	0
Hypernatraemia	1 (14.3)	1 (14.3)	0
Hyperphosphataemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (28.6)	2 (28.6)	0
Coccydynia	1 (14.3)	1 (14.3)	0
Myalgia	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	4 (57.1)	1 (14.3)	3 (42.9)

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	3 (42.9)	0	3 (42.9)
Asterixis	1 (14.3)	1 (14.3)	0
Ataxia	1 (14.3)	0	1 (14.3)
Dysarthria	1 (14.3)	1 (14.3)	0
Encephalopathy	1 (14.3)	1 (14.3)	0
Myoclonus	1 (14.3)	1 (14.3)	0
Neuropathy peripheral	1 (14.3)	0	1 (14.3)
Pleocytosis	1 (14.3)	1 (14.3)	0
Seizure	1 (14.3)	0	1 (14.3)
Tremor	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	1 (14.3)	0	1 (14.3)
Adjustment disorder	1 (14.3)	0	1 (14.3)
Agitation	1 (14.3)	0	1 (14.3)
Anxiety	1 (14.3)	0	1 (14.3)
Delirium	1 (14.3)	0	1 (14.3)
Suicidal ideation	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	1 (14.3)	1 (14.3)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Acute kidney injury	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (28.6)	0	2 (28.6)
Epistaxis	1 (14.3)	0	1 (14.3)
Haemoptysis	1 (14.3)	1 (14.3)	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	2 (28.6)	2 (28.6)	0
Dry skin	2 (28.6)	2 (28.6)	0
Erythema	1 (14.3)	1 (14.3)	0
Hyperhidrosis	1 (14.3)	1 (14.3)	0
Pruritus	1 (14.3)	1 (14.3)	0
Rash vesicular	1 (14.3)	1 (14.3)	0
Skin exfoliation	1 (14.3)	1 (14.3)	0
Skin fissures	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	2 (28.6)	0	2 (28.6)

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Orthostatic hypotension	1 (14.3)	0	1 (14.3)
Secondary hypertension	1 (14.3)	0	1 (14.3)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	28 (63.6)	7 (15.9)	21 (47.7)
Blood and lymphatic system disorders			
-Total	1 (2.3)	1 (2.3)	0
Anaemia	1 (2.3)	1 (2.3)	0
Cardiac disorders			
-Total	1 (2.3)	0	1 (2.3)
Sinus tachycardia	1 (2.3)	0	1 (2.3)
Endocrine disorders			
-Total	1 (2.3)	1 (2.3)	0
Adrenal insufficiency	1 (2.3)	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eye disorders			
-Total	2 (4.5)	1 (2.3)	1 (2.3)
Dry eye	1 (2.3)	0	1 (2.3)
Vision blurred	1 (2.3)	1 (2.3)	0
Gastrointestinal disorders			
-Total	12 (27.3)	7 (15.9)	5 (11.4)
Vomiting	8 (18.2)	5 (11.4)	3 (6.8)
Diarrhoea	6 (13.6)	5 (11.4)	1 (2.3)
Abdominal pain	3 (6.8)	2 (4.5)	1 (2.3)
Nausea	3 (6.8)	0	3 (6.8)
Abdominal pain upper	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
-Total	9 (20.5)	6 (13.6)	3 (6.8)
Pyrexia	6 (13.6)	4 (9.1)	2 (4.5)
Fatigue	2 (4.5)	2 (4.5)	0
Catheter site pain	1 (2.3)	0	1 (2.3)
Chills	1 (2.3)	1 (2.3)	0
Malaise	1 (2.3)	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain	1 (2.3)	1 (2.3)	0
Immune system disorders			
-Total	7 (15.9)	1 (2.3)	6 (13.6)
Hypogammaglobulinaemia	6 (13.6)	0	6 (13.6)
Seasonal allergy	1 (2.3)	1 (2.3)	0
Infections and infestations			
-Total	10 (22.7)	4 (9.1)	6 (13.6)
Upper respiratory tract infection	6 (13.6)	3 (6.8)	3 (6.8)
Urinary tract infection	2 (4.5)	0	2 (4.5)
Cytomegalovirus infection	1 (2.3)	1 (2.3)	0
Otitis media	1 (2.3)	0	1 (2.3)
Viral infection	1 (2.3)	1 (2.3)	0
Viral upper respiratory tract infection	1 (2.3)	1 (2.3)	0
Injury, poisoning and procedural complications			
-Total	1 (2.3)	1 (2.3)	0
Procedural pain	1 (2.3)	1 (2.3)	0
Investigations			
-Total	6 (13.6)	2 (4.5)	4 (9.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
White blood cell count decreased	4 (9.1)	2 (4.5)	2 (4.5)
Platelet count decreased	3 (6.8)	3 (6.8)	0
Neutrophil count decreased	2 (4.5)	1 (2.3)	1 (2.3)
Aspartate aminotransferase increased	1 (2.3)	1 (2.3)	0
Haemoglobin decreased	1 (2.3)	1 (2.3)	0
Lymphocyte count decreased	1 (2.3)	0	1 (2.3)
Metabolism and nutrition disorders			
-Total	3 (6.8)	2 (4.5)	1 (2.3)
Hyperphosphataemia	2 (4.5)	2 (4.5)	0
Decreased appetite	1 (2.3)	0	1 (2.3)
Musculoskeletal and connective tissue disorders			
-Total	8 (18.2)	5 (11.4)	3 (6.8)
Pain in extremity	5 (11.4)	3 (6.8)	2 (4.5)
Arthralgia	2 (4.5)	1 (2.3)	1 (2.3)
Joint range of motion decreased	1 (2.3)	1 (2.3)	0
Muscular weakness	1 (2.3)	1 (2.3)	0
Nervous system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (13.6)	5 (11.4)	1 (2.3)
Headache	5 (11.4)	4 (9.1)	1 (2.3)
Dizziness	3 (6.8)	3 (6.8)	0
Psychiatric disorders			
-Total	1 (2.3)	1 (2.3)	0
Anxiety	1 (2.3)	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	11 (25.0)	6 (13.6)	5 (11.4)
Cough	4 (9.1)	2 (4.5)	2 (4.5)
Nasal congestion	3 (6.8)	3 (6.8)	0
Oropharyngeal pain	3 (6.8)	2 (4.5)	1 (2.3)
Rhinorrhoea	3 (6.8)	2 (4.5)	1 (2.3)
Rhinitis allergic	2 (4.5)	1 (2.3)	1 (2.3)
Epistaxis	1 (2.3)	1 (2.3)	0
Skin and subcutaneous tissue disorders			
-Total	3 (6.8)	2 (4.5)	1 (2.3)
Erythema	2 (4.5)	2 (4.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperhidrosis	1 (2.3)	1 (2.3)	0
Pruritus	1 (2.3)	1 (2.3)	0
Rash	1 (2.3)	0	1 (2.3)
Vascular disorders			
-Total	2 (4.5)	1 (2.3)	1 (2.3)
Hypertension	2 (4.5)	1 (2.3)	1 (2.3)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (80.0)	2 (40.0)	2 (40.0)
Blood and lymphatic system disorders			
-Total	1 (20.0)	0	1 (20.0)
Lymphopenia	1 (20.0)	0	1 (20.0)
General disorders and administration site conditions			
-Total	2 (40.0)	2 (40.0)	0
Pyrexia	2 (40.0)	2 (40.0)	0
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Molluscum contagiosum	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	1 (20.0)	1 (20.0)	0
Blood uric acid increased	1 (20.0)	1 (20.0)	0
Neutrophil count decreased	1 (20.0)	1 (20.0)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (60.0)	2 (40.0)	1 (20.0)
Joint range of motion decreased	1 (20.0)	1 (20.0)	0
Osteonecrosis	1 (20.0)	0	1 (20.0)
Pain in extremity	1 (20.0)	1 (20.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (20.0)	0	1 (20.0)
Rash	1 (20.0)	0	1 (20.0)

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Table 225c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (71.4)	1 (14.3)	4 (57.1)
Blood and lymphatic system disorders			
-Total	1 (14.3)	0	1 (14.3)
Lymphadenopathy	1 (14.3)	0	1 (14.3)
Eye disorders			
-Total	1 (14.3)	1 (14.3)	0
Dry eye	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	2 (28.6)	2 (28.6)	0
Diarrhoea	1 (14.3)	1 (14.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	1 (14.3)	1 (14.3)	0
Pyrexia	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Immunodeficiency common variable	2 (28.6)	0	2 (28.6)
Hypogammaglobulinaemia	1 (14.3)	0	1 (14.3)
Seasonal allergy	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	3 (42.9)	0	3 (42.9)
Oral herpes	1 (14.3)	0	1 (14.3)
Rhinitis	1 (14.3)	1 (14.3)	0
Urinary tract infection	1 (14.3)	0	1 (14.3)
Vulvovaginal mycotic infection	1 (14.3)	0	1 (14.3)
Injury, poisoning and procedural complications			
-Total	1 (14.3)	0	1 (14.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthropod bite	1 (14.3)	1 (14.3)	0
Procedural pain	1 (14.3)	0	1 (14.3)
Investigations			
-Total	2 (28.6)	2 (28.6)	0
Blood creatinine increased	1 (14.3)	1 (14.3)	0
Haemoglobin decreased	1 (14.3)	1 (14.3)	0
Lymphocyte count decreased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	2 (28.6)	2 (28.6)	0
Decreased appetite	1 (14.3)	1 (14.3)	0
Hypokalaemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (42.9)	3 (42.9)	0
Pain in extremity	2 (28.6)	2 (28.6)	0
Muscular weakness	1 (14.3)	1 (14.3)	0
Musculoskeletal chest pain	1 (14.3)	1 (14.3)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (14.3)	0	1 (14.3)
Myelodysplastic syndrome	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (57.1)	4 (57.1)	0
Cough	3 (42.9)	3 (42.9)	0
Nasal congestion	1 (14.3)	1 (14.3)	0
Rhinitis allergic	1 (14.3)	1 (14.3)	0
Rhinorrhoea	1 (14.3)	1 (14.3)	0
Skin and subcutaneous tissue disorders			
-Total	5 (71.4)	4 (57.1)	1 (14.3)
Rash	2 (28.6)	1 (14.3)	1 (14.3)
Dermatitis	1 (14.3)	1 (14.3)	0
Dermatitis atopic	1 (14.3)	1 (14.3)	0
Dry skin	1 (14.3)	1 (14.3)	0
Eczema	1 (14.3)	1 (14.3)	0

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Table 225c
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Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (28.6)	1 (3.6)	7 (25.0)
Gastrointestinal disorders			
-Total	2 (7.1)	0	2 (7.1)
Diarrhoea	2 (7.1)	0	2 (7.1)
Abdominal pain	1 (3.6)	0	1 (3.6)
Infections and infestations			
-Total	4 (14.3)	0	4 (14.3)
Otitis media	2 (7.1)	0	2 (7.1)
Urinary tract infection	2 (7.1)	0	2 (7.1)
Upper respiratory tract infection	1 (3.6)	0	1 (3.6)

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	3 (10.7)	1 (3.6)	2 (7.1)
Lymphocyte count decreased	2 (7.1)	1 (3.6)	1 (3.6)
Alanine aminotransferase increased	1 (3.6)	0	1 (3.6)
Neutrophil count decreased	1 (3.6)	1 (3.6)	0
Nervous system disorders			
-Total	1 (3.6)	0	1 (3.6)
Dizziness	1 (3.6)	1 (3.6)	0
Headache	1 (3.6)	0	1 (3.6)
Renal and urinary disorders			
-Total	1 (3.6)	0	1 (3.6)
Acute kidney injury	1 (3.6)	0	1 (3.6)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.6)	1 (3.6)	0
Oropharyngeal pain	1 (3.6)	1 (3.6)	0
Rhinorrhoea	1 (3.6)	1 (3.6)	0

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total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Gingivitis	1 (50.0)	1 (50.0)	0
Viral infection	1 (50.0)	1 (50.0)	0

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Table 225c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	1 (25.0)	3 (75.0)
Gastrointestinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Nausea	1 (25.0)	0	1 (25.0)
General disorders and administration site conditions			
-Total	1 (25.0)	0	1 (25.0)
Chills	1 (25.0)	0	1 (25.0)
Pyrexia	1 (25.0)	0	1 (25.0)
Immune system disorders			
-Total	1 (25.0)	0	1 (25.0)

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immunodeficiency	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Meningitis aseptic	1 (25.0)	0	1 (25.0)
Otitis media	1 (25.0)	0	1 (25.0)
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0
Investigations			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Aspartate aminotransferase increased	1 (25.0)	1 (25.0)	0
Blood alkaline phosphatase increased	1 (25.0)	1 (25.0)	0
Blood lactate dehydrogenase increased	1 (25.0)	1 (25.0)	0
C-reactive protein increased	1 (25.0)	1 (25.0)	0
Lymphocyte count decreased	1 (25.0)	1 (25.0)	0
Neutrophil count decreased	1 (25.0)	0	1 (25.0)
White blood cell count decreased	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (75.0)	3 (75.0)	0
Cough	2 (50.0)	2 (50.0)	0
Epistaxis	1 (25.0)	1 (25.0)	0
Rhinitis allergic	1 (25.0)	1 (25.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (25.0)	1 (25.0)	0
Pruritus	1 (25.0)	1 (25.0)	0

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Table 225c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	52 (100)	2 (3.8)	50 (96.2)
Blood and lymphatic system disorders			
-Total	11 (21.2)	4 (7.7)	7 (13.5)
Anaemia	9 (17.3)	4 (7.7)	5 (9.6)
Disseminated intravascular coagulation	2 (3.8)	0	2 (3.8)
Lymphopenia	1 (1.9)	0	1 (1.9)
Cardiac disorders			
-Total	16 (30.8)	7 (13.5)	9 (17.3)
Tachycardia	11 (21.2)	5 (9.6)	6 (11.5)
Sinus tachycardia	6 (11.5)	3 (5.8)	3 (5.8)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Endocrine disorders			
-Total	1 (1.9)	1 (1.9)	0
Adrenal insufficiency	1 (1.9)	1 (1.9)	0
Eye disorders			
-Total	8 (15.4)	4 (7.7)	4 (7.7)
Periorbital oedema	3 (5.8)	2 (3.8)	1 (1.9)
Vision blurred	3 (5.8)	2 (3.8)	1 (1.9)
Conjunctival haemorrhage	2 (3.8)	2 (3.8)	0
Dry eye	1 (1.9)	0	1 (1.9)
Uveitis	1 (1.9)	0	1 (1.9)
Gastrointestinal disorders			
-Total	31 (59.6)	13 (25.0)	18 (34.6)
Vomiting	20 (38.5)	11 (21.2)	9 (17.3)
Diarrhoea	19 (36.5)	12 (23.1)	7 (13.5)
Nausea	16 (30.8)	3 (5.8)	13 (25.0)
Abdominal pain	9 (17.3)	5 (9.6)	4 (7.7)
Constipation	6 (11.5)	5 (9.6)	1 (1.9)
Abdominal pain upper	2 (3.8)	1 (1.9)	1 (1.9)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	27 (51.9)	11 (21.2)	16 (30.8)
Pyrexia	17 (32.7)	5 (9.6)	12 (23.1)
Fatigue	11 (21.2)	8 (15.4)	3 (5.8)
Chills	9 (17.3)	9 (17.3)	0
Catheter site pain	3 (5.8)	0	3 (5.8)
Malaise	3 (5.8)	1 (1.9)	2 (3.8)
Pain	1 (1.9)	1 (1.9)	0
Immune system disorders			
-Total	42 (80.8)	4 (7.7)	38 (73.1)
Cytokine release syndrome	36 (69.2)	5 (9.6)	31 (59.6)
Hypogammaglobulinaemia	21 (40.4)	1 (1.9)	20 (38.5)
Seasonal allergy	1 (1.9)	1 (1.9)	0
Infections and infestations			
-Total	18 (34.6)	4 (7.7)	14 (26.9)
Upper respiratory tract infection	7 (13.5)	3 (5.8)	4 (7.7)
Clostridium difficile infection	3 (5.8)	0	3 (5.8)
Otitis media	3 (5.8)	0	3 (5.8)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Urinary tract infection	3 (5.8)	0	3 (5.8)
Clostridium difficile colitis	2 (3.8)	1 (1.9)	1 (1.9)
Viral infection	2 (3.8)	1 (1.9)	1 (1.9)
Cytomegalovirus infection	1 (1.9)	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Injury, poisoning and procedural complications			
-Total	5 (9.6)	3 (5.8)	2 (3.8)
Procedural pain	3 (5.8)	2 (3.8)	1 (1.9)
Transfusion reaction	2 (3.8)	1 (1.9)	1 (1.9)
Investigations			
-Total	28 (53.8)	2 (3.8)	26 (50.0)
White blood cell count decreased	12 (23.1)	4 (7.7)	8 (15.4)
Alanine aminotransferase increased	9 (17.3)	4 (7.7)	5 (9.6)
Aspartate aminotransferase increased	9 (17.3)	5 (9.6)	4 (7.7)
Prothrombin time prolonged	7 (13.5)	4 (7.7)	3 (5.8)
Blood bilirubin increased	6 (11.5)	2 (3.8)	4 (7.7)
International normalised ratio increased	6 (11.5)	6 (11.5)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Platelet count decreased	6 (11.5)	3 (5.8)	3 (5.8)
Blood creatinine increased	5 (9.6)	4 (7.7)	1 (1.9)
Lymphocyte count decreased	5 (9.6)	1 (1.9)	4 (7.7)
Activated partial thromboplastin time prolonged	4 (7.7)	2 (3.8)	2 (3.8)
Blood immunoglobulin m decreased	3 (5.8)	3 (5.8)	0
Neutrophil count decreased	3 (5.8)	1 (1.9)	2 (3.8)
Blood immunoglobulin a decreased	1 (1.9)	1 (1.9)	0
Blood uric acid increased	1 (1.9)	1 (1.9)	0
Haemoglobin decreased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	23 (44.2)	10 (19.2)	13 (25.0)
Decreased appetite	10 (19.2)	5 (9.6)	5 (9.6)
Hypokalaemia	10 (19.2)	3 (5.8)	7 (13.5)
Hyperphosphataemia	6 (11.5)	6 (11.5)	0
Hypernatraemia	3 (5.8)	0	3 (5.8)
Hyperuricaemia	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	13 (25.0)	8 (15.4)	5 (9.6)
Pain in extremity	6 (11.5)	3 (5.8)	3 (5.8)
Arthralgia	4 (7.7)	3 (5.8)	1 (1.9)
Myalgia	3 (5.8)	2 (3.8)	1 (1.9)
Muscular weakness	2 (3.8)	1 (1.9)	1 (1.9)
Joint range of motion decreased	1 (1.9)	1 (1.9)	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0
Nervous system disorders			
-Total	26 (50.0)	16 (30.8)	10 (19.2)
Headache	19 (36.5)	13 (25.0)	6 (11.5)
Dizziness	6 (11.5)	6 (11.5)	0
Encephalopathy	2 (3.8)	0	2 (3.8)
Dysarthria	1 (1.9)	0	1 (1.9)
Seizure	1 (1.9)	0	1 (1.9)
Tremor	1 (1.9)	1 (1.9)	0
Psychiatric disorders			
-Total	12 (23.1)	7 (13.5)	5 (9.6)
Confusional state	6 (11.5)	3 (5.8)	3 (5.8)
Anxiety	5 (9.6)	3 (5.8)	2 (3.8)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Delirium	3 (5.8)	2 (3.8)	1 (1.9)
Agitation	1 (1.9)	0	1 (1.9)
Renal and urinary disorders			
-Total	3 (5.8)	1 (1.9)	2 (3.8)
Acute kidney injury	2 (3.8)	0	2 (3.8)
Dysuria	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	26 (50.0)	16 (30.8)	10 (19.2)
Cough	11 (21.2)	9 (17.3)	2 (3.8)
Pleural effusion	6 (11.5)	2 (3.8)	4 (7.7)
Oropharyngeal pain	5 (9.6)	4 (7.7)	1 (1.9)
Rhinorrhoea	5 (9.6)	4 (7.7)	1 (1.9)
Epistaxis	4 (7.7)	3 (5.8)	1 (1.9)
Nasal congestion	4 (7.7)	4 (7.7)	0
Rhinitis allergic	3 (5.8)	2 (3.8)	1 (1.9)
Skin and subcutaneous tissue disorders			
-Total	14 (26.9)	13 (25.0)	1 (1.9)

Timing: Any time post CTL019 infusion, Race: White

Group term Preferred term	All patients N=52 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Rash	5 (9.6)	4 (7.7)	1 (1.9)
Erythema	4 (7.7)	4 (7.7)	0
Hyperhidrosis	3 (5.8)	3 (5.8)	0
Dry skin	2 (3.8)	2 (3.8)	0
Pruritus	2 (3.8)	2 (3.8)	0
Vascular disorders			
-Total	11 (21.2)	4 (7.7)	7 (13.5)
Hypertension	10 (19.2)	3 (5.8)	7 (13.5)
Orthostatic hypotension	1 (1.9)	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (100)	0	5 (100)
Blood and lymphatic system disorders			
-Total	1 (20.0)	0	1 (20.0)
Anaemia	1 (20.0)	0	1 (20.0)
Lymphopenia	1 (20.0)	0	1 (20.0)
Cardiac disorders			
-Total	1 (20.0)	1 (20.0)	0
Atrioventricular block second degree	1 (20.0)	1 (20.0)	0
Gastrointestinal disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	1 (20.0)	0	1 (20.0)
Nausea	1 (20.0)	1 (20.0)	0
Vomiting	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	5 (100)	3 (60.0)	2 (40.0)
Fatigue	3 (60.0)	3 (60.0)	0
Pyrexia	2 (40.0)	1 (20.0)	1 (20.0)
Pain	1 (20.0)	0	1 (20.0)
Immune system disorders			
-Total	5 (100)	0	5 (100)
Cytokine release syndrome	4 (80.0)	0	4 (80.0)
Hypogammaglobulinaemia	3 (60.0)	1 (20.0)	2 (40.0)
Infections and infestations			
-Total	3 (60.0)	1 (20.0)	2 (40.0)
Gingivitis	1 (20.0)	1 (20.0)	0
Molluscum contagiosum	1 (20.0)	1 (20.0)	0
Pharyngitis	1 (20.0)	0	1 (20.0)
Streptococcal infection	1 (20.0)	0	1 (20.0)

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Viral infection	1 (20.0)	1 (20.0)	0
Viral upper respiratory tract infection	1 (20.0)	0	1 (20.0)
Investigations			
-Total	1 (20.0)	0	1 (20.0)
Blood immunoglobulin a decreased	1 (20.0)	1 (20.0)	0
Blood uric acid increased	1 (20.0)	1 (20.0)	0
International normalised ratio increased	1 (20.0)	1 (20.0)	0
Lymphocyte count decreased	1 (20.0)	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	1 (20.0)
White blood cell count decreased	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	2 (40.0)	2 (40.0)	0
Decreased appetite	1 (20.0)	1 (20.0)	0
Hyperphosphataemia	1 (20.0)	1 (20.0)	0
Hyperuricaemia	1 (20.0)	1 (20.0)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (80.0)	2 (40.0)	2 (40.0)

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	3 (60.0)	2 (40.0)	1 (20.0)
Arthralgia	1 (20.0)	1 (20.0)	0
Joint range of motion decreased	1 (20.0)	1 (20.0)	0
Myalgia	1 (20.0)	1 (20.0)	0
Osteonecrosis	1 (20.0)	0	1 (20.0)
Nervous system disorders			
-Total	2 (40.0)	2 (40.0)	0
Headache	2 (40.0)	2 (40.0)	0
Renal and urinary disorders			
-Total	1 (20.0)	0	1 (20.0)
Dysuria	1 (20.0)	0	1 (20.0)
Pollakiuria	1 (20.0)	1 (20.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (20.0)	0	1 (20.0)
Rash	1 (20.0)	0	1 (20.0)
Vascular disorders			
-Total	1 (20.0)	0	1 (20.0)
Hypertension	1 (20.0)	0	1 (20.0)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (100)	0	7 (100)
Blood and lymphatic system disorders			
-Total	3 (42.9)	0	3 (42.9)
Anaemia	1 (14.3)	0	1 (14.3)
Disseminated intravascular coagulation	1 (14.3)	0	1 (14.3)
Lymphadenopathy	1 (14.3)	0	1 (14.3)
Cardiac disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Tachycardia	3 (42.9)	3 (42.9)	0
Ventricular tachycardia	1 (14.3)	0	1 (14.3)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Endocrine disorders			
-Total	1 (14.3)	0	1 (14.3)
Adrenal insufficiency	1 (14.3)	0	1 (14.3)
Eye disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Conjunctival haemorrhage	1 (14.3)	1 (14.3)	0
Dry eye	1 (14.3)	1 (14.3)	0
Periorbital oedema	1 (14.3)	1 (14.3)	0
Uveitis	1 (14.3)	0	1 (14.3)
Vision blurred	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	6 (85.7)	1 (14.3)	5 (71.4)
Nausea	6 (85.7)	2 (28.6)	4 (57.1)
Vomiting	4 (57.1)	4 (57.1)	0
Diarrhoea	2 (28.6)	1 (14.3)	1 (14.3)
Abdominal pain	1 (14.3)	1 (14.3)	0
Abdominal pain upper	1 (14.3)	0	1 (14.3)
Constipation	1 (14.3)	1 (14.3)	0
Dysphagia	1 (14.3)	0	1 (14.3)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Flatulence	1 (14.3)	1 (14.3)	0
Lip pain	1 (14.3)	0	1 (14.3)
General disorders and administration site conditions			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Pyrexia	3 (42.9)	2 (28.6)	1 (14.3)
Catheter site haemorrhage	1 (14.3)	1 (14.3)	0
Catheter site pain	1 (14.3)	1 (14.3)	0
Chills	1 (14.3)	0	1 (14.3)
Fatigue	1 (14.3)	1 (14.3)	0
Injection site haematoma	1 (14.3)	1 (14.3)	0
Malaise	1 (14.3)	0	1 (14.3)
Hepatobiliary disorders			
-Total	1 (14.3)	1 (14.3)	0
Gallbladder enlargement	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
Cytokine release syndrome	5 (71.4)	2 (28.6)	3 (42.9)
Hypogammaglobulinaemia	3 (42.9)	1 (14.3)	2 (28.6)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immunodeficiency common variable	2 (28.6)	0	2 (28.6)
Immunodeficiency	1 (14.3)	0	1 (14.3)
Seasonal allergy	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	4 (57.1)	0	4 (57.1)
Catheter site cellulitis	1 (14.3)	1 (14.3)	0
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)
Clostridium difficile infection	1 (14.3)	0	1 (14.3)
Cytomegalovirus infection	1 (14.3)	1 (14.3)	0
Herpes simplex	1 (14.3)	1 (14.3)	0
Meningitis aseptic	1 (14.3)	0	1 (14.3)
Oral herpes	1 (14.3)	0	1 (14.3)
Otitis media	1 (14.3)	0	1 (14.3)
Rhinitis	1 (14.3)	1 (14.3)	0
Upper respiratory tract infection	1 (14.3)	1 (14.3)	0
Urinary tract infection	1 (14.3)	0	1 (14.3)
Vulvovaginal mycotic infection	1 (14.3)	0	1 (14.3)
Injury, poisoning and procedural complications			

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Procedural pain	2 (28.6)	0	2 (28.6)
Arthropod bite	1 (14.3)	1 (14.3)	0
Post procedural haemorrhage	1 (14.3)	1 (14.3)	0
Transfusion reaction	1 (14.3)	1 (14.3)	0
Investigations			
-Total	5 (71.4)	1 (14.3)	4 (57.1)
Aspartate aminotransferase increased	4 (57.1)	2 (28.6)	2 (28.6)
Alanine aminotransferase increased	2 (28.6)	1 (14.3)	1 (14.3)
Blood creatinine increased	2 (28.6)	1 (14.3)	1 (14.3)
Prothrombin time prolonged	2 (28.6)	1 (14.3)	1 (14.3)
White blood cell count decreased	2 (28.6)	1 (14.3)	1 (14.3)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0
Blood alkaline phosphatase increased	1 (14.3)	1 (14.3)	0
Blood immunoglobulin a decreased	1 (14.3)	1 (14.3)	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood lactate dehydrogenase increased	1 (14.3)	1 (14.3)	0
C-reactive protein increased	1 (14.3)	1 (14.3)	0
Culture stool positive	1 (14.3)	1 (14.3)	0
Haemoglobin decreased	1 (14.3)	1 (14.3)	0
Hepatic enzyme increased	1 (14.3)	0	1 (14.3)
International normalised ratio increased	1 (14.3)	1 (14.3)	0
Lymphocyte count decreased	1 (14.3)	1 (14.3)	0
Neutrophil count decreased	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	4 (57.1)	4 (57.1)	0
Decreased appetite	2 (28.6)	2 (28.6)	0
Acidosis	1 (14.3)	1 (14.3)	0
Hypernatraemia	1 (14.3)	1 (14.3)	0
Hyperphosphataemia	1 (14.3)	1 (14.3)	0
Hypokalaemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (42.9)	3 (42.9)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	2 (28.6)	2 (28.6)	0
Coccydynia	1 (14.3)	1 (14.3)	0
Muscular weakness	1 (14.3)	1 (14.3)	0
Musculoskeletal chest pain	1 (14.3)	1 (14.3)	0
Myalgia	1 (14.3)	1 (14.3)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (14.3)	0	1 (14.3)
Myelodysplastic syndrome	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Headache	3 (42.9)	0	3 (42.9)
Asterixis	1 (14.3)	1 (14.3)	0
Ataxia	1 (14.3)	0	1 (14.3)
Dysarthria	1 (14.3)	1 (14.3)	0
Encephalopathy	1 (14.3)	1 (14.3)	0
Myoclonus	1 (14.3)	1 (14.3)	0
Neuropathy peripheral	1 (14.3)	0	1 (14.3)
Pleocytosis	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Seizure	1 (14.3)	0	1 (14.3)
Tremor	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	1 (14.3)	0	1 (14.3)
Adjustment disorder	1 (14.3)	0	1 (14.3)
Agitation	1 (14.3)	0	1 (14.3)
Anxiety	1 (14.3)	0	1 (14.3)
Delirium	1 (14.3)	0	1 (14.3)
Suicidal ideation	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	1 (14.3)	1 (14.3)	0
Acute kidney injury	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (71.4)	3 (42.9)	2 (28.6)
Cough	3 (42.9)	3 (42.9)	0
Epistaxis	2 (28.6)	1 (14.3)	1 (14.3)
Haemoptysis	1 (14.3)	1 (14.3)	0
Nasal congestion	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oropharyngeal pain	1 (14.3)	0	1 (14.3)
Rhinitis allergic	1 (14.3)	1 (14.3)	0
Rhinorrhoea	1 (14.3)	1 (14.3)	0
Skin and subcutaneous tissue disorders			
-Total	5 (71.4)	4 (57.1)	1 (14.3)
Dry skin	3 (42.9)	3 (42.9)	0
Pruritus	2 (28.6)	2 (28.6)	0
Rash	2 (28.6)	1 (14.3)	1 (14.3)
Dermatitis	1 (14.3)	1 (14.3)	0
Dermatitis atopic	1 (14.3)	1 (14.3)	0
Eczema	1 (14.3)	1 (14.3)	0
Erythema	1 (14.3)	1 (14.3)	0
Hyperhidrosis	1 (14.3)	1 (14.3)	0
Rash vesicular	1 (14.3)	1 (14.3)	0
Skin exfoliation	1 (14.3)	1 (14.3)	0
Skin fissures	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	2 (28.6)	0	2 (28.6)

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Orthostatic hypotension	1 (14.3)	0	1 (14.3)
Secondary hypertension	1 (14.3)	0	1 (14.3)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	25 (100)	1 (4.0)	24 (96.0)
Blood and lymphatic system disorders			
-Total	7 (28.0)	3 (12.0)	4 (16.0)
Anaemia	6 (24.0)	3 (12.0)	3 (12.0)
Thrombocytopenia	1 (4.0)	0	1 (4.0)
Cardiac disorders			
-Total	8 (32.0)	6 (24.0)	2 (8.0)
Tachycardia	7 (28.0)	6 (24.0)	1 (4.0)
Sinus tachycardia	1 (4.0)	0	1 (4.0)
Gastrointestinal disorders			
-Total	10 (40.0)	3 (12.0)	7 (28.0)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	7 (28.0)	1 (4.0)	6 (24.0)
Vomiting	6 (24.0)	4 (16.0)	2 (8.0)
Diarrhoea	4 (16.0)	3 (12.0)	1 (4.0)
Abdominal pain	3 (12.0)	3 (12.0)	0
Constipation	2 (8.0)	2 (8.0)	0
General disorders and administration site conditions			
-Total	5 (20.0)	4 (16.0)	1 (4.0)
Chills	2 (8.0)	2 (8.0)	0
Fatigue	2 (8.0)	2 (8.0)	0
Pyrexia	2 (8.0)	1 (4.0)	1 (4.0)
Immune system disorders			
-Total	21 (84.0)	1 (4.0)	20 (80.0)
Cytokine release syndrome	18 (72.0)	2 (8.0)	16 (64.0)
Hypogammaglobulinaemia	11 (44.0)	0	11 (44.0)
Infections and infestations			
-Total	1 (4.0)	1 (4.0)	0
Influenza	1 (4.0)	1 (4.0)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	2 (8.0)	1 (4.0)	1 (4.0)
Procedural pain	2 (8.0)	1 (4.0)	1 (4.0)
Investigations			
-Total	11 (44.0)	3 (12.0)	8 (32.0)
Platelet count decreased	5 (20.0)	3 (12.0)	2 (8.0)
Blood creatinine increased	4 (16.0)	4 (16.0)	0
Activated partial thromboplastin time prolonged	3 (12.0)	2 (8.0)	1 (4.0)
Aspartate aminotransferase increased	3 (12.0)	2 (8.0)	1 (4.0)
White blood cell count decreased	3 (12.0)	0	3 (12.0)
Alanine aminotransferase increased	2 (8.0)	1 (4.0)	1 (4.0)
Blood bilirubin increased	2 (8.0)	1 (4.0)	1 (4.0)
Prothrombin time prolonged	2 (8.0)	1 (4.0)	1 (4.0)
International normalised ratio increased	1 (4.0)	1 (4.0)	0
Lymphocyte count decreased	1 (4.0)	1 (4.0)	0
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (44.0)	4 (16.0)	7 (28.0)
Decreased appetite	5 (20.0)	2 (8.0)	3 (12.0)
Hyperphosphataemia	4 (16.0)	4 (16.0)	0
Hypokalaemia	4 (16.0)	1 (4.0)	3 (12.0)
Hypoalbuminaemia	1 (4.0)	0	1 (4.0)
Nervous system disorders			
-Total	10 (40.0)	6 (24.0)	4 (16.0)
Headache	10 (40.0)	6 (24.0)	4 (16.0)
Dizziness	1 (4.0)	1 (4.0)	0
Psychiatric disorders			
-Total	2 (8.0)	1 (4.0)	1 (4.0)
Anxiety	1 (4.0)	0	1 (4.0)
Confusional state	1 (4.0)	1 (4.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	8 (32.0)	6 (24.0)	2 (8.0)
Tachypnoea	3 (12.0)	3 (12.0)	0
Cough	1 (4.0)	1 (4.0)	0
Epistaxis	1 (4.0)	1 (4.0)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoxia	1 (4.0)	0	1 (4.0)
Nasal congestion	1 (4.0)	1 (4.0)	0
Oropharyngeal pain	1 (4.0)	0	1 (4.0)
Rhinorrhoea	1 (4.0)	1 (4.0)	0
Skin and subcutaneous tissue disorders			
-Total	4 (16.0)	4 (16.0)	0
Dry skin	2 (8.0)	2 (8.0)	0
Erythema	1 (4.0)	1 (4.0)	0
Rash	1 (4.0)	1 (4.0)	0
Vascular disorders			
-Total	2 (8.0)	0	2 (8.0)
Hypertension	2 (8.0)	0	2 (8.0)

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Table 225d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

		All patients N=39	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	37 (94.9)	2 (5.1)	35 (89.7)
Blood and lymphatic system disorders			
-Total	5 (12.8)	1 (2.6)	4 (10.3)
Anaemia	5 (12.8)	1 (2.6)	4 (10.3)
Thrombocytopenia	2 (5.1)	0	2 (5.1)
Cardiac disorders			
-Total	10 (25.6)	4 (10.3)	6 (15.4)
Tachycardia	7 (17.9)	2 (5.1)	5 (12.8)
Sinus tachycardia	4 (10.3)	3 (7.7)	1 (2.6)
Gastrointestinal disorders			
-Total	22 (56.4)	9 (23.1)	13 (33.3)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	14 (35.9)	9 (23.1)	5 (12.8)
Diarrhoea	13 (33.3)	8 (20.5)	5 (12.8)
Nausea	13 (33.3)	5 (12.8)	8 (20.5)
Abdominal pain	5 (12.8)	3 (7.7)	2 (5.1)
Constipation	5 (12.8)	4 (10.3)	1 (2.6)
General disorders and administration site conditions			
-Total	21 (53.8)	9 (23.1)	12 (30.8)
Pyrexia	12 (30.8)	2 (5.1)	10 (25.6)
Fatigue	11 (28.2)	8 (20.5)	3 (7.7)
Chills	6 (15.4)	6 (15.4)	0
Immune system disorders			
-Total	31 (79.5)	5 (12.8)	26 (66.7)
Cytokine release syndrome	27 (69.2)	5 (12.8)	22 (56.4)
Hypogammaglobulinaemia	10 (25.6)	3 (7.7)	7 (17.9)
Infections and infestations			
-Total	4 (10.3)	3 (7.7)	1 (2.6)
Rhinovirus infection	3 (7.7)	3 (7.7)	0
Upper respiratory tract infection	1 (2.6)	0	1 (2.6)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (2.6)	0	1 (2.6)
Procedural pain	1 (2.6)	0	1 (2.6)
Investigations			
-Total	20 (51.3)	1 (2.6)	19 (48.7)
Aspartate aminotransferase increased	9 (23.1)	4 (10.3)	5 (12.8)
Alanine aminotransferase increased	8 (20.5)	4 (10.3)	4 (10.3)
White blood cell count decreased	8 (20.5)	3 (7.7)	5 (12.8)
International normalised ratio increased	7 (17.9)	7 (17.9)	0
Prothrombin time prolonged	7 (17.9)	4 (10.3)	3 (7.7)
Blood bilirubin increased	4 (10.3)	1 (2.6)	3 (7.7)
Blood creatinine increased	3 (7.7)	1 (2.6)	2 (5.1)
Lymphocyte count decreased	3 (7.7)	0	3 (7.7)
Activated partial thromboplastin time prolonged	2 (5.1)	1 (2.6)	1 (2.6)
Platelet count decreased	1 (2.6)	0	1 (2.6)
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	16 (41.0)	8 (20.5)	8 (20.5)
Decreased appetite	6 (15.4)	5 (12.8)	1 (2.6)
Hypokalaemia	6 (15.4)	2 (5.1)	4 (10.3)
Hyperphosphataemia	4 (10.3)	4 (10.3)	0
Hypoalbuminaemia	4 (10.3)	1 (2.6)	3 (7.7)
Musculoskeletal and connective tissue disorders			
-Total	8 (20.5)	5 (12.8)	3 (7.7)
Myalgia	5 (12.8)	4 (10.3)	1 (2.6)
Pain in extremity	4 (10.3)	2 (5.1)	2 (5.1)
Nervous system disorders			
-Total	16 (41.0)	12 (30.8)	4 (10.3)
Headache	14 (35.9)	10 (25.6)	4 (10.3)
Dizziness	3 (7.7)	3 (7.7)	0
Psychiatric disorders			
-Total	8 (20.5)	4 (10.3)	4 (10.3)
Confusional state	5 (12.8)	2 (5.1)	3 (7.7)
Anxiety	4 (10.3)	2 (5.1)	2 (5.1)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	16 (41.0)	6 (15.4)	10 (25.6)
Cough	7 (17.9)	7 (17.9)	0
Pleural effusion	6 (15.4)	2 (5.1)	4 (10.3)
Hypoxia	4 (10.3)	0	4 (10.3)
Epistaxis	3 (7.7)	1 (2.6)	2 (5.1)
Oropharyngeal pain	1 (2.6)	1 (2.6)	0
Tachypnoea	1 (2.6)	0	1 (2.6)
Skin and subcutaneous tissue disorders			
-Total	8 (20.5)	8 (20.5)	0
Hyperhidrosis	3 (7.7)	3 (7.7)	0
Rash	3 (7.7)	3 (7.7)	0
Dry skin	2 (5.1)	2 (5.1)	0
Erythema	2 (5.1)	2 (5.1)	0
Vascular disorders			
-Total	7 (17.9)	2 (5.1)	5 (12.8)
Hypertension	7 (17.9)	2 (5.1)	5 (12.8)

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Table 225d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=23	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (87.0)	3 (13.0)	17 (73.9)
Blood and lymphatic system disorders			
-Total	1 (4.3)	1 (4.3)	0
Anaemia	1 (4.3)	1 (4.3)	0
Cardiac disorders			
-Total	1 (4.3)	0	1 (4.3)
Sinus tachycardia	1 (4.3)	0	1 (4.3)
Gastrointestinal disorders			
-Total	8 (34.8)	4 (17.4)	4 (17.4)
Vomiting	6 (26.1)	4 (17.4)	2 (8.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	3 (13.0)	2 (8.7)	1 (4.3)
Nausea	2 (8.7)	0	2 (8.7)
Abdominal pain	1 (4.3)	0	1 (4.3)
General disorders and administration site conditions			
-Total	3 (13.0)	2 (8.7)	1 (4.3)
Pyrexia	3 (13.0)	2 (8.7)	1 (4.3)
Chills	1 (4.3)	1 (4.3)	0
Fatigue	1 (4.3)	1 (4.3)	0
Immune system disorders			
-Total	4 (17.4)	0	4 (17.4)
Hypogammaglobulinaemia	4 (17.4)	0	4 (17.4)
Infections and infestations			
-Total	11 (47.8)	2 (8.7)	9 (39.1)
Upper respiratory tract infection	4 (17.4)	2 (8.7)	2 (8.7)
Influenza	3 (13.0)	0	3 (13.0)
Urinary tract infection	3 (13.0)	0	3 (13.0)
Otitis media	1 (4.3)	0	1 (4.3)
Rhinovirus infection	1 (4.3)	1 (4.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (4.3)	0	1 (4.3)
Procedural pain	1 (4.3)	0	1 (4.3)
Investigations			
-Total	4 (17.4)	2 (8.7)	2 (8.7)
Platelet count decreased	3 (13.0)	3 (13.0)	0
White blood cell count decreased	3 (13.0)	2 (8.7)	1 (4.3)
Aspartate aminotransferase increased	1 (4.3)	1 (4.3)	0
Lymphocyte count decreased	1 (4.3)	0	1 (4.3)
Metabolism and nutrition disorders			
-Total	4 (17.4)	3 (13.0)	1 (4.3)
Hyperphosphataemia	2 (8.7)	2 (8.7)	0
Decreased appetite	1 (4.3)	0	1 (4.3)
Hypokalaemia	1 (4.3)	1 (4.3)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (13.0)	3 (13.0)	0
Pain in extremity	3 (13.0)	3 (13.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nervous system disorders			
-Total	3 (13.0)	3 (13.0)	0
Headache	3 (13.0)	3 (13.0)	0
Dizziness	1 (4.3)	1 (4.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (39.1)	6 (26.1)	3 (13.0)
Cough	4 (17.4)	2 (8.7)	2 (8.7)
Nasal congestion	4 (17.4)	4 (17.4)	0
Rhinorrhoea	4 (17.4)	3 (13.0)	1 (4.3)
Oropharyngeal pain	2 (8.7)	2 (8.7)	0
Epistaxis	1 (4.3)	1 (4.3)	0
Skin and subcutaneous tissue disorders			
-Total	2 (8.7)	1 (4.3)	1 (4.3)
Dry skin	1 (4.3)	1 (4.3)	0
Rash	1 (4.3)	0	1 (4.3)
Vascular disorders			
-Total	1 (4.3)	0	1 (4.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	1 (4.3)	0	1 (4.3)

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Table 225d
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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	16 (48.5)	7 (21.2)	9 (27.3)
Blood and lymphatic system disorders			
-Total	1 (3.0)	0	1 (3.0)
Thrombocytopenia	1 (3.0)	0	1 (3.0)
Gastrointestinal disorders			
-Total	5 (15.2)	4 (12.1)	1 (3.0)
Diarrhoea	4 (12.1)	4 (12.1)	0
Abdominal pain	2 (6.1)	2 (6.1)	0
Nausea	2 (6.1)	1 (3.0)	1 (3.0)
Vomiting	2 (6.1)	1 (3.0)	1 (3.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	7 (21.2)	6 (18.2)	1 (3.0)
Pyrexia	6 (18.2)	5 (15.2)	1 (3.0)
Fatigue	1 (3.0)	1 (3.0)	0
Immune system disorders			
-Total	3 (9.1)	0	3 (9.1)
Hypogammaglobulinaemia	3 (9.1)	0	3 (9.1)
Infections and infestations			
-Total	3 (9.1)	2 (6.1)	1 (3.0)
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)
Rhinovirus infection	1 (3.0)	1 (3.0)	0
Injury, poisoning and procedural complications			
-Total	1 (3.0)	1 (3.0)	0
Procedural pain	1 (3.0)	1 (3.0)	0
Investigations			
-Total	3 (9.1)	2 (6.1)	1 (3.0)
Blood creatinine increased	1 (3.0)	1 (3.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Lymphocyte count decreased	1 (3.0)	1 (3.0)	0
White blood cell count decreased	1 (3.0)	0	1 (3.0)
Metabolism and nutrition disorders			
-Total	1 (3.0)	1 (3.0)	0
Decreased appetite	1 (3.0)	1 (3.0)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (15.2)	3 (9.1)	2 (6.1)
Pain in extremity	5 (15.2)	3 (9.1)	2 (6.1)
Nervous system disorders			
-Total	3 (9.1)	2 (6.1)	1 (3.0)
Dizziness	2 (6.1)	2 (6.1)	0
Headache	2 (6.1)	1 (3.0)	1 (3.0)
Psychiatric disorders			
-Total	1 (3.0)	1 (3.0)	0
Anxiety	1 (3.0)	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (12.1)	3 (9.1)	1 (3.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	3 (9.1)	3 (9.1)	0
Oropharyngeal pain	1 (3.0)	0	1 (3.0)
Skin and subcutaneous tissue disorders			
-Total	5 (15.2)	3 (9.1)	2 (6.1)
Rash	3 (9.1)	1 (3.0)	2 (6.1)
Erythema	2 (6.1)	2 (6.1)	0
Hyperhidrosis	1 (3.0)	1 (3.0)	0
Vascular disorders			
-Total	1 (3.0)	1 (3.0)	0
Hypertension	1 (3.0)	1 (3.0)	0

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Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=17	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (35.3)	2 (11.8)	4 (23.5)
Gastrointestinal disorders			
-Total	2 (11.8)	0	2 (11.8)
Diarrhoea	1 (5.9)	0	1 (5.9)
Nausea	1 (5.9)	0	1 (5.9)
General disorders and administration site conditions			
-Total	1 (5.9)	0	1 (5.9)
Chills	1 (5.9)	0	1 (5.9)
Pyrexia	1 (5.9)	0	1 (5.9)
Infections and infestations			

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (11.8)	0	2 (11.8)
Otitis media	2 (11.8)	0	2 (11.8)
Urinary tract infection	1 (5.9)	0	1 (5.9)
Investigations			
-Total	3 (17.6)	2 (11.8)	1 (5.9)
Alanine aminotransferase increased	1 (5.9)	0	1 (5.9)
Aspartate aminotransferase increased	1 (5.9)	1 (5.9)	0
Lymphocyte count decreased	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (11.8)	2 (11.8)	0
Cough	1 (5.9)	1 (5.9)	0
Epistaxis	1 (5.9)	1 (5.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (35.3)	2 (11.8)	4 (23.5)
Blood and lymphatic system disorders			
-Total	1 (5.9)	1 (5.9)	0
Thrombocytopenia	1 (5.9)	1 (5.9)	0
Gastrointestinal disorders			
-Total	1 (5.9)	0	1 (5.9)
Abdominal pain	1 (5.9)	0	1 (5.9)
Diarrhoea	1 (5.9)	0	1 (5.9)
Infections and infestations			
-Total	4 (23.5)	1 (5.9)	3 (17.6)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	2 (11.8)	1 (5.9)	1 (5.9)
Otitis media	1 (5.9)	0	1 (5.9)
Urinary tract infection	1 (5.9)	0	1 (5.9)
Investigations			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Lymphocyte count decreased	2 (11.8)	1 (5.9)	1 (5.9)
White blood cell count decreased	1 (5.9)	1 (5.9)	0
Nervous system disorders			
-Total	1 (5.9)	0	1 (5.9)
Dizziness	1 (5.9)	1 (5.9)	0
Headache	1 (5.9)	0	1 (5.9)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (11.8)	2 (11.8)	0
Cough	1 (5.9)	1 (5.9)	0
Oropharyngeal pain	1 (5.9)	1 (5.9)	0
Rhinorrhoea	1 (5.9)	1 (5.9)	0

- A patient with multiple adverse events within a group term is counted only once in the

total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	25 (100)	0	25 (100)
Blood and lymphatic system disorders			
-Total	7 (28.0)	3 (12.0)	4 (16.0)
Anaemia	6 (24.0)	3 (12.0)	3 (12.0)
Thrombocytopenia	1 (4.0)	0	1 (4.0)
Cardiac disorders			
-Total	9 (36.0)	6 (24.0)	3 (12.0)
Tachycardia	7 (28.0)	6 (24.0)	1 (4.0)
Sinus tachycardia	2 (8.0)	0	2 (8.0)
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	15 (60.0)	5 (20.0)	10 (40.0)
Vomiting	11 (44.0)	8 (32.0)	3 (12.0)
Nausea	9 (36.0)	1 (4.0)	8 (32.0)
Diarrhoea	7 (28.0)	4 (16.0)	3 (12.0)
Abdominal pain	4 (16.0)	3 (12.0)	1 (4.0)
Constipation	2 (8.0)	2 (8.0)	0
General disorders and administration site conditions			
-Total	9 (36.0)	6 (24.0)	3 (12.0)
Pyrexia	6 (24.0)	3 (12.0)	3 (12.0)
Chills	4 (16.0)	3 (12.0)	1 (4.0)
Fatigue	3 (12.0)	3 (12.0)	0
Immune system disorders			
-Total	22 (88.0)	1 (4.0)	21 (84.0)
Cytokine release syndrome	18 (72.0)	2 (8.0)	16 (64.0)
Hypogammaglobulinaemia	14 (56.0)	0	14 (56.0)
Infections and infestations			
-Total	13 (52.0)	3 (12.0)	10 (40.0)
Influenza	4 (16.0)	1 (4.0)	3 (12.0)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	4 (16.0)	2 (8.0)	2 (8.0)
Otitis media	3 (12.0)	0	3 (12.0)
Urinary tract infection	3 (12.0)	0	3 (12.0)
Rhinovirus infection	1 (4.0)	1 (4.0)	0
Injury, poisoning and procedural complications			
-Total	3 (12.0)	1 (4.0)	2 (8.0)
Procedural pain	3 (12.0)	1 (4.0)	2 (8.0)
Investigations			
-Total	12 (48.0)	2 (8.0)	10 (40.0)
Platelet count decreased	5 (20.0)	3 (12.0)	2 (8.0)
White blood cell count decreased	5 (20.0)	1 (4.0)	4 (16.0)
Aspartate aminotransferase increased	4 (16.0)	3 (12.0)	1 (4.0)
Blood creatinine increased	4 (16.0)	4 (16.0)	0
Activated partial thromboplastin time prolonged	3 (12.0)	2 (8.0)	1 (4.0)
Alanine aminotransferase increased	3 (12.0)	1 (4.0)	2 (8.0)
Blood bilirubin increased	2 (8.0)	1 (4.0)	1 (4.0)
Lymphocyte count decreased	2 (8.0)	1 (4.0)	1 (4.0)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Prothrombin time prolonged	2 (8.0)	1 (4.0)	1 (4.0)
International normalised ratio increased	1 (4.0)	1 (4.0)	0
Metabolism and nutrition disorders			
-Total	12 (48.0)	5 (20.0)	7 (28.0)
Decreased appetite	6 (24.0)	2 (8.0)	4 (16.0)
Hypokalaemia	5 (20.0)	2 (8.0)	3 (12.0)
Hyperphosphataemia	4 (16.0)	4 (16.0)	0
Hypoalbuminaemia	1 (4.0)	0	1 (4.0)
Musculoskeletal and connective tissue disorders			
-Total	3 (12.0)	3 (12.0)	0
Pain in extremity	3 (12.0)	3 (12.0)	0
Nervous system disorders			
-Total	10 (40.0)	6 (24.0)	4 (16.0)
Headache	10 (40.0)	6 (24.0)	4 (16.0)
Dizziness	2 (8.0)	2 (8.0)	0
Psychiatric disorders			
-Total	2 (8.0)	1 (4.0)	1 (4.0)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Anxiety	1 (4.0)	0	1 (4.0)
Confusional state	1 (4.0)	1 (4.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	15 (60.0)	11 (44.0)	4 (16.0)
Cough	5 (20.0)	3 (12.0)	2 (8.0)
Nasal congestion	5 (20.0)	5 (20.0)	0
Rhinorrhoea	5 (20.0)	4 (16.0)	1 (4.0)
Epistaxis	3 (12.0)	3 (12.0)	0
Oropharyngeal pain	3 (12.0)	2 (8.0)	1 (4.0)
Tachypnoea	3 (12.0)	3 (12.0)	0
Hypoxia	1 (4.0)	0	1 (4.0)
Skin and subcutaneous tissue disorders			
-Total	6 (24.0)	5 (20.0)	1 (4.0)
Dry skin	3 (12.0)	3 (12.0)	0
Rash	2 (8.0)	1 (4.0)	1 (4.0)
Erythema	1 (4.0)	1 (4.0)	0
Vascular disorders			

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (12.0)	0	3 (12.0)
Hypertension	3 (12.0)	0	3 (12.0)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

		All patients N=39	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	39 (100)	3 (7.7)	36 (92.3)
Blood and lymphatic system disorders			
-Total	7 (17.9)	2 (5.1)	5 (12.8)
Anaemia	5 (12.8)	1 (2.6)	4 (10.3)
Thrombocytopenia	4 (10.3)	1 (2.6)	3 (7.7)
Cardiac disorders			
-Total	10 (25.6)	4 (10.3)	6 (15.4)
Tachycardia	7 (17.9)	2 (5.1)	5 (12.8)
Sinus tachycardia	4 (10.3)	3 (7.7)	1 (2.6)
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	23 (59.0)	9 (23.1)	14 (35.9)
Diarrhoea	15 (38.5)	9 (23.1)	6 (15.4)
Nausea	14 (35.9)	5 (12.8)	9 (23.1)
Vomiting	14 (35.9)	8 (20.5)	6 (15.4)
Abdominal pain	6 (15.4)	3 (7.7)	3 (7.7)
Constipation	5 (12.8)	4 (10.3)	1 (2.6)
General disorders and administration site conditions			
-Total	24 (61.5)	11 (28.2)	13 (33.3)
Pyrexia	16 (41.0)	5 (12.8)	11 (28.2)
Fatigue	12 (30.8)	9 (23.1)	3 (7.7)
Chills	6 (15.4)	6 (15.4)	0
Immune system disorders			
-Total	31 (79.5)	5 (12.8)	26 (66.7)
Cytokine release syndrome	27 (69.2)	5 (12.8)	22 (56.4)
Hypogammaglobulinaemia	13 (33.3)	3 (7.7)	10 (25.6)
Infections and infestations			
-Total	10 (25.6)	6 (15.4)	4 (10.3)
Rhinovirus infection	4 (10.3)	4 (10.3)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	4 (10.3)	2 (5.1)	2 (5.1)
Otitis media	1 (2.6)	0	1 (2.6)
Urinary tract infection	1 (2.6)	0	1 (2.6)
Injury, poisoning and procedural complications			
-Total	2 (5.1)	1 (2.6)	1 (2.6)
Procedural pain	2 (5.1)	1 (2.6)	1 (2.6)
Investigations			
-Total	21 (53.8)	1 (2.6)	20 (51.3)
White blood cell count decreased	10 (25.6)	4 (10.3)	6 (15.4)
Aspartate aminotransferase increased	9 (23.1)	4 (10.3)	5 (12.8)
Alanine aminotransferase increased	8 (20.5)	4 (10.3)	4 (10.3)
International normalised ratio increased	7 (17.9)	7 (17.9)	0
Prothrombin time prolonged	7 (17.9)	4 (10.3)	3 (7.7)
Lymphocyte count decreased	5 (12.8)	1 (2.6)	4 (10.3)
Blood bilirubin increased	4 (10.3)	1 (2.6)	3 (7.7)
Blood creatinine increased	3 (7.7)	1 (2.6)	2 (5.1)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Activated partial thromboplastin time prolonged	2 (5.1)	1 (2.6)	1 (2.6)
Platelet count decreased	1 (2.6)	0	1 (2.6)
Metabolism and nutrition disorders			
-Total	16 (41.0)	8 (20.5)	8 (20.5)
Decreased appetite	7 (17.9)	6 (15.4)	1 (2.6)
Hypokalaemia	6 (15.4)	2 (5.1)	4 (10.3)
Hyperphosphataemia	4 (10.3)	4 (10.3)	0
Hypoalbuminaemia	4 (10.3)	1 (2.6)	3 (7.7)
Musculoskeletal and connective tissue disorders			
-Total	11 (28.2)	6 (15.4)	5 (12.8)
Pain in extremity	8 (20.5)	4 (10.3)	4 (10.3)
Myalgia	5 (12.8)	4 (10.3)	1 (2.6)
Nervous system disorders			
-Total	17 (43.6)	12 (30.8)	5 (12.8)
Headache	14 (35.9)	9 (23.1)	5 (12.8)
Dizziness	4 (10.3)	4 (10.3)	0
Psychiatric disorders			

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	9 (23.1)	5 (12.8)	4 (10.3)
Anxiety	5 (12.8)	3 (7.7)	2 (5.1)
Confusional state	5 (12.8)	2 (5.1)	3 (7.7)
Respiratory, thoracic and mediastinal disorders			
-Total	17 (43.6)	6 (15.4)	11 (28.2)
Cough	9 (23.1)	9 (23.1)	0
Pleural effusion	6 (15.4)	2 (5.1)	4 (10.3)
Hypoxia	4 (10.3)	0	4 (10.3)
Epistaxis	3 (7.7)	1 (2.6)	2 (5.1)
Oropharyngeal pain	3 (7.7)	2 (5.1)	1 (2.6)
Rhinorrhoea	1 (2.6)	1 (2.6)	0
Tachypnoea	1 (2.6)	0	1 (2.6)
Skin and subcutaneous tissue disorders			
-Total	12 (30.8)	10 (25.6)	2 (5.1)
Rash	6 (15.4)	4 (10.3)	2 (5.1)
Erythema	4 (10.3)	4 (10.3)	0
Hyperhidrosis	4 (10.3)	4 (10.3)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dry skin	2 (5.1)	2 (5.1)	0
Vascular disorders			
-Total	8 (20.5)	3 (7.7)	5 (12.8)
Hypertension	8 (20.5)	3 (7.7)	5 (12.8)

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Table 225e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (100)	0	7 (100)
Blood and lymphatic system disorders			
-Total	2 (28.6)	2 (28.6)	0
Anaemia	2 (28.6)	2 (28.6)	0
Cardiac disorders			
-Total	2 (28.6)	2 (28.6)	0
Palpitations	1 (14.3)	1 (14.3)	0
Pericardial effusion	1 (14.3)	1 (14.3)	0
Tachycardia	1 (14.3)	1 (14.3)	0
Eye disorders			
-Total	1 (14.3)	1 (14.3)	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eye pain	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Diarrhoea	3 (42.9)	2 (28.6)	1 (14.3)
Nausea	3 (42.9)	1 (14.3)	2 (28.6)
Vomiting	3 (42.9)	1 (14.3)	2 (28.6)
Constipation	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	2 (28.6)	0	2 (28.6)
Pyrexia	2 (28.6)	0	2 (28.6)
Asthenia	1 (14.3)	1 (14.3)	0
Chills	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			
-Total	1 (14.3)	0	1 (14.3)
Hepatomegaly	1 (14.3)	0	1 (14.3)
Immune system disorders			
-Total	7 (100)	0	7 (100)
Cytokine release syndrome	5 (71.4)	0	5 (71.4)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)
Infections and infestations			
-Total	2 (28.6)	0	2 (28.6)
Gastroenteritis	1 (14.3)	0	1 (14.3)
Viral infection	1 (14.3)	0	1 (14.3)
Injury, poisoning and procedural complications			
-Total	1 (14.3)	0	1 (14.3)
Tracheal haemorrhage	1 (14.3)	0	1 (14.3)
Investigations			
-Total	5 (71.4)	1 (14.3)	4 (57.1)
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)
White blood cell count decreased	2 (28.6)	1 (14.3)	1 (14.3)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0
Blood creatinine increased	1 (14.3)	0	1 (14.3)
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0
Blood phosphorus increased	1 (14.3)	1 (14.3)	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood uric acid increased	1 (14.3)	1 (14.3)	0
Cardiac murmur	1 (14.3)	1 (14.3)	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0
Neutrophil count decreased	1 (14.3)	0	1 (14.3)
Prothrombin time prolonged	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Decreased appetite	2 (28.6)	1 (14.3)	1 (14.3)
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)
Hypernatraemia	1 (14.3)	0	1 (14.3)
Hypoalbuminaemia	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	4 (57.1)	4 (57.1)	0
Headache	3 (42.9)	3 (42.9)	0
Dizziness	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)
Delirium	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Cough	2 (28.6)	2 (28.6)	0
Hypoxia	1 (14.3)	0	1 (14.3)
Pleural effusion	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	4 (57.1)	4 (57.1)	0
Dermatitis diaper	1 (14.3)	1 (14.3)	0
Dry skin	1 (14.3)	1 (14.3)	0
Erythema	1 (14.3)	1 (14.3)	0
Livedo reticularis	1 (14.3)	1 (14.3)	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	2 (28.6)	0	2 (28.6)
Haematoma	1 (14.3)	0	1 (14.3)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	1 (14.3)	0	1 (14.3)

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Table 225e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=57	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	55 (96.5)	2 (3.5)	53 (93.0)
Blood and lymphatic system disorders			
-Total	9 (15.8)	2 (3.5)	7 (12.3)
Anaemia	9 (15.8)	2 (3.5)	7 (12.3)
Cardiac disorders			
-Total	18 (31.6)	9 (15.8)	9 (15.8)
Tachycardia	13 (22.8)	7 (12.3)	6 (10.5)
Sinus tachycardia	5 (8.8)	3 (5.3)	2 (3.5)
Pericardial effusion	1 (1.8)	0	1 (1.8)
Endocrine disorders			
-Total	1 (1.8)	0	1 (1.8)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Adrenal insufficiency	1 (1.8)	0	1 (1.8)
Eye disorders			
-Total	2 (3.5)	0	2 (3.5)
Eye pain	2 (3.5)	0	2 (3.5)
Gastrointestinal disorders			
-Total	28 (49.1)	10 (17.5)	18 (31.6)
Nausea	17 (29.8)	5 (8.8)	12 (21.1)
Vomiting	17 (29.8)	12 (21.1)	5 (8.8)
Diarrhoea	14 (24.6)	9 (15.8)	5 (8.8)
Abdominal pain	8 (14.0)	6 (10.5)	2 (3.5)
Constipation	6 (10.5)	5 (8.8)	1 (1.8)
General disorders and administration site conditions			
-Total	25 (43.9)	13 (22.8)	12 (21.1)
Fatigue	13 (22.8)	10 (17.5)	3 (5.3)
Pyrexia	12 (21.1)	3 (5.3)	9 (15.8)
Chills	7 (12.3)	7 (12.3)	0
Catheter site pain	3 (5.3)	1 (1.8)	2 (3.5)
Hepatobiliary disorders			

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=57	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (3.5)	1 (1.8)	1 (1.8)
Hepatomegaly	2 (3.5)	1 (1.8)	1 (1.8)
Immune system disorders			
-Total	45 (78.9)	6 (10.5)	39 (68.4)
Cytokine release syndrome	40 (70.2)	7 (12.3)	33 (57.9)
Hypogammaglobulinaemia	17 (29.8)	3 (5.3)	14 (24.6)
Infections and infestations			
-Total	5 (8.8)	3 (5.3)	2 (3.5)
Rhinovirus infection	3 (5.3)	3 (5.3)	0
Skin infection	1 (1.8)	0	1 (1.8)
Upper respiratory tract infection	1 (1.8)	0	1 (1.8)
Injury, poisoning and procedural complications			
-Total	3 (5.3)	1 (1.8)	2 (3.5)
Infusion related reaction	2 (3.5)	0	2 (3.5)
Contusion	1 (1.8)	1 (1.8)	0
Investigations			
-Total	27 (47.4)	4 (7.0)	23 (40.4)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=57	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	12 (21.1)	6 (10.5)	6 (10.5)
Alanine aminotransferase increased	10 (17.5)	5 (8.8)	5 (8.8)
White blood cell count decreased	9 (15.8)	2 (3.5)	7 (12.3)
Prothrombin time prolonged	8 (14.0)	5 (8.8)	3 (5.3)
International normalised ratio increased	7 (12.3)	7 (12.3)	0
Blood bilirubin increased	6 (10.5)	2 (3.5)	4 (7.0)
Blood creatinine increased	6 (10.5)	5 (8.8)	1 (1.8)
Platelet count decreased	6 (10.5)	3 (5.3)	3 (5.3)
Activated partial thromboplastin time prolonged	4 (7.0)	2 (3.5)	2 (3.5)
Blood immunoglobulin m decreased	3 (5.3)	3 (5.3)	0
Blood fibrinogen decreased	2 (3.5)	0	2 (3.5)
Lymphocyte count decreased	2 (3.5)	0	2 (3.5)
Blood phosphorus increased	1 (1.8)	1 (1.8)	0
Neutrophil count decreased	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders			
-Total	25 (43.9)	11 (19.3)	14 (24.6)
Decreased appetite	9 (15.8)	6 (10.5)	3 (5.3)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	8 (14.0)	8 (14.0)	0
Hypokalaemia	8 (14.0)	2 (3.5)	6 (10.5)
Hypoalbuminaemia	4 (7.0)	0	4 (7.0)
Hypernatraemia	3 (5.3)	1 (1.8)	2 (3.5)
Musculoskeletal and connective tissue disorders			
-Total	6 (10.5)	3 (5.3)	3 (5.3)
Pain in extremity	4 (7.0)	2 (3.5)	2 (3.5)
Arthralgia	3 (5.3)	3 (5.3)	0
Muscular weakness	1 (1.8)	0	1 (1.8)
Nervous system disorders			
-Total	22 (38.6)	14 (24.6)	8 (14.0)
Headache	21 (36.8)	13 (22.8)	8 (14.0)
Dizziness	3 (5.3)	3 (5.3)	0
Psychiatric disorders			
-Total	10 (17.5)	5 (8.8)	5 (8.8)
Anxiety	5 (8.8)	2 (3.5)	3 (5.3)
Confusional state	4 (7.0)	2 (3.5)	2 (3.5)
Delirium	3 (5.3)	1 (1.8)	2 (3.5)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	19 (33.3)	9 (15.8)	10 (17.5)
Cough	6 (10.5)	6 (10.5)	0
Pleural effusion	5 (8.8)	2 (3.5)	3 (5.3)
Epistaxis	4 (7.0)	2 (3.5)	2 (3.5)
Hypoxia	4 (7.0)	0	4 (7.0)
Oropharyngeal pain	2 (3.5)	1 (1.8)	1 (1.8)
Nasal congestion	1 (1.8)	1 (1.8)	0
Rhinorrhoea	1 (1.8)	1 (1.8)	0
Skin and subcutaneous tissue disorders			
-Total	10 (17.5)	9 (15.8)	1 (1.8)
Rash	4 (7.0)	4 (7.0)	0
Dry skin	3 (5.3)	3 (5.3)	0
Erythema	2 (3.5)	2 (3.5)	0
Rash erythematous	1 (1.8)	1 (1.8)	0
Rash maculo-papular	1 (1.8)	0	1 (1.8)
Vascular disorders			

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	8 (14.0)	2 (3.5)	6 (10.5)
Hypertension	8 (14.0)	2 (3.5)	6 (10.5)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (80.0)	0	4 (80.0)
Endocrine disorders			
-Total	1 (20.0)	1 (20.0)	0
Adrenal insufficiency	1 (20.0)	1 (20.0)	0
Gastrointestinal disorders			
-Total	4 (80.0)	3 (60.0)	1 (20.0)
Diarrhoea	2 (40.0)	2 (40.0)	0
Vomiting	2 (40.0)	2 (40.0)	0
Abdominal pain	1 (20.0)	1 (20.0)	0
Nausea	1 (20.0)	0	1 (20.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oral pain	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	3 (60.0)	2 (40.0)	1 (20.0)
Catheter site pain	1 (20.0)	0	1 (20.0)
Fatigue	1 (20.0)	1 (20.0)	0
Pyrexia	1 (20.0)	1 (20.0)	0
Immune system disorders			
-Total	1 (20.0)	0	1 (20.0)
Graft versus host disease	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	3 (60.0)	1 (20.0)	2 (40.0)
Upper respiratory tract infection	2 (40.0)	0	2 (40.0)
Ear infection	1 (20.0)	1 (20.0)	0
Rhinovirus infection	1 (20.0)	1 (20.0)	0
Tinea capitis	1 (20.0)	1 (20.0)	0
Viral infection	1 (20.0)	1 (20.0)	0
Injury, poisoning and procedural complications			

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (20.0)	0	1 (20.0)
Contusion	1 (20.0)	1 (20.0)	0
Infusion related reaction	1 (20.0)	0	1 (20.0)
Procedural nausea	1 (20.0)	0	1 (20.0)
Sunburn	1 (20.0)	1 (20.0)	0
Investigations			
-Total	2 (40.0)	2 (40.0)	0
Blood magnesium decreased	1 (20.0)	1 (20.0)	0
Weight decreased	1 (20.0)	1 (20.0)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (60.0)	3 (60.0)	0
Pain in extremity	2 (40.0)	2 (40.0)	0
Arthralgia	1 (20.0)	1 (20.0)	0
Muscular weakness	1 (20.0)	1 (20.0)	0
Pain in jaw	1 (20.0)	1 (20.0)	0
Nervous system disorders			
-Total	2 (40.0)	2 (40.0)	0
Headache	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Peroneal nerve palsy	1 (20.0)	1 (20.0)	0
Psychiatric disorders			
-Total	1 (20.0)	0	1 (20.0)
Anxiety	1 (20.0)	1 (20.0)	0
Depression	1 (20.0)	1 (20.0)	0
Sleep disorder	1 (20.0)	0	1 (20.0)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (80.0)	2 (40.0)	2 (40.0)
Rhinorrhoea	2 (40.0)	1 (20.0)	1 (20.0)
Cough	1 (20.0)	1 (20.0)	0
Nasal congestion	1 (20.0)	1 (20.0)	0
Oropharyngeal pain	1 (20.0)	0	1 (20.0)
Pharyngeal erythema	1 (20.0)	1 (20.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (20.0)	0	1 (20.0)
Alopecia	1 (20.0)	0	1 (20.0)
Erythema	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash erythematous	1 (20.0)	0	1 (20.0)
Vascular disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Hypertension	2 (40.0)	1 (20.0)	1 (20.0)
Hot flush	1 (20.0)	1 (20.0)	0

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Table 225e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=51	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	34 (66.7)	12 (23.5)	22 (43.1)
Blood and lymphatic system disorders			
-Total	1 (2.0)	1 (2.0)	0
Anaemia	1 (2.0)	1 (2.0)	0
Cardiac disorders			
-Total	1 (2.0)	0	1 (2.0)
Sinus tachycardia	1 (2.0)	0	1 (2.0)
Gastrointestinal disorders			
-Total	9 (17.6)	5 (9.8)	4 (7.8)
Vomiting	6 (11.8)	3 (5.9)	3 (5.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	5 (9.8)	4 (7.8)	1 (2.0)
Nausea	3 (5.9)	1 (2.0)	2 (3.9)
Abdominal pain	2 (3.9)	1 (2.0)	1 (2.0)
General disorders and administration site conditions			
-Total	8 (15.7)	6 (11.8)	2 (3.9)
Pyrexia	8 (15.7)	6 (11.8)	2 (3.9)
Chills	1 (2.0)	1 (2.0)	0
Fatigue	1 (2.0)	1 (2.0)	0
Immune system disorders			
-Total	8 (15.7)	1 (2.0)	7 (13.7)
Hypogammaglobulinaemia	7 (13.7)	0	7 (13.7)
Graft versus host disease	1 (2.0)	1 (2.0)	0
Infections and infestations			
-Total	9 (17.6)	5 (9.8)	4 (7.8)
Upper respiratory tract infection	4 (7.8)	3 (5.9)	1 (2.0)
Gastroenteritis	3 (5.9)	1 (2.0)	2 (3.9)
Ear infection	1 (2.0)	0	1 (2.0)
Rhinovirus infection	1 (2.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	2 (3.9)	2 (3.9)	0
Contusion	1 (2.0)	1 (2.0)	0
Infusion related reaction	1 (2.0)	1 (2.0)	0
Investigations			
-Total	11 (21.6)	4 (7.8)	7 (13.7)
White blood cell count decreased	4 (7.8)	2 (3.9)	2 (3.9)
Neutrophil count decreased	3 (5.9)	2 (3.9)	1 (2.0)
Platelet count decreased	3 (5.9)	3 (5.9)	0
Weight decreased	3 (5.9)	0	3 (5.9)
Lymphocyte count decreased	2 (3.9)	1 (2.0)	1 (2.0)
Aspartate aminotransferase increased	1 (2.0)	1 (2.0)	0
Blood creatinine increased	1 (2.0)	1 (2.0)	0
Blood uric acid increased	1 (2.0)	1 (2.0)	0
Metabolism and nutrition disorders			
-Total	5 (9.8)	4 (7.8)	1 (2.0)
Decreased appetite	2 (3.9)	1 (2.0)	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	2 (3.9)	2 (3.9)	0
Hypokalaemia	1 (2.0)	1 (2.0)	0
Musculoskeletal and connective tissue disorders			
-Total	8 (15.7)	5 (9.8)	3 (5.9)
Pain in extremity	6 (11.8)	4 (7.8)	2 (3.9)
Arthralgia	1 (2.0)	0	1 (2.0)
Muscular weakness	1 (2.0)	1 (2.0)	0
Nervous system disorders			
-Total	6 (11.8)	4 (7.8)	2 (3.9)
Headache	4 (7.8)	3 (5.9)	1 (2.0)
Dizziness	3 (5.9)	3 (5.9)	0
Peroneal nerve palsy	1 (2.0)	0	1 (2.0)
Psychiatric disorders			
-Total	1 (2.0)	1 (2.0)	0
Depression	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (17.6)	7 (13.7)	2 (3.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	6 (11.8)	4 (7.8)	2 (3.9)
Nasal congestion	3 (5.9)	3 (5.9)	0
Oropharyngeal pain	2 (3.9)	2 (3.9)	0
Rhinorrhoea	2 (3.9)	2 (3.9)	0
Epistaxis	1 (2.0)	1 (2.0)	0
Skin and subcutaneous tissue disorders			
-Total	8 (15.7)	5 (9.8)	3 (5.9)
Rash	4 (7.8)	1 (2.0)	3 (5.9)
Rash maculo-papular	2 (3.9)	2 (3.9)	0
Dry skin	1 (2.0)	1 (2.0)	0
Erythema	1 (2.0)	1 (2.0)	0

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Table 225e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	1 (20.0)	0	1 (20.0)
Skin infection	1 (20.0)	0	1 (20.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 225e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=29	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (34.5)	3 (10.3)	7 (24.1)
Gastrointestinal disorders			
-Total	3 (10.3)	0	3 (10.3)
Diarrhoea	2 (6.9)	0	2 (6.9)
Abdominal pain	1 (3.4)	0	1 (3.4)
Nausea	1 (3.4)	0	1 (3.4)
General disorders and administration site conditions			
-Total	1 (3.4)	0	1 (3.4)
Chills	1 (3.4)	0	1 (3.4)
Pyrexia	1 (3.4)	0	1 (3.4)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=29	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	3 (10.3)	2 (6.9)	1 (3.4)
Upper respiratory tract infection	2 (6.9)	1 (3.4)	1 (3.4)
Viral infection	1 (3.4)	1 (3.4)	0
Investigations			
-Total	5 (17.2)	2 (6.9)	3 (10.3)
Lymphocyte count decreased	3 (10.3)	2 (6.9)	1 (3.4)
Neutrophil count decreased	2 (6.9)	1 (3.4)	1 (3.4)
Alanine aminotransferase increased	1 (3.4)	0	1 (3.4)
Aspartate aminotransferase increased	1 (3.4)	1 (3.4)	0
White blood cell count decreased	1 (3.4)	1 (3.4)	0
Nervous system disorders			
-Total	1 (3.4)	0	1 (3.4)
Dizziness	1 (3.4)	1 (3.4)	0
Headache	1 (3.4)	0	1 (3.4)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (13.8)	4 (13.8)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	2 (6.9)	2 (6.9)	0
Epistaxis	1 (3.4)	1 (3.4)	0
Oropharyngeal pain	1 (3.4)	1 (3.4)	0
Rhinorrhoea	1 (3.4)	1 (3.4)	0

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Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (100)	0	7 (100)
Blood and lymphatic system disorders			
-Total	2 (28.6)	2 (28.6)	0
Anaemia	2 (28.6)	2 (28.6)	0
Cardiac disorders			
-Total	2 (28.6)	2 (28.6)	0
Palpitations	1 (14.3)	1 (14.3)	0
Pericardial effusion	1 (14.3)	1 (14.3)	0
Tachycardia	1 (14.3)	1 (14.3)	0
Endocrine disorders			

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (14.3)	1 (14.3)	0
Adrenal insufficiency	1 (14.3)	1 (14.3)	0
Eye disorders			
-Total	1 (14.3)	1 (14.3)	0
Eye pain	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	6 (85.7)	3 (42.9)	3 (42.9)
Vomiting	5 (71.4)	3 (42.9)	2 (28.6)
Diarrhoea	4 (57.1)	3 (42.9)	1 (14.3)
Nausea	4 (57.1)	1 (14.3)	3 (42.9)
Abdominal pain	1 (14.3)	1 (14.3)	0
Constipation	1 (14.3)	1 (14.3)	0
Oral pain	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Pyrexia	3 (42.9)	1 (14.3)	2 (28.6)
Asthenia	1 (14.3)	1 (14.3)	0
Catheter site pain	1 (14.3)	0	1 (14.3)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Chills	1 (14.3)	1 (14.3)	0
Fatigue	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			
-Total	1 (14.3)	0	1 (14.3)
Hepatomegaly	1 (14.3)	0	1 (14.3)
Immune system disorders			
-Total	7 (100)	0	7 (100)
Cytokine release syndrome	5 (71.4)	0	5 (71.4)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)
Graft versus host disease	1 (14.3)	0	1 (14.3)
Infections and infestations			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Upper respiratory tract infection	2 (28.6)	0	2 (28.6)
Viral infection	2 (28.6)	1 (14.3)	1 (14.3)
Ear infection	1 (14.3)	1 (14.3)	0
Gastroenteritis	1 (14.3)	0	1 (14.3)
Rhinovirus infection	1 (14.3)	1 (14.3)	0
Skin infection	1 (14.3)	0	1 (14.3)
Tinea capitis	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	2 (28.6)	0	2 (28.6)
Contusion	1 (14.3)	1 (14.3)	0
Infusion related reaction	1 (14.3)	0	1 (14.3)
Procedural nausea	1 (14.3)	0	1 (14.3)
Sunburn	1 (14.3)	1 (14.3)	0
Tracheal haemorrhage	1 (14.3)	0	1 (14.3)
Investigations			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)
White blood cell count decreased	2 (28.6)	1 (14.3)	1 (14.3)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0
Blood creatinine increased	1 (14.3)	0	1 (14.3)
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0
Blood magnesium decreased	1 (14.3)	1 (14.3)	0
Blood phosphorus increased	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood uric acid increased	1 (14.3)	1 (14.3)	0
Cardiac murmur	1 (14.3)	1 (14.3)	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0
Neutrophil count decreased	1 (14.3)	0	1 (14.3)
Prothrombin time prolonged	1 (14.3)	0	1 (14.3)
Weight decreased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Decreased appetite	2 (28.6)	1 (14.3)	1 (14.3)
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)
Hypernatraemia	1 (14.3)	0	1 (14.3)
Hypoalbuminaemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (42.9)	3 (42.9)	0
Pain in extremity	2 (28.6)	2 (28.6)	0
Arthralgia	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Muscular weakness	1 (14.3)	1 (14.3)	0
Pain in jaw	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	4 (57.1)	4 (57.1)	0
Headache	3 (42.9)	3 (42.9)	0
Dizziness	1 (14.3)	1 (14.3)	0
Peroneal nerve palsy	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)
Anxiety	1 (14.3)	1 (14.3)	0
Delirium	1 (14.3)	1 (14.3)	0
Depression	1 (14.3)	1 (14.3)	0
Sleep disorder	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
Cough	3 (42.9)	3 (42.9)	0
Rhinorrhoea	2 (28.6)	1 (14.3)	1 (14.3)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoxia	1 (14.3)	0	1 (14.3)
Nasal congestion	1 (14.3)	1 (14.3)	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)
Pharyngeal erythema	1 (14.3)	1 (14.3)	0
Pleural effusion	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	4 (57.1)	3 (42.9)	1 (14.3)
Erythema	2 (28.6)	2 (28.6)	0
Alopecia	1 (14.3)	0	1 (14.3)
Dermatitis diaper	1 (14.3)	1 (14.3)	0
Dry skin	1 (14.3)	1 (14.3)	0
Livedo reticularis	1 (14.3)	1 (14.3)	0
Rash erythematous	1 (14.3)	0	1 (14.3)
Rash maculo-papular	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Hypertension	3 (42.9)	1 (14.3)	2 (28.6)
Haematoma	1 (14.3)	0	1 (14.3)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hot flush	1 (14.3)	1 (14.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=57	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	56 (98.2)	2 (3.5)	54 (94.7)
Blood and lymphatic system disorders			
-Total	9 (15.8)	2 (3.5)	7 (12.3)
Anaemia	9 (15.8)	2 (3.5)	7 (12.3)
Cardiac disorders			
-Total	19 (33.3)	9 (15.8)	10 (17.5)
Tachycardia	13 (22.8)	7 (12.3)	6 (10.5)
Sinus tachycardia	6 (10.5)	3 (5.3)	3 (5.3)
Pericardial effusion	1 (1.8)	0	1 (1.8)
Endocrine disorders			

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (1.8)	0	1 (1.8)
Adrenal insufficiency	1 (1.8)	0	1 (1.8)
Eye disorders			
-Total	2 (3.5)	0	2 (3.5)
Eye pain	2 (3.5)	0	2 (3.5)
Gastrointestinal disorders			
-Total	32 (56.1)	11 (19.3)	21 (36.8)
Vomiting	20 (35.1)	13 (22.8)	7 (12.3)
Nausea	19 (33.3)	5 (8.8)	14 (24.6)
Diarrhoea	18 (31.6)	10 (17.5)	8 (14.0)
Abdominal pain	9 (15.8)	5 (8.8)	4 (7.0)
Constipation	6 (10.5)	5 (8.8)	1 (1.8)
General disorders and administration site conditions			
-Total	31 (54.4)	16 (28.1)	15 (26.3)
Pyrexia	19 (33.3)	7 (12.3)	12 (21.1)
Fatigue	14 (24.6)	11 (19.3)	3 (5.3)
Chills	9 (15.8)	8 (14.0)	1 (1.8)
Catheter site pain	3 (5.3)	1 (1.8)	2 (3.5)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatobiliary disorders			
-Total	2 (3.5)	1 (1.8)	1 (1.8)
Hepatomegaly	2 (3.5)	1 (1.8)	1 (1.8)
Immune system disorders			
-Total	47 (82.5)	7 (12.3)	40 (70.2)
Cytokine release syndrome	40 (70.2)	7 (12.3)	33 (57.9)
Hypogammaglobulinaemia	23 (40.4)	3 (5.3)	20 (35.1)
Graft versus host disease	1 (1.8)	1 (1.8)	0
Infections and infestations			
-Total	15 (26.3)	9 (15.8)	6 (10.5)
Upper respiratory tract infection	6 (10.5)	4 (7.0)	2 (3.5)
Rhinovirus infection	4 (7.0)	4 (7.0)	0
Gastroenteritis	3 (5.3)	1 (1.8)	2 (3.5)
Ear infection	1 (1.8)	0	1 (1.8)
Skin infection	1 (1.8)	0	1 (1.8)
Viral infection	1 (1.8)	1 (1.8)	0
Injury, poisoning and procedural complications			
-Total	5 (8.8)	3 (5.3)	2 (3.5)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infusion related reaction	3 (5.3)	1 (1.8)	2 (3.5)
Contusion	2 (3.5)	2 (3.5)	0
Investigations			
-Total	31 (54.4)	3 (5.3)	28 (49.1)
Aspartate aminotransferase increased	13 (22.8)	7 (12.3)	6 (10.5)
White blood cell count decreased	13 (22.8)	4 (7.0)	9 (15.8)
Alanine aminotransferase increased	11 (19.3)	5 (8.8)	6 (10.5)
Prothrombin time prolonged	8 (14.0)	5 (8.8)	3 (5.3)
International normalised ratio increased	7 (12.3)	7 (12.3)	0
Blood bilirubin increased	6 (10.5)	2 (3.5)	4 (7.0)
Blood creatinine increased	6 (10.5)	5 (8.8)	1 (1.8)
Platelet count decreased	6 (10.5)	3 (5.3)	3 (5.3)
Lymphocyte count decreased	5 (8.8)	1 (1.8)	4 (7.0)
Activated partial thromboplastin time prolonged	4 (7.0)	2 (3.5)	2 (3.5)
Neutrophil count decreased	4 (7.0)	1 (1.8)	3 (5.3)
Blood immunoglobulin m decreased	3 (5.3)	3 (5.3)	0
Weight decreased	3 (5.3)	0	3 (5.3)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood fibrinogen decreased	2 (3.5)	0	2 (3.5)
Blood phosphorus increased	1 (1.8)	1 (1.8)	0
Blood uric acid increased	1 (1.8)	1 (1.8)	0
Metabolism and nutrition disorders			
-Total	26 (45.6)	12 (21.1)	14 (24.6)
Decreased appetite	11 (19.3)	7 (12.3)	4 (7.0)
Hypokalaemia	9 (15.8)	3 (5.3)	6 (10.5)
Hyperphosphataemia	8 (14.0)	8 (14.0)	0
Hypoalbuminaemia	4 (7.0)	0	4 (7.0)
Hypernatraemia	3 (5.3)	1 (1.8)	2 (3.5)
Musculoskeletal and connective tissue disorders			
-Total	12 (21.1)	7 (12.3)	5 (8.8)
Pain in extremity	9 (15.8)	5 (8.8)	4 (7.0)
Arthralgia	4 (7.0)	3 (5.3)	1 (1.8)
Muscular weakness	2 (3.5)	1 (1.8)	1 (1.8)
Nervous system disorders			
-Total	24 (42.1)	14 (24.6)	10 (17.5)
Headache	21 (36.8)	12 (21.1)	9 (15.8)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dizziness	5 (8.8)	5 (8.8)	0
Peroneal nerve palsy	1 (1.8)	0	1 (1.8)
Psychiatric disorders			
-Total	11 (19.3)	6 (10.5)	5 (8.8)
Anxiety	5 (8.8)	2 (3.5)	3 (5.3)
Confusional state	4 (7.0)	2 (3.5)	2 (3.5)
Delirium	3 (5.3)	1 (1.8)	2 (3.5)
Depression	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	25 (43.9)	14 (24.6)	11 (19.3)
Cough	11 (19.3)	9 (15.8)	2 (3.5)
Epistaxis	6 (10.5)	4 (7.0)	2 (3.5)
Oropharyngeal pain	5 (8.8)	4 (7.0)	1 (1.8)
Pleural effusion	5 (8.8)	2 (3.5)	3 (5.3)
Hypoxia	4 (7.0)	0	4 (7.0)
Nasal congestion	4 (7.0)	4 (7.0)	0
Rhinorrhoea	4 (7.0)	4 (7.0)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	17 (29.8)	13 (22.8)	4 (7.0)
Rash	8 (14.0)	5 (8.8)	3 (5.3)
Dry skin	4 (7.0)	4 (7.0)	0
Erythema	3 (5.3)	3 (5.3)	0
Rash maculo-papular	3 (5.3)	2 (3.5)	1 (1.8)
Rash erythematous	1 (1.8)	1 (1.8)	0
Vascular disorders			
-Total	8 (14.0)	2 (3.5)	6 (10.5)
Hypertension	8 (14.0)	2 (3.5)	6 (10.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	0	1 (50.0)
Anaemia	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
-Total	1 (50.0)	1 (50.0)	0
Fatigue	1 (50.0)	1 (50.0)	0
Immune system disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Graft versus host disease in skin	1 (50.0)	1 (50.0)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)
Injury, poisoning and procedural complications			
-Total	1 (50.0)	1 (50.0)	0
Skin abrasion	1 (50.0)	1 (50.0)	0
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Blood immunoglobulin a decreased	1 (50.0)	1 (50.0)	0
International normalised ratio increased	1 (50.0)	1 (50.0)	0
Lymphocyte count decreased	1 (50.0)	0	1 (50.0)
Neutrophil count decreased	1 (50.0)	0	1 (50.0)
White blood cell count decreased	1 (50.0)	0	1 (50.0)
Metabolism and nutrition disorders			
-Total	1 (50.0)	1 (50.0)	0
Hyperphosphataemia	1 (50.0)	1 (50.0)	0
Hyperuricaemia	1 (50.0)	1 (50.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (50.0)	1 (50.0)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	1 (50.0)	1 (50.0)	0
Myalgia	1 (50.0)	1 (50.0)	0
Pain in extremity	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	2 (100)	2 (100)	0
Headache	2 (100)	2 (100)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	1 (50.0)	0
Cough	1 (50.0)	1 (50.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (50.0)	1 (50.0)	0
Skin irritation	1 (50.0)	1 (50.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	60 (96.8)	1 (1.6)	59 (95.2)
Blood and lymphatic system disorders			
-Total	11 (17.7)	4 (6.5)	7 (11.3)
Anaemia	10 (16.1)	4 (6.5)	6 (9.7)
Lymphopenia	1 (1.6)	0	1 (1.6)
Cardiac disorders			
-Total	18 (29.0)	10 (16.1)	8 (12.9)
Tachycardia	14 (22.6)	8 (12.9)	6 (9.7)
Sinus tachycardia	5 (8.1)	3 (4.8)	2 (3.2)
Gastrointestinal disorders			
-Total	32 (51.6)	12 (19.4)	20 (32.3)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	20 (32.3)	6 (9.7)	14 (22.6)
Vomiting	20 (32.3)	13 (21.0)	7 (11.3)
Diarrhoea	17 (27.4)	11 (17.7)	6 (9.7)
Abdominal pain	8 (12.9)	6 (9.7)	2 (3.2)
Constipation	7 (11.3)	6 (9.7)	1 (1.6)
General disorders and administration site conditions			
-Total	25 (40.3)	11 (17.7)	14 (22.6)
Pyrexia	14 (22.6)	3 (4.8)	11 (17.7)
Fatigue	12 (19.4)	9 (14.5)	3 (4.8)
Chills	8 (12.9)	8 (12.9)	0
Pain	1 (1.6)	0	1 (1.6)
Immune system disorders			
-Total	51 (82.3)	6 (9.7)	45 (72.6)
Cytokine release syndrome	45 (72.6)	7 (11.3)	38 (61.3)
Hypogammaglobulinaemia	20 (32.3)	3 (4.8)	17 (27.4)
Infections and infestations			
-Total	1 (1.6)	0	1 (1.6)
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	29 (46.8)	7 (11.3)	22 (35.5)
Aspartate aminotransferase increased	12 (19.4)	6 (9.7)	6 (9.7)
Alanine aminotransferase increased	10 (16.1)	5 (8.1)	5 (8.1)
White blood cell count decreased	10 (16.1)	3 (4.8)	7 (11.3)
Prothrombin time prolonged	9 (14.5)	5 (8.1)	4 (6.5)
Blood creatinine increased	7 (11.3)	5 (8.1)	2 (3.2)
International normalised ratio increased	7 (11.3)	7 (11.3)	0
Lymphocyte count decreased	3 (4.8)	1 (1.6)	2 (3.2)
Blood immunoglobulin a decreased	2 (3.2)	2 (3.2)	0
Blood uric acid increased	1 (1.6)	1 (1.6)	0
Neutrophil count decreased	1 (1.6)	0	1 (1.6)
Metabolism and nutrition disorders			
-Total	24 (38.7)	13 (21.0)	11 (17.7)
Decreased appetite	11 (17.7)	7 (11.3)	4 (6.5)
Hypokalaemia	10 (16.1)	3 (4.8)	7 (11.3)
Hyperphosphataemia	7 (11.3)	7 (11.3)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperuricaemia	1 (1.6)	1 (1.6)	0
Musculoskeletal and connective tissue disorders			
-Total	9 (14.5)	6 (9.7)	3 (4.8)
Myalgia	4 (6.5)	3 (4.8)	1 (1.6)
Pain in extremity	3 (4.8)	1 (1.6)	2 (3.2)
Arthralgia	2 (3.2)	2 (3.2)	0
Muscle spasms	1 (1.6)	1 (1.6)	0
Nervous system disorders			
-Total	22 (35.5)	14 (22.6)	8 (12.9)
Headache	22 (35.5)	14 (22.6)	8 (12.9)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (11.3)	7 (11.3)	0
Cough	7 (11.3)	7 (11.3)	0
Skin and subcutaneous tissue disorders			
-Total	7 (11.3)	6 (9.7)	1 (1.6)
Rash	4 (6.5)	4 (6.5)	0
Rash maculo-papular	2 (3.2)	1 (1.6)	1 (1.6)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Macule	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	9 (14.5)	2 (3.2)	7 (11.3)
Hypertension	9 (14.5)	2 (3.2)	7 (11.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	2 (100)	0	2 (100)
Eosinophilia	1 (50.0)	0	1 (50.0)
Lymphopenia	1 (50.0)	0	1 (50.0)
Cardiac disorders			
-Total	1 (50.0)	0	1 (50.0)
Sinus tachycardia	1 (50.0)	0	1 (50.0)
Gastrointestinal disorders			
-Total	1 (50.0)	1 (50.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pigmentation lip	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	0	1 (50.0)
Chills	1 (50.0)	1 (50.0)	0
Pain	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	0	1 (50.0)
Immune system disorders			
-Total	1 (50.0)	1 (50.0)	0
Graft versus host disease	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Cellulitis of male external genital organ	1 (50.0)	0	1 (50.0)
Urinary tract infection	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	1 (50.0)	0
Blood uric acid increased	1 (50.0)	1 (50.0)	0
Neutrophil count decreased	1 (50.0)	1 (50.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	1 (50.0)	1 (50.0)	0
Vitamin d deficiency	1 (50.0)	1 (50.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (100)	2 (100)	0
Joint range of motion decreased	2 (100)	2 (100)	0
Back pain	1 (50.0)	1 (50.0)	0
Muscle spasms	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	1 (50.0)	1 (50.0)	0
Headache	1 (50.0)	1 (50.0)	0
Reproductive system and breast disorders			
-Total	1 (50.0)	0	1 (50.0)
Scrotal pain	1 (50.0)	0	1 (50.0)
Skin and subcutaneous tissue disorders			
-Total	1 (50.0)	1 (50.0)	0
Macule	1 (50.0)	1 (50.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash maculo-papular	1 (50.0)	1 (50.0)	0

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Table 225f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	32 (59.3)	9 (16.7)	23 (42.6)
Blood and lymphatic system disorders			
-Total	1 (1.9)	1 (1.9)	0
Anaemia	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	13 (24.1)	8 (14.8)	5 (9.3)
Vomiting	8 (14.8)	5 (9.3)	3 (5.6)
Diarrhoea	7 (13.0)	6 (11.1)	1 (1.9)
Nausea	4 (7.4)	1 (1.9)	3 (5.6)
Abdominal pain	3 (5.6)	2 (3.7)	1 (1.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	9 (16.7)	8 (14.8)	1 (1.9)
Pyrexia	8 (14.8)	7 (13.0)	1 (1.9)
Fatigue	2 (3.7)	2 (3.7)	0
Immune system disorders			
-Total	8 (14.8)	0	8 (14.8)
Hypogammaglobulinaemia	7 (13.0)	0	7 (13.0)
Graft versus host disease	1 (1.9)	0	1 (1.9)
Infections and infestations			
-Total	8 (14.8)	2 (3.7)	6 (11.1)
Upper respiratory tract infection	6 (11.1)	3 (5.6)	3 (5.6)
Urinary tract infection	2 (3.7)	0	2 (3.7)
Otitis media	1 (1.9)	0	1 (1.9)
Injury, poisoning and procedural complications			
-Total	1 (1.9)	1 (1.9)	0
Skin abrasion	1 (1.9)	1 (1.9)	0
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	8 (14.8)	4 (7.4)	4 (7.4)
White blood cell count decreased	4 (7.4)	2 (3.7)	2 (3.7)
Lymphocyte count decreased	2 (3.7)	1 (1.9)	1 (1.9)
Neutrophil count decreased	2 (3.7)	1 (1.9)	1 (1.9)
Aspartate aminotransferase increased	1 (1.9)	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	5 (9.3)	4 (7.4)	1 (1.9)
Decreased appetite	2 (3.7)	1 (1.9)	1 (1.9)
Hyperphosphataemia	2 (3.7)	2 (3.7)	0
Hypokalaemia	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			
-Total	10 (18.5)	7 (13.0)	3 (5.6)
Pain in extremity	8 (14.8)	6 (11.1)	2 (3.7)
Arthralgia	2 (3.7)	1 (1.9)	1 (1.9)
Nervous system disorders			
-Total	4 (7.4)	3 (5.6)	1 (1.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	4 (7.4)	3 (5.6)	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (13.0)	5 (9.3)	2 (3.7)
Cough	7 (13.0)	5 (9.3)	2 (3.7)
Skin and subcutaneous tissue disorders			
-Total	5 (9.3)	2 (3.7)	3 (5.6)
Rash	4 (7.4)	1 (1.9)	3 (5.6)
Rash maculo-papular	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	2 (3.7)	1 (1.9)	1 (1.9)
Hypertension	2 (3.7)	1 (1.9)	1 (1.9)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Gastrointestinal disorders			
-Total	1 (100)	0	1 (100)
Diarrhoea	1 (100)	0	1 (100)
Infections and infestations			
-Total	1 (100)	0	1 (100)
Otitis media	1 (100)	0	1 (100)
Urinary tract infection	1 (100)	0	1 (100)

- A patient with multiple adverse events within a group term is counted only once in the

total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (30.3)	2 (6.1)	8 (24.2)
Gastrointestinal disorders			
-Total	2 (6.1)	0	2 (6.1)
Abdominal pain	1 (3.0)	0	1 (3.0)
Diarrhoea	1 (3.0)	0	1 (3.0)
Nausea	1 (3.0)	0	1 (3.0)
General disorders and administration site conditions			
-Total	1 (3.0)	0	1 (3.0)
Chills	1 (3.0)	0	1 (3.0)
Pyrexia	1 (3.0)	0	1 (3.0)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	5 (15.2)	1 (3.0)	4 (12.1)
Otitis media	2 (6.1)	0	2 (6.1)
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)
Urinary tract infection	1 (3.0)	0	1 (3.0)
Investigations			
-Total	5 (15.2)	2 (6.1)	3 (9.1)
Lymphocyte count decreased	3 (9.1)	2 (6.1)	1 (3.0)
Neutrophil count decreased	2 (6.1)	1 (3.0)	1 (3.0)
Alanine aminotransferase increased	1 (3.0)	0	1 (3.0)
Aspartate aminotransferase increased	1 (3.0)	1 (3.0)	0
White blood cell count decreased	1 (3.0)	1 (3.0)	0
Metabolism and nutrition disorders			
-Total	1 (3.0)	1 (3.0)	0
Vitamin d deficiency	1 (3.0)	1 (3.0)	0
Nervous system disorders			
-Total	1 (3.0)	0	1 (3.0)
Headache	1 (3.0)	0	1 (3.0)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.1)	2 (6.1)	0
Cough	2 (6.1)	2 (6.1)	0

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Table 225f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	2 (100)	0	2 (100)
Anaemia	1 (50.0)	0	1 (50.0)
Eosinophilia	1 (50.0)	0	1 (50.0)
Lymphopenia	1 (50.0)	0	1 (50.0)
Cardiac disorders			
-Total	1 (50.0)	0	1 (50.0)
Sinus tachycardia	1 (50.0)	0	1 (50.0)
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (50.0)	0	1 (50.0)
Diarrhoea	1 (50.0)	0	1 (50.0)
Pigmentation lip	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	2 (100)	1 (50.0)	1 (50.0)
Chills	1 (50.0)	1 (50.0)	0
Fatigue	1 (50.0)	1 (50.0)	0
Pain	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	0	1 (50.0)
Immune system disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Graft versus host disease	1 (50.0)	1 (50.0)	0
Graft versus host disease in skin	1 (50.0)	1 (50.0)	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Cellulitis of male external genital organ	1 (50.0)	0	1 (50.0)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Otitis media	1 (50.0)	0	1 (50.0)
Urinary tract infection	1 (50.0)	0	1 (50.0)
Injury, poisoning and procedural complications			
-Total	1 (50.0)	1 (50.0)	0
Skin abrasion	1 (50.0)	1 (50.0)	0
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Blood immunoglobulin a decreased	1 (50.0)	1 (50.0)	0
Blood uric acid increased	1 (50.0)	1 (50.0)	0
International normalised ratio increased	1 (50.0)	1 (50.0)	0
Lymphocyte count decreased	1 (50.0)	0	1 (50.0)
Neutrophil count decreased	1 (50.0)	0	1 (50.0)
White blood cell count decreased	1 (50.0)	0	1 (50.0)
Metabolism and nutrition disorders			
-Total	2 (100)	2 (100)	0
Hyperphosphataemia	1 (50.0)	1 (50.0)	0
Hyperuricaemia	1 (50.0)	1 (50.0)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vitamin d deficiency	1 (50.0)	1 (50.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (100)	2 (100)	0
Joint range of motion decreased	2 (100)	2 (100)	0
Arthralgia	1 (50.0)	1 (50.0)	0
Back pain	1 (50.0)	1 (50.0)	0
Muscle spasms	1 (50.0)	1 (50.0)	0
Myalgia	1 (50.0)	1 (50.0)	0
Pain in extremity	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	2 (100)	2 (100)	0
Headache	2 (100)	2 (100)	0
Reproductive system and breast disorders			
-Total	1 (50.0)	0	1 (50.0)
Scrotal pain	1 (50.0)	0	1 (50.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	1 (50.0)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	1 (50.0)	1 (50.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (50.0)	1 (50.0)	0
Macule	1 (50.0)	1 (50.0)	0
Rash maculo-papular	1 (50.0)	1 (50.0)	0
Skin irritation	1 (50.0)	1 (50.0)	0

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Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	62 (100)	2 (3.2)	60 (96.8)
Blood and lymphatic system disorders			
-Total	11 (17.7)	4 (6.5)	7 (11.3)
Anaemia	10 (16.1)	4 (6.5)	6 (9.7)
Lymphopenia	1 (1.6)	0	1 (1.6)
Cardiac disorders			
-Total	18 (29.0)	10 (16.1)	8 (12.9)
Tachycardia	14 (22.6)	8 (12.9)	6 (9.7)
Sinus tachycardia	5 (8.1)	3 (4.8)	2 (3.2)
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	37 (59.7)	14 (22.6)	23 (37.1)
Vomiting	25 (40.3)	16 (25.8)	9 (14.5)
Nausea	23 (37.1)	6 (9.7)	17 (27.4)
Diarrhoea	21 (33.9)	13 (21.0)	8 (12.9)
Abdominal pain	10 (16.1)	6 (9.7)	4 (6.5)
Constipation	7 (11.3)	6 (9.7)	1 (1.6)
General disorders and administration site conditions			
-Total	31 (50.0)	15 (24.2)	16 (25.8)
Pyrexia	21 (33.9)	8 (12.9)	13 (21.0)
Fatigue	14 (22.6)	11 (17.7)	3 (4.8)
Chills	9 (14.5)	8 (12.9)	1 (1.6)
Pain	1 (1.6)	0	1 (1.6)
Immune system disorders			
-Total	52 (83.9)	6 (9.7)	46 (74.2)
Cytokine release syndrome	45 (72.6)	7 (11.3)	38 (61.3)
Hypogammaglobulinaemia	26 (41.9)	3 (4.8)	23 (37.1)
Graft versus host disease	1 (1.6)	0	1 (1.6)
Infections and infestations			

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	13 (21.0)	3 (4.8)	10 (16.1)
Upper respiratory tract infection	8 (12.9)	4 (6.5)	4 (6.5)
Otitis media	3 (4.8)	0	3 (4.8)
Urinary tract infection	3 (4.8)	0	3 (4.8)
Injury, poisoning and procedural complications			
-Total	1 (1.6)	1 (1.6)	0
Skin abrasion	1 (1.6)	1 (1.6)	0
Investigations			
-Total	32 (51.6)	5 (8.1)	27 (43.5)
White blood cell count decreased	14 (22.6)	5 (8.1)	9 (14.5)
Aspartate aminotransferase increased	13 (21.0)	7 (11.3)	6 (9.7)
Alanine aminotransferase increased	11 (17.7)	5 (8.1)	6 (9.7)
Prothrombin time prolonged	9 (14.5)	5 (8.1)	4 (6.5)
Blood creatinine increased	7 (11.3)	5 (8.1)	2 (3.2)
International normalised ratio increased	7 (11.3)	7 (11.3)	0
Lymphocyte count decreased	6 (9.7)	2 (3.2)	4 (6.5)
Neutrophil count decreased	4 (6.5)	1 (1.6)	3 (4.8)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood immunoglobulin a decreased	2 (3.2)	2 (3.2)	0
Blood uric acid increased	1 (1.6)	1 (1.6)	0
Metabolism and nutrition disorders			
-Total	26 (41.9)	15 (24.2)	11 (17.7)
Decreased appetite	13 (21.0)	8 (12.9)	5 (8.1)
Hypokalaemia	11 (17.7)	4 (6.5)	7 (11.3)
Hyperphosphataemia	7 (11.3)	7 (11.3)	0
Hyperuricaemia	1 (1.6)	1 (1.6)	0
Vitamin d deficiency	1 (1.6)	1 (1.6)	0
Musculoskeletal and connective tissue disorders			
-Total	16 (25.8)	11 (17.7)	5 (8.1)
Pain in extremity	10 (16.1)	6 (9.7)	4 (6.5)
Arthralgia	4 (6.5)	3 (4.8)	1 (1.6)
Myalgia	4 (6.5)	3 (4.8)	1 (1.6)
Muscle spasms	1 (1.6)	1 (1.6)	0
Nervous system disorders			
-Total	22 (35.5)	13 (21.0)	9 (14.5)
Headache	22 (35.5)	13 (21.0)	9 (14.5)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	13 (21.0)	11 (17.7)	2 (3.2)
Cough	13 (21.0)	11 (17.7)	2 (3.2)
Skin and subcutaneous tissue disorders			
-Total	12 (19.4)	8 (12.9)	4 (6.5)
Rash	8 (12.9)	5 (8.1)	3 (4.8)
Rash maculo-papular	3 (4.8)	2 (3.2)	1 (1.6)
Macule	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	11 (17.7)	3 (4.8)	8 (12.9)
Hypertension	11 (17.7)	3 (4.8)	8 (12.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (100)	0	3 (100)
Cardiac disorders			
-Total	1 (33.3)	0	1 (33.3)
Bradycardia	1 (33.3)	0	1 (33.3)
Pericardial effusion	1 (33.3)	0	1 (33.3)
Eye disorders			
-Total	1 (33.3)	1 (33.3)	0
Conjunctival haemorrhage	1 (33.3)	1 (33.3)	0
Periorbital oedema	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	1 (33.3)	0	1 (33.3)
Nausea	1 (33.3)	0	1 (33.3)
Vomiting	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	2 (66.7)	0	2 (66.7)
Asthenia	1 (33.3)	1 (33.3)	0
Chills	1 (33.3)	1 (33.3)	0
Mucosal haemorrhage	1 (33.3)	0	1 (33.3)
Pyrexia	1 (33.3)	0	1 (33.3)
Hepatobiliary disorders			
-Total	1 (33.3)	0	1 (33.3)
Hepatomegaly	1 (33.3)	0	1 (33.3)
Immune system disorders			
-Total	2 (66.7)	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	2 (66.7)
Injury, poisoning and procedural complications			
-Total	2 (66.7)	1 (33.3)	1 (33.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Procedural complication	1 (33.3)	1 (33.3)	0
Tracheal haemorrhage	1 (33.3)	0	1 (33.3)
Investigations			
-Total	3 (100)	0	3 (100)
Aspartate aminotransferase increased	1 (33.3)	0	1 (33.3)
Blood fibrinogen decreased	1 (33.3)	0	1 (33.3)
Blood phosphorus decreased	1 (33.3)	1 (33.3)	0
International normalised ratio increased	1 (33.3)	1 (33.3)	0
Prothrombin time prolonged	1 (33.3)	0	1 (33.3)
White blood cell count decreased	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Hyperalbuminaemia	1 (33.3)	1 (33.3)	0
Hypercalcaemia	1 (33.3)	1 (33.3)	0
Hyperchloraemia	1 (33.3)	1 (33.3)	0
Hypermagnesaemia	1 (33.3)	1 (33.3)	0
Hypernatraemia	1 (33.3)	0	1 (33.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)
Hypokalaemia	1 (33.3)	1 (33.3)	0
Hypophosphataemia	1 (33.3)	1 (33.3)	0
Metabolic alkalosis	1 (33.3)	1 (33.3)	0
Nervous system disorders			
-Total	1 (33.3)	1 (33.3)	0
Dizziness	1 (33.3)	1 (33.3)	0
Psychiatric disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Confusional state	1 (33.3)	1 (33.3)	0
Delirium	1 (33.3)	0	1 (33.3)
Insomnia	1 (33.3)	0	1 (33.3)
Irritability	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (66.7)	0	2 (66.7)
Cough	1 (33.3)	1 (33.3)	0
Epistaxis	1 (33.3)	0	1 (33.3)
Pleural effusion	1 (33.3)	0	1 (33.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	1 (33.3)	1 (33.3)	0
Hyperhidrosis	1 (33.3)	1 (33.3)	0
Rash papular	1 (33.3)	1 (33.3)	0
Vascular disorders			
-Total	2 (66.7)	0	2 (66.7)
Hypertension	2 (66.7)	0	2 (66.7)
Flushing	1 (33.3)	1 (33.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	59 (96.7)	3 (4.9)	56 (91.8)
Blood and lymphatic system disorders			
-Total	11 (18.0)	4 (6.6)	7 (11.5)
Anaemia	11 (18.0)	4 (6.6)	7 (11.5)
Cardiac disorders			
-Total	14 (23.0)	8 (13.1)	6 (9.8)
Tachycardia	14 (23.0)	8 (13.1)	6 (9.8)
Pericardial effusion	1 (1.6)	1 (1.6)	0
Eye disorders			
-Total	3 (4.9)	2 (3.3)	1 (1.6)
Periorbital oedema	3 (4.9)	2 (3.3)	1 (1.6)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctival haemorrhage	2 (3.3)	2 (3.3)	0
Gastrointestinal disorders			
-Total	31 (50.8)	12 (19.7)	19 (31.1)
Nausea	19 (31.1)	6 (9.8)	13 (21.3)
Vomiting	19 (31.1)	13 (21.3)	6 (9.8)
Diarrhoea	16 (26.2)	11 (18.0)	5 (8.2)
Abdominal pain	8 (13.1)	6 (9.8)	2 (3.3)
Constipation	7 (11.5)	6 (9.8)	1 (1.6)
General disorders and administration site conditions			
-Total	25 (41.0)	13 (21.3)	12 (19.7)
Fatigue	13 (21.3)	10 (16.4)	3 (4.9)
Pyrexia	13 (21.3)	3 (4.9)	10 (16.4)
Chills	7 (11.5)	7 (11.5)	0
Hepatobiliary disorders			
-Total	2 (3.3)	1 (1.6)	1 (1.6)
Hepatomegaly	2 (3.3)	1 (1.6)	1 (1.6)
Immune system disorders			
-Total	50 (82.0)	6 (9.8)	44 (72.1)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cytokine release syndrome	43 (70.5)	7 (11.5)	36 (59.0)
Hypogammaglobulinaemia	21 (34.4)	3 (4.9)	18 (29.5)
Infections and infestations			
-Total	1 (1.6)	0	1 (1.6)
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)
Investigations			
-Total	27 (44.3)	7 (11.5)	20 (32.8)
Aspartate aminotransferase increased	11 (18.0)	6 (9.8)	5 (8.2)
Alanine aminotransferase increased	10 (16.4)	5 (8.2)	5 (8.2)
White blood cell count decreased	10 (16.4)	3 (4.9)	7 (11.5)
Prothrombin time prolonged	8 (13.1)	5 (8.2)	3 (4.9)
Blood creatinine increased	7 (11.5)	5 (8.2)	2 (3.3)
International normalised ratio increased	7 (11.5)	7 (11.5)	0
Lymphocyte count decreased	4 (6.6)	1 (1.6)	3 (4.9)
Blood fibrinogen decreased	2 (3.3)	0	2 (3.3)
Blood urea increased	2 (3.3)	1 (1.6)	1 (1.6)
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	28 (45.9)	13 (21.3)	15 (24.6)
Decreased appetite	11 (18.0)	7 (11.5)	4 (6.6)
Hypokalaemia	9 (14.8)	2 (3.3)	7 (11.5)
Hyperphosphataemia	8 (13.1)	8 (13.1)	0
Hypoalbuminaemia	4 (6.6)	1 (1.6)	3 (4.9)
Hypernatraemia	3 (4.9)	1 (1.6)	2 (3.3)
Hypophosphataemia	2 (3.3)	2 (3.3)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (6.6)	2 (3.3)	2 (3.3)
Pain in extremity	4 (6.6)	2 (3.3)	2 (3.3)
Nervous system disorders			
-Total	25 (41.0)	17 (27.9)	8 (13.1)
Headache	24 (39.3)	16 (26.2)	8 (13.1)
Dizziness	3 (4.9)	3 (4.9)	0
Psychiatric disorders			
-Total	8 (13.1)	4 (6.6)	4 (6.6)
Confusional state	5 (8.2)	2 (3.3)	3 (4.9)
Delirium	3 (4.9)	2 (3.3)	1 (1.6)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Irritability	1 (1.6)	1 (1.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	13 (21.3)	9 (14.8)	4 (6.6)
Cough	7 (11.5)	7 (11.5)	0
Pleural effusion	5 (8.2)	2 (3.3)	3 (4.9)
Epistaxis	3 (4.9)	2 (3.3)	1 (1.6)
Skin and subcutaneous tissue disorders			
-Total	7 (11.5)	7 (11.5)	0
Rash	4 (6.6)	4 (6.6)	0
Hyperhidrosis	2 (3.3)	2 (3.3)	0
Rash papular	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	8 (13.1)	3 (4.9)	5 (8.2)
Hypertension	7 (11.5)	2 (3.3)	5 (8.2)
Flushing	1 (1.6)	1 (1.6)	0

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AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	1 (50.0)	0
Investigations			
-Total	1 (50.0)	1 (50.0)	0
Blood urea increased	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	1 (50.0)	1 (50.0)	0
Hyperalbuminaemia	1 (50.0)	1 (50.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypercalcaemia	1 (50.0)	1 (50.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (50.0)	1 (50.0)	0
Papule	1 (50.0)	1 (50.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 225g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	31 (57.4)	11 (20.4)	20 (37.0)
Blood and lymphatic system disorders			
-Total	1 (1.9)	1 (1.9)	0
Anaemia	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	13 (24.1)	8 (14.8)	5 (9.3)
Vomiting	8 (14.8)	5 (9.3)	3 (5.6)
Diarrhoea	7 (13.0)	6 (11.1)	1 (1.9)
Nausea	4 (7.4)	1 (1.9)	3 (5.6)
Abdominal pain	3 (5.6)	2 (3.7)	1 (1.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	10 (18.5)	8 (14.8)	2 (3.7)
Pyrexia	9 (16.7)	7 (13.0)	2 (3.7)
Fatigue	2 (3.7)	2 (3.7)	0
Chills	1 (1.9)	1 (1.9)	0
Immune system disorders			
-Total	7 (13.0)	0	7 (13.0)
Hypogammaglobulinaemia	7 (13.0)	0	7 (13.0)
Infections and infestations			
-Total	5 (9.3)	2 (3.7)	3 (5.6)
Upper respiratory tract infection	5 (9.3)	2 (3.7)	3 (5.6)
Investigations			
-Total	7 (13.0)	4 (7.4)	3 (5.6)
White blood cell count decreased	4 (7.4)	2 (3.7)	2 (3.7)
Lymphocyte count decreased	2 (3.7)	1 (1.9)	1 (1.9)
Aspartate aminotransferase increased	1 (1.9)	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	5 (9.3)	4 (7.4)	1 (1.9)
Decreased appetite	2 (3.7)	1 (1.9)	1 (1.9)
Hyperphosphataemia	2 (3.7)	2 (3.7)	0
Hypokalaemia	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			
-Total	8 (14.8)	6 (11.1)	2 (3.7)
Pain in extremity	8 (14.8)	6 (11.1)	2 (3.7)
Nervous system disorders			
-Total	6 (11.1)	5 (9.3)	1 (1.9)
Headache	5 (9.3)	4 (7.4)	1 (1.9)
Dizziness	3 (5.6)	3 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	8 (14.8)	6 (11.1)	2 (3.7)
Cough	7 (13.0)	5 (9.3)	2 (3.7)
Epistaxis	1 (1.9)	1 (1.9)	0
Skin and subcutaneous tissue disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	5 (9.3)	2 (3.7)	3 (5.6)
Rash	4 (7.4)	1 (1.9)	3 (5.6)
Hyperhidrosis	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	2 (3.7)	1 (1.9)	1 (1.9)
Hypertension	2 (3.7)	1 (1.9)	1 (1.9)

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Table 225g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (30.3)	4 (12.1)	6 (18.2)
Gastrointestinal disorders			
-Total	3 (9.1)	0	3 (9.1)
Diarrhoea	2 (6.1)	0	2 (6.1)
Abdominal pain	1 (3.0)	0	1 (3.0)
Nausea	1 (3.0)	0	1 (3.0)
General disorders and administration site conditions			
-Total	1 (3.0)	0	1 (3.0)
Chills	1 (3.0)	0	1 (3.0)
Pyrexia	1 (3.0)	0	1 (3.0)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)
Investigations			
-Total	5 (15.2)	3 (9.1)	2 (6.1)
Lymphocyte count decreased	3 (9.1)	2 (6.1)	1 (3.0)
Alanine aminotransferase increased	1 (3.0)	0	1 (3.0)
Aspartate aminotransferase increased	1 (3.0)	1 (3.0)	0
White blood cell count decreased	1 (3.0)	1 (3.0)	0
Nervous system disorders			
-Total	1 (3.0)	0	1 (3.0)
Dizziness	1 (3.0)	1 (3.0)	0
Headache	1 (3.0)	0	1 (3.0)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (9.1)	3 (9.1)	0
Cough	2 (6.1)	2 (6.1)	0
Epistaxis	1 (3.0)	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	1 (3.0)	1 (3.0)	0
Papule	1 (3.0)	1 (3.0)	0

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Table 225g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (100)	0	3 (100)
Cardiac disorders			
-Total	1 (33.3)	0	1 (33.3)
Bradycardia	1 (33.3)	0	1 (33.3)
Pericardial effusion	1 (33.3)	0	1 (33.3)
Eye disorders			
-Total	1 (33.3)	1 (33.3)	0
Conjunctival haemorrhage	1 (33.3)	1 (33.3)	0
Periorbital oedema	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (33.3)	0	1 (33.3)
Diarrhoea	1 (33.3)	0	1 (33.3)
Nausea	1 (33.3)	0	1 (33.3)
Vomiting	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	2 (66.7)	0	2 (66.7)
Asthenia	1 (33.3)	1 (33.3)	0
Chills	1 (33.3)	1 (33.3)	0
Mucosal haemorrhage	1 (33.3)	0	1 (33.3)
Pyrexia	1 (33.3)	0	1 (33.3)
Hepatobiliary disorders			
-Total	1 (33.3)	0	1 (33.3)
Hepatomegaly	1 (33.3)	0	1 (33.3)
Immune system disorders			
-Total	2 (66.7)	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	2 (66.7)
Infections and infestations			
-Total	1 (33.3)	1 (33.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	1 (33.3)	1 (33.3)	0
Injury, poisoning and procedural complications			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Procedural complication	1 (33.3)	1 (33.3)	0
Tracheal haemorrhage	1 (33.3)	0	1 (33.3)
Investigations			
-Total	3 (100)	0	3 (100)
Aspartate aminotransferase increased	1 (33.3)	0	1 (33.3)
Blood fibrinogen decreased	1 (33.3)	0	1 (33.3)
Blood phosphorus decreased	1 (33.3)	1 (33.3)	0
Blood urea increased	1 (33.3)	1 (33.3)	0
International normalised ratio increased	1 (33.3)	1 (33.3)	0
Prothrombin time prolonged	1 (33.3)	0	1 (33.3)
White blood cell count decreased	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Hyperalbuminaemia	1 (33.3)	1 (33.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypercalcaemia	1 (33.3)	1 (33.3)	0
Hyperchloraemia	1 (33.3)	1 (33.3)	0
Hypermagnesaemia	1 (33.3)	1 (33.3)	0
Hypernatraemia	1 (33.3)	0	1 (33.3)
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)
Hypokalaemia	1 (33.3)	1 (33.3)	0
Hypophosphataemia	1 (33.3)	1 (33.3)	0
Metabolic alkalosis	1 (33.3)	1 (33.3)	0
Nervous system disorders			
-Total	1 (33.3)	1 (33.3)	0
Dizziness	1 (33.3)	1 (33.3)	0
Psychiatric disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Confusional state	1 (33.3)	1 (33.3)	0
Delirium	1 (33.3)	0	1 (33.3)
Insomnia	1 (33.3)	0	1 (33.3)
Irritability	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (66.7)	0	2 (66.7)
Cough	1 (33.3)	1 (33.3)	0
Epistaxis	1 (33.3)	0	1 (33.3)
Pleural effusion	1 (33.3)	0	1 (33.3)
Skin and subcutaneous tissue disorders			
-Total	1 (33.3)	1 (33.3)	0
Hyperhidrosis	1 (33.3)	1 (33.3)	0
Papule	1 (33.3)	1 (33.3)	0
Rash papular	1 (33.3)	1 (33.3)	0
Vascular disorders			
-Total	2 (66.7)	0	2 (66.7)
Hypertension	2 (66.7)	0	2 (66.7)
Flushing	1 (33.3)	1 (33.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of

adverse events.

Table 225g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	60 (98.4)	3 (4.9)	57 (93.4)
Blood and lymphatic system disorders			
-Total	11 (18.0)	4 (6.6)	7 (11.5)
Anaemia	11 (18.0)	4 (6.6)	7 (11.5)
Cardiac disorders			
-Total	14 (23.0)	8 (13.1)	6 (9.8)
Tachycardia	14 (23.0)	8 (13.1)	6 (9.8)
Pericardial effusion	1 (1.6)	1 (1.6)	0
Eye disorders			
-Total	3 (4.9)	2 (3.3)	1 (1.6)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Periorbital oedema	3 (4.9)	2 (3.3)	1 (1.6)
Conjunctival haemorrhage	2 (3.3)	2 (3.3)	0
Gastrointestinal disorders			
-Total	37 (60.7)	14 (23.0)	23 (37.7)
Vomiting	24 (39.3)	16 (26.2)	8 (13.1)
Nausea	22 (36.1)	6 (9.8)	16 (26.2)
Diarrhoea	21 (34.4)	13 (21.3)	8 (13.1)
Abdominal pain	10 (16.4)	6 (9.8)	4 (6.6)
Constipation	7 (11.5)	6 (9.8)	1 (1.6)
General disorders and administration site conditions			
-Total	32 (52.5)	17 (27.9)	15 (24.6)
Pyrexia	21 (34.4)	8 (13.1)	13 (21.3)
Fatigue	15 (24.6)	12 (19.7)	3 (4.9)
Chills	9 (14.8)	8 (13.1)	1 (1.6)
Hepatobiliary disorders			
-Total	2 (3.3)	1 (1.6)	1 (1.6)
Hepatomegaly	2 (3.3)	1 (1.6)	1 (1.6)
Immune system disorders			

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	51 (83.6)	6 (9.8)	45 (73.8)
Cytokine release syndrome	43 (70.5)	7 (11.5)	36 (59.0)
Hypogammaglobulinaemia	27 (44.3)	3 (4.9)	24 (39.3)
Infections and infestations			
-Total	7 (11.5)	3 (4.9)	4 (6.6)
Upper respiratory tract infection	7 (11.5)	3 (4.9)	4 (6.6)
Investigations			
-Total	29 (47.5)	5 (8.2)	24 (39.3)
White blood cell count decreased	14 (23.0)	5 (8.2)	9 (14.8)
Aspartate aminotransferase increased	12 (19.7)	7 (11.5)	5 (8.2)
Alanine aminotransferase increased	11 (18.0)	5 (8.2)	6 (9.8)
Prothrombin time prolonged	8 (13.1)	5 (8.2)	3 (4.9)
Blood creatinine increased	7 (11.5)	5 (8.2)	2 (3.3)
International normalised ratio increased	7 (11.5)	7 (11.5)	0
Lymphocyte count decreased	7 (11.5)	2 (3.3)	5 (8.2)
Blood fibrinogen decreased	2 (3.3)	0	2 (3.3)
Blood urea increased	2 (3.3)	1 (1.6)	1 (1.6)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	29 (47.5)	14 (23.0)	15 (24.6)
Decreased appetite	13 (21.3)	8 (13.1)	5 (8.2)
Hypokalaemia	10 (16.4)	3 (4.9)	7 (11.5)
Hyperphosphataemia	8 (13.1)	8 (13.1)	0
Hypoalbuminaemia	4 (6.6)	1 (1.6)	3 (4.9)
Hypernatraemia	3 (4.9)	1 (1.6)	2 (3.3)
Hypophosphataemia	2 (3.3)	2 (3.3)	0
Musculoskeletal and connective tissue disorders			
-Total	11 (18.0)	7 (11.5)	4 (6.6)
Pain in extremity	11 (18.0)	7 (11.5)	4 (6.6)
Nervous system disorders			
-Total	26 (42.6)	17 (27.9)	9 (14.8)
Headache	24 (39.3)	15 (24.6)	9 (14.8)
Dizziness	5 (8.2)	5 (8.2)	0
Psychiatric disorders			
-Total	8 (13.1)	4 (6.6)	4 (6.6)
Confusional state	5 (8.2)	2 (3.3)	3 (4.9)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Delirium	3 (4.9)	2 (3.3)	1 (1.6)
Irritability	1 (1.6)	1 (1.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	20 (32.8)	14 (23.0)	6 (9.8)
Cough	13 (21.3)	11 (18.0)	2 (3.3)
Epistaxis	5 (8.2)	4 (6.6)	1 (1.6)
Pleural effusion	5 (8.2)	2 (3.3)	3 (4.9)
Skin and subcutaneous tissue disorders			
-Total	12 (19.7)	9 (14.8)	3 (4.9)
Rash	8 (13.1)	5 (8.2)	3 (4.9)
Hyperhidrosis	3 (4.9)	3 (4.9)	0
Papule	1 (1.6)	1 (1.6)	0
Rash papular	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	10 (16.4)	4 (6.6)	6 (9.8)
Hypertension	9 (14.8)	3 (4.9)	6 (9.8)
Flushing	1 (1.6)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Gastrointestinal disorders			
-Total	1 (100)	0	1 (100)
Haematemesis	1 (100)	1 (100)	0
Nausea	1 (100)	0	1 (100)
Vomiting	1 (100)	0	1 (100)
Immune system disorders			
-Total	1 (100)	0	1 (100)
Cytokine release syndrome	1 (100)	0	1 (100)
Investigations			
-Total	1 (100)	0	1 (100)

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Activated partial thromboplastin time prolonged	1 (100)	0	1 (100)
Aspartate aminotransferase increased	1 (100)	0	1 (100)
Blood phosphorus increased	1 (100)	1 (100)	0
International normalised ratio increased	1 (100)	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0
Nervous system disorders			
-Total	1 (100)	0	1 (100)
Encephalopathy	1 (100)	0	1 (100)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

		All patients N=63	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	61 (96.8)	3 (4.8)	58 (92.1)
Blood and lymphatic system disorders			
-Total	11 (17.5)	4 (6.3)	7 (11.1)
Anaemia	11 (17.5)	4 (6.3)	7 (11.1)
Cardiac disorders			
-Total	14 (22.2)	8 (12.7)	6 (9.5)
Tachycardia	14 (22.2)	8 (12.7)	6 (9.5)
Gastrointestinal disorders			
-Total	31 (49.2)	12 (19.0)	19 (30.2)
Nausea	19 (30.2)	6 (9.5)	13 (20.6)
Vomiting	19 (30.2)	13 (20.6)	6 (9.5)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	17 (27.0)	11 (17.5)	6 (9.5)
Abdominal pain	8 (12.7)	6 (9.5)	2 (3.2)
Constipation	7 (11.1)	6 (9.5)	1 (1.6)
Haematemesis	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	26 (41.3)	13 (20.6)	13 (20.6)
Pyrexia	14 (22.2)	3 (4.8)	11 (17.5)
Fatigue	13 (20.6)	10 (15.9)	3 (4.8)
Chills	8 (12.7)	8 (12.7)	0
Immune system disorders			
-Total	51 (81.0)	6 (9.5)	45 (71.4)
Cytokine release syndrome	44 (69.8)	7 (11.1)	37 (58.7)
Hypogammaglobulinaemia	21 (33.3)	3 (4.8)	18 (28.6)
Infections and infestations			
-Total	1 (1.6)	0	1 (1.6)
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)
Investigations			
-Total	30 (47.6)	7 (11.1)	23 (36.5)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	11 (17.5)	6 (9.5)	5 (7.9)
Alanine aminotransferase increased	10 (15.9)	5 (7.9)	5 (7.9)
White blood cell count decreased	10 (15.9)	2 (3.2)	8 (12.7)
Prothrombin time prolonged	9 (14.3)	5 (7.9)	4 (6.3)
Blood creatinine increased	7 (11.1)	5 (7.9)	2 (3.2)
International normalised ratio increased	7 (11.1)	7 (11.1)	0
Activated partial thromboplastin time prolonged	4 (6.3)	3 (4.8)	1 (1.6)
Lymphocyte count decreased	4 (6.3)	1 (1.6)	3 (4.8)
Blood phosphorus increased	1 (1.6)	1 (1.6)	0
Metabolism and nutrition disorders			
-Total	25 (39.7)	14 (22.2)	11 (17.5)
Decreased appetite	11 (17.5)	7 (11.1)	4 (6.3)
Hypokalaemia	10 (15.9)	3 (4.8)	7 (11.1)
Hyperphosphataemia	8 (12.7)	8 (12.7)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (6.3)	2 (3.2)	2 (3.2)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	4 (6.3)	2 (3.2)	2 (3.2)
Nervous system disorders			
-Total	26 (41.3)	17 (27.0)	9 (14.3)
Headache	24 (38.1)	16 (25.4)	8 (12.7)
Encephalopathy	2 (3.2)	1 (1.6)	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (12.7)	8 (12.7)	0
Cough	8 (12.7)	8 (12.7)	0
Skin and subcutaneous tissue disorders			
-Total	4 (6.3)	4 (6.3)	0
Rash	4 (6.3)	4 (6.3)	0
Vascular disorders			
-Total	9 (14.3)	2 (3.2)	7 (11.1)
Hypertension	9 (14.3)	2 (3.2)	7 (11.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group

term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	31 (56.4)	11 (20.0)	20 (36.4)
Blood and lymphatic system disorders			
-Total	1 (1.8)	1 (1.8)	0
Anaemia	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	13 (23.6)	8 (14.5)	5 (9.1)
Vomiting	8 (14.5)	5 (9.1)	3 (5.5)
Diarrhoea	7 (12.7)	6 (10.9)	1 (1.8)
Nausea	4 (7.3)	1 (1.8)	3 (5.5)
Abdominal pain	3 (5.5)	2 (3.6)	1 (1.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	10 (18.2)	8 (14.5)	2 (3.6)
Pyrexia	9 (16.4)	7 (12.7)	2 (3.6)
Fatigue	2 (3.6)	2 (3.6)	0
Chills	1 (1.8)	1 (1.8)	0
Immune system disorders			
-Total	7 (12.7)	0	7 (12.7)
Hypogammaglobulinaemia	7 (12.7)	0	7 (12.7)
Infections and infestations			
-Total	6 (10.9)	3 (5.5)	3 (5.5)
Upper respiratory tract infection	6 (10.9)	3 (5.5)	3 (5.5)
Investigations			
-Total	7 (12.7)	4 (7.3)	3 (5.5)
White blood cell count decreased	4 (7.3)	2 (3.6)	2 (3.6)
Lymphocyte count decreased	2 (3.6)	1 (1.8)	1 (1.8)
Aspartate aminotransferase increased	1 (1.8)	1 (1.8)	0
Blood creatinine increased	1 (1.8)	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	5 (9.1)	4 (7.3)	1 (1.8)
Decreased appetite	2 (3.6)	1 (1.8)	1 (1.8)
Hyperphosphataemia	2 (3.6)	2 (3.6)	0
Hypokalaemia	1 (1.8)	1 (1.8)	0
Musculoskeletal and connective tissue disorders			
-Total	8 (14.5)	6 (10.9)	2 (3.6)
Pain in extremity	8 (14.5)	6 (10.9)	2 (3.6)
Nervous system disorders			
-Total	5 (9.1)	4 (7.3)	1 (1.8)
Headache	5 (9.1)	4 (7.3)	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (12.7)	5 (9.1)	2 (3.6)
Cough	7 (12.7)	5 (9.1)	2 (3.6)
Skin and subcutaneous tissue disorders			
-Total	4 (7.3)	1 (1.8)	3 (5.5)
Rash	4 (7.3)	1 (1.8)	3 (5.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	2 (3.6)	1 (1.8)	1 (1.8)
Hypertension	2 (3.6)	1 (1.8)	1 (1.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (24.2)	2 (6.1)	6 (18.2)
Gastrointestinal disorders			
-Total	3 (9.1)	0	3 (9.1)
Diarrhoea	2 (6.1)	0	2 (6.1)
Abdominal pain	1 (3.0)	0	1 (3.0)
Nausea	1 (3.0)	0	1 (3.0)
General disorders and administration site conditions			
-Total	1 (3.0)	0	1 (3.0)
Chills	1 (3.0)	0	1 (3.0)
Pyrexia	1 (3.0)	0	1 (3.0)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)
Investigations			
-Total	5 (15.2)	3 (9.1)	2 (6.1)
Lymphocyte count decreased	3 (9.1)	2 (6.1)	1 (3.0)
Alanine aminotransferase increased	1 (3.0)	0	1 (3.0)
Aspartate aminotransferase increased	1 (3.0)	1 (3.0)	0
White blood cell count decreased	1 (3.0)	1 (3.0)	0
Nervous system disorders			
-Total	1 (3.0)	0	1 (3.0)
Headache	1 (3.0)	0	1 (3.0)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.1)	2 (6.1)	0
Cough	2 (6.1)	2 (6.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the

AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Gastrointestinal disorders			
-Total	1 (100)	0	1 (100)
Haematemesis	1 (100)	1 (100)	0
Nausea	1 (100)	0	1 (100)
Vomiting	1 (100)	0	1 (100)
Immune system disorders			
-Total	1 (100)	0	1 (100)
Cytokine release syndrome	1 (100)	0	1 (100)
Investigations			

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (100)	0	1 (100)
Activated partial thromboplastin time prolonged	1 (100)	0	1 (100)
Aspartate aminotransferase increased	1 (100)	0	1 (100)
Blood phosphorus increased	1 (100)	1 (100)	0
International normalised ratio increased	1 (100)	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0
Nervous system disorders			
-Total	1 (100)	0	1 (100)
Encephalopathy	1 (100)	0	1 (100)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 225h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	62 (98.4)	3 (4.8)	59 (93.7)
Blood and lymphatic system disorders			
-Total	11 (17.5)	4 (6.3)	7 (11.1)
Anaemia	11 (17.5)	4 (6.3)	7 (11.1)
Cardiac disorders			
-Total	14 (22.2)	8 (12.7)	6 (9.5)
Tachycardia	14 (22.2)	8 (12.7)	6 (9.5)
Gastrointestinal disorders			
-Total	37 (58.7)	14 (22.2)	23 (36.5)
Vomiting	24 (38.1)	16 (25.4)	8 (12.7)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	22 (34.9)	13 (20.6)	9 (14.3)
Nausea	22 (34.9)	6 (9.5)	16 (25.4)
Abdominal pain	10 (15.9)	6 (9.5)	4 (6.3)
Constipation	7 (11.1)	6 (9.5)	1 (1.6)
Haematemesis	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	33 (52.4)	17 (27.0)	16 (25.4)
Pyrexia	22 (34.9)	8 (12.7)	14 (22.2)
Fatigue	15 (23.8)	12 (19.0)	3 (4.8)
Chills	10 (15.9)	9 (14.3)	1 (1.6)
Immune system disorders			
-Total	52 (82.5)	6 (9.5)	46 (73.0)
Cytokine release syndrome	44 (69.8)	7 (11.1)	37 (58.7)
Hypogammaglobulinaemia	27 (42.9)	3 (4.8)	24 (38.1)
Infections and infestations			
-Total	8 (12.7)	4 (6.3)	4 (6.3)
Upper respiratory tract infection	8 (12.7)	4 (6.3)	4 (6.3)
Investigations			

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	32 (50.8)	5 (7.9)	27 (42.9)
White blood cell count decreased	14 (22.2)	4 (6.3)	10 (15.9)
Aspartate aminotransferase increased	12 (19.0)	7 (11.1)	5 (7.9)
Alanine aminotransferase increased	11 (17.5)	5 (7.9)	6 (9.5)
Prothrombin time prolonged	9 (14.3)	5 (7.9)	4 (6.3)
Blood creatinine increased	7 (11.1)	5 (7.9)	2 (3.2)
International normalised ratio increased	7 (11.1)	7 (11.1)	0
Lymphocyte count decreased	7 (11.1)	2 (3.2)	5 (7.9)
Activated partial thromboplastin time prolonged	4 (6.3)	3 (4.8)	1 (1.6)
Blood phosphorus increased	1 (1.6)	1 (1.6)	0
Metabolism and nutrition disorders			
-Total	26 (41.3)	15 (23.8)	11 (17.5)
Decreased appetite	13 (20.6)	8 (12.7)	5 (7.9)
Hypokalaemia	11 (17.5)	4 (6.3)	7 (11.1)
Hyperphosphataemia	8 (12.7)	8 (12.7)	0
Musculoskeletal and connective tissue disorders			

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (17.5)	7 (11.1)	4 (6.3)
Pain in extremity	11 (17.5)	7 (11.1)	4 (6.3)
Nervous system disorders			
-Total	26 (41.3)	16 (25.4)	10 (15.9)
Headache	24 (38.1)	15 (23.8)	9 (14.3)
Encephalopathy	2 (3.2)	1 (1.6)	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (22.2)	12 (19.0)	2 (3.2)
Cough	14 (22.2)	12 (19.0)	2 (3.2)
Skin and subcutaneous tissue disorders			
-Total	8 (12.7)	5 (7.9)	3 (4.8)
Rash	8 (12.7)	5 (7.9)	3 (4.8)
Vascular disorders			
-Total	11 (17.5)	3 (4.8)	8 (12.7)
Hypertension	11 (17.5)	3 (4.8)	8 (12.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the

AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	0	4 (100)
Blood and lymphatic system disorders			
-Total	2 (50.0)	0	2 (50.0)
Anaemia	2 (50.0)	0	2 (50.0)
Cardiac disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Cardiac dysfunction	1 (25.0)	1 (25.0)	0
Sinus tachycardia	1 (25.0)	0	1 (25.0)
Tachycardia	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	3 (75.0)	1 (25.0)	2 (50.0)

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	3 (75.0)	2 (50.0)	1 (25.0)
Abdominal pain	2 (50.0)	2 (50.0)	0
Nausea	2 (50.0)	1 (25.0)	1 (25.0)
Abdominal distension	1 (25.0)	0	1 (25.0)
Abdominal tenderness	1 (25.0)	1 (25.0)	0
Constipation	1 (25.0)	1 (25.0)	0
Gastrooesophageal reflux disease	1 (25.0)	1 (25.0)	0
Vomiting	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Fatigue	3 (75.0)	3 (75.0)	0
Pain	1 (25.0)	0	1 (25.0)
Immune system disorders			
-Total	4 (100)	0	4 (100)
Hypogammaglobulinaemia	4 (100)	0	4 (100)
Cytokine release syndrome	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	2 (50.0)	0	2 (50.0)

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Clostridium difficile infection	1 (25.0)	0	1 (25.0)
Pharyngitis	1 (25.0)	0	1 (25.0)
Streptococcal infection	1 (25.0)	0	1 (25.0)
Injury, poisoning and procedural complications			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Contusion	1 (25.0)	1 (25.0)	0
Infusion related reaction	1 (25.0)	0	1 (25.0)
Procedural pain	1 (25.0)	0	1 (25.0)
Procedural site reaction	1 (25.0)	1 (25.0)	0
Investigations			
-Total	3 (75.0)	0	3 (75.0)
International normalised ratio increased	2 (50.0)	2 (50.0)	0
Activated partial thromboplastin time prolonged	1 (25.0)	1 (25.0)	0
Blood bilirubin increased	1 (25.0)	0	1 (25.0)
Blood creatinine increased	1 (25.0)	1 (25.0)	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0
Lymphocyte count decreased	1 (25.0)	0	1 (25.0)

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Neutrophil count decreased	1 (25.0)	0	1 (25.0)
Platelet count decreased	1 (25.0)	0	1 (25.0)
Pulmonary function test decreased	1 (25.0)	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Hyperphosphataemia	2 (50.0)	2 (50.0)	0
Decreased appetite	1 (25.0)	1 (25.0)	0
Hyperuricaemia	1 (25.0)	1 (25.0)	0
Hypokalaemia	1 (25.0)	0	1 (25.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Arthralgia	2 (50.0)	2 (50.0)	0
Musculoskeletal chest pain	1 (25.0)	1 (25.0)	0
Musculoskeletal pain	1 (25.0)	0	1 (25.0)
Myalgia	1 (25.0)	1 (25.0)	0
Pain in extremity	1 (25.0)	1 (25.0)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (25.0)	0	1 (25.0)
Skin papilloma	1 (25.0)	0	1 (25.0)
Nervous system disorders			
-Total	3 (75.0)	3 (75.0)	0
Headache	3 (75.0)	3 (75.0)	0
Dizziness	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Rhinorrhoea	1 (25.0)	1 (25.0)	0
Tachypnoea	1 (25.0)	1 (25.0)	0
Wheezing	1 (25.0)	0	1 (25.0)
Skin and subcutaneous tissue disorders			
-Total	2 (50.0)	2 (50.0)	0
Petechiae	1 (25.0)	1 (25.0)	0
Rash follicular	1 (25.0)	1 (25.0)	0
Rash papular	1 (25.0)	1 (25.0)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

		All patients N=60	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	58 (96.7)	3 (5.0)	55 (91.7)
Blood and lymphatic system disorders			
-Total	10 (16.7)	4 (6.7)	6 (10.0)
Anaemia	9 (15.0)	4 (6.7)	5 (8.3)
Lymphopenia	1 (1.7)	0	1 (1.7)
Cardiac disorders			
-Total	16 (26.7)	9 (15.0)	7 (11.7)
Tachycardia	13 (21.7)	7 (11.7)	6 (10.0)
Sinus tachycardia	4 (6.7)	3 (5.0)	1 (1.7)
Gastrointestinal disorders			
-Total	29 (48.3)	11 (18.3)	18 (30.0)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	19 (31.7)	12 (20.0)	7 (11.7)
Nausea	18 (30.0)	5 (8.3)	13 (21.7)
Diarrhoea	14 (23.3)	9 (15.0)	5 (8.3)
Abdominal pain	6 (10.0)	4 (6.7)	2 (3.3)
Constipation	6 (10.0)	5 (8.3)	1 (1.7)
Abdominal distension	1 (1.7)	0	1 (1.7)
General disorders and administration site conditions			
-Total	23 (38.3)	10 (16.7)	13 (21.7)
Pyrexia	14 (23.3)	3 (5.0)	11 (18.3)
Fatigue	10 (16.7)	7 (11.7)	3 (5.0)
Chills	8 (13.3)	8 (13.3)	0
Immune system disorders			
-Total	48 (80.0)	6 (10.0)	42 (70.0)
Cytokine release syndrome	44 (73.3)	7 (11.7)	37 (61.7)
Hypogammaglobulinaemia	17 (28.3)	3 (5.0)	14 (23.3)
Infections and infestations			
-Total	5 (8.3)	0	5 (8.3)
Clostridium difficile infection	3 (5.0)	0	3 (5.0)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0
Upper respiratory tract infection	1 (1.7)	0	1 (1.7)
Viral infection	1 (1.7)	0	1 (1.7)
Injury, poisoning and procedural complications			
-Total	3 (5.0)	1 (1.7)	2 (3.3)
Procedural pain	2 (3.3)	1 (1.7)	1 (1.7)
Infusion related reaction	1 (1.7)	0	1 (1.7)
Investigations			
-Total	29 (48.3)	4 (6.7)	25 (41.7)
Aspartate aminotransferase increased	12 (20.0)	6 (10.0)	6 (10.0)
Alanine aminotransferase increased	10 (16.7)	5 (8.3)	5 (8.3)
White blood cell count decreased	10 (16.7)	3 (5.0)	7 (11.7)
Prothrombin time prolonged	9 (15.0)	5 (8.3)	4 (6.7)
Blood creatinine increased	6 (10.0)	4 (6.7)	2 (3.3)
International normalised ratio increased	6 (10.0)	6 (10.0)	0
Blood bilirubin increased	5 (8.3)	2 (3.3)	3 (5.0)
Platelet count decreased	5 (8.3)	3 (5.0)	2 (3.3)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Activated partial thromboplastin time prolonged	4 (6.7)	2 (3.3)	2 (3.3)
Lymphocyte count decreased	3 (5.0)	1 (1.7)	2 (3.3)
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0
Blood uric acid increased	1 (1.7)	1 (1.7)	0
Neutrophil count decreased	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	22 (36.7)	12 (20.0)	10 (16.7)
Decreased appetite	10 (16.7)	6 (10.0)	4 (6.7)
Hypokalaemia	9 (15.0)	3 (5.0)	6 (10.0)
Hyperphosphataemia	6 (10.0)	6 (10.0)	0
Hyperuricaemia	1 (1.7)	1 (1.7)	0
Musculoskeletal and connective tissue disorders			
-Total	10 (16.7)	7 (11.7)	3 (5.0)
Myalgia	4 (6.7)	3 (5.0)	1 (1.7)
Pain in extremity	3 (5.0)	1 (1.7)	2 (3.3)
Musculoskeletal pain	2 (3.3)	2 (3.3)	0
Arthralgia	1 (1.7)	1 (1.7)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nervous system disorders			
-Total	23 (38.3)	15 (25.0)	8 (13.3)
Headache	21 (35.0)	13 (21.7)	8 (13.3)
Dizziness	3 (5.0)	3 (5.0)	0
Psychiatric disorders			
-Total	10 (16.7)	5 (8.3)	5 (8.3)
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)
Anxiety	5 (8.3)	2 (3.3)	3 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	19 (31.7)	12 (20.0)	7 (11.7)
Cough	8 (13.3)	8 (13.3)	0
Pleural effusion	6 (10.0)	2 (3.3)	4 (6.7)
Epistaxis	4 (6.7)	2 (3.3)	2 (3.3)
Tachypnoea	3 (5.0)	2 (3.3)	1 (1.7)
Oropharyngeal pain	2 (3.3)	1 (1.7)	1 (1.7)
Skin and subcutaneous tissue disorders			
-Total	6 (10.0)	5 (8.3)	1 (1.7)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash	4 (6.7)	4 (6.7)	0
Petechiae	2 (3.3)	1 (1.7)	1 (1.7)
Rash papular	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	9 (15.0)	2 (3.3)	7 (11.7)
Hypertension	9 (15.0)	2 (3.3)	7 (11.7)

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Table 225i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=4	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	0	4 (100)
Blood and lymphatic system disorders			
-Total	1 (25.0)	0	1 (25.0)
Lymphopenia	1 (25.0)	0	1 (25.0)
Eye disorders			
-Total	1 (25.0)	0	1 (25.0)
Dry eye	1 (25.0)	0	1 (25.0)
Gastrointestinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Vomiting	1 (25.0)	0	1 (25.0)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	1 (25.0)	1 (25.0)	0
Fatigue	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Cytomegalovirus infection	1 (25.0)	1 (25.0)	0
Otitis media acute	1 (25.0)	0	1 (25.0)
Parainfluenzae virus infection	1 (25.0)	1 (25.0)	0
Sinusitis	1 (25.0)	0	1 (25.0)
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0
Investigations			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Blood uric acid increased	1 (25.0)	1 (25.0)	0
Neutrophil count decreased	1 (25.0)	1 (25.0)	0
Platelet count decreased	1 (25.0)	1 (25.0)	0
White blood cell count decreased	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (25.0)	0	1 (25.0)
Decreased appetite	1 (25.0)	0	1 (25.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Joint range of motion decreased	1 (25.0)	1 (25.0)	0
Osteonecrosis	1 (25.0)	0	1 (25.0)
Skin and subcutaneous tissue disorders			
-Total	1 (25.0)	0	1 (25.0)
Rash	1 (25.0)	0	1 (25.0)

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Table 225i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	30 (57.7)	10 (19.2)	20 (38.5)
Blood and lymphatic system disorders			
-Total	1 (1.9)	1 (1.9)	0
Anaemia	1 (1.9)	1 (1.9)	0
Cardiac disorders			
-Total	1 (1.9)	0	1 (1.9)
Sinus tachycardia	1 (1.9)	0	1 (1.9)
Eye disorders			
-Total	1 (1.9)	1 (1.9)	0
Dry eye	1 (1.9)	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	12 (23.1)	8 (15.4)	4 (7.7)
Diarrhoea	7 (13.5)	6 (11.5)	1 (1.9)
Vomiting	7 (13.5)	5 (9.6)	2 (3.8)
Nausea	4 (7.7)	1 (1.9)	3 (5.8)
Abdominal pain	3 (5.8)	2 (3.8)	1 (1.9)
General disorders and administration site conditions			
-Total	9 (17.3)	7 (13.5)	2 (3.8)
Pyrexia	8 (15.4)	6 (11.5)	2 (3.8)
Chills	1 (1.9)	1 (1.9)	0
Fatigue	1 (1.9)	1 (1.9)	0
Pain	1 (1.9)	1 (1.9)	0
Immune system disorders			
-Total	7 (13.5)	0	7 (13.5)
Hypogammaglobulinaemia	7 (13.5)	0	7 (13.5)
Infections and infestations			
-Total	7 (13.5)	3 (5.8)	4 (7.7)
Upper respiratory tract infection	5 (9.6)	2 (3.8)	3 (5.8)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sinusitis	1 (1.9)	0	1 (1.9)
Viral infection	1 (1.9)	1 (1.9)	0
Injury, poisoning and procedural complications			
-Total	4 (7.7)	2 (3.8)	2 (3.8)
Contusion	2 (3.8)	2 (3.8)	0
Infusion related reaction	2 (3.8)	1 (1.9)	1 (1.9)
Procedural pain	2 (3.8)	1 (1.9)	1 (1.9)
Investigations			
-Total	7 (13.5)	4 (7.7)	3 (5.8)
White blood cell count decreased	3 (5.8)	2 (3.8)	1 (1.9)
Lymphocyte count decreased	2 (3.8)	1 (1.9)	1 (1.9)
Neutrophil count decreased	2 (3.8)	1 (1.9)	1 (1.9)
Platelet count decreased	2 (3.8)	2 (3.8)	0
Aspartate aminotransferase increased	1 (1.9)	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	4 (7.7)	4 (7.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	2 (3.8)	2 (3.8)	0
Decreased appetite	1 (1.9)	1 (1.9)	0
Hypokalaemia	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			
-Total	11 (21.2)	8 (15.4)	3 (5.8)
Pain in extremity	8 (15.4)	6 (11.5)	2 (3.8)
Arthralgia	2 (3.8)	1 (1.9)	1 (1.9)
Joint range of motion decreased	1 (1.9)	1 (1.9)	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0
Nervous system disorders			
-Total	6 (11.5)	5 (9.6)	1 (1.9)
Headache	5 (9.6)	4 (7.7)	1 (1.9)
Dizziness	3 (5.8)	3 (5.8)	0
Psychiatric disorders			
-Total	1 (1.9)	1 (1.9)	0
Anxiety	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (21.2)	7 (13.5)	4 (7.7)
Cough	7 (13.5)	5 (9.6)	2 (3.8)
Rhinorrhoea	4 (7.7)	3 (5.8)	1 (1.9)
Oropharyngeal pain	3 (5.8)	2 (3.8)	1 (1.9)
Epistaxis	1 (1.9)	1 (1.9)	0
Skin and subcutaneous tissue disorders			
-Total	4 (7.7)	2 (3.8)	2 (3.8)
Rash	3 (5.8)	1 (1.9)	2 (3.8)
Petechiae	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	2 (3.8)	1 (1.9)	1 (1.9)
Hypertension	2 (3.8)	1 (1.9)	1 (1.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (66.7)	1 (33.3)	1 (33.3)
Infections and infestations			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Gingivitis	1 (33.3)	1 (33.3)	0
Otitis media acute	1 (33.3)	0	1 (33.3)
Viral infection	1 (33.3)	1 (33.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (35.5)	2 (6.5)	9 (29.0)
Gastrointestinal disorders			
-Total	3 (9.7)	0	3 (9.7)
Diarrhoea	2 (6.5)	0	2 (6.5)
Abdominal pain	1 (3.2)	0	1 (3.2)
Nausea	1 (3.2)	0	1 (3.2)
General disorders and administration site conditions			
-Total	1 (3.2)	0	1 (3.2)
Chills	1 (3.2)	0	1 (3.2)
Pyrexia	1 (3.2)	0	1 (3.2)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	4 (12.9)	1 (3.2)	3 (9.7)
Sinusitis	3 (9.7)	0	3 (9.7)
Upper respiratory tract infection	2 (6.5)	1 (3.2)	1 (3.2)
Otitis media acute	1 (3.2)	0	1 (3.2)
Investigations			
-Total	5 (16.1)	2 (6.5)	3 (9.7)
Lymphocyte count decreased	3 (9.7)	2 (6.5)	1 (3.2)
Neutrophil count decreased	2 (6.5)	1 (3.2)	1 (3.2)
Alanine aminotransferase increased	1 (3.2)	0	1 (3.2)
Aspartate aminotransferase increased	1 (3.2)	1 (3.2)	0
White blood cell count decreased	1 (3.2)	1 (3.2)	0
Nervous system disorders			
-Total	1 (3.2)	0	1 (3.2)
Dizziness	1 (3.2)	1 (3.2)	0
Headache	1 (3.2)	0	1 (3.2)
Respiratory, thoracic and mediastinal disorders			

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (12.9)	4 (12.9)	0
Cough	2 (6.5)	2 (6.5)	0
Epistaxis	1 (3.2)	1 (3.2)	0
Oropharyngeal pain	1 (3.2)	1 (3.2)	0
Rhinorrhoea	1 (3.2)	1 (3.2)	0

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Table 225i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	0	4 (100)
Blood and lymphatic system disorders			
-Total	2 (50.0)	0	2 (50.0)
Anaemia	2 (50.0)	0	2 (50.0)
Lymphopenia	1 (25.0)	0	1 (25.0)
Cardiac disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Cardiac dysfunction	1 (25.0)	1 (25.0)	0
Sinus tachycardia	1 (25.0)	0	1 (25.0)
Tachycardia	1 (25.0)	1 (25.0)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eye disorders			
-Total	1 (25.0)	0	1 (25.0)
Dry eye	1 (25.0)	0	1 (25.0)
Gastrointestinal disorders			
-Total	3 (75.0)	1 (25.0)	2 (50.0)
Diarrhoea	3 (75.0)	2 (50.0)	1 (25.0)
Abdominal pain	2 (50.0)	2 (50.0)	0
Nausea	2 (50.0)	1 (25.0)	1 (25.0)
Vomiting	2 (50.0)	1 (25.0)	1 (25.0)
Abdominal distension	1 (25.0)	0	1 (25.0)
Abdominal tenderness	1 (25.0)	1 (25.0)	0
Constipation	1 (25.0)	1 (25.0)	0
Gastrooesophageal reflux disease	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	4 (100)	3 (75.0)	1 (25.0)
Fatigue	4 (100)	4 (100)	0
Pain	1 (25.0)	0	1 (25.0)
Pyrexia	1 (25.0)	1 (25.0)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	4 (100)	0	4 (100)
Hypogammaglobulinaemia	4 (100)	0	4 (100)
Cytokine release syndrome	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	3 (75.0)	1 (25.0)	2 (50.0)
Clostridium difficile infection	1 (25.0)	0	1 (25.0)
Cytomegalovirus infection	1 (25.0)	1 (25.0)	0
Gingivitis	1 (25.0)	1 (25.0)	0
Otitis media acute	1 (25.0)	0	1 (25.0)
Parainfluenzae virus infection	1 (25.0)	1 (25.0)	0
Pharyngitis	1 (25.0)	0	1 (25.0)
Sinusitis	1 (25.0)	0	1 (25.0)
Streptococcal infection	1 (25.0)	0	1 (25.0)
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0
Viral infection	1 (25.0)	1 (25.0)	0
Injury, poisoning and procedural complications			
-Total	2 (50.0)	1 (25.0)	1 (25.0)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Contusion	1 (25.0)	1 (25.0)	0
Infusion related reaction	1 (25.0)	0	1 (25.0)
Procedural pain	1 (25.0)	0	1 (25.0)
Procedural site reaction	1 (25.0)	1 (25.0)	0
Investigations			
-Total	3 (75.0)	0	3 (75.0)
International normalised ratio increased	2 (50.0)	2 (50.0)	0
White blood cell count decreased	2 (50.0)	0	2 (50.0)
Activated partial thromboplastin time prolonged	1 (25.0)	1 (25.0)	0
Blood bilirubin increased	1 (25.0)	0	1 (25.0)
Blood creatinine increased	1 (25.0)	1 (25.0)	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0
Blood uric acid increased	1 (25.0)	1 (25.0)	0
Lymphocyte count decreased	1 (25.0)	0	1 (25.0)
Neutrophil count decreased	1 (25.0)	0	1 (25.0)
Platelet count decreased	1 (25.0)	0	1 (25.0)
Pulmonary function test decreased	1 (25.0)	0	1 (25.0)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Decreased appetite	2 (50.0)	1 (25.0)	1 (25.0)
Hyperphosphataemia	2 (50.0)	2 (50.0)	0
Hyperuricaemia	1 (25.0)	1 (25.0)	0
Hypokalaemia	1 (25.0)	0	1 (25.0)
Musculoskeletal and connective tissue disorders			
-Total	3 (75.0)	1 (25.0)	2 (50.0)
Arthralgia	2 (50.0)	2 (50.0)	0
Joint range of motion decreased	1 (25.0)	1 (25.0)	0
Musculoskeletal chest pain	1 (25.0)	1 (25.0)	0
Musculoskeletal pain	1 (25.0)	0	1 (25.0)
Myalgia	1 (25.0)	1 (25.0)	0
Osteonecrosis	1 (25.0)	0	1 (25.0)
Pain in extremity	1 (25.0)	1 (25.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (25.0)	0	1 (25.0)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin papilloma	1 (25.0)	0	1 (25.0)
Nervous system disorders			
-Total	3 (75.0)	3 (75.0)	0
Headache	3 (75.0)	3 (75.0)	0
Dizziness	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Rhinorrhoea	1 (25.0)	1 (25.0)	0
Tachypnoea	1 (25.0)	1 (25.0)	0
Wheezing	1 (25.0)	0	1 (25.0)
Skin and subcutaneous tissue disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Petechiae	1 (25.0)	1 (25.0)	0
Rash	1 (25.0)	0	1 (25.0)
Rash follicular	1 (25.0)	1 (25.0)	0
Rash papular	1 (25.0)	1 (25.0)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	60 (100)	2 (3.3)	58 (96.7)
Blood and lymphatic system disorders			
-Total	10 (16.7)	4 (6.7)	6 (10.0)
Anaemia	9 (15.0)	4 (6.7)	5 (8.3)
Lymphopenia	1 (1.7)	0	1 (1.7)
Cardiac disorders			
-Total	17 (28.3)	9 (15.0)	8 (13.3)
Tachycardia	13 (21.7)	7 (11.7)	6 (10.0)
Sinus tachycardia	5 (8.3)	3 (5.0)	2 (3.3)
Eye disorders			

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (1.7)	1 (1.7)	0
Dry eye	1 (1.7)	1 (1.7)	0
Gastrointestinal disorders			
-Total	35 (58.3)	13 (21.7)	22 (36.7)
Vomiting	23 (38.3)	15 (25.0)	8 (13.3)
Nausea	21 (35.0)	5 (8.3)	16 (26.7)
Diarrhoea	19 (31.7)	11 (18.3)	8 (13.3)
Abdominal pain	8 (13.3)	4 (6.7)	4 (6.7)
Constipation	6 (10.0)	5 (8.3)	1 (1.7)
Abdominal distension	1 (1.7)	0	1 (1.7)
General disorders and administration site conditions			
-Total	29 (48.3)	13 (21.7)	16 (26.7)
Pyrexia	21 (35.0)	7 (11.7)	14 (23.3)
Fatigue	11 (18.3)	8 (13.3)	3 (5.0)
Chills	10 (16.7)	9 (15.0)	1 (1.7)
Pain	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	49 (81.7)	6 (10.0)	43 (71.7)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cytokine release syndrome	44 (73.3)	7 (11.7)	37 (61.7)
Hypogammaglobulinaemia	23 (38.3)	3 (5.0)	20 (33.3)
Infections and infestations			
-Total	14 (23.3)	4 (6.7)	10 (16.7)
Upper respiratory tract infection	7 (11.7)	3 (5.0)	4 (6.7)
Clostridium difficile infection	3 (5.0)	0	3 (5.0)
Sinusitis	3 (5.0)	0	3 (5.0)
Viral infection	2 (3.3)	1 (1.7)	1 (1.7)
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0
Otitis media acute	1 (1.7)	0	1 (1.7)
Injury, poisoning and procedural complications			
-Total	7 (11.7)	3 (5.0)	4 (6.7)
Procedural pain	4 (6.7)	2 (3.3)	2 (3.3)
Infusion related reaction	3 (5.0)	1 (1.7)	2 (3.3)
Contusion	2 (3.3)	2 (3.3)	0
Investigations			
-Total	32 (53.3)	3 (5.0)	29 (48.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	13 (21.7)	7 (11.7)	6 (10.0)
White blood cell count decreased	13 (21.7)	5 (8.3)	8 (13.3)
Alanine aminotransferase increased	11 (18.3)	5 (8.3)	6 (10.0)
Prothrombin time prolonged	9 (15.0)	5 (8.3)	4 (6.7)
Blood creatinine increased	6 (10.0)	4 (6.7)	2 (3.3)
International normalised ratio increased	6 (10.0)	6 (10.0)	0
Lymphocyte count decreased	6 (10.0)	2 (3.3)	4 (6.7)
Blood bilirubin increased	5 (8.3)	2 (3.3)	3 (5.0)
Platelet count decreased	5 (8.3)	3 (5.0)	2 (3.3)
Activated partial thromboplastin time prolonged	4 (6.7)	2 (3.3)	2 (3.3)
Neutrophil count decreased	4 (6.7)	1 (1.7)	3 (5.0)
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0
Blood uric acid increased	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	23 (38.3)	13 (21.7)	10 (16.7)
Decreased appetite	11 (18.3)	7 (11.7)	4 (6.7)
Hypokalaemia	10 (16.7)	4 (6.7)	6 (10.0)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	6 (10.0)	6 (10.0)	0
Hyperuricaemia	1 (1.7)	1 (1.7)	0
Musculoskeletal and connective tissue disorders			
-Total	18 (30.0)	13 (21.7)	5 (8.3)
Pain in extremity	10 (16.7)	6 (10.0)	4 (6.7)
Myalgia	4 (6.7)	3 (5.0)	1 (1.7)
Arthralgia	3 (5.0)	2 (3.3)	1 (1.7)
Musculoskeletal pain	2 (3.3)	2 (3.3)	0
Joint range of motion decreased	1 (1.7)	1 (1.7)	0
Musculoskeletal chest pain	1 (1.7)	1 (1.7)	0
Nervous system disorders			
-Total	24 (40.0)	15 (25.0)	9 (15.0)
Headache	21 (35.0)	12 (20.0)	9 (15.0)
Dizziness	5 (8.3)	5 (8.3)	0
Psychiatric disorders			
-Total	11 (18.3)	6 (10.0)	5 (8.3)
Anxiety	6 (10.0)	3 (5.0)	3 (5.0)
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	27 (45.0)	16 (26.7)	11 (18.3)
Cough	14 (23.3)	12 (20.0)	2 (3.3)
Epistaxis	6 (10.0)	4 (6.7)	2 (3.3)
Oropharyngeal pain	6 (10.0)	4 (6.7)	2 (3.3)
Pleural effusion	6 (10.0)	2 (3.3)	4 (6.7)
Rhinorrhoea	5 (8.3)	4 (6.7)	1 (1.7)
Tachypnoea	3 (5.0)	2 (3.3)	1 (1.7)
Skin and subcutaneous tissue disorders			
-Total	10 (16.7)	7 (11.7)	3 (5.0)
Rash	7 (11.7)	5 (8.3)	2 (3.3)
Petechiae	3 (5.0)	2 (3.3)	1 (1.7)
Rash papular	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	11 (18.3)	3 (5.0)	8 (13.3)
Hypertension	11 (18.3)	3 (5.0)	8 (13.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (100)	1 (5.3)	18 (94.7)
Blood and lymphatic system disorders			
-Total	3 (15.8)	1 (5.3)	2 (10.5)
Anaemia	3 (15.8)	1 (5.3)	2 (10.5)
Thrombocytopenia	2 (10.5)	0	2 (10.5)
Cardiac disorders			
-Total	6 (31.6)	3 (15.8)	3 (15.8)
Tachycardia	4 (21.1)	2 (10.5)	2 (10.5)
Sinus tachycardia	2 (10.5)	1 (5.3)	1 (5.3)
Eye disorders			
-Total	6 (31.6)	4 (21.1)	2 (10.5)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Periorbital oedema	3 (15.8)	2 (10.5)	1 (5.3)
Conjunctival haemorrhage	2 (10.5)	2 (10.5)	0
Photophobia	2 (10.5)	1 (5.3)	1 (5.3)
Vision blurred	2 (10.5)	1 (5.3)	1 (5.3)
Gastrointestinal disorders			
-Total	11 (57.9)	3 (15.8)	8 (42.1)
Vomiting	8 (42.1)	6 (31.6)	2 (10.5)
Diarrhoea	7 (36.8)	4 (21.1)	3 (15.8)
Nausea	6 (31.6)	2 (10.5)	4 (21.1)
Abdominal pain	4 (21.1)	3 (15.8)	1 (5.3)
Constipation	3 (15.8)	2 (10.5)	1 (5.3)
General disorders and administration site conditions			
-Total	10 (52.6)	2 (10.5)	8 (42.1)
Pyrexia	7 (36.8)	1 (5.3)	6 (31.6)
Fatigue	5 (26.3)	3 (15.8)	2 (10.5)
Chills	2 (10.5)	2 (10.5)	0
Malaise	2 (10.5)	0	2 (10.5)
Pain	1 (5.3)	0	1 (5.3)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatobiliary disorders			
-Total	2 (10.5)	0	2 (10.5)
Hyperbilirubinaemia	2 (10.5)	0	2 (10.5)
Immune system disorders			
-Total	17 (89.5)	2 (10.5)	15 (78.9)
Cytokine release syndrome	16 (84.2)	2 (10.5)	14 (73.7)
Hypogammaglobulinaemia	7 (36.8)	2 (10.5)	5 (26.3)
Infections and infestations			
-Total	5 (26.3)	2 (10.5)	3 (15.8)
Clostridium difficile colitis	2 (10.5)	1 (5.3)	1 (5.3)
Rhinovirus infection	2 (10.5)	2 (10.5)	0
Gastroenteritis	1 (5.3)	0	1 (5.3)
Upper respiratory tract infection	1 (5.3)	0	1 (5.3)
Injury, poisoning and procedural complications			
-Total	3 (15.8)	3 (15.8)	0
Transfusion reaction	2 (10.5)	2 (10.5)	0
Skin abrasion	1 (5.3)	1 (5.3)	0
Investigations			

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	9 (47.4)	2 (10.5)	7 (36.8)
Aspartate aminotransferase increased	5 (26.3)	3 (15.8)	2 (10.5)
Alanine aminotransferase increased	4 (21.1)	2 (10.5)	2 (10.5)
Prothrombin time prolonged	4 (21.1)	2 (10.5)	2 (10.5)
Blood creatinine increased	3 (15.8)	2 (10.5)	1 (5.3)
Blood bilirubin increased	2 (10.5)	1 (5.3)	1 (5.3)
Blood immunoglobulin a decreased	2 (10.5)	2 (10.5)	0
Blood immunoglobulin m decreased	2 (10.5)	2 (10.5)	0
International normalised ratio increased	2 (10.5)	2 (10.5)	0
Blood urea increased	1 (5.3)	0	1 (5.3)
Platelet count decreased	1 (5.3)	1 (5.3)	0
White blood cell count decreased	1 (5.3)	0	1 (5.3)
Metabolism and nutrition disorders			
-Total	11 (57.9)	4 (21.1)	7 (36.8)
Decreased appetite	4 (21.1)	2 (10.5)	2 (10.5)
Fluid overload	2 (10.5)	0	2 (10.5)
Hypernatraemia	2 (10.5)	0	2 (10.5)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	2 (10.5)	2 (10.5)	0
Hypoalbuminaemia	2 (10.5)	0	2 (10.5)
Hypokalaemia	2 (10.5)	1 (5.3)	1 (5.3)
Hypophosphataemia	2 (10.5)	2 (10.5)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (21.1)	2 (10.5)	2 (10.5)
Myalgia	2 (10.5)	1 (5.3)	1 (5.3)
Pain in extremity	2 (10.5)	1 (5.3)	1 (5.3)
Muscle spasms	1 (5.3)	1 (5.3)	0
Nervous system disorders			
-Total	9 (47.4)	6 (31.6)	3 (15.8)
Headache	7 (36.8)	5 (26.3)	2 (10.5)
Encephalopathy	2 (10.5)	1 (5.3)	1 (5.3)
Dizziness	1 (5.3)	1 (5.3)	0
Psychiatric disorders			
-Total	7 (36.8)	3 (15.8)	4 (21.1)
Anxiety	3 (15.8)	1 (5.3)	2 (10.5)
Confusional state	2 (10.5)	0	2 (10.5)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Delirium	2 (10.5)	1 (5.3)	1 (5.3)
Hallucination	2 (10.5)	1 (5.3)	1 (5.3)
Irritability	2 (10.5)	2 (10.5)	0
Renal and urinary disorders			
-Total	2 (10.5)	0	2 (10.5)
Haematuria	2 (10.5)	0	2 (10.5)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (47.4)	4 (21.1)	5 (26.3)
Cough	4 (21.1)	4 (21.1)	0
Epistaxis	3 (15.8)	1 (5.3)	2 (10.5)
Hypoxia	2 (10.5)	0	2 (10.5)
Pleural effusion	1 (5.3)	0	1 (5.3)
Skin and subcutaneous tissue disorders			
-Total	5 (26.3)	4 (21.1)	1 (5.3)
Erythema	2 (10.5)	2 (10.5)	0
Hyperhidrosis	2 (10.5)	2 (10.5)	0
Pruritus	1 (5.3)	1 (5.3)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash	1 (5.3)	1 (5.3)	0
Rash maculo-papular	1 (5.3)	0	1 (5.3)
Vascular disorders			
-Total	3 (15.8)	2 (10.5)	1 (5.3)
Flushing	2 (10.5)	2 (10.5)	0
Hypertension	2 (10.5)	1 (5.3)	1 (5.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	43 (95.6)	1 (2.2)	42 (93.3)
Blood and lymphatic system disorders			
-Total	9 (20.0)	3 (6.7)	6 (13.3)
Anaemia	8 (17.8)	3 (6.7)	5 (11.1)
Thrombocytopenia	1 (2.2)	0	1 (2.2)
Cardiac disorders			
-Total	12 (26.7)	7 (15.6)	5 (11.1)
Tachycardia	10 (22.2)	6 (13.3)	4 (8.9)
Sinus tachycardia	3 (6.7)	2 (4.4)	1 (2.2)
Eye disorders			
-Total	1 (2.2)	0	1 (2.2)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=45	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctival haemorrhage	1 (2.2)	1 (2.2)	0
Periorbital oedema	1 (2.2)	1 (2.2)	0
Vision blurred	1 (2.2)	0	1 (2.2)
Gastrointestinal disorders			
-Total	21 (46.7)	9 (20.0)	12 (26.7)
Nausea	14 (31.1)	4 (8.9)	10 (22.2)
Vomiting	12 (26.7)	7 (15.6)	5 (11.1)
Diarrhoea	10 (22.2)	7 (15.6)	3 (6.7)
Abdominal pain	4 (8.9)	3 (6.7)	1 (2.2)
Constipation	4 (8.9)	4 (8.9)	0
General disorders and administration site conditions			
-Total	17 (37.8)	10 (22.2)	7 (15.6)
Fatigue	8 (17.8)	7 (15.6)	1 (2.2)
Pyrexia	7 (15.6)	2 (4.4)	5 (11.1)
Chills	6 (13.3)	6 (13.3)	0
Malaise	1 (2.2)	0	1 (2.2)
Immune system disorders			
-Total	35 (77.8)	4 (8.9)	31 (68.9)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cytokine release syndrome	29 (64.4)	5 (11.1)	24 (53.3)
Hypogammaglobulinaemia	14 (31.1)	1 (2.2)	13 (28.9)
Infections and infestations			
-Total	2 (4.4)	1 (2.2)	1 (2.2)
Clostridium difficile colitis	1 (2.2)	0	1 (2.2)
Rhinovirus infection	1 (2.2)	1 (2.2)	0
Injury, poisoning and procedural complications			
-Total	1 (2.2)	0	1 (2.2)
Transfusion reaction	1 (2.2)	0	1 (2.2)
Investigations			
-Total	21 (46.7)	2 (4.4)	19 (42.2)
White blood cell count decreased	10 (22.2)	3 (6.7)	7 (15.6)
Aspartate aminotransferase increased	7 (15.6)	3 (6.7)	4 (8.9)
Alanine aminotransferase increased	6 (13.3)	3 (6.7)	3 (6.7)
International normalised ratio increased	6 (13.3)	6 (13.3)	0
Platelet count decreased	5 (11.1)	2 (4.4)	3 (6.7)
Prothrombin time prolonged	5 (11.1)	3 (6.7)	2 (4.4)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=45	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood bilirubin increased	4 (8.9)	1 (2.2)	3 (6.7)
Blood creatinine increased	4 (8.9)	3 (6.7)	1 (2.2)
Lymphocyte count decreased	4 (8.9)	1 (2.2)	3 (6.7)
Blood immunoglobulin m decreased	2 (4.4)	2 (4.4)	0
Neutrophil count decreased	2 (4.4)	0	2 (4.4)
Blood immunoglobulin a decreased	1 (2.2)	1 (2.2)	0
Blood urea increased	1 (2.2)	1 (2.2)	0
Metabolism and nutrition disorders			
-Total	21 (46.7)	11 (24.4)	10 (22.2)
Hypokalaemia	8 (17.8)	2 (4.4)	6 (13.3)
Decreased appetite	7 (15.6)	5 (11.1)	2 (4.4)
Hyperphosphataemia	6 (13.3)	6 (13.3)	0
Hypoalbuminaemia	3 (6.7)	1 (2.2)	2 (4.4)
Hypernatraemia	2 (4.4)	1 (2.2)	1 (2.2)
Fluid overload	1 (2.2)	1 (2.2)	0
Hypophosphataemia	1 (2.2)	1 (2.2)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (8.9)	3 (6.7)	1 (2.2)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Myalgia	3 (6.7)	3 (6.7)	0
Pain in extremity	2 (4.4)	1 (2.2)	1 (2.2)
Nervous system disorders			
-Total	20 (44.4)	13 (28.9)	7 (15.6)
Headache	17 (37.8)	11 (24.4)	6 (13.3)
Dizziness	3 (6.7)	3 (6.7)	0
Encephalopathy	1 (2.2)	0	1 (2.2)
Psychiatric disorders			
-Total	7 (15.6)	5 (11.1)	2 (4.4)
Confusional state	4 (8.9)	3 (6.7)	1 (2.2)
Anxiety	2 (4.4)	1 (2.2)	1 (2.2)
Delirium	2 (4.4)	1 (2.2)	1 (2.2)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (26.7)	5 (11.1)	7 (15.6)
Pleural effusion	5 (11.1)	2 (4.4)	3 (6.7)
Cough	4 (8.9)	4 (8.9)	0
Hypoxia	3 (6.7)	0	3 (6.7)
Oropharyngeal pain	2 (4.4)	1 (2.2)	1 (2.2)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	1 (2.2)	1 (2.2)	0
Rhinitis allergic	1 (2.2)	1 (2.2)	0
Rhinorrhoea	1 (2.2)	1 (2.2)	0
Skin and subcutaneous tissue disorders			
-Total	7 (15.6)	7 (15.6)	0
Rash	3 (6.7)	3 (6.7)	0
Erythema	1 (2.2)	1 (2.2)	0
Hyperhidrosis	1 (2.2)	1 (2.2)	0
Pruritus	1 (2.2)	1 (2.2)	0
Rash maculo-papular	1 (2.2)	1 (2.2)	0
Vascular disorders			
-Total	7 (15.6)	1 (2.2)	6 (13.3)
Hypertension	7 (15.6)	1 (2.2)	6 (13.3)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of

adverse events.

Table 225j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	16 (88.9)	4 (22.2)	12 (66.7)
Blood and lymphatic system disorders			
-Total	1 (5.6)	1 (5.6)	0
Anaemia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
-Total	1 (5.6)	0	1 (5.6)
Sinus tachycardia	1 (5.6)	0	1 (5.6)
Eye disorders			
-Total	1 (5.6)	1 (5.6)	0
Vision blurred	1 (5.6)	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	5 (27.8)	4 (22.2)	1 (5.6)
Diarrhoea	3 (16.7)	3 (16.7)	0
Vomiting	3 (16.7)	2 (11.1)	1 (5.6)
Nausea	2 (11.1)	1 (5.6)	1 (5.6)
Abdominal pain	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	6 (33.3)	4 (22.2)	2 (11.1)
Pyrexia	6 (33.3)	4 (22.2)	2 (11.1)
Chills	1 (5.6)	1 (5.6)	0
Pain	1 (5.6)	1 (5.6)	0
Immune system disorders			
-Total	2 (11.1)	0	2 (11.1)
Hypogammaglobulinaemia	2 (11.1)	0	2 (11.1)
Infections and infestations			
-Total	8 (44.4)	3 (16.7)	5 (27.8)
Upper respiratory tract infection	3 (16.7)	1 (5.6)	2 (11.1)
Ear infection	2 (11.1)	1 (5.6)	1 (5.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastroenteritis	2 (11.1)	1 (5.6)	1 (5.6)
Rhinovirus infection	1 (5.6)	1 (5.6)	0
Urinary tract infection	1 (5.6)	0	1 (5.6)
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Skin abrasion	1 (5.6)	1 (5.6)	0
Investigations			
-Total	7 (38.9)	3 (16.7)	4 (22.2)
Lymphocyte count decreased	2 (11.1)	1 (5.6)	1 (5.6)
Weight decreased	2 (11.1)	0	2 (11.1)
White blood cell count decreased	2 (11.1)	1 (5.6)	1 (5.6)
Blood creatinine increased	1 (5.6)	1 (5.6)	0
Blood urea increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	1 (5.6)	0
Platelet count decreased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	3 (16.7)	3 (16.7)	0
Decreased appetite	1 (5.6)	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	1 (5.6)	1 (5.6)	0
Vitamin d deficiency	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders			
-Total	7 (38.9)	5 (27.8)	2 (11.1)
Pain in extremity	6 (33.3)	4 (22.2)	2 (11.1)
Muscle spasms	1 (5.6)	1 (5.6)	0
Nervous system disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Headache	3 (16.7)	2 (11.1)	1 (5.6)
Dizziness	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (33.3)	4 (22.2)	2 (11.1)
Cough	5 (27.8)	4 (22.2)	1 (5.6)
Rhinitis allergic	2 (11.1)	1 (5.6)	1 (5.6)
Rhinorrhoea	1 (5.6)	1 (5.6)	0
Skin and subcutaneous tissue disorders			
-Total	5 (27.8)	3 (16.7)	2 (11.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash	3 (16.7)	1 (5.6)	2 (11.1)
Rash maculo-papular	2 (11.1)	2 (11.1)	0
Pruritus	1 (5.6)	1 (5.6)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=38	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	22 (57.9)	5 (13.2)	17 (44.7)
Blood and lymphatic system disorders			
-Total	1 (2.6)	0	1 (2.6)
Thrombocytopenia	1 (2.6)	0	1 (2.6)
Gastrointestinal disorders			
-Total	8 (21.1)	4 (10.5)	4 (10.5)
Vomiting	5 (13.2)	3 (7.9)	2 (5.3)
Diarrhoea	4 (10.5)	3 (7.9)	1 (2.6)
Abdominal pain	2 (5.3)	1 (2.6)	1 (2.6)
Nausea	2 (5.3)	0	2 (5.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=38	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	5 (13.2)	5 (13.2)	0
Pyrexia	3 (7.9)	3 (7.9)	0
Fatigue	2 (5.3)	2 (5.3)	0
Malaise	1 (2.6)	1 (2.6)	0
Immune system disorders			
-Total	5 (13.2)	0	5 (13.2)
Hypogammaglobulinaemia	5 (13.2)	0	5 (13.2)
Infections and infestations			
-Total	7 (18.4)	3 (7.9)	4 (10.5)
Upper respiratory tract infection	3 (7.9)	2 (5.3)	1 (2.6)
Urinary tract infection	2 (5.3)	0	2 (5.3)
Gastroenteritis	1 (2.6)	0	1 (2.6)
Rhinovirus infection	1 (2.6)	1 (2.6)	0
Investigations			
-Total	6 (15.8)	3 (7.9)	3 (7.9)
Neutrophil count decreased	2 (5.3)	1 (2.6)	1 (2.6)
Platelet count decreased	2 (5.3)	2 (5.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=38	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Weight decreased	2 (5.3)	1 (2.6)	1 (2.6)
White blood cell count decreased	2 (5.3)	1 (2.6)	1 (2.6)
Aspartate aminotransferase increased	1 (2.6)	1 (2.6)	0
Metabolism and nutrition disorders			
-Total	3 (7.9)	2 (5.3)	1 (2.6)
Decreased appetite	1 (2.6)	0	1 (2.6)
Hyperphosphataemia	1 (2.6)	1 (2.6)	0
Hypokalaemia	1 (2.6)	1 (2.6)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.3)	2 (5.3)	0
Pain in extremity	2 (5.3)	2 (5.3)	0
Nervous system disorders			
-Total	3 (7.9)	3 (7.9)	0
Dizziness	2 (5.3)	2 (5.3)	0
Headache	2 (5.3)	2 (5.3)	0
Psychiatric disorders			
-Total	1 (2.6)	1 (2.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=38	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Anxiety	1 (2.6)	1 (2.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (18.4)	4 (10.5)	3 (7.9)
Oropharyngeal pain	3 (7.9)	2 (5.3)	1 (2.6)
Rhinorrhoea	3 (7.9)	2 (5.3)	1 (2.6)
Cough	2 (5.3)	1 (2.6)	1 (2.6)
Epistaxis	1 (2.6)	1 (2.6)	0
Rhinitis allergic	1 (2.6)	1 (2.6)	0
Skin and subcutaneous tissue disorders			
-Total	3 (7.9)	2 (5.3)	1 (2.6)
Erythema	2 (5.3)	2 (5.3)	0
Hyperhidrosis	1 (2.6)	1 (2.6)	0
Rash	1 (2.6)	0	1 (2.6)
Vascular disorders			
-Total	2 (5.3)	1 (2.6)	1 (2.6)
Hypertension	2 (5.3)	1 (2.6)	1 (2.6)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (54.5)	2 (18.2)	4 (36.4)
Gastrointestinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Diarrhoea	2 (18.2)	0	2 (18.2)
Abdominal pain	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Urinary tract infection	2 (18.2)	0	2 (18.2)
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Investigations			

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Lymphocyte count decreased	3 (27.3)	2 (18.2)	1 (9.1)
Neutrophil count decreased	2 (18.2)	1 (9.1)	1 (9.1)
White blood cell count decreased	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			
-Total	1 (9.1)	1 (9.1)	0
Vitamin d deficiency	1 (9.1)	1 (9.1)	0
Nervous system disorders			
-Total	1 (9.1)	0	1 (9.1)
Dizziness	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (18.2)	2 (18.2)	0
Cough	1 (9.1)	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0
Rhinitis allergic	1 (9.1)	1 (9.1)	0
Rhinorrhoea	1 (9.1)	1 (9.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=23	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (26.1)	3 (13.0)	3 (13.0)
Blood and lymphatic system disorders			
-Total	1 (4.3)	1 (4.3)	0
Thrombocytopenia	1 (4.3)	1 (4.3)	0
Gastrointestinal disorders			
-Total	1 (4.3)	0	1 (4.3)
Nausea	1 (4.3)	0	1 (4.3)
General disorders and administration site conditions			
-Total	1 (4.3)	0	1 (4.3)
Chills	1 (4.3)	0	1 (4.3)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	1 (4.3)	0	1 (4.3)
Infections and infestations			
-Total	1 (4.3)	0	1 (4.3)
Upper respiratory tract infection	1 (4.3)	0	1 (4.3)
Investigations			
-Total	2 (8.7)	1 (4.3)	1 (4.3)
Alanine aminotransferase increased	1 (4.3)	0	1 (4.3)
Aspartate aminotransferase increased	1 (4.3)	1 (4.3)	0
Renal and urinary disorders			
-Total	1 (4.3)	1 (4.3)	0
Haematuria	1 (4.3)	1 (4.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (8.7)	2 (8.7)	0
Cough	1 (4.3)	1 (4.3)	0
Epistaxis	1 (4.3)	1 (4.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (4.3)	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=23	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pruritus	1 (4.3)	1 (4.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (100)	0	19 (100)
Blood and lymphatic system disorders			
-Total	3 (15.8)	1 (5.3)	2 (10.5)
Anaemia	3 (15.8)	1 (5.3)	2 (10.5)
Thrombocytopenia	2 (10.5)	0	2 (10.5)
Cardiac disorders			
-Total	7 (36.8)	3 (15.8)	4 (21.1)
Tachycardia	4 (21.1)	2 (10.5)	2 (10.5)
Sinus tachycardia	3 (15.8)	1 (5.3)	2 (10.5)
Eye disorders			

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	7 (36.8)	5 (26.3)	2 (10.5)
Periorbital oedema	3 (15.8)	2 (10.5)	1 (5.3)
Vision blurred	3 (15.8)	2 (10.5)	1 (5.3)
Conjunctival haemorrhage	2 (10.5)	2 (10.5)	0
Photophobia	2 (10.5)	1 (5.3)	1 (5.3)
Gastrointestinal disorders			
-Total	13 (68.4)	3 (15.8)	10 (52.6)
Diarrhoea	10 (52.6)	5 (26.3)	5 (26.3)
Vomiting	9 (47.4)	6 (31.6)	3 (15.8)
Nausea	7 (36.8)	2 (10.5)	5 (26.3)
Abdominal pain	4 (21.1)	2 (10.5)	2 (10.5)
Constipation	3 (15.8)	2 (10.5)	1 (5.3)
General disorders and administration site conditions			
-Total	13 (68.4)	3 (15.8)	10 (52.6)
Pyrexia	11 (57.9)	3 (15.8)	8 (42.1)
Fatigue	5 (26.3)	3 (15.8)	2 (10.5)
Chills	3 (15.8)	3 (15.8)	0
Malaise	2 (10.5)	0	2 (10.5)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain	2 (10.5)	1 (5.3)	1 (5.3)
Hepatobiliary disorders			
-Total	2 (10.5)	0	2 (10.5)
Hyperbilirubinaemia	2 (10.5)	0	2 (10.5)
Immune system disorders			
-Total	17 (89.5)	2 (10.5)	15 (78.9)
Cytokine release syndrome	16 (84.2)	2 (10.5)	14 (73.7)
Hypogammaglobulinaemia	9 (47.4)	2 (10.5)	7 (36.8)
Infections and infestations			
-Total	10 (52.6)	4 (21.1)	6 (31.6)
Upper respiratory tract infection	4 (21.1)	2 (10.5)	2 (10.5)
Gastroenteritis	3 (15.8)	1 (5.3)	2 (10.5)
Rhinovirus infection	3 (15.8)	3 (15.8)	0
Clostridium difficile colitis	2 (10.5)	1 (5.3)	1 (5.3)
Ear infection	2 (10.5)	1 (5.3)	1 (5.3)
Urinary tract infection	2 (10.5)	0	2 (10.5)
Injury, poisoning and procedural complications			
-Total	4 (21.1)	4 (21.1)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin abrasion	2 (10.5)	2 (10.5)	0
Transfusion reaction	2 (10.5)	2 (10.5)	0
Investigations			
-Total	11 (57.9)	1 (5.3)	10 (52.6)
Aspartate aminotransferase increased	5 (26.3)	3 (15.8)	2 (10.5)
Alanine aminotransferase increased	4 (21.1)	2 (10.5)	2 (10.5)
Prothrombin time prolonged	4 (21.1)	2 (10.5)	2 (10.5)
White blood cell count decreased	4 (21.1)	2 (10.5)	2 (10.5)
Blood creatinine increased	3 (15.8)	2 (10.5)	1 (5.3)
Lymphocyte count decreased	3 (15.8)	1 (5.3)	2 (10.5)
Blood bilirubin increased	2 (10.5)	1 (5.3)	1 (5.3)
Blood immunoglobulin a decreased	2 (10.5)	2 (10.5)	0
Blood immunoglobulin m decreased	2 (10.5)	2 (10.5)	0
Blood urea increased	2 (10.5)	1 (5.3)	1 (5.3)
International normalised ratio increased	2 (10.5)	2 (10.5)	0
Neutrophil count decreased	2 (10.5)	1 (5.3)	1 (5.3)
Weight decreased	2 (10.5)	0	2 (10.5)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Platelet count decreased	1 (5.3)	1 (5.3)	0
Metabolism and nutrition disorders			
-Total	13 (68.4)	6 (31.6)	7 (36.8)
Decreased appetite	5 (26.3)	3 (15.8)	2 (10.5)
Fluid overload	2 (10.5)	0	2 (10.5)
Hypernatraemia	2 (10.5)	0	2 (10.5)
Hyperphosphataemia	2 (10.5)	2 (10.5)	0
Hypoalbuminaemia	2 (10.5)	0	2 (10.5)
Hypokalaemia	2 (10.5)	1 (5.3)	1 (5.3)
Hypophosphataemia	2 (10.5)	2 (10.5)	0
Vitamin d deficiency	2 (10.5)	2 (10.5)	0
Musculoskeletal and connective tissue disorders			
-Total	9 (47.4)	5 (26.3)	4 (21.1)
Pain in extremity	7 (36.8)	4 (21.1)	3 (15.8)
Muscle spasms	2 (10.5)	2 (10.5)	0
Myalgia	2 (10.5)	1 (5.3)	1 (5.3)
Nervous system disorders			
-Total	9 (47.4)	5 (26.3)	4 (21.1)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	7 (36.8)	4 (21.1)	3 (15.8)
Encephalopathy	2 (10.5)	1 (5.3)	1 (5.3)
Dizziness	1 (5.3)	1 (5.3)	0
Psychiatric disorders			
-Total	7 (36.8)	3 (15.8)	4 (21.1)
Anxiety	3 (15.8)	1 (5.3)	2 (10.5)
Confusional state	2 (10.5)	0	2 (10.5)
Delirium	2 (10.5)	1 (5.3)	1 (5.3)
Hallucination	2 (10.5)	1 (5.3)	1 (5.3)
Irritability	2 (10.5)	2 (10.5)	0
Renal and urinary disorders			
-Total	2 (10.5)	0	2 (10.5)
Haematuria	2 (10.5)	0	2 (10.5)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (63.2)	6 (31.6)	6 (31.6)
Cough	8 (42.1)	7 (36.8)	1 (5.3)
Epistaxis	3 (15.8)	1 (5.3)	2 (10.5)
Hypoxia	2 (10.5)	0	2 (10.5)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinitis allergic	2 (10.5)	1 (5.3)	1 (5.3)
Rhinorrhoea	2 (10.5)	2 (10.5)	0
Oropharyngeal pain	1 (5.3)	1 (5.3)	0
Pleural effusion	1 (5.3)	0	1 (5.3)
Skin and subcutaneous tissue disorders			
-Total	9 (47.4)	6 (31.6)	3 (15.8)
Rash	4 (21.1)	2 (10.5)	2 (10.5)
Rash maculo-papular	3 (15.8)	2 (10.5)	1 (5.3)
Erythema	2 (10.5)	2 (10.5)	0
Hyperhidrosis	2 (10.5)	2 (10.5)	0
Pruritus	2 (10.5)	2 (10.5)	0
Vascular disorders			
-Total	3 (15.8)	2 (10.5)	1 (5.3)
Flushing	2 (10.5)	2 (10.5)	0
Hypertension	2 (10.5)	1 (5.3)	1 (5.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the

AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=45	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	44 (97.8)	2 (4.4)	42 (93.3)
Blood and lymphatic system disorders			
-Total	11 (24.4)	4 (8.9)	7 (15.6)
Anaemia	8 (17.8)	3 (6.7)	5 (11.1)
Thrombocytopenia	3 (6.7)	1 (2.2)	2 (4.4)
Cardiac disorders			
-Total	12 (26.7)	7 (15.6)	5 (11.1)
Tachycardia	10 (22.2)	6 (13.3)	4 (8.9)
Sinus tachycardia	3 (6.7)	2 (4.4)	1 (2.2)
Eye disorders			

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (2.2)	0	1 (2.2)
Conjunctival haemorrhage	1 (2.2)	1 (2.2)	0
Periorbital oedema	1 (2.2)	1 (2.2)	0
Vision blurred	1 (2.2)	0	1 (2.2)
Gastrointestinal disorders			
-Total	25 (55.6)	11 (24.4)	14 (31.1)
Nausea	16 (35.6)	4 (8.9)	12 (26.7)
Vomiting	16 (35.6)	10 (22.2)	6 (13.3)
Diarrhoea	12 (26.7)	8 (17.8)	4 (8.9)
Abdominal pain	6 (13.3)	4 (8.9)	2 (4.4)
Constipation	4 (8.9)	4 (8.9)	0
General disorders and administration site conditions			
-Total	22 (48.9)	14 (31.1)	8 (17.8)
Pyrexia	11 (24.4)	5 (11.1)	6 (13.3)
Fatigue	10 (22.2)	9 (20.0)	1 (2.2)
Chills	7 (15.6)	6 (13.3)	1 (2.2)
Malaise	2 (4.4)	1 (2.2)	1 (2.2)
Immune system disorders			

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	36 (80.0)	4 (8.9)	32 (71.1)
Cytokine release syndrome	29 (64.4)	5 (11.1)	24 (53.3)
Hypogammaglobulinaemia	18 (40.0)	1 (2.2)	17 (37.8)
Infections and infestations			
-Total	10 (22.2)	4 (8.9)	6 (13.3)
Upper respiratory tract infection	4 (8.9)	2 (4.4)	2 (4.4)
Rhinovirus infection	2 (4.4)	2 (4.4)	0
Urinary tract infection	2 (4.4)	0	2 (4.4)
Clostridium difficile colitis	1 (2.2)	0	1 (2.2)
Gastroenteritis	1 (2.2)	0	1 (2.2)
Injury, poisoning and procedural complications			
-Total	1 (2.2)	0	1 (2.2)
Transfusion reaction	1 (2.2)	0	1 (2.2)
Investigations			
-Total	24 (53.3)	3 (6.7)	21 (46.7)
White blood cell count decreased	11 (24.4)	3 (6.7)	8 (17.8)
Aspartate aminotransferase increased	8 (17.8)	4 (8.9)	4 (8.9)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	7 (15.6)	3 (6.7)	4 (8.9)
International normalised ratio increased	6 (13.3)	6 (13.3)	0
Platelet count decreased	5 (11.1)	2 (4.4)	3 (6.7)
Prothrombin time prolonged	5 (11.1)	3 (6.7)	2 (4.4)
Blood bilirubin increased	4 (8.9)	1 (2.2)	3 (6.7)
Blood creatinine increased	4 (8.9)	3 (6.7)	1 (2.2)
Lymphocyte count decreased	4 (8.9)	1 (2.2)	3 (6.7)
Neutrophil count decreased	3 (6.7)	0	3 (6.7)
Blood immunoglobulin m decreased	2 (4.4)	2 (4.4)	0
Weight decreased	2 (4.4)	1 (2.2)	1 (2.2)
Blood immunoglobulin a decreased	1 (2.2)	1 (2.2)	0
Blood urea increased	1 (2.2)	1 (2.2)	0
Metabolism and nutrition disorders			
-Total	22 (48.9)	12 (26.7)	10 (22.2)
Hypokalaemia	9 (20.0)	3 (6.7)	6 (13.3)
Decreased appetite	8 (17.8)	5 (11.1)	3 (6.7)
Hyperphosphataemia	6 (13.3)	6 (13.3)	0
Hypoalbuminaemia	3 (6.7)	1 (2.2)	2 (4.4)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypernatraemia	2 (4.4)	1 (2.2)	1 (2.2)
Fluid overload	1 (2.2)	1 (2.2)	0
Hypophosphataemia	1 (2.2)	1 (2.2)	0
Musculoskeletal and connective tissue disorders			
-Total	6 (13.3)	5 (11.1)	1 (2.2)
Pain in extremity	4 (8.9)	3 (6.7)	1 (2.2)
Myalgia	3 (6.7)	3 (6.7)	0
Nervous system disorders			
-Total	21 (46.7)	14 (31.1)	7 (15.6)
Headache	17 (37.8)	11 (24.4)	6 (13.3)
Dizziness	5 (11.1)	5 (11.1)	0
Encephalopathy	1 (2.2)	0	1 (2.2)
Psychiatric disorders			
-Total	7 (15.6)	5 (11.1)	2 (4.4)
Confusional state	4 (8.9)	3 (6.7)	1 (2.2)
Anxiety	3 (6.7)	2 (4.4)	1 (2.2)
Delirium	2 (4.4)	1 (2.2)	1 (2.2)
Renal and urinary disorders			

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (2.2)	1 (2.2)	0
Haematuria	1 (2.2)	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	19 (42.2)	9 (20.0)	10 (22.2)
Cough	6 (13.3)	5 (11.1)	1 (2.2)
Oropharyngeal pain	5 (11.1)	3 (6.7)	2 (4.4)
Pleural effusion	5 (11.1)	2 (4.4)	3 (6.7)
Rhinorrhoea	4 (8.9)	3 (6.7)	1 (2.2)
Epistaxis	3 (6.7)	3 (6.7)	0
Hypoxia	3 (6.7)	0	3 (6.7)
Rhinitis allergic	2 (4.4)	2 (4.4)	0
Skin and subcutaneous tissue disorders			
-Total	10 (22.2)	9 (20.0)	1 (2.2)
Rash	4 (8.9)	3 (6.7)	1 (2.2)
Erythema	3 (6.7)	3 (6.7)	0
Hyperhidrosis	2 (4.4)	2 (4.4)	0
Pruritus	2 (4.4)	2 (4.4)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash maculo-papular	1 (2.2)	1 (2.2)	0
Vascular disorders			
-Total	9 (20.0)	2 (4.4)	7 (15.6)
Hypertension	9 (20.0)	2 (4.4)	7 (15.6)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

		All patients N=64	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	62 (96.9)	3 (4.7)	59 (92.2)
Blood and lymphatic system disorders			
-Total	11 (17.2)	4 (6.3)	7 (10.9)
Anaemia	11 (17.2)	4 (6.3)	7 (10.9)
Cardiac disorders			
-Total	14 (21.9)	8 (12.5)	6 (9.4)
Tachycardia	14 (21.9)	8 (12.5)	6 (9.4)
Gastrointestinal disorders			
-Total	32 (50.0)	12 (18.8)	20 (31.3)
Nausea	20 (31.3)	6 (9.4)	14 (21.9)
Vomiting	20 (31.3)	13 (20.3)	7 (10.9)

Timing: within 8 weeks post infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	17 (26.6)	11 (17.2)	6 (9.4)
Abdominal pain	8 (12.5)	6 (9.4)	2 (3.1)
Constipation	7 (10.9)	6 (9.4)	1 (1.6)
General disorders and administration site conditions			
-Total	26 (40.6)	13 (20.3)	13 (20.3)
Pyrexia	14 (21.9)	3 (4.7)	11 (17.2)
Fatigue	13 (20.3)	10 (15.6)	3 (4.7)
Chills	8 (12.5)	8 (12.5)	0
Immune system disorders			
-Total	52 (81.3)	6 (9.4)	46 (71.9)
Cytokine release syndrome	45 (70.3)	7 (10.9)	38 (59.4)
Hypogammaglobulinaemia	21 (32.8)	3 (4.7)	18 (28.1)
Infections and infestations			
-Total	1 (1.6)	0	1 (1.6)
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)
Investigations			
-Total	30 (46.9)	7 (10.9)	23 (35.9)

Timing: within 8 weeks post infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	12 (18.8)	6 (9.4)	6 (9.4)
White blood cell count decreased	11 (17.2)	3 (4.7)	8 (12.5)
Alanine aminotransferase increased	10 (15.6)	5 (7.8)	5 (7.8)
Prothrombin time prolonged	9 (14.1)	5 (7.8)	4 (6.3)
International normalised ratio increased	8 (12.5)	8 (12.5)	0
Blood creatinine increased	7 (10.9)	5 (7.8)	2 (3.1)
Lymphocyte count decreased	4 (6.3)	1 (1.6)	3 (4.7)
Metabolism and nutrition disorders			
-Total	25 (39.1)	14 (21.9)	11 (17.2)
Decreased appetite	11 (17.2)	7 (10.9)	4 (6.3)
Hypokalaemia	10 (15.6)	3 (4.7)	7 (10.9)
Hyperphosphataemia	8 (12.5)	8 (12.5)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (6.3)	2 (3.1)	2 (3.1)
Pain in extremity	4 (6.3)	2 (3.1)	2 (3.1)
Nervous system disorders			
-Total	24 (37.5)	16 (25.0)	8 (12.5)

Timing: within 8 weeks post infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	24 (37.5)	16 (25.0)	8 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (12.5)	8 (12.5)	0
Cough	8 (12.5)	8 (12.5)	0
Skin and subcutaneous tissue disorders			
-Total	4 (6.3)	4 (6.3)	0
Rash	4 (6.3)	4 (6.3)	0
Vascular disorders			
-Total	9 (14.1)	2 (3.1)	7 (10.9)
Hypertension	9 (14.1)	2 (3.1)	7 (10.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

		All patients N=56	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	31 (55.4)	11 (19.6)	20 (35.7)
Blood and lymphatic system disorders			
-Total	1 (1.8)	1 (1.8)	0
Anaemia	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	13 (23.2)	8 (14.3)	5 (8.9)
Vomiting	8 (14.3)	5 (8.9)	3 (5.4)
Diarrhoea	7 (12.5)	6 (10.7)	1 (1.8)
Nausea	4 (7.1)	1 (1.8)	3 (5.4)
Abdominal pain	3 (5.4)	2 (3.6)	1 (1.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	10 (17.9)	8 (14.3)	2 (3.6)
Pyrexia	9 (16.1)	7 (12.5)	2 (3.6)
Fatigue	2 (3.6)	2 (3.6)	0
Chills	1 (1.8)	1 (1.8)	0
Immune system disorders			
-Total	7 (12.5)	0	7 (12.5)
Hypogammaglobulinaemia	7 (12.5)	0	7 (12.5)
Infections and infestations			
-Total	6 (10.7)	3 (5.4)	3 (5.4)
Upper respiratory tract infection	6 (10.7)	3 (5.4)	3 (5.4)
Investigations			
-Total	7 (12.5)	4 (7.1)	3 (5.4)
White blood cell count decreased	4 (7.1)	2 (3.6)	2 (3.6)
Lymphocyte count decreased	2 (3.6)	1 (1.8)	1 (1.8)
Aspartate aminotransferase increased	1 (1.8)	1 (1.8)	0
Blood creatinine increased	1 (1.8)	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	5 (8.9)	4 (7.1)	1 (1.8)
Decreased appetite	2 (3.6)	1 (1.8)	1 (1.8)
Hyperphosphataemia	2 (3.6)	2 (3.6)	0
Hypokalaemia	1 (1.8)	1 (1.8)	0
Musculoskeletal and connective tissue disorders			
-Total	8 (14.3)	6 (10.7)	2 (3.6)
Pain in extremity	8 (14.3)	6 (10.7)	2 (3.6)
Nervous system disorders			
-Total	5 (8.9)	4 (7.1)	1 (1.8)
Headache	5 (8.9)	4 (7.1)	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (12.5)	5 (8.9)	2 (3.6)
Cough	7 (12.5)	5 (8.9)	2 (3.6)
Skin and subcutaneous tissue disorders			
-Total	4 (7.1)	1 (1.8)	3 (5.4)
Rash	4 (7.1)	1 (1.8)	3 (5.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	2 (3.6)	1 (1.8)	1 (1.8)
Hypertension	2 (3.6)	1 (1.8)	1 (1.8)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (23.5)	2 (5.9)	6 (17.6)
Gastrointestinal disorders			
-Total	3 (8.8)	0	3 (8.8)
Diarrhoea	2 (5.9)	0	2 (5.9)
Abdominal pain	1 (2.9)	0	1 (2.9)
Nausea	1 (2.9)	0	1 (2.9)
General disorders and administration site conditions			
-Total	1 (2.9)	0	1 (2.9)
Chills	1 (2.9)	0	1 (2.9)
Pyrexia	1 (2.9)	0	1 (2.9)

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	2 (5.9)	1 (2.9)	1 (2.9)
Upper respiratory tract infection	2 (5.9)	1 (2.9)	1 (2.9)
Investigations			
-Total	5 (14.7)	3 (8.8)	2 (5.9)
Lymphocyte count decreased	3 (8.8)	2 (5.9)	1 (2.9)
Alanine aminotransferase increased	1 (2.9)	0	1 (2.9)
Aspartate aminotransferase increased	1 (2.9)	1 (2.9)	0
White blood cell count decreased	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	1 (2.9)	0	1 (2.9)
Headache	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (5.9)	2 (5.9)	0
Cough	2 (5.9)	2 (5.9)	0

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AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	63 (98.4)	3 (4.7)	60 (93.8)
Blood and lymphatic system disorders			
-Total	11 (17.2)	4 (6.3)	7 (10.9)
Anaemia	11 (17.2)	4 (6.3)	7 (10.9)
Cardiac disorders			
-Total	14 (21.9)	8 (12.5)	6 (9.4)
Tachycardia	14 (21.9)	8 (12.5)	6 (9.4)
Gastrointestinal disorders			
-Total	38 (59.4)	14 (21.9)	24 (37.5)
Vomiting	25 (39.1)	16 (25.0)	9 (14.1)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	23 (35.9)	6 (9.4)	17 (26.6)
Diarrhoea	22 (34.4)	13 (20.3)	9 (14.1)
Abdominal pain	10 (15.6)	6 (9.4)	4 (6.3)
Constipation	7 (10.9)	6 (9.4)	1 (1.6)
General disorders and administration site conditions			
-Total	33 (51.6)	17 (26.6)	16 (25.0)
Pyrexia	22 (34.4)	8 (12.5)	14 (21.9)
Fatigue	15 (23.4)	12 (18.8)	3 (4.7)
Chills	10 (15.6)	9 (14.1)	1 (1.6)
Immune system disorders			
-Total	53 (82.8)	6 (9.4)	47 (73.4)
Cytokine release syndrome	45 (70.3)	7 (10.9)	38 (59.4)
Hypogammaglobulinaemia	27 (42.2)	3 (4.7)	24 (37.5)
Infections and infestations			
-Total	8 (12.5)	4 (6.3)	4 (6.3)
Upper respiratory tract infection	8 (12.5)	4 (6.3)	4 (6.3)
Investigations			
-Total	32 (50.0)	5 (7.8)	27 (42.2)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
White blood cell count decreased	15 (23.4)	5 (7.8)	10 (15.6)
Aspartate aminotransferase increased	13 (20.3)	7 (10.9)	6 (9.4)
Alanine aminotransferase increased	11 (17.2)	5 (7.8)	6 (9.4)
Prothrombin time prolonged	9 (14.1)	5 (7.8)	4 (6.3)
International normalised ratio increased	8 (12.5)	8 (12.5)	0
Blood creatinine increased	7 (10.9)	5 (7.8)	2 (3.1)
Lymphocyte count decreased	7 (10.9)	2 (3.1)	5 (7.8)
Metabolism and nutrition disorders			
-Total	26 (40.6)	15 (23.4)	11 (17.2)
Decreased appetite	13 (20.3)	8 (12.5)	5 (7.8)
Hypokalaemia	11 (17.2)	4 (6.3)	7 (10.9)
Hyperphosphataemia	8 (12.5)	8 (12.5)	0
Musculoskeletal and connective tissue disorders			
-Total	11 (17.2)	7 (10.9)	4 (6.3)
Pain in extremity	11 (17.2)	7 (10.9)	4 (6.3)
Nervous system disorders			
-Total	24 (37.5)	15 (23.4)	9 (14.1)

Timing: Any time post CTL019 infusion, Region: US

Group term Preferred term	All patients N=64 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Headache	24 (37.5)	15 (23.4)	9 (14.1)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (21.9)	12 (18.8)	2 (3.1)
Cough	14 (21.9)	12 (18.8)	2 (3.1)
Skin and subcutaneous tissue disorders			
-Total	8 (12.5)	5 (7.8)	3 (4.7)
Rash	8 (12.5)	5 (7.8)	3 (4.7)
Vascular disorders			
-Total	11 (17.2)	3 (4.7)	8 (12.5)
Hypertension	11 (17.2)	3 (4.7)	8 (12.5)

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Table 225l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	27 (96.4)	1 (3.6)	26 (92.9)
Blood and lymphatic system disorders			
-Total	7 (25.0)	2 (7.1)	5 (17.9)
Anaemia	7 (25.0)	2 (7.1)	5 (17.9)
Cardiac disorders			
-Total	10 (35.7)	4 (14.3)	6 (21.4)
Tachycardia	7 (25.0)	3 (10.7)	4 (14.3)
Sinus tachycardia	4 (14.3)	2 (7.1)	2 (7.1)
Gastrointestinal disorders			
-Total	16 (57.1)	6 (21.4)	10 (35.7)
Nausea	11 (39.3)	5 (17.9)	6 (21.4)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	10 (35.7)	7 (25.0)	3 (10.7)
Vomiting	9 (32.1)	8 (28.6)	1 (3.6)
Abdominal pain	7 (25.0)	5 (17.9)	2 (7.1)
Constipation	2 (7.1)	2 (7.1)	0
General disorders and administration site conditions			
-Total	13 (46.4)	8 (28.6)	5 (17.9)
Fatigue	8 (28.6)	6 (21.4)	2 (7.1)
Pyrexia	6 (21.4)	3 (10.7)	3 (10.7)
Chills	3 (10.7)	3 (10.7)	0
Immune system disorders			
-Total	22 (78.6)	5 (17.9)	17 (60.7)
Cytokine release syndrome	18 (64.3)	4 (14.3)	14 (50.0)
Hypogammaglobulinaemia	8 (28.6)	2 (7.1)	6 (21.4)
Infections and infestations			
-Total	3 (10.7)	0	3 (10.7)
Clostridium difficile infection	3 (10.7)	0	3 (10.7)
Rhinovirus infection	1 (3.6)	1 (3.6)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	3 (10.7)	2 (7.1)	1 (3.6)
Transfusion reaction	3 (10.7)	2 (7.1)	1 (3.6)
Investigations			
-Total	18 (64.3)	3 (10.7)	15 (53.6)
Aspartate aminotransferase increased	8 (28.6)	5 (17.9)	3 (10.7)
Alanine aminotransferase increased	7 (25.0)	4 (14.3)	3 (10.7)
Prothrombin time prolonged	6 (21.4)	4 (14.3)	2 (7.1)
Blood bilirubin increased	5 (17.9)	2 (7.1)	3 (10.7)
Blood creatinine increased	5 (17.9)	4 (14.3)	1 (3.6)
International normalised ratio increased	5 (17.9)	5 (17.9)	0
White blood cell count decreased	5 (17.9)	0	5 (17.9)
Blood immunoglobulin a decreased	3 (10.7)	3 (10.7)	0
Blood immunoglobulin m decreased	3 (10.7)	3 (10.7)	0
Platelet count decreased	3 (10.7)	2 (7.1)	1 (3.6)
Lymphocyte count decreased	2 (7.1)	0	2 (7.1)
Neutrophil count decreased	1 (3.6)	0	1 (3.6)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	14 (50.0)	9 (32.1)	5 (17.9)
Hyperphosphataemia	7 (25.0)	7 (25.0)	0
Decreased appetite	6 (21.4)	4 (14.3)	2 (7.1)
Hypokalaemia	4 (14.3)	1 (3.6)	3 (10.7)
Musculoskeletal and connective tissue disorders			
-Total	7 (25.0)	5 (17.9)	2 (7.1)
Myalgia	5 (17.9)	4 (14.3)	1 (3.6)
Pain in extremity	3 (10.7)	2 (7.1)	1 (3.6)
Nervous system disorders			
-Total	13 (46.4)	7 (25.0)	6 (21.4)
Headache	12 (42.9)	6 (21.4)	6 (21.4)
Dizziness	3 (10.7)	3 (10.7)	0
Psychiatric disorders			
-Total	3 (10.7)	1 (3.6)	2 (7.1)
Anxiety	2 (7.1)	1 (3.6)	1 (3.6)
Confusional state	2 (7.1)	0	2 (7.1)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	12 (42.9)	5 (17.9)	7 (25.0)
Cough	4 (14.3)	4 (14.3)	0
Hypoxia	4 (14.3)	0	4 (14.3)
Pleural effusion	3 (10.7)	1 (3.6)	2 (7.1)
Epistaxis	2 (7.1)	1 (3.6)	1 (3.6)
Oropharyngeal pain	1 (3.6)	1 (3.6)	0
Rhinitis allergic	1 (3.6)	1 (3.6)	0
Rhinorrhoea	1 (3.6)	1 (3.6)	0
Skin and subcutaneous tissue disorders			
-Total	3 (10.7)	2 (7.1)	1 (3.6)
Petechiae	2 (7.1)	1 (3.6)	1 (3.6)
Rash	2 (7.1)	2 (7.1)	0
Vascular disorders			
-Total	4 (14.3)	1 (3.6)	3 (10.7)
Hypertension	4 (14.3)	1 (3.6)	3 (10.7)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

		All patients N=36	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	35 (97.2)	2 (5.6)	33 (91.7)
Blood and lymphatic system disorders			
-Total	4 (11.1)	2 (5.6)	2 (5.6)
Anaemia	4 (11.1)	2 (5.6)	2 (5.6)
Cardiac disorders			
-Total	8 (22.2)	6 (16.7)	2 (5.6)
Tachycardia	7 (19.4)	5 (13.9)	2 (5.6)
Sinus tachycardia	1 (2.8)	1 (2.8)	0
Gastrointestinal disorders			
-Total	16 (44.4)	6 (16.7)	10 (27.8)
Vomiting	11 (30.6)	5 (13.9)	6 (16.7)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	9 (25.0)	1 (2.8)	8 (22.2)
Diarrhoea	7 (19.4)	4 (11.1)	3 (8.3)
Constipation	5 (13.9)	4 (11.1)	1 (2.8)
Abdominal pain	1 (2.8)	1 (2.8)	0
General disorders and administration site conditions			
-Total	13 (36.1)	5 (13.9)	8 (22.2)
Pyrexia	8 (22.2)	0	8 (22.2)
Chills	5 (13.9)	5 (13.9)	0
Fatigue	5 (13.9)	4 (11.1)	1 (2.8)
Immune system disorders			
-Total	30 (83.3)	1 (2.8)	29 (80.6)
Cytokine release syndrome	27 (75.0)	3 (8.3)	24 (66.7)
Hypogammaglobulinaemia	13 (36.1)	1 (2.8)	12 (33.3)
Infections and infestations			
-Total	5 (13.9)	2 (5.6)	3 (8.3)
Rhinovirus infection	2 (5.6)	2 (5.6)	0
Clostridium difficile infection	1 (2.8)	0	1 (2.8)
Gastroenteritis	1 (2.8)	0	1 (2.8)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	1 (2.8)	0	1 (2.8)
Investigations			
-Total	12 (33.3)	1 (2.8)	11 (30.6)
White blood cell count decreased	6 (16.7)	3 (8.3)	3 (8.3)
Aspartate aminotransferase increased	4 (11.1)	1 (2.8)	3 (8.3)
Alanine aminotransferase increased	3 (8.3)	1 (2.8)	2 (5.6)
International normalised ratio increased	3 (8.3)	3 (8.3)	0
Platelet count decreased	3 (8.3)	1 (2.8)	2 (5.6)
Prothrombin time prolonged	3 (8.3)	1 (2.8)	2 (5.6)
Blood creatinine increased	2 (5.6)	1 (2.8)	1 (2.8)
Lymphocyte count decreased	2 (5.6)	1 (2.8)	1 (2.8)
Blood bilirubin increased	1 (2.8)	0	1 (2.8)
Blood immunoglobulin m decreased	1 (2.8)	1 (2.8)	0
Neutrophil count decreased	1 (2.8)	0	1 (2.8)
Metabolism and nutrition disorders			
-Total	14 (38.9)	6 (16.7)	8 (22.2)
Hypokalaemia	6 (16.7)	2 (5.6)	4 (11.1)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	5 (13.9)	3 (8.3)	2 (5.6)
Hypernatraemia	4 (11.1)	1 (2.8)	3 (8.3)
Hyperphosphataemia	1 (2.8)	1 (2.8)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (2.8)	0	1 (2.8)
Pain in extremity	1 (2.8)	0	1 (2.8)
Nervous system disorders			
-Total	13 (36.1)	11 (30.6)	2 (5.6)
Headache	12 (33.3)	10 (27.8)	2 (5.6)
Dizziness	1 (2.8)	1 (2.8)	0
Psychiatric disorders			
-Total	10 (27.8)	6 (16.7)	4 (11.1)
Confusional state	4 (11.1)	3 (8.3)	1 (2.8)
Delirium	4 (11.1)	2 (5.6)	2 (5.6)
Anxiety	3 (8.3)	1 (2.8)	2 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (27.8)	5 (13.9)	5 (13.9)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	4 (11.1)	4 (11.1)	0
Pleural effusion	3 (8.3)	1 (2.8)	2 (5.6)
Epistaxis	2 (5.6)	1 (2.8)	1 (2.8)
Hypoxia	1 (2.8)	0	1 (2.8)
Nasal congestion	1 (2.8)	1 (2.8)	0
Oropharyngeal pain	1 (2.8)	0	1 (2.8)
Skin and subcutaneous tissue disorders			
-Total	3 (8.3)	3 (8.3)	0
Rash	2 (5.6)	2 (5.6)	0
Petechiae	1 (2.8)	1 (2.8)	0
Vascular disorders			
-Total	5 (13.9)	1 (2.8)	4 (11.1)
Hypertension	5 (13.9)	1 (2.8)	4 (11.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of

adverse events.

Table 225l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (60.0)	4 (16.0)	11 (44.0)
Blood and lymphatic system disorders			
-Total	1 (4.0)	1 (4.0)	0
Anaemia	1 (4.0)	1 (4.0)	0
Cardiac disorders			
-Total	1 (4.0)	0	1 (4.0)
Sinus tachycardia	1 (4.0)	0	1 (4.0)
Gastrointestinal disorders			
-Total	7 (28.0)	3 (12.0)	4 (16.0)
Vomiting	5 (20.0)	2 (8.0)	3 (12.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	3 (12.0)	2 (8.0)	1 (4.0)
Nausea	3 (12.0)	1 (4.0)	2 (8.0)
Abdominal pain	2 (8.0)	1 (4.0)	1 (4.0)
General disorders and administration site conditions			
-Total	6 (24.0)	5 (20.0)	1 (4.0)
Pyrexia	6 (24.0)	5 (20.0)	1 (4.0)
Chills	1 (4.0)	1 (4.0)	0
Fatigue	1 (4.0)	1 (4.0)	0
Immune system disorders			
-Total	5 (20.0)	0	5 (20.0)
Hypogammaglobulinaemia	5 (20.0)	0	5 (20.0)
Infections and infestations			
-Total	4 (16.0)	0	4 (16.0)
Upper respiratory tract infection	2 (8.0)	2 (8.0)	0
Urinary tract infection	2 (8.0)	0	2 (8.0)
Otitis media	1 (4.0)	0	1 (4.0)
Sinusitis	1 (4.0)	0	1 (4.0)
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (24.0)	4 (16.0)	2 (8.0)
Platelet count decreased	3 (12.0)	3 (12.0)	0
Lymphocyte count decreased	2 (8.0)	1 (4.0)	1 (4.0)
Neutrophil count decreased	2 (8.0)	2 (8.0)	0
White blood cell count decreased	2 (8.0)	1 (4.0)	1 (4.0)
Aspartate aminotransferase increased	1 (4.0)	1 (4.0)	0
Blood creatinine increased	1 (4.0)	1 (4.0)	0
Metabolism and nutrition disorders			
-Total	5 (20.0)	4 (16.0)	1 (4.0)
Decreased appetite	2 (8.0)	1 (4.0)	1 (4.0)
Hyperphosphataemia	2 (8.0)	2 (8.0)	0
Hypokalaemia	1 (4.0)	1 (4.0)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (12.0)	2 (8.0)	1 (4.0)
Pain in extremity	3 (12.0)	2 (8.0)	1 (4.0)
Nervous system disorders			
-Total	3 (12.0)	2 (8.0)	1 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	3 (12.0)	2 (8.0)	1 (4.0)
Dizziness	2 (8.0)	2 (8.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (24.0)	5 (20.0)	1 (4.0)
Cough	4 (16.0)	3 (12.0)	1 (4.0)
Rhinitis allergic	2 (8.0)	2 (8.0)	0
Epistaxis	1 (4.0)	1 (4.0)	0
Nasal congestion	1 (4.0)	1 (4.0)	0
Oropharyngeal pain	1 (4.0)	1 (4.0)	0
Skin and subcutaneous tissue disorders			
-Total	3 (12.0)	2 (8.0)	1 (4.0)
Rash	2 (8.0)	1 (4.0)	1 (4.0)
Petechiae	1 (4.0)	1 (4.0)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	23 (74.2)	7 (22.6)	16 (51.6)
Gastrointestinal disorders			
-Total	6 (19.4)	5 (16.1)	1 (3.2)
Diarrhoea	4 (12.9)	4 (12.9)	0
Vomiting	3 (9.7)	3 (9.7)	0
Abdominal pain	1 (3.2)	1 (3.2)	0
Nausea	1 (3.2)	0	1 (3.2)
General disorders and administration site conditions			
-Total	4 (12.9)	3 (9.7)	1 (3.2)
Pyrexia	3 (9.7)	2 (6.5)	1 (3.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fatigue	1 (3.2)	1 (3.2)	0
Immune system disorders			
-Total	2 (6.5)	0	2 (6.5)
Hypogammaglobulinaemia	2 (6.5)	0	2 (6.5)
Infections and infestations			
-Total	11 (35.5)	4 (12.9)	7 (22.6)
Upper respiratory tract infection	4 (12.9)	1 (3.2)	3 (9.7)
Gastroenteritis	3 (9.7)	1 (3.2)	2 (6.5)
Rhinovirus infection	2 (6.5)	2 (6.5)	0
Sinusitis	1 (3.2)	0	1 (3.2)
Urinary tract infection	1 (3.2)	0	1 (3.2)
Investigations			
-Total	3 (9.7)	1 (3.2)	2 (6.5)
White blood cell count decreased	2 (6.5)	1 (3.2)	1 (3.2)
Neutrophil count decreased	1 (3.2)	0	1 (3.2)
Musculoskeletal and connective tissue disorders			
-Total	5 (16.1)	4 (12.9)	1 (3.2)
Pain in extremity	5 (16.1)	4 (12.9)	1 (3.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nervous system disorders			
-Total	3 (9.7)	3 (9.7)	0
Headache	2 (6.5)	2 (6.5)	0
Dizziness	1 (3.2)	1 (3.2)	0
Psychiatric disorders			
-Total	1 (3.2)	1 (3.2)	0
Anxiety	1 (3.2)	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (29.0)	5 (16.1)	4 (12.9)
Rhinorrhoea	4 (12.9)	3 (9.7)	1 (3.2)
Cough	3 (9.7)	2 (6.5)	1 (3.2)
Nasal congestion	3 (9.7)	3 (9.7)	0
Oropharyngeal pain	2 (6.5)	1 (3.2)	1 (3.2)
Rhinitis allergic	1 (3.2)	0	1 (3.2)
Skin and subcutaneous tissue disorders			
-Total	2 (6.5)	0	2 (6.5)
Rash	2 (6.5)	0	2 (6.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	2 (6.5)	1 (3.2)	1 (3.2)
Hypertension	2 (6.5)	1 (3.2)	1 (3.2)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (50.0)	2 (14.3)	5 (35.7)
Gastrointestinal disorders			
-Total	2 (14.3)	0	2 (14.3)
Diarrhoea	2 (14.3)	0	2 (14.3)
Abdominal pain	1 (7.1)	0	1 (7.1)
Infections and infestations			
-Total	5 (35.7)	1 (7.1)	4 (28.6)
Otitis media	2 (14.3)	0	2 (14.3)
Sinusitis	2 (14.3)	0	2 (14.3)
Upper respiratory tract infection	2 (14.3)	1 (7.1)	1 (7.1)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Urinary tract infection	2 (14.3)	0	2 (14.3)
Investigations			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Lymphocyte count decreased	2 (14.3)	2 (14.3)	0
Neutrophil count decreased	2 (14.3)	1 (7.1)	1 (7.1)
White blood cell count decreased	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	1 (7.1)	0	1 (7.1)
Dizziness	1 (7.1)	1 (7.1)	0
Headache	1 (7.1)	0	1 (7.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (21.4)	3 (21.4)	0
Cough	1 (7.1)	1 (7.1)	0
Epistaxis	1 (7.1)	1 (7.1)	0
Oropharyngeal pain	1 (7.1)	1 (7.1)	0
Rhinitis allergic	1 (7.1)	1 (7.1)	0
Rhinorrhoea	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 225l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (25.0)	0	5 (25.0)
Gastrointestinal disorders			
-Total	1 (5.0)	0	1 (5.0)
Nausea	1 (5.0)	0	1 (5.0)
General disorders and administration site conditions			
-Total	1 (5.0)	0	1 (5.0)
Chills	1 (5.0)	0	1 (5.0)
Pyrexia	1 (5.0)	0	1 (5.0)
Infections and infestations			
-Total	2 (10.0)	0	2 (10.0)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Otitis media	1 (5.0)	0	1 (5.0)
Sinusitis	1 (5.0)	0	1 (5.0)
Investigations			
-Total	3 (15.0)	1 (5.0)	2 (10.0)
Alanine aminotransferase increased	1 (5.0)	0	1 (5.0)
Aspartate aminotransferase increased	1 (5.0)	1 (5.0)	0
Lymphocyte count decreased	1 (5.0)	0	1 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.0)	1 (5.0)	0
Cough	1 (5.0)	1 (5.0)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	28 (100)	0	28 (100)
Blood and lymphatic system disorders			
-Total	7 (25.0)	2 (7.1)	5 (17.9)
Anaemia	7 (25.0)	2 (7.1)	5 (17.9)
Cardiac disorders			
-Total	11 (39.3)	4 (14.3)	7 (25.0)
Tachycardia	7 (25.0)	3 (10.7)	4 (14.3)
Sinus tachycardia	5 (17.9)	2 (7.1)	3 (10.7)
Gastrointestinal disorders			
-Total	18 (64.3)	6 (21.4)	12 (42.9)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	12 (42.9)	6 (21.4)	6 (21.4)
Nausea	12 (42.9)	5 (17.9)	7 (25.0)
Vomiting	12 (42.9)	9 (32.1)	3 (10.7)
Abdominal pain	8 (28.6)	4 (14.3)	4 (14.3)
Constipation	2 (7.1)	2 (7.1)	0
General disorders and administration site conditions			
-Total	17 (60.7)	11 (39.3)	6 (21.4)
Pyrexia	11 (39.3)	7 (25.0)	4 (14.3)
Fatigue	9 (32.1)	7 (25.0)	2 (7.1)
Chills	4 (14.3)	4 (14.3)	0
Immune system disorders			
-Total	23 (82.1)	5 (17.9)	18 (64.3)
Cytokine release syndrome	18 (64.3)	4 (14.3)	14 (50.0)
Hypogammaglobulinaemia	12 (42.9)	2 (7.1)	10 (35.7)
Infections and infestations			
-Total	9 (32.1)	1 (3.6)	8 (28.6)
Upper respiratory tract infection	4 (14.3)	3 (10.7)	1 (3.6)
Clostridium difficile infection	3 (10.7)	0	3 (10.7)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Otitis media	3 (10.7)	0	3 (10.7)
Sinusitis	3 (10.7)	0	3 (10.7)
Urinary tract infection	3 (10.7)	0	3 (10.7)
Rhinovirus infection	1 (3.6)	1 (3.6)	0
Injury, poisoning and procedural complications			
-Total	3 (10.7)	2 (7.1)	1 (3.6)
Transfusion reaction	3 (10.7)	2 (7.1)	1 (3.6)
Investigations			
-Total	18 (64.3)	2 (7.1)	16 (57.1)
Aspartate aminotransferase increased	8 (28.6)	5 (17.9)	3 (10.7)
White blood cell count decreased	8 (28.6)	2 (7.1)	6 (21.4)
Alanine aminotransferase increased	7 (25.0)	4 (14.3)	3 (10.7)
Prothrombin time prolonged	6 (21.4)	4 (14.3)	2 (7.1)
Blood bilirubin increased	5 (17.9)	2 (7.1)	3 (10.7)
Blood creatinine increased	5 (17.9)	4 (14.3)	1 (3.6)
International normalised ratio increased	5 (17.9)	5 (17.9)	0
Lymphocyte count decreased	4 (14.3)	1 (3.6)	3 (10.7)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood immunoglobulin a decreased	3 (10.7)	3 (10.7)	0
Blood immunoglobulin m decreased	3 (10.7)	3 (10.7)	0
Neutrophil count decreased	3 (10.7)	1 (3.6)	2 (7.1)
Platelet count decreased	3 (10.7)	2 (7.1)	1 (3.6)
Metabolism and nutrition disorders			
-Total	15 (53.6)	10 (35.7)	5 (17.9)
Decreased appetite	8 (28.6)	5 (17.9)	3 (10.7)
Hyperphosphataemia	7 (25.0)	7 (25.0)	0
Hypokalaemia	5 (17.9)	2 (7.1)	3 (10.7)
Musculoskeletal and connective tissue disorders			
-Total	8 (28.6)	5 (17.9)	3 (10.7)
Myalgia	5 (17.9)	4 (14.3)	1 (3.6)
Pain in extremity	5 (17.9)	3 (10.7)	2 (7.1)
Nervous system disorders			
-Total	13 (46.4)	6 (21.4)	7 (25.0)
Headache	12 (42.9)	5 (17.9)	7 (25.0)
Dizziness	4 (14.3)	4 (14.3)	0
Psychiatric disorders			

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (10.7)	1 (3.6)	2 (7.1)
Anxiety	2 (7.1)	1 (3.6)	1 (3.6)
Confusional state	2 (7.1)	0	2 (7.1)
Respiratory, thoracic and mediastinal disorders			
-Total	16 (57.1)	9 (32.1)	7 (25.0)
Cough	7 (25.0)	6 (21.4)	1 (3.6)
Epistaxis	4 (14.3)	3 (10.7)	1 (3.6)
Hypoxia	4 (14.3)	0	4 (14.3)
Oropharyngeal pain	3 (10.7)	3 (10.7)	0
Pleural effusion	3 (10.7)	1 (3.6)	2 (7.1)
Rhinitis allergic	3 (10.7)	3 (10.7)	0
Rhinorrhoea	2 (7.1)	2 (7.1)	0
Nasal congestion	1 (3.6)	1 (3.6)	0
Skin and subcutaneous tissue disorders			
-Total	6 (21.4)	4 (14.3)	2 (7.1)
Rash	4 (14.3)	3 (10.7)	1 (3.6)
Petechiae	3 (10.7)	2 (7.1)	1 (3.6)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	4 (14.3)	1 (3.6)	3 (10.7)
Hypertension	4 (14.3)	1 (3.6)	3 (10.7)

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Table 225l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	36 (100)	2 (5.6)	34 (94.4)
Blood and lymphatic system disorders			
-Total	4 (11.1)	2 (5.6)	2 (5.6)
Anaemia	4 (11.1)	2 (5.6)	2 (5.6)
Cardiac disorders			
-Total	8 (22.2)	6 (16.7)	2 (5.6)
Tachycardia	7 (19.4)	5 (13.9)	2 (5.6)
Sinus tachycardia	1 (2.8)	1 (2.8)	0
Gastrointestinal disorders			
-Total	20 (55.6)	8 (22.2)	12 (33.3)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	13 (36.1)	7 (19.4)	6 (16.7)
Nausea	11 (30.6)	1 (2.8)	10 (27.8)
Diarrhoea	10 (27.8)	7 (19.4)	3 (8.3)
Constipation	5 (13.9)	4 (11.1)	1 (2.8)
Abdominal pain	2 (5.6)	2 (5.6)	0
General disorders and administration site conditions			
-Total	16 (44.4)	6 (16.7)	10 (27.8)
Pyrexia	11 (30.6)	1 (2.8)	10 (27.8)
Chills	6 (16.7)	5 (13.9)	1 (2.8)
Fatigue	6 (16.7)	5 (13.9)	1 (2.8)
Immune system disorders			
-Total	30 (83.3)	1 (2.8)	29 (80.6)
Cytokine release syndrome	27 (75.0)	3 (8.3)	24 (66.7)
Hypogammaglobulinaemia	15 (41.7)	1 (2.8)	14 (38.9)
Infections and infestations			
-Total	14 (38.9)	5 (13.9)	9 (25.0)
Gastroenteritis	4 (11.1)	1 (2.8)	3 (8.3)
Rhinovirus infection	4 (11.1)	4 (11.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	4 (11.1)	1 (2.8)	3 (8.3)
Clostridium difficile infection	1 (2.8)	0	1 (2.8)
Otitis media	1 (2.8)	0	1 (2.8)
Sinusitis	1 (2.8)	0	1 (2.8)
Urinary tract infection	1 (2.8)	0	1 (2.8)
Investigations			
-Total	15 (41.7)	1 (2.8)	14 (38.9)
White blood cell count decreased	7 (19.4)	3 (8.3)	4 (11.1)
Aspartate aminotransferase increased	5 (13.9)	2 (5.6)	3 (8.3)
Alanine aminotransferase increased	4 (11.1)	1 (2.8)	3 (8.3)
International normalised ratio increased	3 (8.3)	3 (8.3)	0
Lymphocyte count decreased	3 (8.3)	1 (2.8)	2 (5.6)
Platelet count decreased	3 (8.3)	1 (2.8)	2 (5.6)
Prothrombin time prolonged	3 (8.3)	1 (2.8)	2 (5.6)
Blood creatinine increased	2 (5.6)	1 (2.8)	1 (2.8)
Neutrophil count decreased	2 (5.6)	0	2 (5.6)
Blood bilirubin increased	1 (2.8)	0	1 (2.8)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood immunoglobulin m decreased	1 (2.8)	1 (2.8)	0
Metabolism and nutrition disorders			
-Total	14 (38.9)	6 (16.7)	8 (22.2)
Hypokalaemia	6 (16.7)	2 (5.6)	4 (11.1)
Decreased appetite	5 (13.9)	3 (8.3)	2 (5.6)
Hypernatraemia	4 (11.1)	1 (2.8)	3 (8.3)
Hyperphosphataemia	1 (2.8)	1 (2.8)	0
Musculoskeletal and connective tissue disorders			
-Total	6 (16.7)	4 (11.1)	2 (5.6)
Pain in extremity	6 (16.7)	4 (11.1)	2 (5.6)
Nervous system disorders			
-Total	14 (38.9)	12 (33.3)	2 (5.6)
Headache	12 (33.3)	10 (27.8)	2 (5.6)
Dizziness	2 (5.6)	2 (5.6)	0
Psychiatric disorders			
-Total	10 (27.8)	6 (16.7)	4 (11.1)
Anxiety	4 (11.1)	2 (5.6)	2 (5.6)
Confusional state	4 (11.1)	3 (8.3)	1 (2.8)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Delirium	4 (11.1)	2 (5.6)	2 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	17 (47.2)	8 (22.2)	9 (25.0)
Cough	7 (19.4)	6 (16.7)	1 (2.8)
Nasal congestion	4 (11.1)	4 (11.1)	0
Rhinorrhoea	4 (11.1)	3 (8.3)	1 (2.8)
Oropharyngeal pain	3 (8.3)	1 (2.8)	2 (5.6)
Pleural effusion	3 (8.3)	1 (2.8)	2 (5.6)
Epistaxis	2 (5.6)	1 (2.8)	1 (2.8)
Hypoxia	1 (2.8)	0	1 (2.8)
Rhinitis allergic	1 (2.8)	0	1 (2.8)
Skin and subcutaneous tissue disorders			
-Total	5 (13.9)	3 (8.3)	2 (5.6)
Rash	4 (11.1)	2 (5.6)	2 (5.6)
Petechiae	1 (2.8)	1 (2.8)	0
Vascular disorders			
-Total	7 (19.4)	2 (5.6)	5 (13.9)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	7 (19.4)	2 (5.6)	5 (13.9)

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Table 225m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (100)	0	14 (100)
Blood and lymphatic system disorders			
-Total	4 (28.6)	2 (14.3)	2 (14.3)
Anaemia	3 (21.4)	2 (14.3)	1 (7.1)
Thrombocytopenia	1 (7.1)	0	1 (7.1)
Cardiac disorders			
-Total	3 (21.4)	3 (21.4)	0
Tachycardia	2 (14.3)	2 (14.3)	0
Sinus tachycardia	1 (7.1)	1 (7.1)	0
Gastrointestinal disorders			
-Total	4 (28.6)	1 (7.1)	3 (21.4)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	3 (21.4)	0	3 (21.4)
Constipation	2 (14.3)	1 (7.1)	1 (7.1)
Abdominal pain	1 (7.1)	1 (7.1)	0
Diarrhoea	1 (7.1)	1 (7.1)	0
Vomiting	1 (7.1)	0	1 (7.1)
General disorders and administration site conditions			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Chills	1 (7.1)	1 (7.1)	0
Fatigue	1 (7.1)	1 (7.1)	0
Pyrexia	1 (7.1)	0	1 (7.1)
Immune system disorders			
-Total	12 (85.7)	0	12 (85.7)
Cytokine release syndrome	11 (78.6)	0	11 (78.6)
Hypogammaglobulinaemia	7 (50.0)	1 (7.1)	6 (42.9)
Injury, poisoning and procedural complications			
-Total	1 (7.1)	1 (7.1)	0
Procedural pain	1 (7.1)	1 (7.1)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	4 (28.6)	1 (7.1)	3 (21.4)
Alanine aminotransferase increased	2 (14.3)	0	2 (14.3)
Blood bilirubin increased	2 (14.3)	1 (7.1)	1 (7.1)
White blood cell count decreased	2 (14.3)	1 (7.1)	1 (7.1)
Aspartate aminotransferase increased	1 (7.1)	0	1 (7.1)
Blood creatinine increased	1 (7.1)	1 (7.1)	0
International normalised ratio increased	1 (7.1)	1 (7.1)	0
Lymphocyte count decreased	1 (7.1)	1 (7.1)	0
Platelet count decreased	1 (7.1)	1 (7.1)	0
Prothrombin time prolonged	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			
-Total	5 (35.7)	3 (21.4)	2 (14.3)
Decreased appetite	2 (14.3)	1 (7.1)	1 (7.1)
Hyperphosphataemia	2 (14.3)	2 (14.3)	0
Hypokalaemia	2 (14.3)	1 (7.1)	1 (7.1)
Musculoskeletal and connective tissue disorders			

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (14.3)	0	2 (14.3)
Arthralgia	1 (7.1)	1 (7.1)	0
Muscular weakness	1 (7.1)	0	1 (7.1)
Pain in extremity	1 (7.1)	0	1 (7.1)
Nervous system disorders			
-Total	3 (21.4)	2 (14.3)	1 (7.1)
Headache	3 (21.4)	2 (14.3)	1 (7.1)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (14.3)	2 (14.3)	0
Cough	1 (7.1)	1 (7.1)	0
Nasal congestion	1 (7.1)	1 (7.1)	0
Pleural effusion	1 (7.1)	1 (7.1)	0
Skin and subcutaneous tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Rash	1 (7.1)	1 (7.1)	0
Vascular disorders			
-Total	2 (14.3)	0	2 (14.3)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	2 (14.3)	0	2 (14.3)

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Table 225m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	48 (96.0)	3 (6.0)	45 (90.0)
Blood and lymphatic system disorders			
-Total	8 (16.0)	2 (4.0)	6 (12.0)
Anaemia	8 (16.0)	2 (4.0)	6 (12.0)
Thrombocytopenia	2 (4.0)	0	2 (4.0)
Cardiac disorders			
-Total	15 (30.0)	7 (14.0)	8 (16.0)
Tachycardia	12 (24.0)	6 (12.0)	6 (12.0)
Sinus tachycardia	4 (8.0)	2 (4.0)	2 (4.0)
Gastrointestinal disorders			
-Total	28 (56.0)	11 (22.0)	17 (34.0)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	19 (38.0)	13 (26.0)	6 (12.0)
Nausea	17 (34.0)	6 (12.0)	11 (22.0)
Diarrhoea	16 (32.0)	10 (20.0)	6 (12.0)
Abdominal pain	7 (14.0)	5 (10.0)	2 (4.0)
Constipation	5 (10.0)	5 (10.0)	0
General disorders and administration site conditions			
-Total	24 (48.0)	12 (24.0)	12 (24.0)
Pyrexia	13 (26.0)	3 (6.0)	10 (20.0)
Fatigue	12 (24.0)	9 (18.0)	3 (6.0)
Chills	7 (14.0)	7 (14.0)	0
Immune system disorders			
-Total	40 (80.0)	6 (12.0)	34 (68.0)
Cytokine release syndrome	34 (68.0)	7 (14.0)	27 (54.0)
Hypogammaglobulinaemia	14 (28.0)	2 (4.0)	12 (24.0)
Infections and infestations			
-Total	2 (4.0)	1 (2.0)	1 (2.0)
Influenza	1 (2.0)	1 (2.0)	0
Upper respiratory tract infection	1 (2.0)	0	1 (2.0)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	2 (4.0)	0	2 (4.0)
Procedural pain	2 (4.0)	0	2 (4.0)
Investigations			
-Total	27 (54.0)	3 (6.0)	24 (48.0)
Aspartate aminotransferase increased	11 (22.0)	6 (12.0)	5 (10.0)
White blood cell count decreased	9 (18.0)	2 (4.0)	7 (14.0)
Alanine aminotransferase increased	8 (16.0)	5 (10.0)	3 (6.0)
Prothrombin time prolonged	8 (16.0)	4 (8.0)	4 (8.0)
International normalised ratio increased	7 (14.0)	7 (14.0)	0
Blood creatinine increased	6 (12.0)	4 (8.0)	2 (4.0)
Activated partial thromboplastin time prolonged	5 (10.0)	3 (6.0)	2 (4.0)
Platelet count decreased	5 (10.0)	2 (4.0)	3 (6.0)
Blood bilirubin increased	4 (8.0)	1 (2.0)	3 (6.0)
Lymphocyte count decreased	3 (6.0)	0	3 (6.0)
Neutrophil count decreased	2 (4.0)	0	2 (4.0)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	20 (40.0)	11 (22.0)	9 (18.0)
Decreased appetite	9 (18.0)	6 (12.0)	3 (6.0)
Hypokalaemia	8 (16.0)	2 (4.0)	6 (12.0)
Hyperphosphataemia	6 (12.0)	6 (12.0)	0
Musculoskeletal and connective tissue disorders			
-Total	8 (16.0)	6 (12.0)	2 (4.0)
Myalgia	5 (10.0)	4 (8.0)	1 (2.0)
Pain in extremity	3 (6.0)	2 (4.0)	1 (2.0)
Arthralgia	2 (4.0)	2 (4.0)	0
Nervous system disorders			
-Total	23 (46.0)	16 (32.0)	7 (14.0)
Headache	21 (42.0)	14 (28.0)	7 (14.0)
Dizziness	4 (8.0)	4 (8.0)	0
Psychiatric disorders			
-Total	10 (20.0)	5 (10.0)	5 (10.0)
Confusional state	6 (12.0)	3 (6.0)	3 (6.0)
Anxiety	5 (10.0)	2 (4.0)	3 (6.0)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	17 (34.0)	10 (20.0)	7 (14.0)
Cough	7 (14.0)	7 (14.0)	0
Pleural effusion	5 (10.0)	1 (2.0)	4 (8.0)
Epistaxis	4 (8.0)	2 (4.0)	2 (4.0)
Oropharyngeal pain	2 (4.0)	1 (2.0)	1 (2.0)
Rhinorrhoea	1 (2.0)	1 (2.0)	0
Skin and subcutaneous tissue disorders			
-Total	3 (6.0)	3 (6.0)	0
Rash	3 (6.0)	3 (6.0)	0
Vascular disorders			
-Total	7 (14.0)	2 (4.0)	5 (10.0)
Hypertension	7 (14.0)	2 (4.0)	5 (10.0)

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Table 225m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (83.3)	1 (8.3)	9 (75.0)
Blood and lymphatic system disorders			
-Total	2 (16.7)	1 (8.3)	1 (8.3)
Anaemia	1 (8.3)	1 (8.3)	0
Thrombocytopenia	1 (8.3)	0	1 (8.3)
Gastrointestinal disorders			
-Total	3 (25.0)	2 (16.7)	1 (8.3)
Vomiting	2 (16.7)	2 (16.7)	0
Diarrhoea	1 (8.3)	1 (8.3)	0
Nausea	1 (8.3)	0	1 (8.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	2 (16.7)	1 (8.3)	1 (8.3)
Pyrexia	2 (16.7)	1 (8.3)	1 (8.3)
Infections and infestations			
-Total	4 (33.3)	0	4 (33.3)
Influenza	2 (16.7)	0	2 (16.7)
Urinary tract infection	2 (16.7)	0	2 (16.7)
Injury, poisoning and procedural complications			
-Total	1 (8.3)	1 (8.3)	0
Procedural pain	1 (8.3)	1 (8.3)	0
Investigations			
-Total	2 (16.7)	0	2 (16.7)
Neutrophil count decreased	2 (16.7)	1 (8.3)	1 (8.3)
Lymphocyte count decreased	1 (8.3)	0	1 (8.3)
Platelet count decreased	1 (8.3)	1 (8.3)	0
White blood cell count decreased	1 (8.3)	1 (8.3)	0
Metabolism and nutrition disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (16.7)	2 (16.7)	0
Hyperphosphataemia	1 (8.3)	1 (8.3)	0
Hypokalaemia	1 (8.3)	1 (8.3)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (41.7)	4 (33.3)	1 (8.3)
Pain in extremity	3 (25.0)	3 (25.0)	0
Arthralgia	1 (8.3)	0	1 (8.3)
Muscular weakness	1 (8.3)	1 (8.3)	0
Nervous system disorders			
-Total	1 (8.3)	1 (8.3)	0
Dizziness	1 (8.3)	1 (8.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (33.3)	1 (8.3)	3 (25.0)
Cough	2 (16.7)	0	2 (16.7)
Nasal congestion	2 (16.7)	2 (16.7)	0
Rhinorrhoea	2 (16.7)	1 (8.3)	1 (8.3)
Oropharyngeal pain	1 (8.3)	1 (8.3)	0

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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

		All patients N=44	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	26 (59.1)	9 (20.5)	17 (38.6)
Cardiac disorders			
-Total	1 (2.3)	0	1 (2.3)
Sinus tachycardia	1 (2.3)	0	1 (2.3)
Gastrointestinal disorders			
-Total	10 (22.7)	6 (13.6)	4 (9.1)
Diarrhoea	6 (13.6)	5 (11.4)	1 (2.3)
Vomiting	6 (13.6)	3 (6.8)	3 (6.8)
Abdominal pain	3 (6.8)	2 (4.5)	1 (2.3)
Nausea	3 (6.8)	1 (2.3)	2 (4.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	8 (18.2)	7 (15.9)	1 (2.3)
Pyrexia	7 (15.9)	6 (13.6)	1 (2.3)
Fatigue	2 (4.5)	2 (4.5)	0
Chills	1 (2.3)	1 (2.3)	0
Immune system disorders			
-Total	7 (15.9)	0	7 (15.9)
Hypogammaglobulinaemia	7 (15.9)	0	7 (15.9)
Infections and infestations			
-Total	8 (18.2)	3 (6.8)	5 (11.4)
Upper respiratory tract infection	6 (13.6)	3 (6.8)	3 (6.8)
Influenza	1 (2.3)	0	1 (2.3)
Urinary tract infection	1 (2.3)	0	1 (2.3)
Injury, poisoning and procedural complications			
-Total	1 (2.3)	0	1 (2.3)
Procedural pain	1 (2.3)	0	1 (2.3)
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	7 (15.9)	5 (11.4)	2 (4.5)
White blood cell count decreased	3 (6.8)	1 (2.3)	2 (4.5)
Platelet count decreased	2 (4.5)	2 (4.5)	0
Aspartate aminotransferase increased	1 (2.3)	1 (2.3)	0
Blood creatinine increased	1 (2.3)	1 (2.3)	0
Lymphocyte count decreased	1 (2.3)	1 (2.3)	0
Neutrophil count decreased	1 (2.3)	1 (2.3)	0
Metabolism and nutrition disorders			
-Total	3 (6.8)	2 (4.5)	1 (2.3)
Decreased appetite	2 (4.5)	1 (2.3)	1 (2.3)
Hyperphosphataemia	1 (2.3)	1 (2.3)	0
Musculoskeletal and connective tissue disorders			
-Total	6 (13.6)	4 (9.1)	2 (4.5)
Pain in extremity	5 (11.4)	3 (6.8)	2 (4.5)
Arthralgia	1 (2.3)	1 (2.3)	0
Muscular weakness	1 (2.3)	1 (2.3)	0
Nervous system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	5 (11.4)	4 (9.1)	1 (2.3)
Headache	5 (11.4)	4 (9.1)	1 (2.3)
Dizziness	2 (4.5)	2 (4.5)	0
Psychiatric disorders			
-Total	1 (2.3)	1 (2.3)	0
Anxiety	1 (2.3)	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (20.5)	8 (18.2)	1 (2.3)
Cough	5 (11.4)	5 (11.4)	0
Nasal congestion	2 (4.5)	2 (4.5)	0
Oropharyngeal pain	2 (4.5)	1 (2.3)	1 (2.3)
Rhinorrhoea	2 (4.5)	2 (4.5)	0
Epistaxis	1 (2.3)	1 (2.3)	0
Skin and subcutaneous tissue disorders			
-Total	4 (9.1)	1 (2.3)	3 (6.8)
Rash	4 (9.1)	1 (2.3)	3 (6.8)
Vascular disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (4.5)	1 (2.3)	1 (2.3)
Hypertension	2 (4.5)	1 (2.3)	1 (2.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (22.2)	2 (22.2)	0
Investigations			
-Total	1 (11.1)	1 (11.1)	0
Lymphocyte count decreased	1 (11.1)	1 (11.1)	0
Neutrophil count decreased	1 (11.1)	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (11.1)	1 (11.1)	0
Epistaxis	1 (11.1)	1 (11.1)	0

- A patient with multiple adverse events within a group term is counted only once in the

total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (32.0)	1 (4.0)	7 (28.0)
Blood and lymphatic system disorders			
-Total	1 (4.0)	1 (4.0)	0
Thrombocytopenia	1 (4.0)	1 (4.0)	0
Gastrointestinal disorders			
-Total	3 (12.0)	0	3 (12.0)
Diarrhoea	2 (8.0)	0	2 (8.0)
Abdominal pain	1 (4.0)	0	1 (4.0)
Nausea	1 (4.0)	0	1 (4.0)
General disorders and administration site conditions			

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (4.0)	0	1 (4.0)
Chills	1 (4.0)	0	1 (4.0)
Pyrexia	1 (4.0)	0	1 (4.0)
Infections and infestations			
-Total	4 (16.0)	1 (4.0)	3 (12.0)
Upper respiratory tract infection	2 (8.0)	1 (4.0)	1 (4.0)
Urinary tract infection	2 (8.0)	0	2 (8.0)
Investigations			
-Total	4 (16.0)	1 (4.0)	3 (12.0)
Lymphocyte count decreased	2 (8.0)	1 (4.0)	1 (4.0)
Alanine aminotransferase increased	1 (4.0)	0	1 (4.0)
Aspartate aminotransferase increased	1 (4.0)	1 (4.0)	0
Neutrophil count decreased	1 (4.0)	0	1 (4.0)
White blood cell count decreased	1 (4.0)	1 (4.0)	0
Nervous system disorders			
-Total	1 (4.0)	0	1 (4.0)
Dizziness	1 (4.0)	1 (4.0)	0
Headache	1 (4.0)	0	1 (4.0)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	3 (12.0)	3 (12.0)	0
Cough	2 (8.0)	2 (8.0)	0
Oropharyngeal pain	1 (4.0)	1 (4.0)	0
Rhinorrhoea	1 (4.0)	1 (4.0)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (100)	0	14 (100)
Blood and lymphatic system disorders			
-Total	5 (35.7)	2 (14.3)	3 (21.4)
Anaemia	3 (21.4)	2 (14.3)	1 (7.1)
Thrombocytopenia	2 (14.3)	0	2 (14.3)
Cardiac disorders			
-Total	3 (21.4)	3 (21.4)	0
Tachycardia	2 (14.3)	2 (14.3)	0
Sinus tachycardia	1 (7.1)	1 (7.1)	0
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (42.9)	2 (14.3)	4 (28.6)
Nausea	4 (28.6)	0	4 (28.6)
Vomiting	3 (21.4)	2 (14.3)	1 (7.1)
Constipation	2 (14.3)	1 (7.1)	1 (7.1)
Diarrhoea	2 (14.3)	2 (14.3)	0
Abdominal pain	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Pyrexia	2 (14.3)	0	2 (14.3)
Chills	1 (7.1)	1 (7.1)	0
Fatigue	1 (7.1)	1 (7.1)	0
Immune system disorders			
-Total	12 (85.7)	0	12 (85.7)
Cytokine release syndrome	11 (78.6)	0	11 (78.6)
Hypogammaglobulinaemia	7 (50.0)	1 (7.1)	6 (42.9)
Infections and infestations			
-Total	4 (28.6)	0	4 (28.6)
Influenza	2 (14.3)	0	2 (14.3)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Urinary tract infection	2 (14.3)	0	2 (14.3)
Injury, poisoning and procedural complications			
-Total	2 (14.3)	2 (14.3)	0
Procedural pain	2 (14.3)	2 (14.3)	0
Investigations			
-Total	5 (35.7)	0	5 (35.7)
White blood cell count decreased	3 (21.4)	2 (14.3)	1 (7.1)
Alanine aminotransferase increased	2 (14.3)	0	2 (14.3)
Blood bilirubin increased	2 (14.3)	1 (7.1)	1 (7.1)
Lymphocyte count decreased	2 (14.3)	1 (7.1)	1 (7.1)
Neutrophil count decreased	2 (14.3)	1 (7.1)	1 (7.1)
Aspartate aminotransferase increased	1 (7.1)	0	1 (7.1)
Blood creatinine increased	1 (7.1)	1 (7.1)	0
International normalised ratio increased	1 (7.1)	1 (7.1)	0
Platelet count decreased	1 (7.1)	1 (7.1)	0
Prothrombin time prolonged	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (42.9)	4 (28.6)	2 (14.3)
Hypokalaemia	3 (21.4)	2 (14.3)	1 (7.1)
Decreased appetite	2 (14.3)	1 (7.1)	1 (7.1)
Hyperphosphataemia	2 (14.3)	2 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	6 (42.9)	4 (28.6)	2 (14.3)
Pain in extremity	4 (28.6)	3 (21.4)	1 (7.1)
Arthralgia	2 (14.3)	1 (7.1)	1 (7.1)
Muscular weakness	2 (14.3)	1 (7.1)	1 (7.1)
Nervous system disorders			
-Total	4 (28.6)	3 (21.4)	1 (7.1)
Headache	3 (21.4)	2 (14.3)	1 (7.1)
Dizziness	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (50.0)	4 (28.6)	3 (21.4)
Cough	3 (21.4)	1 (7.1)	2 (14.3)
Nasal congestion	3 (21.4)	3 (21.4)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinorrhoea	2 (14.3)	1 (7.1)	1 (7.1)
Epistaxis	1 (7.1)	1 (7.1)	0
Oropharyngeal pain	1 (7.1)	1 (7.1)	0
Pleural effusion	1 (7.1)	1 (7.1)	0
Skin and subcutaneous tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Rash	1 (7.1)	1 (7.1)	0
Vascular disorders			
-Total	2 (14.3)	0	2 (14.3)
Hypertension	2 (14.3)	0	2 (14.3)

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Table 225m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	49 (98.0)	3 (6.0)	46 (92.0)
Blood and lymphatic system disorders			
-Total	9 (18.0)	3 (6.0)	6 (12.0)
Anaemia	8 (16.0)	2 (4.0)	6 (12.0)
Thrombocytopenia	3 (6.0)	1 (2.0)	2 (4.0)
Cardiac disorders			
-Total	16 (32.0)	7 (14.0)	9 (18.0)
Tachycardia	12 (24.0)	6 (12.0)	6 (12.0)
Sinus tachycardia	5 (10.0)	2 (4.0)	3 (6.0)
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	32 (64.0)	12 (24.0)	20 (40.0)
Vomiting	22 (44.0)	14 (28.0)	8 (16.0)
Diarrhoea	20 (40.0)	11 (22.0)	9 (18.0)
Nausea	19 (38.0)	6 (12.0)	13 (26.0)
Abdominal pain	9 (18.0)	5 (10.0)	4 (8.0)
Constipation	5 (10.0)	5 (10.0)	0
General disorders and administration site conditions			
-Total	30 (60.0)	16 (32.0)	14 (28.0)
Pyrexia	20 (40.0)	8 (16.0)	12 (24.0)
Fatigue	14 (28.0)	11 (22.0)	3 (6.0)
Chills	9 (18.0)	8 (16.0)	1 (2.0)
Immune system disorders			
-Total	41 (82.0)	6 (12.0)	35 (70.0)
Cytokine release syndrome	34 (68.0)	7 (14.0)	27 (54.0)
Hypogammaglobulinaemia	20 (40.0)	2 (4.0)	18 (36.0)
Infections and infestations			
-Total	12 (24.0)	5 (10.0)	7 (14.0)
Upper respiratory tract infection	8 (16.0)	4 (8.0)	4 (8.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Influenza	2 (4.0)	1 (2.0)	1 (2.0)
Urinary tract infection	2 (4.0)	0	2 (4.0)
Injury, poisoning and procedural complications			
-Total	3 (6.0)	0	3 (6.0)
Procedural pain	3 (6.0)	0	3 (6.0)
Investigations			
-Total	29 (58.0)	3 (6.0)	26 (52.0)
Aspartate aminotransferase increased	12 (24.0)	7 (14.0)	5 (10.0)
White blood cell count decreased	12 (24.0)	3 (6.0)	9 (18.0)
Alanine aminotransferase increased	9 (18.0)	5 (10.0)	4 (8.0)
Prothrombin time prolonged	8 (16.0)	4 (8.0)	4 (8.0)
International normalised ratio increased	7 (14.0)	7 (14.0)	0
Blood creatinine increased	6 (12.0)	4 (8.0)	2 (4.0)
Activated partial thromboplastin time prolonged	5 (10.0)	3 (6.0)	2 (4.0)
Lymphocyte count decreased	5 (10.0)	1 (2.0)	4 (8.0)
Platelet count decreased	5 (10.0)	2 (4.0)	3 (6.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood bilirubin increased	4 (8.0)	1 (2.0)	3 (6.0)
Neutrophil count decreased	3 (6.0)	0	3 (6.0)
Metabolism and nutrition disorders			
-Total	20 (40.0)	11 (22.0)	9 (18.0)
Decreased appetite	11 (22.0)	7 (14.0)	4 (8.0)
Hypokalaemia	8 (16.0)	2 (4.0)	6 (12.0)
Hyperphosphataemia	6 (12.0)	6 (12.0)	0
Musculoskeletal and connective tissue disorders			
-Total	12 (24.0)	8 (16.0)	4 (8.0)
Pain in extremity	7 (14.0)	4 (8.0)	3 (6.0)
Myalgia	5 (10.0)	4 (8.0)	1 (2.0)
Arthralgia	3 (6.0)	3 (6.0)	0
Muscular weakness	1 (2.0)	1 (2.0)	0
Nervous system disorders			
-Total	23 (46.0)	15 (30.0)	8 (16.0)
Headache	21 (42.0)	13 (26.0)	8 (16.0)
Dizziness	5 (10.0)	5 (10.0)	0
Psychiatric disorders			

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (22.0)	6 (12.0)	5 (10.0)
Anxiety	6 (12.0)	3 (6.0)	3 (6.0)
Confusional state	6 (12.0)	3 (6.0)	3 (6.0)
Respiratory, thoracic and mediastinal disorders			
-Total	22 (44.0)	14 (28.0)	8 (16.0)
Cough	11 (22.0)	11 (22.0)	0
Epistaxis	5 (10.0)	3 (6.0)	2 (4.0)
Oropharyngeal pain	5 (10.0)	3 (6.0)	2 (4.0)
Pleural effusion	5 (10.0)	1 (2.0)	4 (8.0)
Rhinorrhoea	4 (8.0)	4 (8.0)	0
Nasal congestion	2 (4.0)	2 (4.0)	0
Skin and subcutaneous tissue disorders			
-Total	7 (14.0)	4 (8.0)	3 (6.0)
Rash	7 (14.0)	4 (8.0)	3 (6.0)
Vascular disorders			
-Total	9 (18.0)	3 (6.0)	6 (12.0)
Hypertension	9 (18.0)	3 (6.0)	6 (12.0)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (95.0)	0	19 (95.0)
Blood and lymphatic system disorders			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Anaemia	4 (20.0)	2 (10.0)	2 (10.0)
Cardiac disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Tachycardia	2 (10.0)	1 (5.0)	1 (5.0)
Eye disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Eye pain	2 (10.0)	1 (5.0)	1 (5.0)
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (55.0)	5 (25.0)	6 (30.0)
Nausea	7 (35.0)	3 (15.0)	4 (20.0)
Vomiting	6 (30.0)	4 (20.0)	2 (10.0)
Constipation	3 (15.0)	2 (10.0)	1 (5.0)
Diarrhoea	3 (15.0)	1 (5.0)	2 (10.0)
Abdominal pain	2 (10.0)	1 (5.0)	1 (5.0)
Abdominal pain upper	1 (5.0)	0	1 (5.0)
General disorders and administration site conditions			
-Total	6 (30.0)	5 (25.0)	1 (5.0)
Fatigue	4 (20.0)	4 (20.0)	0
Chills	2 (10.0)	2 (10.0)	0
Catheter site pain	1 (5.0)	1 (5.0)	0
Pyrexia	1 (5.0)	0	1 (5.0)
Immune system disorders			
-Total	17 (85.0)	1 (5.0)	16 (80.0)
Cytokine release syndrome	15 (75.0)	0	15 (75.0)
Hypogammaglobulinaemia	8 (40.0)	1 (5.0)	7 (35.0)
Infections and infestations			

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (10.0)	0	2 (10.0)
Upper respiratory tract infection	1 (5.0)	0	1 (5.0)
Viral infection	1 (5.0)	0	1 (5.0)
Investigations			
-Total	7 (35.0)	2 (10.0)	5 (25.0)
Aspartate aminotransferase increased	3 (15.0)	0	3 (15.0)
Blood bilirubin increased	3 (15.0)	2 (10.0)	1 (5.0)
Blood creatinine increased	3 (15.0)	3 (15.0)	0
International normalised ratio increased	3 (15.0)	3 (15.0)	0
Alanine aminotransferase increased	2 (10.0)	1 (5.0)	1 (5.0)
Platelet count decreased	2 (10.0)	2 (10.0)	0
Prothrombin time prolonged	2 (10.0)	1 (5.0)	1 (5.0)
White blood cell count decreased	2 (10.0)	1 (5.0)	1 (5.0)
Lymphocyte count decreased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	4 (20.0)	3 (15.0)	1 (5.0)
Decreased appetite	3 (15.0)	2 (10.0)	1 (5.0)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	2 (10.0)	2 (10.0)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Myalgia	2 (10.0)	2 (10.0)	0
Pain in extremity	2 (10.0)	0	2 (10.0)
Nervous system disorders			
-Total	8 (40.0)	5 (25.0)	3 (15.0)
Headache	6 (30.0)	4 (20.0)	2 (10.0)
Encephalopathy	2 (10.0)	1 (5.0)	1 (5.0)
Psychiatric disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Anxiety	1 (5.0)	0	1 (5.0)
Confusional state	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (25.0)	2 (10.0)	3 (15.0)
Hypoxia	3 (15.0)	0	3 (15.0)
Cough	2 (10.0)	2 (10.0)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasal congestion	1 (5.0)	1 (5.0)	0
Pleural effusion	1 (5.0)	1 (5.0)	0
Rhinitis allergic	1 (5.0)	1 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	5 (25.0)	4 (20.0)	1 (5.0)
Dry skin	2 (10.0)	2 (10.0)	0
Erythema	2 (10.0)	2 (10.0)	0
Ingrowing nail	1 (5.0)	0	1 (5.0)
Vascular disorders			
-Total	2 (10.0)	0	2 (10.0)
Hypertension	2 (10.0)	0	2 (10.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

		All patients N=44	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	43 (97.7)	3 (6.8)	40 (90.9)
Blood and lymphatic system disorders			
-Total	7 (15.9)	2 (4.5)	5 (11.4)
Anaemia	7 (15.9)	2 (4.5)	5 (11.4)
Cardiac disorders			
-Total	16 (36.4)	9 (20.5)	7 (15.9)
Tachycardia	12 (27.3)	7 (15.9)	5 (11.4)
Sinus tachycardia	5 (11.4)	3 (6.8)	2 (4.5)
Eye disorders			
-Total	1 (2.3)	0	1 (2.3)
Eye pain	1 (2.3)	0	1 (2.3)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	21 (47.7)	7 (15.9)	14 (31.8)
Diarrhoea	14 (31.8)	10 (22.7)	4 (9.1)
Vomiting	14 (31.8)	9 (20.5)	5 (11.4)
Nausea	13 (29.5)	3 (6.8)	10 (22.7)
Abdominal pain	6 (13.6)	5 (11.4)	1 (2.3)
Constipation	4 (9.1)	4 (9.1)	0
Abdominal pain upper	1 (2.3)	0	1 (2.3)
General disorders and administration site conditions			
-Total	21 (47.7)	8 (18.2)	13 (29.5)
Pyrexia	13 (29.5)	3 (6.8)	10 (22.7)
Fatigue	9 (20.5)	6 (13.6)	3 (6.8)
Chills	6 (13.6)	6 (13.6)	0
Catheter site pain	2 (4.5)	0	2 (4.5)
Immune system disorders			
-Total	35 (79.5)	5 (11.4)	30 (68.2)
Cytokine release syndrome	30 (68.2)	7 (15.9)	23 (52.3)
Hypogammaglobulinaemia	13 (29.5)	2 (4.5)	11 (25.0)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

		All patients N=44	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	1 (2.3)	1 (2.3)	0
Influenza	1 (2.3)	1 (2.3)	0
Investigations			
-Total	23 (52.3)	2 (4.5)	21 (47.7)
Aspartate aminotransferase increased	9 (20.5)	6 (13.6)	3 (6.8)
White blood cell count decreased	9 (20.5)	2 (4.5)	7 (15.9)
Alanine aminotransferase increased	8 (18.2)	4 (9.1)	4 (9.1)
Prothrombin time prolonged	7 (15.9)	4 (9.1)	3 (6.8)
International normalised ratio increased	5 (11.4)	5 (11.4)	0
Blood creatinine increased	4 (9.1)	2 (4.5)	2 (4.5)
Platelet count decreased	4 (9.1)	1 (2.3)	3 (6.8)
Blood bilirubin increased	3 (6.8)	0	3 (6.8)
Lymphocyte count decreased	3 (6.8)	0	3 (6.8)
Neutrophil count decreased	2 (4.5)	0	2 (4.5)
Metabolism and nutrition disorders			
-Total	23 (52.3)	9 (20.5)	14 (31.8)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	10 (22.7)	3 (6.8)	7 (15.9)
Decreased appetite	8 (18.2)	5 (11.4)	3 (6.8)
Hyperphosphataemia	6 (13.6)	6 (13.6)	0
Hypoalbuminaemia	5 (11.4)	1 (2.3)	4 (9.1)
Musculoskeletal and connective tissue disorders			
-Total	6 (13.6)	5 (11.4)	1 (2.3)
Arthralgia	3 (6.8)	3 (6.8)	0
Myalgia	3 (6.8)	2 (4.5)	1 (2.3)
Pain in extremity	2 (4.5)	2 (4.5)	0
Nervous system disorders			
-Total	21 (47.7)	14 (31.8)	7 (15.9)
Headache	18 (40.9)	12 (27.3)	6 (13.6)
Dizziness	4 (9.1)	4 (9.1)	0
Encephalopathy	1 (2.3)	0	1 (2.3)
Psychiatric disorders			
-Total	8 (18.2)	4 (9.1)	4 (9.1)
Confusional state	5 (11.4)	2 (4.5)	3 (6.8)
Anxiety	4 (9.1)	2 (4.5)	2 (4.5)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	17 (38.6)	8 (18.2)	9 (20.5)
Cough	6 (13.6)	6 (13.6)	0
Pleural effusion	5 (11.4)	1 (2.3)	4 (9.1)
Epistaxis	4 (9.1)	2 (4.5)	2 (4.5)
Hypoxia	2 (4.5)	0	2 (4.5)
Oropharyngeal pain	2 (4.5)	1 (2.3)	1 (2.3)
Rhinorrhoea	1 (2.3)	1 (2.3)	0
Skin and subcutaneous tissue disorders			
-Total	7 (15.9)	6 (13.6)	1 (2.3)
Rash	4 (9.1)	4 (9.1)	0
Dry skin	2 (4.5)	2 (4.5)	0
Erythema	1 (2.3)	1 (2.3)	0
Ingrowing nail	1 (2.3)	0	1 (2.3)
Vascular disorders			
-Total	7 (15.9)	2 (4.5)	5 (11.4)
Hypertension	7 (15.9)	2 (4.5)	5 (11.4)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	16 (80.0)	3 (15.0)	13 (65.0)
Blood and lymphatic system disorders			
-Total	1 (5.0)	1 (5.0)	0
Anaemia	1 (5.0)	1 (5.0)	0
Gastrointestinal disorders			
-Total	6 (30.0)	5 (25.0)	1 (5.0)
Vomiting	3 (15.0)	3 (15.0)	0
Diarrhoea	2 (10.0)	2 (10.0)	0
Abdominal pain	1 (5.0)	1 (5.0)	0
Abdominal pain upper	1 (5.0)	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	1 (5.0)	0	1 (5.0)
General disorders and administration site conditions			
-Total	7 (35.0)	5 (25.0)	2 (10.0)
Pyrexia	5 (25.0)	4 (20.0)	1 (5.0)
Catheter site pain	1 (5.0)	0	1 (5.0)
Fatigue	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	3 (15.0)	0	3 (15.0)
Hypogammaglobulinaemia	3 (15.0)	0	3 (15.0)
Infections and infestations			
-Total	6 (30.0)	1 (5.0)	5 (25.0)
Upper respiratory tract infection	3 (15.0)	0	3 (15.0)
Influenza	2 (10.0)	0	2 (10.0)
Viral infection	1 (5.0)	1 (5.0)	0
Investigations			
-Total	4 (20.0)	1 (5.0)	3 (15.0)
Lymphocyte count decreased	2 (10.0)	1 (5.0)	1 (5.0)
Neutrophil count decreased	2 (10.0)	1 (5.0)	1 (5.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
White blood cell count decreased	2 (10.0)	1 (5.0)	1 (5.0)
Platelet count decreased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	1 (5.0)	1 (5.0)	0
Hyperphosphataemia	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (25.0)	4 (20.0)	1 (5.0)
Pain in extremity	3 (15.0)	3 (15.0)	0
Arthralgia	2 (10.0)	1 (5.0)	1 (5.0)
Nervous system disorders			
-Total	4 (20.0)	3 (15.0)	1 (5.0)
Headache	2 (10.0)	2 (10.0)	0
Peroneal nerve palsy	2 (10.0)	1 (5.0)	1 (5.0)
Psychiatric disorders			
-Total	2 (10.0)	2 (10.0)	0
Depression	2 (10.0)	2 (10.0)	0
Anxiety	1 (5.0)	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	6 (30.0)	3 (15.0)	3 (15.0)
Cough	3 (15.0)	2 (10.0)	1 (5.0)
Nasal congestion	2 (10.0)	2 (10.0)	0
Rhinorrhoea	2 (10.0)	1 (5.0)	1 (5.0)
Oropharyngeal pain	1 (5.0)	0	1 (5.0)
Rhinitis allergic	1 (5.0)	1 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	4 (20.0)	3 (15.0)	1 (5.0)
Erythema	2 (10.0)	2 (10.0)	0
Ingrowing nail	1 (5.0)	1 (5.0)	0
Rash	1 (5.0)	0	1 (5.0)
Vascular disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Hypertension	2 (10.0)	1 (5.0)	1 (5.0)

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AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	22 (61.1)	9 (25.0)	13 (36.1)
Cardiac disorders			
-Total	1 (2.8)	0	1 (2.8)
Sinus tachycardia	1 (2.8)	0	1 (2.8)
Gastrointestinal disorders			
-Total	8 (22.2)	4 (11.1)	4 (11.1)
Diarrhoea	5 (13.9)	4 (11.1)	1 (2.8)
Vomiting	5 (13.9)	2 (5.6)	3 (8.3)
Nausea	3 (8.3)	1 (2.8)	2 (5.6)
Abdominal pain	2 (5.6)	1 (2.8)	1 (2.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	4 (11.1)	3 (8.3)	1 (2.8)
Pyrexia	4 (11.1)	3 (8.3)	1 (2.8)
Chills	1 (2.8)	1 (2.8)	0
Fatigue	1 (2.8)	1 (2.8)	0
Immune system disorders			
-Total	4 (11.1)	0	4 (11.1)
Hypogammaglobulinaemia	4 (11.1)	0	4 (11.1)
Infections and infestations			
-Total	5 (13.9)	2 (5.6)	3 (8.3)
Upper respiratory tract infection	3 (8.3)	3 (8.3)	0
Sinusitis	2 (5.6)	0	2 (5.6)
Influenza	1 (2.8)	0	1 (2.8)
Investigations			
-Total	5 (13.9)	4 (11.1)	1 (2.8)
Platelet count decreased	2 (5.6)	2 (5.6)	0
White blood cell count decreased	2 (5.6)	1 (2.8)	1 (2.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	1 (2.8)	1 (2.8)	0
Blood creatinine increased	1 (2.8)	1 (2.8)	0
Neutrophil count decreased	1 (2.8)	1 (2.8)	0
Metabolism and nutrition disorders			
-Total	4 (11.1)	3 (8.3)	1 (2.8)
Decreased appetite	2 (5.6)	1 (2.8)	1 (2.8)
Hyperphosphataemia	1 (2.8)	1 (2.8)	0
Hypokalaemia	1 (2.8)	1 (2.8)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (13.9)	3 (8.3)	2 (5.6)
Pain in extremity	5 (13.9)	3 (8.3)	2 (5.6)
Nervous system disorders			
-Total	4 (11.1)	3 (8.3)	1 (2.8)
Dizziness	3 (8.3)	3 (8.3)	0
Headache	3 (8.3)	2 (5.6)	1 (2.8)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (25.0)	7 (19.4)	2 (5.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	4 (11.1)	3 (8.3)	1 (2.8)
Nasal congestion	2 (5.6)	2 (5.6)	0
Oropharyngeal pain	2 (5.6)	2 (5.6)	0
Rhinitis allergic	2 (5.6)	1 (2.8)	1 (2.8)
Rhinorrhoea	2 (5.6)	2 (5.6)	0
Epistaxis	1 (2.8)	1 (2.8)	0
Skin and subcutaneous tissue disorders			
-Total	4 (11.1)	2 (5.6)	2 (5.6)
Rash	3 (8.3)	1 (2.8)	2 (5.6)
Dry skin	1 (2.8)	1 (2.8)	0

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Table 225n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (50.0)	2 (14.3)	5 (35.7)
Infections and infestations			
-Total	4 (28.6)	2 (14.3)	2 (14.3)
Sinusitis	2 (14.3)	0	2 (14.3)
Upper respiratory tract infection	2 (14.3)	1 (7.1)	1 (7.1)
Viral infection	1 (7.1)	1 (7.1)	0
Investigations			
-Total	4 (28.6)	1 (7.1)	3 (21.4)
Lymphocyte count decreased	3 (21.4)	2 (14.3)	1 (7.1)
Neutrophil count decreased	2 (14.3)	1 (7.1)	1 (7.1)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	1 (7.1)	0	1 (7.1)
White blood cell count decreased	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (7.1)	1 (7.1)	0
Cough	1 (7.1)	1 (7.1)	0
Rhinitis allergic	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 225n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (25.0)	1 (5.0)	4 (20.0)
Gastrointestinal disorders			
-Total	3 (15.0)	0	3 (15.0)
Diarrhoea	2 (10.0)	0	2 (10.0)
Abdominal pain	1 (5.0)	0	1 (5.0)
Nausea	1 (5.0)	0	1 (5.0)
General disorders and administration site conditions			
-Total	1 (5.0)	0	1 (5.0)
Chills	1 (5.0)	0	1 (5.0)
Pyrexia	1 (5.0)	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	1 (5.0)	0	1 (5.0)
Sinusitis	1 (5.0)	0	1 (5.0)
Investigations			
-Total	1 (5.0)	1 (5.0)	0
Aspartate aminotransferase increased	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	1 (5.0)	0	1 (5.0)
Dizziness	1 (5.0)	1 (5.0)	0
Headache	1 (5.0)	0	1 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (15.0)	3 (15.0)	0
Cough	1 (5.0)	1 (5.0)	0
Epistaxis	1 (5.0)	1 (5.0)	0
Oropharyngeal pain	1 (5.0)	1 (5.0)	0
Rhinorrhoea	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 225n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (100)	0	20 (100)
Blood and lymphatic system disorders			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Anaemia	4 (20.0)	2 (10.0)	2 (10.0)
Cardiac disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Tachycardia	2 (10.0)	1 (5.0)	1 (5.0)
Eye disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Eye pain	2 (10.0)	1 (5.0)	1 (5.0)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	15 (75.0)	8 (40.0)	7 (35.0)
Vomiting	9 (45.0)	7 (35.0)	2 (10.0)
Nausea	8 (40.0)	3 (15.0)	5 (25.0)
Diarrhoea	4 (20.0)	2 (10.0)	2 (10.0)
Abdominal pain	3 (15.0)	2 (10.0)	1 (5.0)
Constipation	3 (15.0)	2 (10.0)	1 (5.0)
Abdominal pain upper	2 (10.0)	1 (5.0)	1 (5.0)
General disorders and administration site conditions			
-Total	11 (55.0)	8 (40.0)	3 (15.0)
Pyrexia	6 (30.0)	4 (20.0)	2 (10.0)
Fatigue	5 (25.0)	5 (25.0)	0
Catheter site pain	2 (10.0)	1 (5.0)	1 (5.0)
Chills	2 (10.0)	2 (10.0)	0
Immune system disorders			
-Total	17 (85.0)	1 (5.0)	16 (80.0)
Cytokine release syndrome	15 (75.0)	0	15 (75.0)
Hypogammaglobulinaemia	11 (55.0)	1 (5.0)	10 (50.0)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	11 (55.0)	3 (15.0)	8 (40.0)
Upper respiratory tract infection	5 (25.0)	1 (5.0)	4 (20.0)
Viral infection	3 (15.0)	2 (10.0)	1 (5.0)
Influenza	2 (10.0)	0	2 (10.0)
Sinusitis	2 (10.0)	0	2 (10.0)
Investigations			
-Total	9 (45.0)	0	9 (45.0)
White blood cell count decreased	5 (25.0)	3 (15.0)	2 (10.0)
Lymphocyte count decreased	4 (20.0)	2 (10.0)	2 (10.0)
Alanine aminotransferase increased	3 (15.0)	1 (5.0)	2 (10.0)
Aspartate aminotransferase increased	3 (15.0)	0	3 (15.0)
Blood bilirubin increased	3 (15.0)	2 (10.0)	1 (5.0)
Blood creatinine increased	3 (15.0)	3 (15.0)	0
International normalised ratio increased	3 (15.0)	3 (15.0)	0
Neutrophil count decreased	3 (15.0)	1 (5.0)	2 (10.0)
Platelet count decreased	2 (10.0)	2 (10.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Prothrombin time prolonged	2 (10.0)	1 (5.0)	1 (5.0)
Metabolism and nutrition disorders			
-Total	4 (20.0)	3 (15.0)	1 (5.0)
Decreased appetite	3 (15.0)	2 (10.0)	1 (5.0)
Hyperphosphataemia	2 (10.0)	2 (10.0)	0
Musculoskeletal and connective tissue disorders			
-Total	7 (35.0)	5 (25.0)	2 (10.0)
Pain in extremity	5 (25.0)	3 (15.0)	2 (10.0)
Arthralgia	2 (10.0)	1 (5.0)	1 (5.0)
Myalgia	2 (10.0)	2 (10.0)	0
Nervous system disorders			
-Total	9 (45.0)	5 (25.0)	4 (20.0)
Headache	6 (30.0)	4 (20.0)	2 (10.0)
Encephalopathy	2 (10.0)	1 (5.0)	1 (5.0)
Peroneal nerve palsy	2 (10.0)	1 (5.0)	1 (5.0)
Psychiatric disorders			
-Total	4 (20.0)	3 (15.0)	1 (5.0)
Anxiety	2 (10.0)	1 (5.0)	1 (5.0)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Depression	2 (10.0)	2 (10.0)	0
Confusional state	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (45.0)	4 (20.0)	5 (25.0)
Cough	5 (25.0)	4 (20.0)	1 (5.0)
Hypoxia	3 (15.0)	0	3 (15.0)
Nasal congestion	3 (15.0)	3 (15.0)	0
Rhinitis allergic	2 (10.0)	2 (10.0)	0
Rhinorrhoea	2 (10.0)	1 (5.0)	1 (5.0)
Oropharyngeal pain	1 (5.0)	0	1 (5.0)
Pleural effusion	1 (5.0)	1 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	8 (40.0)	6 (30.0)	2 (10.0)
Erythema	4 (20.0)	4 (20.0)	0
Dry skin	2 (10.0)	2 (10.0)	0
Ingrowing nail	2 (10.0)	1 (5.0)	1 (5.0)
Rash	1 (5.0)	0	1 (5.0)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	4 (20.0)	1 (5.0)	3 (15.0)
Hypertension	4 (20.0)	1 (5.0)	3 (15.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=44	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	44 (100)	2 (4.5)	42 (95.5)
Blood and lymphatic system disorders			
-Total	7 (15.9)	2 (4.5)	5 (11.4)
Anaemia	7 (15.9)	2 (4.5)	5 (11.4)
Cardiac disorders			
-Total	17 (38.6)	9 (20.5)	8 (18.2)
Tachycardia	12 (27.3)	7 (15.9)	5 (11.4)
Sinus tachycardia	6 (13.6)	3 (6.8)	3 (6.8)
Eye disorders			
-Total	1 (2.3)	0	1 (2.3)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eye pain	1 (2.3)	0	1 (2.3)
Gastrointestinal disorders			
-Total	24 (54.5)	7 (15.9)	17 (38.6)
Diarrhoea	18 (40.9)	11 (25.0)	7 (15.9)
Vomiting	16 (36.4)	9 (20.5)	7 (15.9)
Nausea	15 (34.1)	3 (6.8)	12 (27.3)
Abdominal pain	7 (15.9)	4 (9.1)	3 (6.8)
Constipation	4 (9.1)	4 (9.1)	0
Abdominal pain upper	1 (2.3)	0	1 (2.3)
General disorders and administration site conditions			
-Total	24 (54.5)	9 (20.5)	15 (34.1)
Pyrexia	16 (36.4)	4 (9.1)	12 (27.3)
Fatigue	10 (22.7)	7 (15.9)	3 (6.8)
Chills	8 (18.2)	7 (15.9)	1 (2.3)
Catheter site pain	2 (4.5)	0	2 (4.5)
Immune system disorders			
-Total	36 (81.8)	5 (11.4)	31 (70.5)
Cytokine release syndrome	30 (68.2)	7 (15.9)	23 (52.3)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	16 (36.4)	2 (4.5)	14 (31.8)
Infections and infestations			
-Total	6 (13.6)	3 (6.8)	3 (6.8)
Upper respiratory tract infection	3 (6.8)	3 (6.8)	0
Influenza	2 (4.5)	1 (2.3)	1 (2.3)
Sinusitis	2 (4.5)	0	2 (4.5)
Investigations			
-Total	24 (54.5)	3 (6.8)	21 (47.7)
Aspartate aminotransferase increased	10 (22.7)	7 (15.9)	3 (6.8)
White blood cell count decreased	10 (22.7)	2 (4.5)	8 (18.2)
Alanine aminotransferase increased	8 (18.2)	4 (9.1)	4 (9.1)
Prothrombin time prolonged	7 (15.9)	4 (9.1)	3 (6.8)
International normalised ratio increased	5 (11.4)	5 (11.4)	0
Blood creatinine increased	4 (9.1)	2 (4.5)	2 (4.5)
Platelet count decreased	4 (9.1)	1 (2.3)	3 (6.8)
Blood bilirubin increased	3 (6.8)	0	3 (6.8)
Lymphocyte count decreased	3 (6.8)	0	3 (6.8)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Neutrophil count decreased	2 (4.5)	0	2 (4.5)
Metabolism and nutrition disorders			
-Total	24 (54.5)	10 (22.7)	14 (31.8)
Hypokalaemia	11 (25.0)	4 (9.1)	7 (15.9)
Decreased appetite	10 (22.7)	6 (13.6)	4 (9.1)
Hyperphosphataemia	6 (13.6)	6 (13.6)	0
Hypoalbuminaemia	5 (11.4)	1 (2.3)	4 (9.1)
Musculoskeletal and connective tissue disorders			
-Total	10 (22.7)	7 (15.9)	3 (6.8)
Pain in extremity	6 (13.6)	4 (9.1)	2 (4.5)
Arthralgia	3 (6.8)	3 (6.8)	0
Myalgia	3 (6.8)	2 (4.5)	1 (2.3)
Nervous system disorders			
-Total	22 (50.0)	14 (31.8)	8 (18.2)
Headache	18 (40.9)	11 (25.0)	7 (15.9)
Dizziness	6 (13.6)	6 (13.6)	0
Encephalopathy	1 (2.3)	0	1 (2.3)
Psychiatric disorders			

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	8 (18.2)	4 (9.1)	4 (9.1)
Confusional state	5 (11.4)	2 (4.5)	3 (6.8)
Anxiety	4 (9.1)	2 (4.5)	2 (4.5)
Respiratory, thoracic and mediastinal disorders			
-Total	24 (54.5)	13 (29.5)	11 (25.0)
Cough	9 (20.5)	8 (18.2)	1 (2.3)
Epistaxis	6 (13.6)	4 (9.1)	2 (4.5)
Oropharyngeal pain	5 (11.4)	4 (9.1)	1 (2.3)
Pleural effusion	5 (11.4)	1 (2.3)	4 (9.1)
Rhinorrhoea	4 (9.1)	4 (9.1)	0
Hypoxia	2 (4.5)	0	2 (4.5)
Nasal congestion	2 (4.5)	2 (4.5)	0
Rhinitis allergic	2 (4.5)	1 (2.3)	1 (2.3)
Skin and subcutaneous tissue disorders			
-Total	10 (22.7)	7 (15.9)	3 (6.8)
Rash	7 (15.9)	5 (11.4)	2 (4.5)
Dry skin	3 (6.8)	3 (6.8)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Erythema	1 (2.3)	1 (2.3)	0
Ingrowing nail	1 (2.3)	0	1 (2.3)
Vascular disorders			
-Total	7 (15.9)	2 (4.5)	5 (11.4)
Hypertension	7 (15.9)	2 (4.5)	5 (11.4)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (80.0)	0	4 (80.0)
Cardiac disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Bradycardia	1 (20.0)	0	1 (20.0)
Pericardial effusion	1 (20.0)	0	1 (20.0)
Tachycardia	1 (20.0)	1 (20.0)	0
Eye disorders			
-Total	1 (20.0)	1 (20.0)	0
Conjunctival haemorrhage	1 (20.0)	1 (20.0)	0
Periorbital oedema	1 (20.0)	1 (20.0)	0
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Abdominal pain	1 (20.0)	1 (20.0)	0
Nausea	1 (20.0)	0	1 (20.0)
Vomiting	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	2 (40.0)	0	2 (40.0)
Malaise	1 (20.0)	0	1 (20.0)
Mucosal haemorrhage	1 (20.0)	0	1 (20.0)
Immune system disorders			
-Total	4 (80.0)	1 (20.0)	3 (60.0)
Cytokine release syndrome	4 (80.0)	2 (40.0)	2 (40.0)
Hypogammaglobulinaemia	2 (40.0)	0	2 (40.0)
Injury, poisoning and procedural complications			
-Total	1 (20.0)	1 (20.0)	0
Procedural complication	1 (20.0)	1 (20.0)	0
Investigations			
-Total	2 (40.0)	0	2 (40.0)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	2 (40.0)	0	2 (40.0)
Activated partial thromboplastin time prolonged	1 (20.0)	1 (20.0)	0
Blood phosphorus decreased	1 (20.0)	1 (20.0)	0
Metabolism and nutrition disorders			
-Total	2 (40.0)	0	2 (40.0)
Decreased appetite	1 (20.0)	0	1 (20.0)
Hyperalbuminaemia	1 (20.0)	1 (20.0)	0
Hypercalcaemia	1 (20.0)	1 (20.0)	0
Hyperchloraemia	1 (20.0)	1 (20.0)	0
Hypermagnesaemia	1 (20.0)	1 (20.0)	0
Hypernatraemia	1 (20.0)	0	1 (20.0)
Hypoalbuminaemia	1 (20.0)	0	1 (20.0)
Hypophosphataemia	1 (20.0)	1 (20.0)	0
Metabolic alkalosis	1 (20.0)	1 (20.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (20.0)	0	1 (20.0)
Arthralgia	1 (20.0)	1 (20.0)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Muscular weakness	1 (20.0)	0	1 (20.0)
Nervous system disorders			
-Total	2 (40.0)	0	2 (40.0)
Dysarthria	1 (20.0)	0	1 (20.0)
Headache	1 (20.0)	0	1 (20.0)
Somnolence	1 (20.0)	1 (20.0)	0
Psychiatric disorders			
-Total	1 (20.0)	0	1 (20.0)
Delirium	1 (20.0)	0	1 (20.0)
Insomnia	1 (20.0)	0	1 (20.0)
Irritability	1 (20.0)	1 (20.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Epistaxis	1 (20.0)	0	1 (20.0)
Oropharyngeal plaque	1 (20.0)	1 (20.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (20.0)	1 (20.0)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperhidrosis	1 (20.0)	1 (20.0)	0
Rash papular	1 (20.0)	1 (20.0)	0
Vascular disorders			
-Total	1 (20.0)	0	1 (20.0)
Flushing	1 (20.0)	1 (20.0)	0
Hypertension	1 (20.0)	0	1 (20.0)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	58 (98.3)	3 (5.1)	55 (93.2)
Blood and lymphatic system disorders			
-Total	11 (18.6)	4 (6.8)	7 (11.9)
Anaemia	11 (18.6)	4 (6.8)	7 (11.9)
Cardiac disorders			
-Total	17 (28.8)	9 (15.3)	8 (13.6)
Tachycardia	13 (22.0)	7 (11.9)	6 (10.2)
Sinus tachycardia	5 (8.5)	3 (5.1)	2 (3.4)
Pericardial effusion	1 (1.7)	1 (1.7)	0
Eye disorders			
-Total	3 (5.1)	2 (3.4)	1 (1.7)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Periorbital oedema	3 (5.1)	2 (3.4)	1 (1.7)
Conjunctival haemorrhage	2 (3.4)	2 (3.4)	0
Gastrointestinal disorders			
-Total	30 (50.8)	11 (18.6)	19 (32.2)
Nausea	19 (32.2)	6 (10.2)	13 (22.0)
Vomiting	19 (32.2)	12 (20.3)	7 (11.9)
Diarrhoea	17 (28.8)	11 (18.6)	6 (10.2)
Abdominal pain	7 (11.9)	5 (8.5)	2 (3.4)
Constipation	7 (11.9)	6 (10.2)	1 (1.7)
General disorders and administration site conditions			
-Total	26 (44.1)	13 (22.0)	13 (22.0)
Pyrexia	14 (23.7)	3 (5.1)	11 (18.6)
Fatigue	13 (22.0)	10 (16.9)	3 (5.1)
Chills	8 (13.6)	8 (13.6)	0
Malaise	2 (3.4)	0	2 (3.4)
Immune system disorders			
-Total	48 (81.4)	5 (8.5)	43 (72.9)
Cytokine release syndrome	41 (69.5)	5 (8.5)	36 (61.0)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	19 (32.2)	3 (5.1)	16 (27.1)
Infections and infestations			
-Total	3 (5.1)	0	3 (5.1)
Gastroenteritis	1 (1.7)	0	1 (1.7)
Pneumonia	1 (1.7)	0	1 (1.7)
Upper respiratory tract infection	1 (1.7)	0	1 (1.7)
Injury, poisoning and procedural complications			
-Total	3 (5.1)	1 (1.7)	2 (3.4)
Procedural pain	3 (5.1)	1 (1.7)	2 (3.4)
Investigations			
-Total	30 (50.8)	4 (6.8)	26 (44.1)
White blood cell count decreased	11 (18.6)	3 (5.1)	8 (13.6)
Alanine aminotransferase increased	10 (16.9)	5 (8.5)	5 (8.5)
Aspartate aminotransferase increased	10 (16.9)	6 (10.2)	4 (6.8)
Prothrombin time prolonged	9 (15.3)	5 (8.5)	4 (6.8)
International normalised ratio increased	8 (13.6)	8 (13.6)	0
Blood creatinine increased	7 (11.9)	5 (8.5)	2 (3.4)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood bilirubin increased	6 (10.2)	2 (3.4)	4 (6.8)
Platelet count decreased	6 (10.2)	3 (5.1)	3 (5.1)
Activated partial thromboplastin time prolonged	4 (6.8)	2 (3.4)	2 (3.4)
Lymphocyte count decreased	4 (6.8)	1 (1.7)	3 (5.1)
Blood urea increased	2 (3.4)	1 (1.7)	1 (1.7)
Serum ferritin increased	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	28 (47.5)	14 (23.7)	14 (23.7)
Decreased appetite	10 (16.9)	7 (11.9)	3 (5.1)
Hypokalaemia	10 (16.9)	3 (5.1)	7 (11.9)
Hyperphosphataemia	8 (13.6)	8 (13.6)	0
Hypoalbuminaemia	4 (6.8)	1 (1.7)	3 (5.1)
Hypernatraemia	3 (5.1)	1 (1.7)	2 (3.4)
Hypophosphataemia	2 (3.4)	2 (3.4)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (8.5)	3 (5.1)	2 (3.4)
Pain in extremity	4 (6.8)	2 (3.4)	2 (3.4)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	2 (3.4)	2 (3.4)	0
Nervous system disorders			
-Total	25 (42.4)	18 (30.5)	7 (11.9)
Headache	23 (39.0)	16 (27.1)	7 (11.9)
Dizziness	4 (6.8)	4 (6.8)	0
Dysarthria	1 (1.7)	1 (1.7)	0
Psychiatric disorders			
-Total	12 (20.3)	7 (11.9)	5 (8.5)
Confusional state	6 (10.2)	3 (5.1)	3 (5.1)
Anxiety	5 (8.5)	2 (3.4)	3 (5.1)
Delirium	3 (5.1)	2 (3.4)	1 (1.7)
Irritability	1 (1.7)	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	17 (28.8)	11 (18.6)	6 (10.2)
Cough	8 (13.6)	8 (13.6)	0
Pleural effusion	6 (10.2)	2 (3.4)	4 (6.8)
Epistaxis	3 (5.1)	2 (3.4)	1 (1.7)
Oropharyngeal pain	2 (3.4)	1 (1.7)	1 (1.7)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinorrhoea	1 (1.7)	1 (1.7)	0
Skin and subcutaneous tissue disorders			
-Total	8 (13.6)	8 (13.6)	0
Rash	4 (6.8)	4 (6.8)	0
Hyperhidrosis	2 (3.4)	2 (3.4)	0
Pruritus	2 (3.4)	2 (3.4)	0
Rash papular	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	9 (15.3)	3 (5.1)	6 (10.2)
Hypertension	8 (13.6)	2 (3.4)	6 (10.2)
Flushing	1 (1.7)	1 (1.7)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

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Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (80.0)	2 (40.0)	2 (40.0)
Blood and lymphatic system disorders			
-Total	1 (20.0)	0	1 (20.0)
Lymphadenopathy	1 (20.0)	0	1 (20.0)
General disorders and administration site conditions			
-Total	1 (20.0)	1 (20.0)	0
Acquired gene mutation	1 (20.0)	1 (20.0)	0
Immune system disorders			
-Total	1 (20.0)	1 (20.0)	0
Seasonal allergy	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Gastroenteritis	1 (20.0)	0	1 (20.0)
Subcutaneous abscess	1 (20.0)	0	1 (20.0)
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0
Injury, poisoning and procedural complications			
-Total	1 (20.0)	0	1 (20.0)
Arthropod bite	1 (20.0)	1 (20.0)	0
Procedural pain	1 (20.0)	0	1 (20.0)
Investigations			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Blood urea increased	1 (20.0)	1 (20.0)	0
Serum ferritin increased	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	1 (20.0)	1 (20.0)	0
Hyperalbuminaemia	1 (20.0)	1 (20.0)	0
Hypercalcaemia	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Cough	1 (20.0)	1 (20.0)	0
Rhinorrhoea	1 (20.0)	1 (20.0)	0
Skin and subcutaneous tissue disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Dermatitis	1 (20.0)	1 (20.0)	0
Papule	1 (20.0)	1 (20.0)	0
Rash	1 (20.0)	0	1 (20.0)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=51	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	30 (58.8)	9 (17.6)	21 (41.2)
Blood and lymphatic system disorders			
-Total	1 (2.0)	1 (2.0)	0
Anaemia	1 (2.0)	1 (2.0)	0
Cardiac disorders			
-Total	1 (2.0)	0	1 (2.0)
Sinus tachycardia	1 (2.0)	0	1 (2.0)
Gastrointestinal disorders			
-Total	13 (25.5)	8 (15.7)	5 (9.8)
Vomiting	8 (15.7)	5 (9.8)	3 (5.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	7 (13.7)	6 (11.8)	1 (2.0)
Nausea	4 (7.8)	1 (2.0)	3 (5.9)
Abdominal pain	3 (5.9)	2 (3.9)	1 (2.0)
General disorders and administration site conditions			
-Total	11 (21.6)	9 (17.6)	2 (3.9)
Pyrexia	9 (17.6)	7 (13.7)	2 (3.9)
Fatigue	2 (3.9)	2 (3.9)	0
Chills	1 (2.0)	1 (2.0)	0
Malaise	1 (2.0)	1 (2.0)	0
Immune system disorders			
-Total	8 (15.7)	1 (2.0)	7 (13.7)
Hypogammaglobulinaemia	7 (13.7)	0	7 (13.7)
Seasonal allergy	1 (2.0)	1 (2.0)	0
Infections and infestations			
-Total	8 (15.7)	1 (2.0)	7 (13.7)
Upper respiratory tract infection	5 (9.8)	2 (3.9)	3 (5.9)
Gastroenteritis	2 (3.9)	1 (2.0)	1 (2.0)
Sinusitis	2 (3.9)	0	2 (3.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Otitis media	1 (2.0)	0	1 (2.0)
Otitis media acute	1 (2.0)	0	1 (2.0)
Injury, poisoning and procedural complications			
-Total	1 (2.0)	1 (2.0)	0
Procedural pain	1 (2.0)	1 (2.0)	0
Investigations			
-Total	7 (13.7)	4 (7.8)	3 (5.9)
White blood cell count decreased	4 (7.8)	2 (3.9)	2 (3.9)
Platelet count decreased	3 (5.9)	3 (5.9)	0
Lymphocyte count decreased	2 (3.9)	1 (2.0)	1 (2.0)
Aspartate aminotransferase increased	1 (2.0)	1 (2.0)	0
Blood creatinine increased	1 (2.0)	1 (2.0)	0
Metabolism and nutrition disorders			
-Total	5 (9.8)	4 (7.8)	1 (2.0)
Decreased appetite	2 (3.9)	1 (2.0)	1 (2.0)
Hyperphosphataemia	2 (3.9)	2 (3.9)	0
Hypokalaemia	1 (2.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	11 (21.6)	8 (15.7)	3 (5.9)
Pain in extremity	8 (15.7)	6 (11.8)	2 (3.9)
Arthralgia	2 (3.9)	1 (2.0)	1 (2.0)
Muscular weakness	2 (3.9)	2 (3.9)	0
Nervous system disorders			
-Total	6 (11.8)	5 (9.8)	1 (2.0)
Headache	5 (9.8)	4 (7.8)	1 (2.0)
Dizziness	3 (5.9)	3 (5.9)	0
Psychiatric disorders			
-Total	1 (2.0)	1 (2.0)	0
Anxiety	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	10 (19.6)	6 (11.8)	4 (7.8)
Cough	6 (11.8)	4 (7.8)	2 (3.9)
Oropharyngeal pain	3 (5.9)	2 (3.9)	1 (2.0)
Rhinorrhoea	3 (5.9)	2 (3.9)	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	1 (2.0)	1 (2.0)	0
Skin and subcutaneous tissue disorders			
-Total	4 (7.8)	2 (3.9)	2 (3.9)
Rash	3 (5.9)	1 (2.0)	2 (3.9)
Hyperhidrosis	1 (2.0)	1 (2.0)	0
Pruritus	1 (2.0)	1 (2.0)	0
Vascular disorders			
-Total	2 (3.9)	1 (2.0)	1 (2.0)
Hypertension	2 (3.9)	1 (2.0)	1 (2.0)

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Table 225o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Ear and labyrinth disorders			
-Total	1 (33.3)	0	1 (33.3)
Tympanic membrane perforation	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Nausea	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	1 (33.3)	0	1 (33.3)
Chills	1 (33.3)	0	1 (33.3)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	1 (33.3)	0	1 (33.3)
Immune system disorders			
-Total	1 (33.3)	0	1 (33.3)
Immunodeficiency	1 (33.3)	0	1 (33.3)
Infections and infestations			
-Total	1 (33.3)	0	1 (33.3)
Haemophilus infection	1 (33.3)	0	1 (33.3)
Otitis media	1 (33.3)	0	1 (33.3)
Otitis media acute	1 (33.3)	0	1 (33.3)
Pneumonia	1 (33.3)	0	1 (33.3)
Sinusitis	1 (33.3)	0	1 (33.3)
Investigations			
-Total	1 (33.3)	1 (33.3)	0
Aspartate aminotransferase increased	1 (33.3)	1 (33.3)	0
Blood alkaline phosphatase increased	1 (33.3)	1 (33.3)	0
Blood lactate dehydrogenase increased	1 (33.3)	1 (33.3)	0
C-reactive protein increased	1 (33.3)	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	1 (33.3)	0
Cough	1 (33.3)	1 (33.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (33.3)	1 (33.3)	0
Pruritus	1 (33.3)	1 (33.3)	0

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Table 225o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (38.7)	4 (12.9)	8 (25.8)
Gastrointestinal disorders			
-Total	2 (6.5)	0	2 (6.5)
Diarrhoea	2 (6.5)	0	2 (6.5)
Abdominal pain	1 (3.2)	0	1 (3.2)
Infections and infestations			
-Total	6 (19.4)	1 (3.2)	5 (16.1)
Otitis media	2 (6.5)	0	2 (6.5)
Sinusitis	2 (6.5)	0	2 (6.5)
Upper respiratory tract infection	2 (6.5)	1 (3.2)	1 (3.2)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Otitis media acute	1 (3.2)	0	1 (3.2)
Pneumonia	1 (3.2)	0	1 (3.2)
Investigations			
-Total	4 (12.9)	2 (6.5)	2 (6.5)
Lymphocyte count decreased	3 (9.7)	2 (6.5)	1 (3.2)
Alanine aminotransferase increased	1 (3.2)	0	1 (3.2)
White blood cell count decreased	1 (3.2)	1 (3.2)	0
Nervous system disorders			
-Total	1 (3.2)	0	1 (3.2)
Dizziness	1 (3.2)	1 (3.2)	0
Headache	1 (3.2)	0	1 (3.2)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (9.7)	3 (9.7)	0
Cough	1 (3.2)	1 (3.2)	0
Epistaxis	1 (3.2)	1 (3.2)	0
Oropharyngeal pain	1 (3.2)	1 (3.2)	0
Rhinorrhoea	1 (3.2)	1 (3.2)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	1 (3.2)	1 (3.2)	0
Papule	1 (3.2)	1 (3.2)	0

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Table 225o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (100)	0	5 (100)
Blood and lymphatic system disorders			
-Total	1 (20.0)	0	1 (20.0)
Lymphadenopathy	1 (20.0)	0	1 (20.0)
Cardiac disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Bradycardia	1 (20.0)	0	1 (20.0)
Pericardial effusion	1 (20.0)	0	1 (20.0)
Tachycardia	1 (20.0)	1 (20.0)	0
Ear and labyrinth disorders			

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (20.0)	0	1 (20.0)
Tympanic membrane perforation	1 (20.0)	0	1 (20.0)
Eye disorders			
-Total	1 (20.0)	1 (20.0)	0
Conjunctival haemorrhage	1 (20.0)	1 (20.0)	0
Periorbital oedema	1 (20.0)	1 (20.0)	0
Gastrointestinal disorders			
-Total	3 (60.0)	1 (20.0)	2 (40.0)
Nausea	2 (40.0)	0	2 (40.0)
Abdominal pain	1 (20.0)	1 (20.0)	0
Vomiting	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	4 (80.0)	1 (20.0)	3 (60.0)
Acquired gene mutation	1 (20.0)	1 (20.0)	0
Chills	1 (20.0)	0	1 (20.0)
Malaise	1 (20.0)	0	1 (20.0)
Mucosal haemorrhage	1 (20.0)	0	1 (20.0)
Pyrexia	1 (20.0)	0	1 (20.0)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	4 (80.0)	1 (20.0)	3 (60.0)
Cytokine release syndrome	4 (80.0)	2 (40.0)	2 (40.0)
Hypogammaglobulinaemia	2 (40.0)	0	2 (40.0)
Immunodeficiency	1 (20.0)	0	1 (20.0)
Seasonal allergy	1 (20.0)	1 (20.0)	0
Infections and infestations			
-Total	3 (60.0)	1 (20.0)	2 (40.0)
Gastroenteritis	1 (20.0)	0	1 (20.0)
Haemophilus infection	1 (20.0)	0	1 (20.0)
Otitis media	1 (20.0)	0	1 (20.0)
Otitis media acute	1 (20.0)	0	1 (20.0)
Pneumonia	1 (20.0)	0	1 (20.0)
Sinusitis	1 (20.0)	0	1 (20.0)
Subcutaneous abscess	1 (20.0)	0	1 (20.0)
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0
Injury, poisoning and procedural complications			
-Total	2 (40.0)	1 (20.0)	1 (20.0)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthropod bite	1 (20.0)	1 (20.0)	0
Procedural complication	1 (20.0)	1 (20.0)	0
Procedural pain	1 (20.0)	0	1 (20.0)
Investigations			
-Total	4 (80.0)	1 (20.0)	3 (60.0)
Aspartate aminotransferase increased	3 (60.0)	1 (20.0)	2 (40.0)
Activated partial thromboplastin time prolonged	1 (20.0)	1 (20.0)	0
Blood alkaline phosphatase increased	1 (20.0)	1 (20.0)	0
Blood lactate dehydrogenase increased	1 (20.0)	1 (20.0)	0
Blood phosphorus decreased	1 (20.0)	1 (20.0)	0
Blood urea increased	1 (20.0)	1 (20.0)	0
C-reactive protein increased	1 (20.0)	1 (20.0)	0
Serum ferritin increased	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	2 (40.0)	0	2 (40.0)
Decreased appetite	1 (20.0)	0	1 (20.0)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperalbuminaemia	1 (20.0)	1 (20.0)	0
Hypercalcaemia	1 (20.0)	1 (20.0)	0
Hyperchloraemia	1 (20.0)	1 (20.0)	0
Hypermagnesaemia	1 (20.0)	1 (20.0)	0
Hypernatraemia	1 (20.0)	0	1 (20.0)
Hypoalbuminaemia	1 (20.0)	0	1 (20.0)
Hypophosphataemia	1 (20.0)	1 (20.0)	0
Metabolic alkalosis	1 (20.0)	1 (20.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (20.0)	0	1 (20.0)
Arthralgia	1 (20.0)	1 (20.0)	0
Muscular weakness	1 (20.0)	0	1 (20.0)
Nervous system disorders			
-Total	2 (40.0)	0	2 (40.0)
Dysarthria	1 (20.0)	0	1 (20.0)
Headache	1 (20.0)	0	1 (20.0)
Somnolence	1 (20.0)	1 (20.0)	0
Psychiatric disorders			

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (20.0)	0	1 (20.0)
Delirium	1 (20.0)	0	1 (20.0)
Insomnia	1 (20.0)	0	1 (20.0)
Irritability	1 (20.0)	1 (20.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (60.0)	2 (40.0)	1 (20.0)
Cough	1 (20.0)	1 (20.0)	0
Epistaxis	1 (20.0)	0	1 (20.0)
Oropharyngeal plaque	1 (20.0)	1 (20.0)	0
Rhinorrhoea	1 (20.0)	1 (20.0)	0
Skin and subcutaneous tissue disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Dermatitis	1 (20.0)	1 (20.0)	0
Hyperhidrosis	1 (20.0)	1 (20.0)	0
Papule	1 (20.0)	1 (20.0)	0
Pruritus	1 (20.0)	1 (20.0)	0
Rash	1 (20.0)	0	1 (20.0)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash papular	1 (20.0)	1 (20.0)	0
Vascular disorders			
-Total	1 (20.0)	0	1 (20.0)
Flushing	1 (20.0)	1 (20.0)	0
Hypertension	1 (20.0)	0	1 (20.0)

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Table 225o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	59 (100)	2 (3.4)	57 (96.6)
Blood and lymphatic system disorders			
-Total	11 (18.6)	4 (6.8)	7 (11.9)
Anaemia	11 (18.6)	4 (6.8)	7 (11.9)
Cardiac disorders			
-Total	18 (30.5)	9 (15.3)	9 (15.3)
Tachycardia	13 (22.0)	7 (11.9)	6 (10.2)
Sinus tachycardia	6 (10.2)	3 (5.1)	3 (5.1)
Pericardial effusion	1 (1.7)	1 (1.7)	0
Eye disorders			

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (5.1)	2 (3.4)	1 (1.7)
Periorbital oedema	3 (5.1)	2 (3.4)	1 (1.7)
Conjunctival haemorrhage	2 (3.4)	2 (3.4)	0
Gastrointestinal disorders			
-Total	35 (59.3)	13 (22.0)	22 (37.3)
Vomiting	24 (40.7)	15 (25.4)	9 (15.3)
Diarrhoea	22 (37.3)	13 (22.0)	9 (15.3)
Nausea	21 (35.6)	6 (10.2)	15 (25.4)
Abdominal pain	9 (15.3)	5 (8.5)	4 (6.8)
Constipation	7 (11.9)	6 (10.2)	1 (1.7)
General disorders and administration site conditions			
-Total	33 (55.9)	18 (30.5)	15 (25.4)
Pyrexia	21 (35.6)	8 (13.6)	13 (22.0)
Fatigue	15 (25.4)	12 (20.3)	3 (5.1)
Chills	9 (15.3)	9 (15.3)	0
Malaise	3 (5.1)	1 (1.7)	2 (3.4)
Immune system disorders			
-Total	49 (83.1)	5 (8.5)	44 (74.6)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cytokine release syndrome	41 (69.5)	5 (8.5)	36 (61.0)
Hypogammaglobulinaemia	25 (42.4)	3 (5.1)	22 (37.3)
Seasonal allergy	1 (1.7)	1 (1.7)	0
Infections and infestations			
-Total	13 (22.0)	2 (3.4)	11 (18.6)
Upper respiratory tract infection	7 (11.9)	3 (5.1)	4 (6.8)
Gastroenteritis	3 (5.1)	1 (1.7)	2 (3.4)
Otitis media	3 (5.1)	0	3 (5.1)
Sinusitis	3 (5.1)	0	3 (5.1)
Pneumonia	2 (3.4)	0	2 (3.4)
Otitis media acute	1 (1.7)	0	1 (1.7)
Injury, poisoning and procedural complications			
-Total	4 (6.8)	2 (3.4)	2 (3.4)
Procedural pain	4 (6.8)	2 (3.4)	2 (3.4)
Investigations			
-Total	31 (52.5)	2 (3.4)	29 (49.2)
White blood cell count decreased	15 (25.4)	5 (8.5)	10 (16.9)
Alanine aminotransferase increased	11 (18.6)	5 (8.5)	6 (10.2)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	10 (16.9)	6 (10.2)	4 (6.8)
Prothrombin time prolonged	9 (15.3)	5 (8.5)	4 (6.8)
International normalised ratio increased	8 (13.6)	8 (13.6)	0
Blood creatinine increased	7 (11.9)	5 (8.5)	2 (3.4)
Lymphocyte count decreased	7 (11.9)	2 (3.4)	5 (8.5)
Blood bilirubin increased	6 (10.2)	2 (3.4)	4 (6.8)
Platelet count decreased	6 (10.2)	3 (5.1)	3 (5.1)
Activated partial thromboplastin time prolonged	4 (6.8)	2 (3.4)	2 (3.4)
Blood urea increased	2 (3.4)	1 (1.7)	1 (1.7)
Serum ferritin increased	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	29 (49.2)	15 (25.4)	14 (23.7)
Decreased appetite	12 (20.3)	8 (13.6)	4 (6.8)
Hypokalaemia	11 (18.6)	4 (6.8)	7 (11.9)
Hyperphosphataemia	8 (13.6)	8 (13.6)	0
Hypoalbuminaemia	4 (6.8)	1 (1.7)	3 (5.1)
Hypernatraemia	3 (5.1)	1 (1.7)	2 (3.4)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypophosphataemia	2 (3.4)	2 (3.4)	0
Musculoskeletal and connective tissue disorders			
-Total	14 (23.7)	10 (16.9)	4 (6.8)
Pain in extremity	11 (18.6)	7 (11.9)	4 (6.8)
Arthralgia	4 (6.8)	3 (5.1)	1 (1.7)
Muscular weakness	2 (3.4)	2 (3.4)	0
Nervous system disorders			
-Total	26 (44.1)	18 (30.5)	8 (13.6)
Headache	23 (39.0)	15 (25.4)	8 (13.6)
Dizziness	6 (10.2)	6 (10.2)	0
Dysarthria	1 (1.7)	1 (1.7)	0
Psychiatric disorders			
-Total	12 (20.3)	7 (11.9)	5 (8.5)
Anxiety	6 (10.2)	3 (5.1)	3 (5.1)
Confusional state	6 (10.2)	3 (5.1)	3 (5.1)
Delirium	3 (5.1)	2 (3.4)	1 (1.7)
Irritability	1 (1.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	25 (42.4)	15 (25.4)	10 (16.9)
Cough	13 (22.0)	11 (18.6)	2 (3.4)
Oropharyngeal pain	6 (10.2)	4 (6.8)	2 (3.4)
Pleural effusion	6 (10.2)	2 (3.4)	4 (6.8)
Epistaxis	5 (8.5)	4 (6.8)	1 (1.7)
Rhinorrhoea	5 (8.5)	4 (6.8)	1 (1.7)
Skin and subcutaneous tissue disorders			
-Total	12 (20.3)	10 (16.9)	2 (3.4)
Rash	7 (11.9)	5 (8.5)	2 (3.4)
Hyperhidrosis	3 (5.1)	3 (5.1)	0
Pruritus	3 (5.1)	3 (5.1)	0
Papule	1 (1.7)	1 (1.7)	0
Rash papular	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	11 (18.6)	4 (6.8)	7 (11.9)
Hypertension	10 (16.9)	3 (5.1)	7 (11.9)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Flushing	1 (1.7)	1 (1.7)	0

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Table 225p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

		All patients N=4	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	1 (25.0)	3 (75.0)
Blood and lymphatic system disorders			
-Total	2 (50.0)	2 (50.0)	0
Anaemia	2 (50.0)	2 (50.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Constipation	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	1 (25.0)	1 (25.0)	0
Fatigue	1 (25.0)	1 (25.0)	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	3 (75.0)	1 (25.0)	2 (50.0)
Cytokine release syndrome	3 (75.0)	1 (25.0)	2 (50.0)
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Fungal skin infection	1 (25.0)	1 (25.0)	0
Viral infection	1 (25.0)	0	1 (25.0)
Investigations			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Blood bilirubin increased	1 (25.0)	1 (25.0)	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0
Fibrin d dimer increased	1 (25.0)	1 (25.0)	0
Lymphocyte count decreased	1 (25.0)	1 (25.0)	0
Platelet count decreased	1 (25.0)	1 (25.0)	0
White blood cell count decreased	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (25.0)	1 (25.0)	0
Decreased appetite	1 (25.0)	1 (25.0)	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0
Nervous system disorders			
-Total	1 (25.0)	0	1 (25.0)
Headache	1 (25.0)	0	1 (25.0)
Tremor	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypoxia	1 (25.0)	0	1 (25.0)
Skin and subcutaneous tissue disorders			
-Total	2 (50.0)	2 (50.0)	0
Dermatitis diaper	1 (25.0)	1 (25.0)	0
Dry skin	1 (25.0)	1 (25.0)	0
Erythema	1 (25.0)	1 (25.0)	0

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AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=60	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	58 (96.7)	1 (1.7)	57 (95.0)
Blood and lymphatic system disorders			
-Total	9 (15.0)	2 (3.3)	7 (11.7)
Anaemia	9 (15.0)	2 (3.3)	7 (11.7)
Cardiac disorders			
-Total	18 (30.0)	10 (16.7)	8 (13.3)
Tachycardia	14 (23.3)	8 (13.3)	6 (10.0)
Sinus tachycardia	5 (8.3)	3 (5.0)	2 (3.3)
Gastrointestinal disorders			
-Total	31 (51.7)	11 (18.3)	20 (33.3)
Nausea	20 (33.3)	6 (10.0)	14 (23.3)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	20 (33.3)	13 (21.7)	7 (11.7)
Diarrhoea	17 (28.3)	11 (18.3)	6 (10.0)
Abdominal pain	8 (13.3)	6 (10.0)	2 (3.3)
Constipation	6 (10.0)	5 (8.3)	1 (1.7)
General disorders and administration site conditions			
-Total	25 (41.7)	12 (20.0)	13 (21.7)
Pyrexia	14 (23.3)	3 (5.0)	11 (18.3)
Fatigue	12 (20.0)	9 (15.0)	3 (5.0)
Chills	8 (13.3)	8 (13.3)	0
Immune system disorders			
-Total	49 (81.7)	5 (8.3)	44 (73.3)
Cytokine release syndrome	42 (70.0)	6 (10.0)	36 (60.0)
Hypogammaglobulinaemia	20 (33.3)	3 (5.0)	17 (28.3)
Infections and infestations			
-Total	1 (1.7)	0	1 (1.7)
Upper respiratory tract infection	1 (1.7)	0	1 (1.7)
Investigations			
-Total	28 (46.7)	3 (5.0)	25 (41.7)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	12 (20.0)	6 (10.0)	6 (10.0)
Alanine aminotransferase increased	10 (16.7)	5 (8.3)	5 (8.3)
White blood cell count decreased	10 (16.7)	3 (5.0)	7 (11.7)
Prothrombin time prolonged	9 (15.0)	5 (8.3)	4 (6.7)
International normalised ratio increased	8 (13.3)	8 (13.3)	0
Blood creatinine increased	6 (10.0)	4 (6.7)	2 (3.3)
Blood bilirubin increased	5 (8.3)	1 (1.7)	4 (6.7)
Platelet count decreased	5 (8.3)	2 (3.3)	3 (5.0)
Blood immunoglobulin m decreased	3 (5.0)	3 (5.0)	0
Lymphocyte count decreased	3 (5.0)	0	3 (5.0)
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0
Neutrophil count decreased	2 (3.3)	0	2 (3.3)
Metabolism and nutrition disorders			
-Total	24 (40.0)	13 (21.7)	11 (18.3)
Decreased appetite	10 (16.7)	6 (10.0)	4 (6.7)
Hypokalaemia	10 (16.7)	3 (5.0)	7 (11.7)
Hyperphosphataemia	7 (11.7)	7 (11.7)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	4 (6.7)	2 (3.3)	2 (3.3)
Pain in extremity	4 (6.7)	2 (3.3)	2 (3.3)
Nervous system disorders			
-Total	25 (41.7)	18 (30.0)	7 (11.7)
Headache	23 (38.3)	16 (26.7)	7 (11.7)
Dizziness	4 (6.7)	4 (6.7)	0
Tremor	1 (1.7)	1 (1.7)	0
Psychiatric disorders			
-Total	10 (16.7)	5 (8.3)	5 (8.3)
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)
Anxiety	5 (8.3)	2 (3.3)	3 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	21 (35.0)	10 (16.7)	11 (18.3)
Cough	8 (13.3)	8 (13.3)	0
Pleural effusion	6 (10.0)	2 (3.3)	4 (6.7)
Epistaxis	4 (6.7)	2 (3.3)	2 (3.3)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoxia	4 (6.7)	0	4 (6.7)
Oropharyngeal pain	2 (3.3)	1 (1.7)	1 (1.7)
Nasal congestion	1 (1.7)	1 (1.7)	0
Rhinorrhoea	1 (1.7)	1 (1.7)	0
Skin and subcutaneous tissue disorders			
-Total	10 (16.7)	9 (15.0)	1 (1.7)
Rash	4 (6.7)	4 (6.7)	0
Dry skin	3 (5.0)	3 (5.0)	0
Erythema	2 (3.3)	2 (3.3)	0
Rash maculo-papular	2 (3.3)	1 (1.7)	1 (1.7)
Vascular disorders			
-Total	9 (15.0)	2 (3.3)	7 (11.7)
Hypertension	9 (15.0)	2 (3.3)	7 (11.7)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of

adverse events.

Table 225p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

		All patients N=4	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (75.0)	0	3 (75.0)
Blood and lymphatic system disorders			
-Total	1 (25.0)	1 (25.0)	0
Anaemia	1 (25.0)	1 (25.0)	0
Eye disorders			
-Total	1 (25.0)	1 (25.0)	0
Ocular hyperaemia	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Vomiting	2 (50.0)	2 (50.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	1 (25.0)	0	1 (25.0)
General disorders and administration site conditions			
-Total	1 (25.0)	1 (25.0)	0
Influenza like illness	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	0	1 (25.0)
Rash pustular	1 (25.0)	0	1 (25.0)
Injury, poisoning and procedural complications			
-Total	1 (25.0)	0	1 (25.0)
Skin laceration	1 (25.0)	0	1 (25.0)
Investigations			
-Total	1 (25.0)	0	1 (25.0)
Lymphocyte count decreased	1 (25.0)	0	1 (25.0)
Neutrophil count decreased	1 (25.0)	1 (25.0)	0
Platelet count decreased	1 (25.0)	1 (25.0)	0
White blood cell count decreased	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (25.0)	1 (25.0)	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (25.0)	1 (25.0)	0
Pain in extremity	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (50.0)	0	2 (50.0)
Cough	1 (25.0)	0	1 (25.0)
Nasal congestion	1 (25.0)	1 (25.0)	0
Rhinorrhoea	1 (25.0)	0	1 (25.0)
Skin and subcutaneous tissue disorders			
-Total	1 (25.0)	1 (25.0)	0
Rash maculo-papular	1 (25.0)	1 (25.0)	0

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term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	33 (63.5)	13 (25.0)	20 (38.5)
Cardiac disorders			
-Total	1 (1.9)	0	1 (1.9)
Sinus tachycardia	1 (1.9)	0	1 (1.9)
Gastrointestinal disorders			
-Total	11 (21.2)	7 (13.5)	4 (7.7)
Diarrhoea	7 (13.5)	6 (11.5)	1 (1.9)
Vomiting	6 (11.5)	3 (5.8)	3 (5.8)
Abdominal pain	3 (5.8)	2 (3.8)	1 (1.9)
Nausea	3 (5.8)	1 (1.9)	2 (3.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	11 (21.2)	9 (17.3)	2 (3.8)
Pyrexia	9 (17.3)	7 (13.5)	2 (3.8)
Fatigue	2 (3.8)	2 (3.8)	0
Chills	1 (1.9)	1 (1.9)	0
Influenza like illness	1 (1.9)	1 (1.9)	0
Immune system disorders			
-Total	7 (13.5)	0	7 (13.5)
Hypogammaglobulinaemia	7 (13.5)	0	7 (13.5)
Infections and infestations			
-Total	7 (13.5)	4 (7.7)	3 (5.8)
Upper respiratory tract infection	6 (11.5)	3 (5.8)	3 (5.8)
Viral infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	8 (15.4)	5 (9.6)	3 (5.8)
White blood cell count decreased	3 (5.8)	1 (1.9)	2 (3.8)
Neutrophil count decreased	2 (3.8)	1 (1.9)	1 (1.9)
Platelet count decreased	2 (3.8)	2 (3.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	1 (1.9)	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0
Lymphocyte count decreased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	4 (7.7)	3 (5.8)	1 (1.9)
Decreased appetite	2 (3.8)	1 (1.9)	1 (1.9)
Hyperphosphataemia	1 (1.9)	1 (1.9)	0
Hypokalaemia	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			
-Total	7 (13.5)	5 (9.6)	2 (3.8)
Pain in extremity	7 (13.5)	5 (9.6)	2 (3.8)
Nervous system disorders			
-Total	6 (11.5)	5 (9.6)	1 (1.9)
Headache	5 (9.6)	4 (7.7)	1 (1.9)
Dizziness	3 (5.8)	3 (5.8)	0
Psychiatric disorders			
-Total	1 (1.9)	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Anxiety	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	11 (21.2)	9 (17.3)	2 (3.8)
Cough	6 (11.5)	5 (9.6)	1 (1.9)
Nasal congestion	3 (5.8)	3 (5.8)	0
Oropharyngeal pain	3 (5.8)	2 (3.8)	1 (1.9)
Rhinorrhoea	3 (5.8)	3 (5.8)	0
Epistaxis	1 (1.9)	1 (1.9)	0
Skin and subcutaneous tissue disorders			
-Total	8 (15.4)	5 (9.6)	3 (5.8)
Rash	4 (7.7)	1 (1.9)	3 (5.8)
Erythema	2 (3.8)	2 (3.8)	0
Dry skin	1 (1.9)	1 (1.9)	0
Rash maculo-papular	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	2 (3.8)	1 (1.9)	1 (1.9)
Hypertension	2 (3.8)	1 (1.9)	1 (1.9)

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Table 225p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (33.3)	1 (33.3)	0
Investigations			
-Total	1 (33.3)	1 (33.3)	0
Lymphocyte count decreased	1 (33.3)	1 (33.3)	0
Neutrophil count decreased	1 (33.3)	1 (33.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	9 (29.0)	2 (6.5)	7 (22.6)
Gastrointestinal disorders			
-Total	3 (9.7)	0	3 (9.7)
Diarrhoea	2 (6.5)	0	2 (6.5)
Abdominal pain	1 (3.2)	0	1 (3.2)
Nausea	1 (3.2)	0	1 (3.2)
General disorders and administration site conditions			
-Total	1 (3.2)	0	1 (3.2)
Chills	1 (3.2)	0	1 (3.2)
Pyrexia	1 (3.2)	0	1 (3.2)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	3 (9.7)	2 (6.5)	1 (3.2)
Upper respiratory tract infection	2 (6.5)	1 (3.2)	1 (3.2)
Viral infection	1 (3.2)	1 (3.2)	0
Investigations			
-Total	4 (12.9)	1 (3.2)	3 (9.7)
Lymphocyte count decreased	2 (6.5)	1 (3.2)	1 (3.2)
Alanine aminotransferase increased	1 (3.2)	0	1 (3.2)
Aspartate aminotransferase increased	1 (3.2)	1 (3.2)	0
Neutrophil count decreased	1 (3.2)	0	1 (3.2)
White blood cell count decreased	1 (3.2)	1 (3.2)	0
Nervous system disorders			
-Total	1 (3.2)	0	1 (3.2)
Dizziness	1 (3.2)	1 (3.2)	0
Headache	1 (3.2)	0	1 (3.2)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (12.9)	4 (12.9)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	2 (6.5)	2 (6.5)	0
Epistaxis	1 (3.2)	1 (3.2)	0
Oropharyngeal pain	1 (3.2)	1 (3.2)	0
Rhinorrhoea	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	0	4 (100)
Blood and lymphatic system disorders			
-Total	2 (50.0)	2 (50.0)	0
Anaemia	2 (50.0)	2 (50.0)	0
Eye disorders			
-Total	1 (25.0)	1 (25.0)	0
Ocular hyperaemia	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Vomiting	2 (50.0)	2 (50.0)	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Constipation	1 (25.0)	1 (25.0)	0
Nausea	1 (25.0)	0	1 (25.0)
General disorders and administration site conditions			
-Total	2 (50.0)	2 (50.0)	0
Fatigue	1 (25.0)	1 (25.0)	0
Influenza like illness	1 (25.0)	1 (25.0)	0
Immune system disorders			
-Total	3 (75.0)	1 (25.0)	2 (50.0)
Cytokine release syndrome	3 (75.0)	1 (25.0)	2 (50.0)
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	3 (75.0)	1 (25.0)	2 (50.0)
Fungal skin infection	1 (25.0)	1 (25.0)	0
Rash pustular	1 (25.0)	0	1 (25.0)
Viral infection	1 (25.0)	0	1 (25.0)
Injury, poisoning and procedural complications			
-Total	1 (25.0)	0	1 (25.0)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin laceration	1 (25.0)	0	1 (25.0)
Investigations			
-Total	2 (50.0)	0	2 (50.0)
Lymphocyte count decreased	2 (50.0)	1 (25.0)	1 (25.0)
White blood cell count decreased	2 (50.0)	1 (25.0)	1 (25.0)
Blood bilirubin increased	1 (25.0)	1 (25.0)	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0
Fibrin d dimer increased	1 (25.0)	1 (25.0)	0
Neutrophil count decreased	1 (25.0)	1 (25.0)	0
Platelet count decreased	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	1 (25.0)	1 (25.0)	0
Decreased appetite	1 (25.0)	1 (25.0)	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (25.0)	1 (25.0)	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	1 (25.0)	1 (25.0)	0
Nervous system disorders			
-Total	1 (25.0)	0	1 (25.0)
Headache	1 (25.0)	0	1 (25.0)
Tremor	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (50.0)	0	2 (50.0)
Cough	1 (25.0)	0	1 (25.0)
Hypoxia	1 (25.0)	0	1 (25.0)
Nasal congestion	1 (25.0)	1 (25.0)	0
Rhinorrhoea	1 (25.0)	0	1 (25.0)
Skin and subcutaneous tissue disorders			
-Total	3 (75.0)	3 (75.0)	0
Dermatitis diaper	1 (25.0)	1 (25.0)	0
Dry skin	1 (25.0)	1 (25.0)	0
Erythema	1 (25.0)	1 (25.0)	0
Rash maculo-papular	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	59 (98.3)	1 (1.7)	58 (96.7)
Blood and lymphatic system disorders			
-Total	9 (15.0)	2 (3.3)	7 (11.7)
Anaemia	9 (15.0)	2 (3.3)	7 (11.7)
Cardiac disorders			
-Total	19 (31.7)	10 (16.7)	9 (15.0)
Tachycardia	14 (23.3)	8 (13.3)	6 (10.0)
Sinus tachycardia	6 (10.0)	3 (5.0)	3 (5.0)
Gastrointestinal disorders			
-Total	35 (58.3)	12 (20.0)	23 (38.3)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	23 (38.3)	14 (23.3)	9 (15.0)
Diarrhoea	22 (36.7)	13 (21.7)	9 (15.0)
Nausea	22 (36.7)	6 (10.0)	16 (26.7)
Abdominal pain	10 (16.7)	6 (10.0)	4 (6.7)
Constipation	6 (10.0)	5 (8.3)	1 (1.7)
General disorders and administration site conditions			
-Total	32 (53.3)	16 (26.7)	16 (26.7)
Pyrexia	22 (36.7)	8 (13.3)	14 (23.3)
Fatigue	14 (23.3)	11 (18.3)	3 (5.0)
Chills	10 (16.7)	9 (15.0)	1 (1.7)
Influenza like illness	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	50 (83.3)	5 (8.3)	45 (75.0)
Cytokine release syndrome	42 (70.0)	6 (10.0)	36 (60.0)
Hypogammaglobulinaemia	26 (43.3)	3 (5.0)	23 (38.3)
Infections and infestations			
-Total	10 (16.7)	6 (10.0)	4 (6.7)
Upper respiratory tract infection	8 (13.3)	4 (6.7)	4 (6.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Viral infection	2 (3.3)	2 (3.3)	0
Investigations			
-Total	31 (51.7)	3 (5.0)	28 (46.7)
Aspartate aminotransferase increased	13 (21.7)	7 (11.7)	6 (10.0)
White blood cell count decreased	13 (21.7)	4 (6.7)	9 (15.0)
Alanine aminotransferase increased	11 (18.3)	5 (8.3)	6 (10.0)
Prothrombin time prolonged	9 (15.0)	5 (8.3)	4 (6.7)
International normalised ratio increased	8 (13.3)	8 (13.3)	0
Blood creatinine increased	6 (10.0)	4 (6.7)	2 (3.3)
Blood bilirubin increased	5 (8.3)	1 (1.7)	4 (6.7)
Lymphocyte count decreased	5 (8.3)	1 (1.7)	4 (6.7)
Platelet count decreased	5 (8.3)	2 (3.3)	3 (5.0)
Neutrophil count decreased	4 (6.7)	0	4 (6.7)
Blood immunoglobulin m decreased	3 (5.0)	3 (5.0)	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0
Metabolism and nutrition disorders			
-Total	25 (41.7)	14 (23.3)	11 (18.3)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	12 (20.0)	7 (11.7)	5 (8.3)
Hypokalaemia	11 (18.3)	4 (6.7)	7 (11.7)
Hyperphosphataemia	7 (11.7)	7 (11.7)	0
Musculoskeletal and connective tissue disorders			
-Total	10 (16.7)	6 (10.0)	4 (6.7)
Pain in extremity	10 (16.7)	6 (10.0)	4 (6.7)
Nervous system disorders			
-Total	26 (43.3)	18 (30.0)	8 (13.3)
Headache	23 (38.3)	15 (25.0)	8 (13.3)
Dizziness	6 (10.0)	6 (10.0)	0
Tremor	1 (1.7)	1 (1.7)	0
Psychiatric disorders			
-Total	11 (18.3)	6 (10.0)	5 (8.3)
Anxiety	6 (10.0)	3 (5.0)	3 (5.0)
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	29 (48.3)	16 (26.7)	13 (21.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	13 (21.7)	12 (20.0)	1 (1.7)
Epistaxis	6 (10.0)	4 (6.7)	2 (3.3)
Oropharyngeal pain	6 (10.0)	4 (6.7)	2 (3.3)
Pleural effusion	6 (10.0)	2 (3.3)	4 (6.7)
Rhinorrhoea	5 (8.3)	5 (8.3)	0
Hypoxia	4 (6.7)	0	4 (6.7)
Nasal congestion	4 (6.7)	4 (6.7)	0
Skin and subcutaneous tissue disorders			
-Total	17 (28.3)	13 (21.7)	4 (6.7)
Rash	8 (13.3)	5 (8.3)	3 (5.0)
Dry skin	4 (6.7)	4 (6.7)	0
Erythema	4 (6.7)	4 (6.7)	0
Rash maculo-papular	3 (5.0)	2 (3.3)	1 (1.7)
Vascular disorders			
-Total	11 (18.3)	3 (5.0)	8 (13.3)
Hypertension	11 (18.3)	3 (5.0)	8 (13.3)

- A patient with multiple adverse events within a group term is counted only once in the

total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	31 (96.9)	0	31 (96.9)
Blood and lymphatic system disorders			
-Total	3 (9.4)	2 (6.3)	1 (3.1)
Anaemia	3 (9.4)	2 (6.3)	1 (3.1)
Cardiac disorders			
-Total	7 (21.9)	5 (15.6)	2 (6.3)
Tachycardia	5 (15.6)	4 (12.5)	1 (3.1)
Sinus tachycardia	2 (6.3)	1 (3.1)	1 (3.1)
Gastrointestinal disorders			
-Total	16 (50.0)	6 (18.8)	10 (31.3)
Nausea	9 (28.1)	2 (6.3)	7 (21.9)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	9 (28.1)	7 (21.9)	2 (6.3)
Diarrhoea	7 (21.9)	5 (15.6)	2 (6.3)
Abdominal pain	5 (15.6)	4 (12.5)	1 (3.1)
Constipation	5 (15.6)	4 (12.5)	1 (3.1)
General disorders and administration site conditions			
-Total	10 (31.3)	3 (9.4)	7 (21.9)
Pyrexia	8 (25.0)	1 (3.1)	7 (21.9)
Fatigue	3 (9.4)	3 (9.4)	0
Immune system disorders			
-Total	28 (87.5)	1 (3.1)	27 (84.4)
Cytokine release syndrome	25 (78.1)	3 (9.4)	22 (68.8)
Hypogammaglobulinaemia	12 (37.5)	1 (3.1)	11 (34.4)
Infections and infestations			
-Total	6 (18.8)	1 (3.1)	5 (15.6)
Clostridium difficile infection	4 (12.5)	0	4 (12.5)
Rhinovirus infection	2 (6.3)	2 (6.3)	0
Upper respiratory tract infection	1 (3.1)	0	1 (3.1)
Investigations			

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (34.4)	3 (9.4)	8 (25.0)
Aspartate aminotransferase increased	5 (15.6)	4 (12.5)	1 (3.1)
White blood cell count decreased	5 (15.6)	0	5 (15.6)
Alanine aminotransferase increased	3 (9.4)	3 (9.4)	0
Blood creatinine increased	3 (9.4)	2 (6.3)	1 (3.1)
Prothrombin time prolonged	3 (9.4)	3 (9.4)	0
Blood bilirubin increased	2 (6.3)	1 (3.1)	1 (3.1)
Platelet count decreased	2 (6.3)	1 (3.1)	1 (3.1)
Metabolism and nutrition disorders			
-Total	10 (31.3)	4 (12.5)	6 (18.8)
Decreased appetite	5 (15.6)	2 (6.3)	3 (9.4)
Hypokalaemia	4 (12.5)	1 (3.1)	3 (9.4)
Hyperphosphataemia	3 (9.4)	3 (9.4)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (9.4)	1 (3.1)	2 (6.3)
Pain in extremity	3 (9.4)	1 (3.1)	2 (6.3)
Nervous system disorders			

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	13 (40.6)	9 (28.1)	4 (12.5)
Headache	13 (40.6)	9 (28.1)	4 (12.5)
Dizziness	1 (3.1)	1 (3.1)	0
Psychiatric disorders			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Confusional state	2 (6.3)	1 (3.1)	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (18.8)	4 (12.5)	2 (6.3)
Cough	3 (9.4)	3 (9.4)	0
Epistaxis	2 (6.3)	1 (3.1)	1 (3.1)
Pleural effusion	1 (3.1)	0	1 (3.1)
Skin and subcutaneous tissue disorders			
-Total	5 (15.6)	5 (15.6)	0
Dry skin	3 (9.4)	3 (9.4)	0
Pruritus	2 (6.3)	2 (6.3)	0
Rash	1 (3.1)	1 (3.1)	0
Vascular disorders			

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (12.5)	2 (6.3)	2 (6.3)
Hypertension	4 (12.5)	2 (6.3)	2 (6.3)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	31 (96.9)	3 (9.4)	28 (87.5)
Blood and lymphatic system disorders			
-Total	9 (28.1)	2 (6.3)	7 (21.9)
Anaemia	8 (25.0)	2 (6.3)	6 (18.8)
Thrombocytopenia	3 (9.4)	0	3 (9.4)
Cardiac disorders			
-Total	11 (34.4)	5 (15.6)	6 (18.8)
Tachycardia	9 (28.1)	4 (12.5)	5 (15.6)
Sinus tachycardia	3 (9.4)	2 (6.3)	1 (3.1)
Eye disorders			
-Total	4 (12.5)	3 (9.4)	1 (3.1)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Periorbital oedema	4 (12.5)	3 (9.4)	1 (3.1)
Gastrointestinal disorders			
-Total	16 (50.0)	6 (18.8)	10 (31.3)
Nausea	11 (34.4)	4 (12.5)	7 (21.9)
Vomiting	11 (34.4)	6 (18.8)	5 (15.6)
Diarrhoea	10 (31.3)	6 (18.8)	4 (12.5)
Abdominal pain	3 (9.4)	2 (6.3)	1 (3.1)
Constipation	2 (6.3)	2 (6.3)	0
General disorders and administration site conditions			
-Total	16 (50.0)	10 (31.3)	6 (18.8)
Fatigue	10 (31.3)	7 (21.9)	3 (9.4)
Chills	8 (25.0)	8 (25.0)	0
Pyrexia	6 (18.8)	2 (6.3)	4 (12.5)
Immune system disorders			
-Total	24 (75.0)	5 (15.6)	19 (59.4)
Cytokine release syndrome	20 (62.5)	4 (12.5)	16 (50.0)
Hypogammaglobulinaemia	9 (28.1)	2 (6.3)	7 (21.9)
Infections and infestations			

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (3.1)	1 (3.1)	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0
Investigations			
-Total	19 (59.4)	1 (3.1)	18 (56.3)
International normalised ratio increased	8 (25.0)	8 (25.0)	0
Alanine aminotransferase increased	7 (21.9)	2 (6.3)	5 (15.6)
Aspartate aminotransferase increased	7 (21.9)	2 (6.3)	5 (15.6)
Prothrombin time prolonged	6 (18.8)	2 (6.3)	4 (12.5)
White blood cell count decreased	6 (18.8)	3 (9.4)	3 (9.4)
Blood bilirubin increased	4 (12.5)	1 (3.1)	3 (9.4)
Blood creatinine increased	4 (12.5)	3 (9.4)	1 (3.1)
Lymphocyte count decreased	4 (12.5)	1 (3.1)	3 (9.4)
Platelet count decreased	4 (12.5)	2 (6.3)	2 (6.3)
Metabolism and nutrition disorders			
-Total	17 (53.1)	8 (25.0)	9 (28.1)
Decreased appetite	6 (18.8)	5 (15.6)	1 (3.1)
Hypokalaemia	6 (18.8)	2 (6.3)	4 (12.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	5 (15.6)	5 (15.6)	0
Hypoalbuminaemia	5 (15.6)	1 (3.1)	4 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	5 (15.6)	4 (12.5)	1 (3.1)
Myalgia	5 (15.6)	4 (12.5)	1 (3.1)
Pain in extremity	1 (3.1)	1 (3.1)	0
Nervous system disorders			
-Total	13 (40.6)	9 (28.1)	4 (12.5)
Headache	11 (34.4)	7 (21.9)	4 (12.5)
Dizziness	3 (9.4)	3 (9.4)	0
Psychiatric disorders			
-Total	4 (12.5)	2 (6.3)	2 (6.3)
Confusional state	4 (12.5)	2 (6.3)	2 (6.3)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (28.1)	5 (15.6)	4 (12.5)
Cough	5 (15.6)	5 (15.6)	0
Pleural effusion	5 (15.6)	2 (6.3)	3 (9.4)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	2 (6.3)	1 (3.1)	1 (3.1)
Skin and subcutaneous tissue disorders			
-Total	4 (12.5)	4 (12.5)	0
Rash	3 (9.4)	3 (9.4)	0
Dry skin	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	5 (15.6)	0	5 (15.6)
Hypertension	5 (15.6)	0	5 (15.6)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=29	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (65.5)	6 (20.7)	13 (44.8)
Blood and lymphatic system disorders			
-Total	2 (6.9)	1 (3.4)	1 (3.4)
Anaemia	1 (3.4)	1 (3.4)	0
Thrombocytopenia	1 (3.4)	0	1 (3.4)
Gastrointestinal disorders			
-Total	10 (34.5)	7 (24.1)	3 (10.3)
Diarrhoea	6 (20.7)	5 (17.2)	1 (3.4)
Vomiting	5 (17.2)	2 (6.9)	3 (10.3)
Abdominal pain	3 (10.3)	2 (6.9)	1 (3.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=29	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	2 (6.9)	1 (3.4)	1 (3.4)
General disorders and administration site conditions			
-Total	7 (24.1)	6 (20.7)	1 (3.4)
Pyrexia	6 (20.7)	5 (17.2)	1 (3.4)
Fatigue	2 (6.9)	2 (6.9)	0
Immune system disorders			
-Total	4 (13.8)	0	4 (13.8)
Hypogammaglobulinaemia	4 (13.8)	0	4 (13.8)
Infections and infestations			
-Total	6 (20.7)	3 (10.3)	3 (10.3)
Upper respiratory tract infection	4 (13.8)	1 (3.4)	3 (10.3)
Rhinovirus infection	2 (6.9)	2 (6.9)	0
Investigations			
-Total	3 (10.3)	1 (3.4)	2 (6.9)
White blood cell count decreased	2 (6.9)	1 (3.4)	1 (3.4)
Blood creatinine increased	1 (3.4)	1 (3.4)	0
Lymphocyte count decreased	1 (3.4)	0	1 (3.4)
Platelet count decreased	1 (3.4)	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	5 (17.2)	4 (13.8)	1 (3.4)
Decreased appetite	2 (6.9)	1 (3.4)	1 (3.4)
Hyperphosphataemia	2 (6.9)	2 (6.9)	0
Hypokalaemia	1 (3.4)	1 (3.4)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (17.2)	3 (10.3)	2 (6.9)
Pain in extremity	5 (17.2)	3 (10.3)	2 (6.9)
Nervous system disorders			
-Total	4 (13.8)	3 (10.3)	1 (3.4)
Headache	3 (10.3)	2 (6.9)	1 (3.4)
Dizziness	2 (6.9)	2 (6.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (20.7)	5 (17.2)	1 (3.4)
Cough	5 (17.2)	4 (13.8)	1 (3.4)
Epistaxis	1 (3.4)	1 (3.4)	0
Skin and subcutaneous tissue disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (13.8)	2 (6.9)	2 (6.9)
Rash	3 (10.3)	1 (3.4)	2 (6.9)
Dry skin	1 (3.4)	1 (3.4)	0
Pruritus	1 (3.4)	1 (3.4)	0
Vascular disorders			
-Total	2 (6.9)	1 (3.4)	1 (3.4)
Hypertension	2 (6.9)	1 (3.4)	1 (3.4)

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Table 225q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (51.9)	6 (22.2)	8 (29.6)
Cardiac disorders			
-Total	1 (3.7)	0	1 (3.7)
Sinus tachycardia	1 (3.7)	0	1 (3.7)
Gastrointestinal disorders			
-Total	3 (11.1)	1 (3.7)	2 (7.4)
Vomiting	3 (11.1)	3 (11.1)	0
Nausea	2 (7.4)	0	2 (7.4)
Diarrhoea	1 (3.7)	1 (3.7)	0
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (11.1)	2 (7.4)	1 (3.7)
Pyrexia	3 (11.1)	2 (7.4)	1 (3.7)
Chills	1 (3.7)	1 (3.7)	0
Immune system disorders			
-Total	3 (11.1)	0	3 (11.1)
Hypogammaglobulinaemia	3 (11.1)	0	3 (11.1)
Infections and infestations			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Upper respiratory tract infection	2 (7.4)	2 (7.4)	0
Otitis media	1 (3.7)	0	1 (3.7)
Investigations			
-Total	4 (14.8)	3 (11.1)	1 (3.7)
Platelet count decreased	2 (7.4)	2 (7.4)	0
White blood cell count decreased	2 (7.4)	1 (3.7)	1 (3.7)
Aspartate aminotransferase increased	1 (3.7)	1 (3.7)	0
Lymphocyte count decreased	1 (3.7)	1 (3.7)	0
Musculoskeletal and connective tissue disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (11.1)	3 (11.1)	0
Pain in extremity	3 (11.1)	3 (11.1)	0
Nervous system disorders			
-Total	2 (7.4)	2 (7.4)	0
Headache	2 (7.4)	2 (7.4)	0
Dizziness	1 (3.7)	1 (3.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Cough	2 (7.4)	1 (3.7)	1 (3.7)
Skin and subcutaneous tissue disorders			
-Total	1 (3.7)	0	1 (3.7)
Rash	1 (3.7)	0	1 (3.7)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (27.8)	2 (11.1)	3 (16.7)
Gastrointestinal disorders			
-Total	2 (11.1)	0	2 (11.1)
Abdominal pain	1 (5.6)	0	1 (5.6)
Diarrhoea	1 (5.6)	0	1 (5.6)
Nausea	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
-Total	1 (5.6)	0	1 (5.6)
Chills	1 (5.6)	0	1 (5.6)
Pyrexia	1 (5.6)	0	1 (5.6)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Lymphocyte count decreased	2 (11.1)	1 (5.6)	1 (5.6)
Aspartate aminotransferase increased	1 (5.6)	1 (5.6)	0
Nervous system disorders			
-Total	1 (5.6)	0	1 (5.6)
Dizziness	1 (5.6)	1 (5.6)	0
Headache	1 (5.6)	0	1 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (11.1)	2 (11.1)	0
Cough	1 (5.6)	1 (5.6)	0
Epistaxis	1 (5.6)	1 (5.6)	0
Skin and subcutaneous tissue disorders			
-Total	1 (5.6)	1 (5.6)	0
Pruritus	1 (5.6)	1 (5.6)	0

- A patient with multiple adverse events within a group term is counted only once in the

total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (43.8)	2 (12.5)	5 (31.3)
Blood and lymphatic system disorders			
-Total	1 (6.3)	1 (6.3)	0
Thrombocytopenia	1 (6.3)	1 (6.3)	0
Gastrointestinal disorders			
-Total	1 (6.3)	0	1 (6.3)
Diarrhoea	1 (6.3)	0	1 (6.3)
Infections and infestations			
-Total	5 (31.3)	1 (6.3)	4 (25.0)
Otitis media	3 (18.8)	0	3 (18.8)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	2 (12.5)	1 (6.3)	1 (6.3)
Investigations			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Alanine aminotransferase increased	1 (6.3)	0	1 (6.3)
Lymphocyte count decreased	1 (6.3)	1 (6.3)	0
White blood cell count decreased	1 (6.3)	1 (6.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (6.3)	1 (6.3)	0
Cough	1 (6.3)	1 (6.3)	0

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Table 225q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	32 (100)	1 (3.1)	31 (96.9)
Blood and lymphatic system disorders			
-Total	4 (12.5)	2 (6.3)	2 (6.3)
Anaemia	3 (9.4)	2 (6.3)	1 (3.1)
Thrombocytopenia	1 (3.1)	0	1 (3.1)
Cardiac disorders			
-Total	7 (21.9)	5 (15.6)	2 (6.3)
Tachycardia	5 (15.6)	4 (12.5)	1 (3.1)
Sinus tachycardia	2 (6.3)	1 (3.1)	1 (3.1)
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	20 (62.5)	8 (25.0)	12 (37.5)
Vomiting	12 (37.5)	8 (25.0)	4 (12.5)
Nausea	11 (34.4)	2 (6.3)	9 (28.1)
Diarrhoea	10 (31.3)	6 (18.8)	4 (12.5)
Abdominal pain	7 (21.9)	4 (12.5)	3 (9.4)
Constipation	5 (15.6)	4 (12.5)	1 (3.1)
General disorders and administration site conditions			
-Total	15 (46.9)	6 (18.8)	9 (28.1)
Pyrexia	13 (40.6)	4 (12.5)	9 (28.1)
Fatigue	5 (15.6)	5 (15.6)	0
Chills	1 (3.1)	0	1 (3.1)
Immune system disorders			
-Total	28 (87.5)	1 (3.1)	27 (84.4)
Cytokine release syndrome	25 (78.1)	3 (9.4)	22 (68.8)
Hypogammaglobulinaemia	16 (50.0)	1 (3.1)	15 (46.9)
Infections and infestations			
-Total	10 (31.3)	3 (9.4)	7 (21.9)
Clostridium difficile infection	4 (12.5)	0	4 (12.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinovirus infection	4 (12.5)	4 (12.5)	0
Upper respiratory tract infection	4 (12.5)	1 (3.1)	3 (9.4)
Investigations			
-Total	13 (40.6)	3 (9.4)	10 (31.3)
White blood cell count decreased	7 (21.9)	1 (3.1)	6 (18.8)
Aspartate aminotransferase increased	6 (18.8)	5 (15.6)	1 (3.1)
Alanine aminotransferase increased	3 (9.4)	3 (9.4)	0
Blood creatinine increased	3 (9.4)	2 (6.3)	1 (3.1)
Prothrombin time prolonged	3 (9.4)	3 (9.4)	0
Blood bilirubin increased	2 (6.3)	1 (3.1)	1 (3.1)
Lymphocyte count decreased	2 (6.3)	0	2 (6.3)
Platelet count decreased	2 (6.3)	1 (3.1)	1 (3.1)
Metabolism and nutrition disorders			
-Total	11 (34.4)	5 (15.6)	6 (18.8)
Decreased appetite	7 (21.9)	3 (9.4)	4 (12.5)
Hypokalaemia	5 (15.6)	2 (6.3)	3 (9.4)
Hyperphosphataemia	3 (9.4)	3 (9.4)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	7 (21.9)	3 (9.4)	4 (12.5)
Pain in extremity	7 (21.9)	3 (9.4)	4 (12.5)
Nervous system disorders			
-Total	14 (43.8)	9 (28.1)	5 (15.6)
Headache	13 (40.6)	8 (25.0)	5 (15.6)
Dizziness	2 (6.3)	2 (6.3)	0
Psychiatric disorders			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Confusional state	2 (6.3)	1 (3.1)	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (34.4)	8 (25.0)	3 (9.4)
Cough	7 (21.9)	6 (18.8)	1 (3.1)
Epistaxis	4 (12.5)	3 (9.4)	1 (3.1)
Pleural effusion	1 (3.1)	0	1 (3.1)
Skin and subcutaneous tissue disorders			
-Total	8 (25.0)	6 (18.8)	2 (6.3)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dry skin	4 (12.5)	4 (12.5)	0
Pruritus	4 (12.5)	4 (12.5)	0
Rash	4 (12.5)	2 (6.3)	2 (6.3)
Vascular disorders			
-Total	6 (18.8)	3 (9.4)	3 (9.4)
Hypertension	6 (18.8)	3 (9.4)	3 (9.4)

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Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	32 (100)	2 (6.3)	30 (93.8)
Blood and lymphatic system disorders			
-Total	10 (31.3)	3 (9.4)	7 (21.9)
Anaemia	8 (25.0)	2 (6.3)	6 (18.8)
Thrombocytopenia	4 (12.5)	1 (3.1)	3 (9.4)
Cardiac disorders			
-Total	12 (37.5)	5 (15.6)	7 (21.9)
Tachycardia	9 (28.1)	4 (12.5)	5 (15.6)
Sinus tachycardia	4 (12.5)	2 (6.3)	2 (6.3)
Eye disorders			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (12.5)	3 (9.4)	1 (3.1)
Periorbital oedema	4 (12.5)	3 (9.4)	1 (3.1)
Gastrointestinal disorders			
-Total	18 (56.3)	6 (18.8)	12 (37.5)
Vomiting	13 (40.6)	8 (25.0)	5 (15.6)
Diarrhoea	12 (37.5)	7 (21.9)	5 (15.6)
Nausea	12 (37.5)	4 (12.5)	8 (25.0)
Abdominal pain	3 (9.4)	2 (6.3)	1 (3.1)
Constipation	2 (6.3)	2 (6.3)	0
General disorders and administration site conditions			
-Total	18 (56.3)	11 (34.4)	7 (21.9)
Fatigue	10 (31.3)	7 (21.9)	3 (9.4)
Chills	9 (28.1)	9 (28.1)	0
Pyrexia	9 (28.1)	4 (12.5)	5 (15.6)
Immune system disorders			
-Total	25 (78.1)	5 (15.6)	20 (62.5)
Cytokine release syndrome	20 (62.5)	4 (12.5)	16 (50.0)
Hypogammaglobulinaemia	11 (34.4)	2 (6.3)	9 (28.1)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	8 (25.0)	3 (9.4)	5 (15.6)
Otitis media	4 (12.5)	0	4 (12.5)
Upper respiratory tract infection	4 (12.5)	3 (9.4)	1 (3.1)
Rhinovirus infection	1 (3.1)	1 (3.1)	0
Investigations			
-Total	19 (59.4)	0	19 (59.4)
Alanine aminotransferase increased	8 (25.0)	2 (6.3)	6 (18.8)
International normalised ratio increased	8 (25.0)	8 (25.0)	0
White blood cell count decreased	8 (25.0)	4 (12.5)	4 (12.5)
Aspartate aminotransferase increased	7 (21.9)	2 (6.3)	5 (15.6)
Prothrombin time prolonged	6 (18.8)	2 (6.3)	4 (12.5)
Lymphocyte count decreased	5 (15.6)	2 (6.3)	3 (9.4)
Blood bilirubin increased	4 (12.5)	1 (3.1)	3 (9.4)
Blood creatinine increased	4 (12.5)	3 (9.4)	1 (3.1)
Platelet count decreased	4 (12.5)	2 (6.3)	2 (6.3)
Metabolism and nutrition disorders			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	17 (53.1)	8 (25.0)	9 (28.1)
Decreased appetite	6 (18.8)	5 (15.6)	1 (3.1)
Hypokalaemia	6 (18.8)	2 (6.3)	4 (12.5)
Hyperphosphataemia	5 (15.6)	5 (15.6)	0
Hypoalbuminaemia	5 (15.6)	1 (3.1)	4 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	7 (21.9)	6 (18.8)	1 (3.1)
Myalgia	5 (15.6)	4 (12.5)	1 (3.1)
Pain in extremity	4 (12.5)	4 (12.5)	0
Nervous system disorders			
-Total	13 (40.6)	9 (28.1)	4 (12.5)
Headache	11 (34.4)	7 (21.9)	4 (12.5)
Dizziness	4 (12.5)	4 (12.5)	0
Psychiatric disorders			
-Total	4 (12.5)	2 (6.3)	2 (6.3)
Confusional state	4 (12.5)	2 (6.3)	2 (6.3)
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (34.4)	6 (18.8)	5 (15.6)
Cough	7 (21.9)	6 (18.8)	1 (3.1)
Pleural effusion	5 (15.6)	2 (6.3)	3 (9.4)
Epistaxis	2 (6.3)	1 (3.1)	1 (3.1)
Skin and subcutaneous tissue disorders			
-Total	5 (15.6)	4 (12.5)	1 (3.1)
Rash	4 (12.5)	3 (9.4)	1 (3.1)
Dry skin	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	5 (15.6)	0	5 (15.6)
Hypertension	5 (15.6)	0	5 (15.6)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (100)	0	7 (100)
Blood and lymphatic system disorders			
-Total	2 (28.6)	2 (28.6)	0
Anaemia	2 (28.6)	2 (28.6)	0
Cardiac disorders			
-Total	2 (28.6)	2 (28.6)	0
Palpitations	1 (14.3)	1 (14.3)	0
Pericardial effusion	1 (14.3)	1 (14.3)	0
Tachycardia	1 (14.3)	1 (14.3)	0
Eye disorders			
-Total	1 (14.3)	1 (14.3)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eye pain	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Diarrhoea	3 (42.9)	2 (28.6)	1 (14.3)
Nausea	3 (42.9)	1 (14.3)	2 (28.6)
Vomiting	3 (42.9)	1 (14.3)	2 (28.6)
Constipation	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	2 (28.6)	0	2 (28.6)
Pyrexia	2 (28.6)	0	2 (28.6)
Asthenia	1 (14.3)	1 (14.3)	0
Chills	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			
-Total	1 (14.3)	0	1 (14.3)
Hepatomegaly	1 (14.3)	0	1 (14.3)
Immune system disorders			
-Total	7 (100)	0	7 (100)
Cytokine release syndrome	5 (71.4)	0	5 (71.4)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)
Infections and infestations			
-Total	2 (28.6)	0	2 (28.6)
Gastroenteritis	1 (14.3)	0	1 (14.3)
Viral infection	1 (14.3)	0	1 (14.3)
Injury, poisoning and procedural complications			
-Total	1 (14.3)	0	1 (14.3)
Tracheal haemorrhage	1 (14.3)	0	1 (14.3)
Investigations			
-Total	5 (71.4)	1 (14.3)	4 (57.1)
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)
White blood cell count decreased	2 (28.6)	1 (14.3)	1 (14.3)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0
Blood creatinine increased	1 (14.3)	0	1 (14.3)
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0
Blood phosphorus increased	1 (14.3)	1 (14.3)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood uric acid increased	1 (14.3)	1 (14.3)	0
Cardiac murmur	1 (14.3)	1 (14.3)	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0
Neutrophil count decreased	1 (14.3)	0	1 (14.3)
Prothrombin time prolonged	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Decreased appetite	2 (28.6)	1 (14.3)	1 (14.3)
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)
Hypernatraemia	1 (14.3)	0	1 (14.3)
Hypoalbuminaemia	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	4 (57.1)	4 (57.1)	0
Headache	3 (42.9)	3 (42.9)	0
Dizziness	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)
Delirium	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Cough	2 (28.6)	2 (28.6)	0
Hypoxia	1 (14.3)	0	1 (14.3)
Pleural effusion	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	4 (57.1)	4 (57.1)	0
Dermatitis diaper	1 (14.3)	1 (14.3)	0
Dry skin	1 (14.3)	1 (14.3)	0
Erythema	1 (14.3)	1 (14.3)	0
Livedo reticularis	1 (14.3)	1 (14.3)	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	2 (28.6)	0	2 (28.6)
Haematoma	1 (14.3)	0	1 (14.3)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	1 (14.3)	0	1 (14.3)

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Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (95.0)	1 (5.0)	18 (90.0)
Blood and lymphatic system disorders			
-Total	5 (25.0)	1 (5.0)	4 (20.0)
Anaemia	3 (15.0)	1 (5.0)	2 (10.0)
Disseminated intravascular coagulation	2 (10.0)	0	2 (10.0)
Cardiac disorders			
-Total	6 (30.0)	3 (15.0)	3 (15.0)
Tachycardia	3 (15.0)	2 (10.0)	1 (5.0)
Sinus tachycardia	2 (10.0)	1 (5.0)	1 (5.0)
Pericardial effusion	1 (5.0)	0	1 (5.0)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Endocrine disorders			
-Total	1 (5.0)	0	1 (5.0)
Adrenal insufficiency	1 (5.0)	0	1 (5.0)
Eye disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Conjunctival haemorrhage	2 (10.0)	2 (10.0)	0
Periorbital oedema	2 (10.0)	2 (10.0)	0
Vision blurred	1 (5.0)	0	1 (5.0)
Gastrointestinal disorders			
-Total	11 (55.0)	4 (20.0)	7 (35.0)
Vomiting	7 (35.0)	4 (20.0)	3 (15.0)
Constipation	5 (25.0)	5 (25.0)	0
Diarrhoea	5 (25.0)	3 (15.0)	2 (10.0)
Nausea	5 (25.0)	1 (5.0)	4 (20.0)
Abdominal pain	2 (10.0)	2 (10.0)	0
General disorders and administration site conditions			
-Total	9 (45.0)	6 (30.0)	3 (15.0)
Fatigue	5 (25.0)	5 (25.0)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	4 (20.0)	1 (5.0)	3 (15.0)
Catheter site pain	1 (5.0)	0	1 (5.0)
Chills	1 (5.0)	1 (5.0)	0
Generalised oedema	1 (5.0)	0	1 (5.0)
Immune system disorders			
-Total	15 (75.0)	1 (5.0)	14 (70.0)
Cytokine release syndrome	14 (70.0)	2 (10.0)	12 (60.0)
Hypogammaglobulinaemia	5 (25.0)	0	5 (25.0)
Infections and infestations			
-Total	3 (15.0)	1 (5.0)	2 (10.0)
Clostridium difficile infection	2 (10.0)	0	2 (10.0)
Influenza	1 (5.0)	1 (5.0)	0
Injury, poisoning and procedural complications			
-Total	1 (5.0)	1 (5.0)	0
Contusion	1 (5.0)	1 (5.0)	0
Investigations			
-Total	10 (50.0)	1 (5.0)	9 (45.0)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	6 (30.0)	3 (15.0)	3 (15.0)
White blood cell count decreased	5 (25.0)	2 (10.0)	3 (15.0)
Activated partial thromboplastin time prolonged	3 (15.0)	1 (5.0)	2 (10.0)
Alanine aminotransferase increased	3 (15.0)	2 (10.0)	1 (5.0)
Blood creatinine increased	3 (15.0)	2 (10.0)	1 (5.0)
International normalised ratio increased	3 (15.0)	3 (15.0)	0
Platelet count decreased	3 (15.0)	0	3 (15.0)
Prothrombin time prolonged	3 (15.0)	3 (15.0)	0
Blood bilirubin increased	2 (10.0)	0	2 (10.0)
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0
Blood phosphorus increased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	9 (45.0)	4 (20.0)	5 (25.0)
Hyperphosphataemia	4 (20.0)	4 (20.0)	0
Decreased appetite	3 (15.0)	2 (10.0)	1 (5.0)
Hypernatraemia	3 (15.0)	1 (5.0)	2 (10.0)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperglycaemia	2 (10.0)	0	2 (10.0)
Hypoalbuminaemia	1 (5.0)	0	1 (5.0)
Hypokalaemia	1 (5.0)	0	1 (5.0)
Hypophosphataemia	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Arthralgia	2 (10.0)	2 (10.0)	0
Muscular weakness	1 (5.0)	0	1 (5.0)
Musculoskeletal chest pain	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	12 (60.0)	6 (30.0)	6 (30.0)
Headache	9 (45.0)	6 (30.0)	3 (15.0)
Dysarthria	2 (10.0)	1 (5.0)	1 (5.0)
Encephalopathy	2 (10.0)	0	2 (10.0)
Tremor	2 (10.0)	2 (10.0)	0
Dizziness	1 (5.0)	1 (5.0)	0
Psychiatric disorders			
-Total	3 (15.0)	1 (5.0)	2 (10.0)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Delirium	2 (10.0)	0	2 (10.0)
Anxiety	1 (5.0)	0	1 (5.0)
Confusional state	1 (5.0)	1 (5.0)	0
Renal and urinary disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Acute kidney injury	2 (10.0)	1 (5.0)	1 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (40.0)	4 (20.0)	4 (20.0)
Tachypnoea	3 (15.0)	2 (10.0)	1 (5.0)
Epistaxis	2 (10.0)	0	2 (10.0)
Pleural effusion	2 (10.0)	1 (5.0)	1 (5.0)
Cough	1 (5.0)	1 (5.0)	0
Nasal congestion	1 (5.0)	1 (5.0)	0
Oropharyngeal pain	1 (5.0)	0	1 (5.0)
Rhinorrhoea	1 (5.0)	1 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	7 (35.0)	7 (35.0)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dry skin	3 (15.0)	3 (15.0)	0
Hyperhidrosis	3 (15.0)	3 (15.0)	0
Petechiae	2 (10.0)	2 (10.0)	0
Erythema	1 (5.0)	1 (5.0)	0
Rash	1 (5.0)	1 (5.0)	0
Rash erythematous	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Hypertension	2 (10.0)	1 (5.0)	1 (5.0)

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

		All patients N=21	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (95.2)	0	20 (95.2)
Blood and lymphatic system disorders			
-Total	4 (19.0)	0	4 (19.0)
Anaemia	3 (14.3)	0	3 (14.3)
Thrombocytopenia	2 (9.5)	0	2 (9.5)
Disseminated intravascular coagulation	1 (4.8)	0	1 (4.8)
Cardiac disorders			
-Total	6 (28.6)	2 (9.5)	4 (19.0)
Tachycardia	5 (23.8)	2 (9.5)	3 (14.3)
Sinus tachycardia	1 (4.8)	0	1 (4.8)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eye disorders			
-Total	4 (19.0)	2 (9.5)	2 (9.5)
Eye pain	2 (9.5)	0	2 (9.5)
Vision blurred	2 (9.5)	1 (4.8)	1 (4.8)
Conjunctival haemorrhage	1 (4.8)	1 (4.8)	0
Periorbital oedema	1 (4.8)	1 (4.8)	0
Gastrointestinal disorders			
-Total	9 (42.9)	3 (14.3)	6 (28.6)
Nausea	6 (28.6)	1 (4.8)	5 (23.8)
Vomiting	5 (23.8)	3 (14.3)	2 (9.5)
Diarrhoea	4 (19.0)	2 (9.5)	2 (9.5)
Abdominal pain	1 (4.8)	1 (4.8)	0
Constipation	1 (4.8)	0	1 (4.8)
General disorders and administration site conditions			
-Total	9 (42.9)	4 (19.0)	5 (23.8)
Chills	5 (23.8)	5 (23.8)	0
Pyrexia	5 (23.8)	1 (4.8)	4 (19.0)
Fatigue	3 (14.3)	2 (9.5)	1 (4.8)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Malaise	2 (9.5)	0	2 (9.5)
Catheter site pain	1 (4.8)	0	1 (4.8)
Hepatobiliary disorders			
-Total	1 (4.8)	1 (4.8)	0
Hepatomegaly	1 (4.8)	1 (4.8)	0
Immune system disorders			
-Total	17 (81.0)	0	17 (81.0)
Cytokine release syndrome	16 (76.2)	1 (4.8)	15 (71.4)
Hypogammaglobulinaemia	7 (33.3)	1 (4.8)	6 (28.6)
Infections and infestations			
-Total	4 (19.0)	2 (9.5)	2 (9.5)
Rhinovirus infection	3 (14.3)	3 (14.3)	0
Clostridium difficile infection	1 (4.8)	0	1 (4.8)
Upper respiratory tract infection	1 (4.8)	0	1 (4.8)
Injury, poisoning and procedural complications			
-Total	1 (4.8)	1 (4.8)	0
Procedural pain	1 (4.8)	1 (4.8)	0
Investigations			

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	10 (47.6)	3 (14.3)	7 (33.3)
Prothrombin time prolonged	4 (19.0)	2 (9.5)	2 (9.5)
Alanine aminotransferase increased	3 (14.3)	2 (9.5)	1 (4.8)
Blood bilirubin increased	2 (9.5)	0	2 (9.5)
Blood fibrinogen decreased	2 (9.5)	0	2 (9.5)
Platelet count decreased	2 (9.5)	2 (9.5)	0
Transaminases increased	2 (9.5)	2 (9.5)	0
White blood cell count decreased	2 (9.5)	0	2 (9.5)
Aspartate aminotransferase increased	1 (4.8)	1 (4.8)	0
Blood creatinine increased	1 (4.8)	1 (4.8)	0
Blood immunoglobulin m decreased	1 (4.8)	1 (4.8)	0
International normalised ratio increased	1 (4.8)	1 (4.8)	0
Metabolism and nutrition disorders			
-Total	9 (42.9)	3 (14.3)	6 (28.6)
Decreased appetite	3 (14.3)	1 (4.8)	2 (9.5)
Hypokalaemia	3 (14.3)	1 (4.8)	2 (9.5)
Hyperphosphataemia	2 (9.5)	2 (9.5)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fluid overload	1 (4.8)	0	1 (4.8)
Hypoalbuminaemia	1 (4.8)	0	1 (4.8)
Musculoskeletal and connective tissue disorders			
-Total	2 (9.5)	1 (4.8)	1 (4.8)
Myalgia	1 (4.8)	1 (4.8)	0
Pain in extremity	1 (4.8)	0	1 (4.8)
Nervous system disorders			
-Total	6 (28.6)	3 (14.3)	3 (14.3)
Headache	6 (28.6)	3 (14.3)	3 (14.3)
Psychiatric disorders			
-Total	5 (23.8)	3 (14.3)	2 (9.5)
Anxiety	2 (9.5)	1 (4.8)	1 (4.8)
Confusional state	2 (9.5)	1 (4.8)	1 (4.8)
Delirium	1 (4.8)	1 (4.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (23.8)	3 (14.3)	2 (9.5)
Cough	3 (14.3)	3 (14.3)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoxia	2 (9.5)	0	2 (9.5)
Epistaxis	1 (4.8)	1 (4.8)	0
Pleural effusion	1 (4.8)	1 (4.8)	0
Rhinitis allergic	1 (4.8)	1 (4.8)	0
Tachypnoea	1 (4.8)	1 (4.8)	0
Skin and subcutaneous tissue disorders			
-Total	3 (14.3)	2 (9.5)	1 (4.8)
Erythema	1 (4.8)	1 (4.8)	0
Rash	1 (4.8)	1 (4.8)	0
Rash maculo-papular	1 (4.8)	0	1 (4.8)
Vascular disorders			
-Total	4 (19.0)	1 (4.8)	3 (14.3)
Hypertension	4 (19.0)	1 (4.8)	3 (14.3)

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Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	16 (100)	1 (6.3)	15 (93.8)
Blood and lymphatic system disorders			
-Total	3 (18.8)	1 (6.3)	2 (12.5)
Anaemia	3 (18.8)	1 (6.3)	2 (12.5)
Thrombocytopenia	1 (6.3)	0	1 (6.3)
Cardiac disorders			
-Total	6 (37.5)	4 (25.0)	2 (12.5)
Tachycardia	5 (31.3)	3 (18.8)	2 (12.5)
Sinus tachycardia	2 (12.5)	2 (12.5)	0
Ear and labyrinth disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (12.5)	2 (12.5)	0
Ear pain	2 (12.5)	2 (12.5)	0
Eye disorders			
-Total	1 (6.3)	0	1 (6.3)
Periorbital oedema	1 (6.3)	0	1 (6.3)
Gastrointestinal disorders			
-Total	8 (50.0)	3 (18.8)	5 (31.3)
Nausea	6 (37.5)	3 (18.8)	3 (18.8)
Abdominal pain	5 (31.3)	3 (18.8)	2 (12.5)
Diarrhoea	5 (31.3)	4 (25.0)	1 (6.3)
Vomiting	5 (31.3)	5 (31.3)	0
Abdominal distension	2 (12.5)	0	2 (12.5)
General disorders and administration site conditions			
-Total	8 (50.0)	3 (18.8)	5 (31.3)
Fatigue	5 (31.3)	3 (18.8)	2 (12.5)
Pyrexia	3 (18.8)	1 (6.3)	2 (12.5)
Catheter site pain	1 (6.3)	1 (6.3)	0
Chills	1 (6.3)	1 (6.3)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Generalised oedema	1 (6.3)	0	1 (6.3)
Malaise	1 (6.3)	0	1 (6.3)
Hepatobiliary disorders			
-Total	1 (6.3)	0	1 (6.3)
Hepatomegaly	1 (6.3)	0	1 (6.3)
Immune system disorders			
-Total	13 (81.3)	5 (31.3)	8 (50.0)
Cytokine release syndrome	10 (62.5)	4 (25.0)	6 (37.5)
Hypogammaglobulinaemia	5 (31.3)	2 (12.5)	3 (18.8)
Infections and infestations			
-Total	3 (18.8)	1 (6.3)	2 (12.5)
Clostridium difficile infection	1 (6.3)	0	1 (6.3)
Skin infection	1 (6.3)	0	1 (6.3)
Vulvovaginal candidiasis	1 (6.3)	1 (6.3)	0
Injury, poisoning and procedural complications			
-Total	3 (18.8)	0	3 (18.8)
Infusion related reaction	2 (12.5)	0	2 (12.5)
Procedural pain	2 (12.5)	0	2 (12.5)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	9 (56.3)	2 (12.5)	7 (43.8)
Aspartate aminotransferase increased	5 (31.3)	2 (12.5)	3 (18.8)
Alanine aminotransferase increased	4 (25.0)	1 (6.3)	3 (18.8)
International normalised ratio increased	3 (18.8)	3 (18.8)	0
Blood bilirubin increased	2 (12.5)	2 (12.5)	0
Blood creatinine increased	2 (12.5)	2 (12.5)	0
Blood immunoglobulin a decreased	2 (12.5)	2 (12.5)	0
Lymphocyte count decreased	2 (12.5)	0	2 (12.5)
White blood cell count decreased	2 (12.5)	0	2 (12.5)
Activated partial thromboplastin time prolonged	1 (6.3)	1 (6.3)	0
Blood immunoglobulin m decreased	1 (6.3)	1 (6.3)	0
Neutrophil count decreased	1 (6.3)	0	1 (6.3)
Platelet count decreased	1 (6.3)	1 (6.3)	0
Prothrombin time prolonged	1 (6.3)	0	1 (6.3)
Metabolism and nutrition disorders			
-Total	10 (62.5)	5 (31.3)	5 (31.3)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	4 (25.0)	1 (6.3)	3 (18.8)
Decreased appetite	3 (18.8)	3 (18.8)	0
Fluid overload	2 (12.5)	1 (6.3)	1 (6.3)
Hyperphosphataemia	2 (12.5)	2 (12.5)	0
Hypoalbuminaemia	2 (12.5)	0	2 (12.5)
Hypophosphataemia	2 (12.5)	2 (12.5)	0
Musculoskeletal and connective tissue disorders			
-Total	6 (37.5)	4 (25.0)	2 (12.5)
Myalgia	4 (25.0)	3 (18.8)	1 (6.3)
Pain in extremity	3 (18.8)	2 (12.5)	1 (6.3)
Arthralgia	1 (6.3)	1 (6.3)	0
Muscle spasms	1 (6.3)	1 (6.3)	0
Nervous system disorders			
-Total	8 (50.0)	6 (37.5)	2 (12.5)
Headache	6 (37.5)	4 (25.0)	2 (12.5)
Dizziness	2 (12.5)	2 (12.5)	0
Encephalopathy	1 (6.3)	1 (6.3)	0
Psychiatric disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Anxiety	2 (12.5)	1 (6.3)	1 (6.3)
Confusional state	1 (6.3)	0	1 (6.3)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (50.0)	4 (25.0)	4 (25.0)
Cough	2 (12.5)	2 (12.5)	0
Hypoxia	2 (12.5)	0	2 (12.5)
Pleural effusion	2 (12.5)	0	2 (12.5)
Epistaxis	1 (6.3)	1 (6.3)	0
Oropharyngeal pain	1 (6.3)	1 (6.3)	0
Skin and subcutaneous tissue disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Rash	2 (12.5)	2 (12.5)	0
Petechiae	1 (6.3)	0	1 (6.3)
Vascular disorders			
-Total	4 (25.0)	1 (6.3)	3 (18.8)
Hypertension	2 (12.5)	0	2 (12.5)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypotension	2 (12.5)	1 (6.3)	1 (6.3)

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Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (80.0)	0	4 (80.0)
Endocrine disorders			
-Total	1 (20.0)	1 (20.0)	0
Adrenal insufficiency	1 (20.0)	1 (20.0)	0
Gastrointestinal disorders			
-Total	4 (80.0)	3 (60.0)	1 (20.0)
Diarrhoea	2 (40.0)	2 (40.0)	0
Vomiting	2 (40.0)	2 (40.0)	0
Abdominal pain	1 (20.0)	1 (20.0)	0
Nausea	1 (20.0)	0	1 (20.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oral pain	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	3 (60.0)	2 (40.0)	1 (20.0)
Catheter site pain	1 (20.0)	0	1 (20.0)
Fatigue	1 (20.0)	1 (20.0)	0
Pyrexia	1 (20.0)	1 (20.0)	0
Immune system disorders			
-Total	1 (20.0)	0	1 (20.0)
Graft versus host disease	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	3 (60.0)	1 (20.0)	2 (40.0)
Upper respiratory tract infection	2 (40.0)	0	2 (40.0)
Ear infection	1 (20.0)	1 (20.0)	0
Rhinovirus infection	1 (20.0)	1 (20.0)	0
Tinea capitis	1 (20.0)	1 (20.0)	0
Viral infection	1 (20.0)	1 (20.0)	0
Injury, poisoning and procedural complications			

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (20.0)	0	1 (20.0)
Contusion	1 (20.0)	1 (20.0)	0
Infusion related reaction	1 (20.0)	0	1 (20.0)
Procedural nausea	1 (20.0)	0	1 (20.0)
Sunburn	1 (20.0)	1 (20.0)	0
Investigations			
-Total	2 (40.0)	2 (40.0)	0
Blood magnesium decreased	1 (20.0)	1 (20.0)	0
Weight decreased	1 (20.0)	1 (20.0)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (60.0)	3 (60.0)	0
Pain in extremity	2 (40.0)	2 (40.0)	0
Arthralgia	1 (20.0)	1 (20.0)	0
Muscular weakness	1 (20.0)	1 (20.0)	0
Pain in jaw	1 (20.0)	1 (20.0)	0
Nervous system disorders			
-Total	2 (40.0)	2 (40.0)	0
Headache	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Peroneal nerve palsy	1 (20.0)	1 (20.0)	0
Psychiatric disorders			
-Total	1 (20.0)	0	1 (20.0)
Anxiety	1 (20.0)	1 (20.0)	0
Depression	1 (20.0)	1 (20.0)	0
Sleep disorder	1 (20.0)	0	1 (20.0)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (80.0)	2 (40.0)	2 (40.0)
Rhinorrhoea	2 (40.0)	1 (20.0)	1 (20.0)
Cough	1 (20.0)	1 (20.0)	0
Nasal congestion	1 (20.0)	1 (20.0)	0
Oropharyngeal pain	1 (20.0)	0	1 (20.0)
Pharyngeal erythema	1 (20.0)	1 (20.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (20.0)	0	1 (20.0)
Alopecia	1 (20.0)	0	1 (20.0)
Erythema	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash erythematous	1 (20.0)	0	1 (20.0)
Vascular disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Hypertension	2 (40.0)	1 (20.0)	1 (20.0)
Hot flush	1 (20.0)	1 (20.0)	0

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Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (68.4)	3 (15.8)	10 (52.6)
Eye disorders			
-Total	1 (5.3)	1 (5.3)	0
Vision blurred	1 (5.3)	1 (5.3)	0
Gastrointestinal disorders			
-Total	3 (15.8)	2 (10.5)	1 (5.3)
Diarrhoea	2 (10.5)	1 (5.3)	1 (5.3)
Abdominal pain	1 (5.3)	0	1 (5.3)
Nausea	1 (5.3)	1 (5.3)	0
Vomiting	1 (5.3)	0	1 (5.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	1 (5.3)	1 (5.3)	0
Generalised oedema	1 (5.3)	1 (5.3)	0
Immune system disorders			
-Total	4 (21.1)	0	4 (21.1)
Hypogammaglobulinaemia	2 (10.5)	0	2 (10.5)
Immunodeficiency common variable	2 (10.5)	0	2 (10.5)
Infections and infestations			
-Total	7 (36.8)	2 (10.5)	5 (26.3)
Gastroenteritis	2 (10.5)	0	2 (10.5)
Influenza	2 (10.5)	0	2 (10.5)
Rhinovirus infection	1 (5.3)	1 (5.3)	0
Upper respiratory tract infection	1 (5.3)	1 (5.3)	0
Urinary tract infection	1 (5.3)	0	1 (5.3)
Investigations			
-Total	4 (21.1)	2 (10.5)	2 (10.5)
White blood cell count decreased	2 (10.5)	1 (5.3)	1 (5.3)
Blood creatinine increased	1 (5.3)	1 (5.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Neutrophil count decreased	1 (5.3)	0	1 (5.3)
Platelet count decreased	1 (5.3)	1 (5.3)	0
Metabolism and nutrition disorders			
-Total	3 (15.8)	3 (15.8)	0
Decreased appetite	1 (5.3)	1 (5.3)	0
Hyperphosphataemia	1 (5.3)	1 (5.3)	0
Hypokalaemia	1 (5.3)	1 (5.3)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (15.8)	2 (10.5)	1 (5.3)
Pain in extremity	2 (10.5)	1 (5.3)	1 (5.3)
Muscular weakness	1 (5.3)	1 (5.3)	0
Musculoskeletal chest pain	1 (5.3)	1 (5.3)	0
Psychiatric disorders			
-Total	1 (5.3)	1 (5.3)	0
Depression	1 (5.3)	1 (5.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (15.8)	3 (15.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	1 (5.3)	1 (5.3)	0
Epistaxis	1 (5.3)	1 (5.3)	0
Nasal congestion	1 (5.3)	1 (5.3)	0
Oropharyngeal pain	1 (5.3)	1 (5.3)	0
Skin and subcutaneous tissue disorders			
-Total	5 (26.3)	4 (21.1)	1 (5.3)
Rash	2 (10.5)	1 (5.3)	1 (5.3)
Dry skin	1 (5.3)	1 (5.3)	0
Papule	1 (5.3)	1 (5.3)	0
Petechiae	1 (5.3)	1 (5.3)	0

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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (77.8)	2 (11.1)	12 (66.7)
Blood and lymphatic system disorders			
-Total	1 (5.6)	0	1 (5.6)
Thrombocytopenia	1 (5.6)	0	1 (5.6)
Gastrointestinal disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Diarrhoea	2 (11.1)	2 (11.1)	0
Vomiting	2 (11.1)	2 (11.1)	0
Nausea	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Pyrexia	3 (16.7)	2 (11.1)	1 (5.6)
Malaise	1 (5.6)	1 (5.6)	0
Immune system disorders			
-Total	3 (16.7)	0	3 (16.7)
Hypogammaglobulinaemia	3 (16.7)	0	3 (16.7)
Infections and infestations			
-Total	4 (22.2)	1 (5.6)	3 (16.7)
Gastroenteritis	1 (5.6)	1 (5.6)	0
Influenza	1 (5.6)	0	1 (5.6)
Upper respiratory tract infection	1 (5.6)	0	1 (5.6)
Urinary tract infection	1 (5.6)	0	1 (5.6)
Injury, poisoning and procedural complications			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Procedural pain	2 (11.1)	1 (5.6)	1 (5.6)
Infusion related reaction	1 (5.6)	1 (5.6)	0
Investigations			
-Total	5 (27.8)	1 (5.6)	4 (22.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Weight decreased	3 (16.7)	0	3 (16.7)
Aspartate aminotransferase increased	1 (5.6)	1 (5.6)	0
Platelet count decreased	1 (5.6)	1 (5.6)	0
Transaminases increased	1 (5.6)	1 (5.6)	0
White blood cell count decreased	1 (5.6)	0	1 (5.6)
Musculoskeletal and connective tissue disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Pain in extremity	2 (11.1)	2 (11.1)	0
Arthralgia	1 (5.6)	0	1 (5.6)
Nervous system disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Dizziness	2 (11.1)	2 (11.1)	0
Headache	2 (11.1)	2 (11.1)	0
Peroneal nerve palsy	1 (5.6)	0	1 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (27.8)	3 (16.7)	2 (11.1)
Cough	2 (11.1)	1 (5.6)	1 (5.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinitis allergic	2 (11.1)	1 (5.6)	1 (5.6)
Rhinorrhoea	2 (11.1)	2 (11.1)	0
Nasal congestion	1 (5.6)	1 (5.6)	0
Oropharyngeal pain	1 (5.6)	1 (5.6)	0
Skin and subcutaneous tissue disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Erythema	1 (5.6)	1 (5.6)	0
Hyperhidrosis	1 (5.6)	1 (5.6)	0
Rash	1 (5.6)	0	1 (5.6)

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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	9 (64.3)	3 (21.4)	6 (42.9)
Blood and lymphatic system disorders			
-Total	1 (7.1)	1 (7.1)	0
Anaemia	1 (7.1)	1 (7.1)	0
Cardiac disorders			
-Total	1 (7.1)	0	1 (7.1)
Sinus tachycardia	1 (7.1)	0	1 (7.1)
Gastrointestinal disorders			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Vomiting	3 (21.4)	1 (7.1)	2 (14.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Abdominal pain	1 (7.1)	1 (7.1)	0
Diarrhoea	1 (7.1)	1 (7.1)	0
Nausea	1 (7.1)	0	1 (7.1)
General disorders and administration site conditions			
-Total	5 (35.7)	4 (28.6)	1 (7.1)
Pyrexia	5 (35.7)	4 (28.6)	1 (7.1)
Chills	1 (7.1)	1 (7.1)	0
Fatigue	1 (7.1)	1 (7.1)	0
Immune system disorders			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Hypogammaglobulinaemia	2 (14.3)	0	2 (14.3)
Graft versus host disease	1 (7.1)	1 (7.1)	0
Infections and infestations			
-Total	4 (28.6)	1 (7.1)	3 (21.4)
Upper respiratory tract infection	2 (14.3)	2 (14.3)	0
Ear infection	1 (7.1)	0	1 (7.1)
Otitis media	1 (7.1)	0	1 (7.1)
Urinary tract infection	1 (7.1)	0	1 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (7.1)	1 (7.1)	0
Contusion	1 (7.1)	1 (7.1)	0
Investigations			
-Total	3 (21.4)	2 (14.3)	1 (7.1)
Lymphocyte count decreased	2 (14.3)	1 (7.1)	1 (7.1)
Neutrophil count decreased	2 (14.3)	2 (14.3)	0
Blood uric acid increased	1 (7.1)	1 (7.1)	0
Platelet count decreased	1 (7.1)	1 (7.1)	0
White blood cell count decreased	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Decreased appetite	1 (7.1)	0	1 (7.1)
Hyperphosphataemia	1 (7.1)	1 (7.1)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (28.6)	3 (21.4)	1 (7.1)
Joint range of motion decreased	2 (14.3)	2 (14.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	2 (14.3)	1 (7.1)	1 (7.1)
Muscle spasms	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Headache	2 (14.3)	1 (7.1)	1 (7.1)
Dizziness	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (21.4)	2 (14.3)	1 (7.1)
Cough	3 (21.4)	2 (14.3)	1 (7.1)
Nasal congestion	1 (7.1)	1 (7.1)	0
Rhinitis allergic	1 (7.1)	1 (7.1)	0
Skin and subcutaneous tissue disorders			
-Total	3 (21.4)	2 (14.3)	1 (7.1)
Rash maculo-papular	2 (14.3)	2 (14.3)	0
Rash	1 (7.1)	0	1 (7.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the

AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	1 (20.0)	0	1 (20.0)
Skin infection	1 (20.0)	0	1 (20.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (45.5)	3 (27.3)	2 (18.2)
Infections and infestations			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Otitis media	2 (18.2)	0	2 (18.2)
Viral infection	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (9.1)	1 (9.1)	0
Epistaxis	1 (9.1)	1 (9.1)	0
Skin and subcutaneous tissue disorders			

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (9.1)	1 (9.1)	0
Papule	1 (9.1)	1 (9.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (50.0)	0	5 (50.0)
Gastrointestinal disorders			
-Total	1 (10.0)	0	1 (10.0)
Nausea	1 (10.0)	0	1 (10.0)
General disorders and administration site conditions			
-Total	1 (10.0)	0	1 (10.0)
Chills	1 (10.0)	0	1 (10.0)
Pyrexia	1 (10.0)	0	1 (10.0)
Infections and infestations			
-Total	1 (10.0)	0	1 (10.0)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	1 (10.0)	0	1 (10.0)
Investigations			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Alanine aminotransferase increased	1 (10.0)	0	1 (10.0)
Aspartate aminotransferase increased	1 (10.0)	1 (10.0)	0
Lymphocyte count decreased	1 (10.0)	0	1 (10.0)
Renal and urinary disorders			
-Total	1 (10.0)	0	1 (10.0)
Acute kidney injury	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (10.0)	1 (10.0)	0
Cough	1 (10.0)	1 (10.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (62.5)	2 (25.0)	3 (37.5)
Blood and lymphatic system disorders			
-Total	1 (12.5)	1 (12.5)	0
Thrombocytopenia	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	2 (25.0)	0	2 (25.0)
Diarrhoea	2 (25.0)	0	2 (25.0)
Abdominal pain	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	3 (37.5)	1 (12.5)	2 (25.0)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Urinary tract infection	2 (25.0)	0	2 (25.0)
Otitis media	1 (12.5)	0	1 (12.5)
Upper respiratory tract infection	1 (12.5)	1 (12.5)	0
Vulvovaginal candidiasis	1 (12.5)	0	1 (12.5)
Investigations			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Lymphocyte count decreased	2 (25.0)	2 (25.0)	0
Neutrophil count decreased	2 (25.0)	1 (12.5)	1 (12.5)
White blood cell count decreased	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	1 (12.5)	0	1 (12.5)
Dizziness	1 (12.5)	1 (12.5)	0
Headache	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	2 (25.0)	0
Cough	1 (12.5)	1 (12.5)	0
Oropharyngeal pain	1 (12.5)	1 (12.5)	0
Rhinitis allergic	1 (12.5)	1 (12.5)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinorrhoea	1 (12.5)	1 (12.5)	0

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Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (100)	0	7 (100)
Blood and lymphatic system disorders			
-Total	2 (28.6)	2 (28.6)	0
Anaemia	2 (28.6)	2 (28.6)	0
Cardiac disorders			
-Total	2 (28.6)	2 (28.6)	0
Palpitations	1 (14.3)	1 (14.3)	0
Pericardial effusion	1 (14.3)	1 (14.3)	0
Tachycardia	1 (14.3)	1 (14.3)	0
Endocrine disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (14.3)	1 (14.3)	0
Adrenal insufficiency	1 (14.3)	1 (14.3)	0
Eye disorders			
-Total	1 (14.3)	1 (14.3)	0
Eye pain	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	6 (85.7)	3 (42.9)	3 (42.9)
Vomiting	5 (71.4)	3 (42.9)	2 (28.6)
Diarrhoea	4 (57.1)	3 (42.9)	1 (14.3)
Nausea	4 (57.1)	1 (14.3)	3 (42.9)
Abdominal pain	1 (14.3)	1 (14.3)	0
Constipation	1 (14.3)	1 (14.3)	0
Oral pain	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Pyrexia	3 (42.9)	1 (14.3)	2 (28.6)
Asthenia	1 (14.3)	1 (14.3)	0
Catheter site pain	1 (14.3)	0	1 (14.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Chills	1 (14.3)	1 (14.3)	0
Fatigue	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			
-Total	1 (14.3)	0	1 (14.3)
Hepatomegaly	1 (14.3)	0	1 (14.3)
Immune system disorders			
-Total	7 (100)	0	7 (100)
Cytokine release syndrome	5 (71.4)	0	5 (71.4)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)
Graft versus host disease	1 (14.3)	0	1 (14.3)
Infections and infestations			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Upper respiratory tract infection	2 (28.6)	0	2 (28.6)
Viral infection	2 (28.6)	1 (14.3)	1 (14.3)
Ear infection	1 (14.3)	1 (14.3)	0
Gastroenteritis	1 (14.3)	0	1 (14.3)
Rhinovirus infection	1 (14.3)	1 (14.3)	0
Skin infection	1 (14.3)	0	1 (14.3)
Tinea capitis	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	2 (28.6)	0	2 (28.6)
Contusion	1 (14.3)	1 (14.3)	0
Infusion related reaction	1 (14.3)	0	1 (14.3)
Procedural nausea	1 (14.3)	0	1 (14.3)
Sunburn	1 (14.3)	1 (14.3)	0
Tracheal haemorrhage	1 (14.3)	0	1 (14.3)
Investigations			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)
White blood cell count decreased	2 (28.6)	1 (14.3)	1 (14.3)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0
Blood creatinine increased	1 (14.3)	0	1 (14.3)
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0
Blood magnesium decreased	1 (14.3)	1 (14.3)	0
Blood phosphorus increased	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood uric acid increased	1 (14.3)	1 (14.3)	0
Cardiac murmur	1 (14.3)	1 (14.3)	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0
Neutrophil count decreased	1 (14.3)	0	1 (14.3)
Prothrombin time prolonged	1 (14.3)	0	1 (14.3)
Weight decreased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Decreased appetite	2 (28.6)	1 (14.3)	1 (14.3)
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)
Hypernatraemia	1 (14.3)	0	1 (14.3)
Hypoalbuminaemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (42.9)	3 (42.9)	0
Pain in extremity	2 (28.6)	2 (28.6)	0
Arthralgia	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Muscular weakness	1 (14.3)	1 (14.3)	0
Pain in jaw	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	4 (57.1)	4 (57.1)	0
Headache	3 (42.9)	3 (42.9)	0
Dizziness	1 (14.3)	1 (14.3)	0
Peroneal nerve palsy	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)
Anxiety	1 (14.3)	1 (14.3)	0
Delirium	1 (14.3)	1 (14.3)	0
Depression	1 (14.3)	1 (14.3)	0
Sleep disorder	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
Cough	3 (42.9)	3 (42.9)	0
Rhinorrhoea	2 (28.6)	1 (14.3)	1 (14.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoxia	1 (14.3)	0	1 (14.3)
Nasal congestion	1 (14.3)	1 (14.3)	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)
Pharyngeal erythema	1 (14.3)	1 (14.3)	0
Pleural effusion	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	4 (57.1)	3 (42.9)	1 (14.3)
Erythema	2 (28.6)	2 (28.6)	0
Alopecia	1 (14.3)	0	1 (14.3)
Dermatitis diaper	1 (14.3)	1 (14.3)	0
Dry skin	1 (14.3)	1 (14.3)	0
Livedo reticularis	1 (14.3)	1 (14.3)	0
Rash erythematous	1 (14.3)	0	1 (14.3)
Rash maculo-papular	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Hypertension	3 (42.9)	1 (14.3)	2 (28.6)
Haematoma	1 (14.3)	0	1 (14.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hot flush	1 (14.3)	1 (14.3)	0

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Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (100)	1 (5.0)	19 (95.0)
Blood and lymphatic system disorders			
-Total	5 (25.0)	1 (5.0)	4 (20.0)
Anaemia	3 (15.0)	1 (5.0)	2 (10.0)
Disseminated intravascular coagulation	2 (10.0)	0	2 (10.0)
Cardiac disorders			
-Total	6 (30.0)	3 (15.0)	3 (15.0)
Tachycardia	3 (15.0)	2 (10.0)	1 (5.0)
Sinus tachycardia	2 (10.0)	1 (5.0)	1 (5.0)
Pericardial effusion	1 (5.0)	0	1 (5.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Endocrine disorders			
-Total	1 (5.0)	0	1 (5.0)
Adrenal insufficiency	1 (5.0)	0	1 (5.0)
Eye disorders			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Conjunctival haemorrhage	2 (10.0)	2 (10.0)	0
Periorbital oedema	2 (10.0)	2 (10.0)	0
Vision blurred	2 (10.0)	1 (5.0)	1 (5.0)
Gastrointestinal disorders			
-Total	11 (55.0)	4 (20.0)	7 (35.0)
Vomiting	7 (35.0)	4 (20.0)	3 (15.0)
Diarrhoea	6 (30.0)	3 (15.0)	3 (15.0)
Nausea	6 (30.0)	2 (10.0)	4 (20.0)
Constipation	5 (25.0)	5 (25.0)	0
Abdominal pain	3 (15.0)	2 (10.0)	1 (5.0)
General disorders and administration site conditions			
-Total	9 (45.0)	6 (30.0)	3 (15.0)
Fatigue	5 (25.0)	5 (25.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	4 (20.0)	1 (5.0)	3 (15.0)
Generalised oedema	2 (10.0)	1 (5.0)	1 (5.0)
Catheter site pain	1 (5.0)	0	1 (5.0)
Chills	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	15 (75.0)	1 (5.0)	14 (70.0)
Cytokine release syndrome	14 (70.0)	2 (10.0)	12 (60.0)
Hypogammaglobulinaemia	7 (35.0)	0	7 (35.0)
Immunodeficiency common variable	2 (10.0)	0	2 (10.0)
Infections and infestations			
-Total	12 (60.0)	4 (20.0)	8 (40.0)
Influenza	3 (15.0)	1 (5.0)	2 (10.0)
Clostridium difficile infection	2 (10.0)	0	2 (10.0)
Gastroenteritis	2 (10.0)	0	2 (10.0)
Otitis media	2 (10.0)	0	2 (10.0)
Rhinovirus infection	1 (5.0)	1 (5.0)	0
Upper respiratory tract infection	1 (5.0)	1 (5.0)	0
Urinary tract infection	1 (5.0)	0	1 (5.0)
Viral infection	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (5.0)	1 (5.0)	0
Contusion	1 (5.0)	1 (5.0)	0
Investigations			
-Total	11 (55.0)	1 (5.0)	10 (50.0)
Aspartate aminotransferase increased	6 (30.0)	3 (15.0)	3 (15.0)
White blood cell count decreased	6 (30.0)	2 (10.0)	4 (20.0)
Activated partial thromboplastin time prolonged	3 (15.0)	1 (5.0)	2 (10.0)
Alanine aminotransferase increased	3 (15.0)	2 (10.0)	1 (5.0)
Blood creatinine increased	3 (15.0)	2 (10.0)	1 (5.0)
International normalised ratio increased	3 (15.0)	3 (15.0)	0
Platelet count decreased	3 (15.0)	0	3 (15.0)
Prothrombin time prolonged	3 (15.0)	3 (15.0)	0
Blood bilirubin increased	2 (10.0)	0	2 (10.0)
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood phosphorus increased	1 (5.0)	1 (5.0)	0
Neutrophil count decreased	1 (5.0)	0	1 (5.0)
Metabolism and nutrition disorders			
-Total	10 (50.0)	5 (25.0)	5 (25.0)
Decreased appetite	4 (20.0)	3 (15.0)	1 (5.0)
Hyperphosphataemia	4 (20.0)	4 (20.0)	0
Hypernatraemia	3 (15.0)	1 (5.0)	2 (10.0)
Hyperglycaemia	2 (10.0)	0	2 (10.0)
Hypokalaemia	2 (10.0)	1 (5.0)	1 (5.0)
Hypoalbuminaemia	1 (5.0)	0	1 (5.0)
Hypophosphataemia	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (25.0)	3 (15.0)	2 (10.0)
Arthralgia	2 (10.0)	2 (10.0)	0
Muscular weakness	2 (10.0)	1 (5.0)	1 (5.0)
Musculoskeletal chest pain	2 (10.0)	2 (10.0)	0
Pain in extremity	2 (10.0)	1 (5.0)	1 (5.0)
Nervous system disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	12 (60.0)	6 (30.0)	6 (30.0)
Headache	9 (45.0)	6 (30.0)	3 (15.0)
Dysarthria	2 (10.0)	1 (5.0)	1 (5.0)
Encephalopathy	2 (10.0)	0	2 (10.0)
Tremor	2 (10.0)	2 (10.0)	0
Dizziness	1 (5.0)	1 (5.0)	0
Psychiatric disorders			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Delirium	2 (10.0)	0	2 (10.0)
Anxiety	1 (5.0)	0	1 (5.0)
Confusional state	1 (5.0)	1 (5.0)	0
Depression	1 (5.0)	1 (5.0)	0
Renal and urinary disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Acute kidney injury	2 (10.0)	1 (5.0)	1 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (50.0)	6 (30.0)	4 (20.0)
Epistaxis	4 (20.0)	2 (10.0)	2 (10.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Tachypnoea	3 (15.0)	2 (10.0)	1 (5.0)
Cough	2 (10.0)	2 (10.0)	0
Nasal congestion	2 (10.0)	2 (10.0)	0
Oropharyngeal pain	2 (10.0)	1 (5.0)	1 (5.0)
Pleural effusion	2 (10.0)	1 (5.0)	1 (5.0)
Rhinorrhoea	1 (5.0)	1 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	11 (55.0)	10 (50.0)	1 (5.0)
Dry skin	4 (20.0)	4 (20.0)	0
Hyperhidrosis	3 (15.0)	3 (15.0)	0
Petechiae	3 (15.0)	3 (15.0)	0
Rash	3 (15.0)	2 (10.0)	1 (5.0)
Papule	2 (10.0)	2 (10.0)	0
Erythema	1 (5.0)	1 (5.0)	0
Rash erythematous	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Hypertension	2 (10.0)	1 (5.0)	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	21 (100)	0	21 (100)
Blood and lymphatic system disorders			
-Total	5 (23.8)	0	5 (23.8)
Anaemia	3 (14.3)	0	3 (14.3)
Thrombocytopenia	3 (14.3)	0	3 (14.3)
Disseminated intravascular coagulation	1 (4.8)	0	1 (4.8)
Cardiac disorders			
-Total	6 (28.6)	2 (9.5)	4 (19.0)
Tachycardia	5 (23.8)	2 (9.5)	3 (14.3)
Sinus tachycardia	1 (4.8)	0	1 (4.8)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eye disorders			
-Total	4 (19.0)	2 (9.5)	2 (9.5)
Eye pain	2 (9.5)	0	2 (9.5)
Vision blurred	2 (9.5)	1 (4.8)	1 (4.8)
Conjunctival haemorrhage	1 (4.8)	1 (4.8)	0
Periorbital oedema	1 (4.8)	1 (4.8)	0
Gastrointestinal disorders			
-Total	11 (52.4)	4 (19.0)	7 (33.3)
Nausea	7 (33.3)	1 (4.8)	6 (28.6)
Diarrhoea	6 (28.6)	4 (19.0)	2 (9.5)
Vomiting	6 (28.6)	4 (19.0)	2 (9.5)
Abdominal pain	1 (4.8)	1 (4.8)	0
Constipation	1 (4.8)	0	1 (4.8)
General disorders and administration site conditions			
-Total	12 (57.1)	5 (23.8)	7 (33.3)
Pyrexia	8 (38.1)	2 (9.5)	6 (28.6)
Chills	6 (28.6)	5 (23.8)	1 (4.8)
Fatigue	3 (14.3)	2 (9.5)	1 (4.8)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Malaise	3 (14.3)	1 (4.8)	2 (9.5)
Catheter site pain	1 (4.8)	0	1 (4.8)
Hepatobiliary disorders			
-Total	1 (4.8)	1 (4.8)	0
Hepatomegaly	1 (4.8)	1 (4.8)	0
Immune system disorders			
-Total	17 (81.0)	0	17 (81.0)
Cytokine release syndrome	16 (76.2)	1 (4.8)	15 (71.4)
Hypogammaglobulinaemia	9 (42.9)	1 (4.8)	8 (38.1)
Infections and infestations			
-Total	7 (33.3)	2 (9.5)	5 (23.8)
Rhinovirus infection	3 (14.3)	3 (14.3)	0
Upper respiratory tract infection	2 (9.5)	0	2 (9.5)
Clostridium difficile infection	1 (4.8)	0	1 (4.8)
Gastroenteritis	1 (4.8)	1 (4.8)	0
Influenza	1 (4.8)	0	1 (4.8)
Urinary tract infection	1 (4.8)	0	1 (4.8)
Injury, poisoning and procedural complications			

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (14.3)	2 (9.5)	1 (4.8)
Procedural pain	3 (14.3)	2 (9.5)	1 (4.8)
Infusion related reaction	1 (4.8)	1 (4.8)	0
Investigations			
-Total	13 (61.9)	3 (14.3)	10 (47.6)
Alanine aminotransferase increased	4 (19.0)	2 (9.5)	2 (9.5)
Prothrombin time prolonged	4 (19.0)	2 (9.5)	2 (9.5)
Transaminases increased	3 (14.3)	3 (14.3)	0
Weight decreased	3 (14.3)	0	3 (14.3)
White blood cell count decreased	3 (14.3)	0	3 (14.3)
Aspartate aminotransferase increased	2 (9.5)	2 (9.5)	0
Blood bilirubin increased	2 (9.5)	0	2 (9.5)
Blood fibrinogen decreased	2 (9.5)	0	2 (9.5)
Platelet count decreased	2 (9.5)	2 (9.5)	0
Blood creatinine increased	1 (4.8)	1 (4.8)	0
Blood immunoglobulin m decreased	1 (4.8)	1 (4.8)	0
International normalised ratio increased	1 (4.8)	1 (4.8)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Lymphocyte count decreased	1 (4.8)	0	1 (4.8)
Metabolism and nutrition disorders			
-Total	9 (42.9)	3 (14.3)	6 (28.6)
Decreased appetite	3 (14.3)	1 (4.8)	2 (9.5)
Hypokalaemia	3 (14.3)	1 (4.8)	2 (9.5)
Hyperphosphataemia	2 (9.5)	2 (9.5)	0
Fluid overload	1 (4.8)	0	1 (4.8)
Hypoalbuminaemia	1 (4.8)	0	1 (4.8)
Musculoskeletal and connective tissue disorders			
-Total	4 (19.0)	3 (14.3)	1 (4.8)
Pain in extremity	3 (14.3)	2 (9.5)	1 (4.8)
Arthralgia	1 (4.8)	0	1 (4.8)
Myalgia	1 (4.8)	1 (4.8)	0
Nervous system disorders			
-Total	8 (38.1)	4 (19.0)	4 (19.0)
Headache	6 (28.6)	3 (14.3)	3 (14.3)
Dizziness	2 (9.5)	2 (9.5)	0
Peroneal nerve palsy	1 (4.8)	0	1 (4.8)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Psychiatric disorders			
-Total	5 (23.8)	3 (14.3)	2 (9.5)
Anxiety	2 (9.5)	1 (4.8)	1 (4.8)
Confusional state	2 (9.5)	1 (4.8)	1 (4.8)
Delirium	1 (4.8)	1 (4.8)	0
Renal and urinary disorders			
-Total	1 (4.8)	0	1 (4.8)
Acute kidney injury	1 (4.8)	0	1 (4.8)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (42.9)	5 (23.8)	4 (19.0)
Cough	5 (23.8)	4 (19.0)	1 (4.8)
Rhinitis allergic	3 (14.3)	2 (9.5)	1 (4.8)
Hypoxia	2 (9.5)	0	2 (9.5)
Rhinorrhoea	2 (9.5)	2 (9.5)	0
Epistaxis	1 (4.8)	1 (4.8)	0
Nasal congestion	1 (4.8)	1 (4.8)	0
Oropharyngeal pain	1 (4.8)	1 (4.8)	0
Pleural effusion	1 (4.8)	1 (4.8)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Tachypnoea	1 (4.8)	1 (4.8)	0
Skin and subcutaneous tissue disorders			
-Total	5 (23.8)	3 (14.3)	2 (9.5)
Erythema	2 (9.5)	2 (9.5)	0
Rash	2 (9.5)	1 (4.8)	1 (4.8)
Hyperhidrosis	1 (4.8)	1 (4.8)	0
Rash maculo-papular	1 (4.8)	0	1 (4.8)
Vascular disorders			
-Total	4 (19.0)	1 (4.8)	3 (14.3)
Hypertension	4 (19.0)	1 (4.8)	3 (14.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	16 (100)	0	16 (100)
Blood and lymphatic system disorders			
-Total	4 (25.0)	2 (12.5)	2 (12.5)
Anaemia	3 (18.8)	1 (6.3)	2 (12.5)
Thrombocytopenia	2 (12.5)	1 (6.3)	1 (6.3)
Cardiac disorders			
-Total	7 (43.8)	4 (25.0)	3 (18.8)
Tachycardia	5 (31.3)	3 (18.8)	2 (12.5)
Sinus tachycardia	3 (18.8)	2 (12.5)	1 (6.3)
Ear and labyrinth disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (12.5)	2 (12.5)	0
Ear pain	2 (12.5)	2 (12.5)	0
Eye disorders			
-Total	1 (6.3)	0	1 (6.3)
Periorbital oedema	1 (6.3)	0	1 (6.3)
Gastrointestinal disorders			
-Total	10 (62.5)	3 (18.8)	7 (43.8)
Vomiting	7 (43.8)	5 (31.3)	2 (12.5)
Diarrhoea	6 (37.5)	3 (18.8)	3 (18.8)
Nausea	6 (37.5)	2 (12.5)	4 (25.0)
Abdominal pain	5 (31.3)	2 (12.5)	3 (18.8)
Abdominal distension	2 (12.5)	0	2 (12.5)
General disorders and administration site conditions			
-Total	11 (68.8)	5 (31.3)	6 (37.5)
Pyrexia	7 (43.8)	4 (25.0)	3 (18.8)
Fatigue	6 (37.5)	4 (25.0)	2 (12.5)
Chills	2 (12.5)	2 (12.5)	0
Catheter site pain	1 (6.3)	1 (6.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Generalised oedema	1 (6.3)	0	1 (6.3)
Malaise	1 (6.3)	0	1 (6.3)
Hepatobiliary disorders			
-Total	1 (6.3)	0	1 (6.3)
Hepatomegaly	1 (6.3)	0	1 (6.3)
Immune system disorders			
-Total	15 (93.8)	6 (37.5)	9 (56.3)
Cytokine release syndrome	10 (62.5)	4 (25.0)	6 (37.5)
Hypogammaglobulinaemia	7 (43.8)	2 (12.5)	5 (31.3)
Graft versus host disease	1 (6.3)	1 (6.3)	0
Infections and infestations			
-Total	7 (43.8)	2 (12.5)	5 (31.3)
Upper respiratory tract infection	3 (18.8)	3 (18.8)	0
Otitis media	2 (12.5)	0	2 (12.5)
Urinary tract infection	2 (12.5)	0	2 (12.5)
Vulvovaginal candidiasis	2 (12.5)	1 (6.3)	1 (6.3)
Clostridium difficile infection	1 (6.3)	0	1 (6.3)
Ear infection	1 (6.3)	0	1 (6.3)
Skin infection	1 (6.3)	0	1 (6.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	4 (25.0)	1 (6.3)	3 (18.8)
Infusion related reaction	2 (12.5)	0	2 (12.5)
Procedural pain	2 (12.5)	0	2 (12.5)
Contusion	1 (6.3)	1 (6.3)	0
Investigations			
-Total	9 (56.3)	1 (6.3)	8 (50.0)
Aspartate aminotransferase increased	5 (31.3)	2 (12.5)	3 (18.8)
Alanine aminotransferase increased	4 (25.0)	1 (6.3)	3 (18.8)
Lymphocyte count decreased	4 (25.0)	1 (6.3)	3 (18.8)
White blood cell count decreased	4 (25.0)	2 (12.5)	2 (12.5)
International normalised ratio increased	3 (18.8)	3 (18.8)	0
Neutrophil count decreased	3 (18.8)	1 (6.3)	2 (12.5)
Blood bilirubin increased	2 (12.5)	2 (12.5)	0
Blood creatinine increased	2 (12.5)	2 (12.5)	0
Blood immunoglobulin a decreased	2 (12.5)	2 (12.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Activated partial thromboplastin time prolonged	1 (6.3)	1 (6.3)	0
Blood immunoglobulin m decreased	1 (6.3)	1 (6.3)	0
Blood uric acid increased	1 (6.3)	1 (6.3)	0
Platelet count decreased	1 (6.3)	1 (6.3)	0
Prothrombin time prolonged	1 (6.3)	0	1 (6.3)
Metabolism and nutrition disorders			
-Total	10 (62.5)	5 (31.3)	5 (31.3)
Decreased appetite	4 (25.0)	3 (18.8)	1 (6.3)
Hypokalaemia	4 (25.0)	1 (6.3)	3 (18.8)
Fluid overload	2 (12.5)	1 (6.3)	1 (6.3)
Hyperphosphataemia	2 (12.5)	2 (12.5)	0
Hypoalbuminaemia	2 (12.5)	0	2 (12.5)
Hypophosphataemia	2 (12.5)	2 (12.5)	0
Musculoskeletal and connective tissue disorders			
-Total	7 (43.8)	4 (25.0)	3 (18.8)
Myalgia	4 (25.0)	3 (18.8)	1 (6.3)
Pain in extremity	4 (25.0)	2 (12.5)	2 (12.5)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Joint range of motion decreased	2 (12.5)	2 (12.5)	0
Muscle spasms	2 (12.5)	2 (12.5)	0
Arthralgia	1 (6.3)	1 (6.3)	0
Nervous system disorders			
-Total	8 (50.0)	5 (31.3)	3 (18.8)
Headache	6 (37.5)	3 (18.8)	3 (18.8)
Dizziness	2 (12.5)	2 (12.5)	0
Encephalopathy	1 (6.3)	1 (6.3)	0
Psychiatric disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Anxiety	2 (12.5)	1 (6.3)	1 (6.3)
Confusional state	1 (6.3)	0	1 (6.3)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (56.3)	5 (31.3)	4 (25.0)
Cough	4 (25.0)	3 (18.8)	1 (6.3)
Hypoxia	2 (12.5)	0	2 (12.5)
Oropharyngeal pain	2 (12.5)	2 (12.5)	0
Pleural effusion	2 (12.5)	0	2 (12.5)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	1 (6.3)	1 (6.3)	0
Nasal congestion	1 (6.3)	1 (6.3)	0
Rhinitis allergic	1 (6.3)	1 (6.3)	0
Rhinorrhoea	1 (6.3)	1 (6.3)	0
Skin and subcutaneous tissue disorders			
-Total	5 (31.3)	3 (18.8)	2 (12.5)
Rash	3 (18.8)	2 (12.5)	1 (6.3)
Rash maculo-papular	2 (12.5)	2 (12.5)	0
Petechiae	1 (6.3)	0	1 (6.3)
Vascular disorders			
-Total	4 (25.0)	1 (6.3)	3 (18.8)
Hypertension	2 (12.5)	0	2 (12.5)
Hypotension	2 (12.5)	1 (6.3)	1 (6.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of

adverse events.

Table 227a
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (22.7)	1 (4.5)	4 (18.2)
Gastrointestinal disorders			
-Total	1 (4.5)	0	1 (4.5)
Nausea	1 (4.5)	0	1 (4.5)
General disorders and administration site conditions			
-Total	2 (9.1)	1 (4.5)	1 (4.5)
Catheter site pain	1 (4.5)	0	1 (4.5)
Pyrexia	1 (4.5)	1 (4.5)	0
Metabolism and nutrition disorders			
-Total	1 (4.5)	0	1 (4.5)

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Decreased appetite	1 (4.5)	0	1 (4.5)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (4.5)	0	1 (4.5)
Pleural effusion	1 (4.5)	0	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227a
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (51.3)	8 (20.5)	12 (30.8)
Gastrointestinal disorders			
-Total	12 (30.8)	5 (12.8)	7 (17.9)
Vomiting	6 (15.4)	4 (10.3)	2 (5.1)
Abdominal pain	4 (10.3)	0	4 (10.3)
Constipation	3 (7.7)	1 (2.6)	2 (5.1)
Nausea	2 (5.1)	0	2 (5.1)
General disorders and administration site conditions			
-Total	9 (23.1)	6 (15.4)	3 (7.7)
Pyrexia	5 (12.8)	3 (7.7)	2 (5.1)

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fatigue	4 (10.3)	3 (7.7)	1 (2.6)
Catheter site pain	1 (2.6)	1 (2.6)	0
Metabolism and nutrition disorders			
-Total	3 (7.7)	2 (5.1)	1 (2.6)
Decreased appetite	3 (7.7)	2 (5.1)	1 (2.6)
Nervous system disorders			
-Total	4 (10.3)	2 (5.1)	2 (5.1)
Headache	4 (10.3)	2 (5.1)	2 (5.1)
Vascular disorders			
-Total	1 (2.6)	1 (2.6)	0
Hypertension	1 (2.6)	1 (2.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227a
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (71.4)	1 (7.1)	9 (64.3)
Cardiac disorders			
-Total	2 (14.3)	0	2 (14.3)
Pericardial effusion	2 (14.3)	0	2 (14.3)
Gastrointestinal disorders			
-Total	5 (35.7)	0	5 (35.7)
Nausea	5 (35.7)	0	5 (35.7)
Abdominal pain	2 (14.3)	1 (7.1)	1 (7.1)
Constipation	2 (14.3)	2 (14.3)	0
Vomiting	2 (14.3)	0	2 (14.3)

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
General disorders and administration site conditions			
-Total	5 (35.7)	2 (14.3)	3 (21.4)
Pyrexia	4 (28.6)	2 (14.3)	2 (14.3)
Catheter site pain	2 (14.3)	0	2 (14.3)
Fatigue	2 (14.3)	1 (7.1)	1 (7.1)
Metabolism and nutrition disorders			
-Total	5 (35.7)	0	5 (35.7)
Hyperglycaemia	3 (21.4)	0	3 (21.4)
Decreased appetite	2 (14.3)	0	2 (14.3)
Nervous system disorders			
-Total	2 (14.3)	0	2 (14.3)
Headache	2 (14.3)	0	2 (14.3)
Psychiatric disorders			
-Total	2 (14.3)	0	2 (14.3)
Anxiety	2 (14.3)	0	2 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (14.3)	0	2 (14.3)

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Epistaxis	2 (14.3)	0	2 (14.3)
Pleural effusion	2 (14.3)	1 (7.1)	1 (7.1)
Vascular disorders			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Hypertension	3 (21.4)	1 (7.1)	2 (14.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227b
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (35.0)	6 (15.0)	8 (20.0)
Gastrointestinal disorders			
-Total	9 (22.5)	4 (10.0)	5 (12.5)
Vomiting	7 (17.5)	4 (10.0)	3 (7.5)
Nausea	4 (10.0)	0	4 (10.0)
Constipation	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	7 (17.5)	4 (10.0)	3 (7.5)
Pyrexia	7 (17.5)	4 (10.0)	3 (7.5)
Metabolism and nutrition disorders			

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	2 (5.0)	0	2 (5.0)
Decreased appetite	2 (5.0)	0	2 (5.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227b
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	9 (25.7)	3 (8.6)	6 (17.1)
Gastrointestinal disorders			
-Total	6 (17.1)	1 (2.9)	5 (14.3)
Constipation	4 (11.4)	2 (5.7)	2 (5.7)
Nausea	4 (11.4)	0	4 (11.4)
Vomiting	1 (2.9)	0	1 (2.9)
General disorders and administration site conditions			
-Total	3 (8.6)	2 (5.7)	1 (2.9)
Pyrexia	3 (8.6)	2 (5.7)	1 (2.9)
Metabolism and nutrition disorders			

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	4 (11.4)	2 (5.7)	2 (5.7)
Decreased appetite	4 (11.4)	2 (5.7)	2 (5.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227c
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	29 (48.3)	7 (11.7)	22 (36.7)
Blood and lymphatic system disorders			
-Total	3 (5.0)	0	3 (5.0)
Anaemia	3 (5.0)	0	3 (5.0)
Cardiac disorders			
-Total	2 (3.3)	0	2 (3.3)
Pericardial effusion	1 (1.7)	0	1 (1.7)
Tachycardia	1 (1.7)	0	1 (1.7)
Gastrointestinal disorders			
-Total	14 (23.3)	4 (6.7)	10 (16.7)
Abdominal pain	5 (8.3)	1 (1.7)	4 (6.7)

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	5 (8.3)	0	5 (8.3)
Vomiting	5 (8.3)	3 (5.0)	2 (3.3)
Constipation	3 (5.0)	2 (3.3)	1 (1.7)
General disorders and administration site conditions			
-Total	14 (23.3)	7 (11.7)	7 (11.7)
Pyrexia	7 (11.7)	4 (6.7)	3 (5.0)
Fatigue	6 (10.0)	4 (6.7)	2 (3.3)
Catheter site pain	3 (5.0)	1 (1.7)	2 (3.3)
Non-cardiac chest pain	1 (1.7)	1 (1.7)	0
Pain	1 (1.7)	0	1 (1.7)
Infections and infestations			
-Total	2 (3.3)	0	2 (3.3)
Conjunctivitis	1 (1.7)	0	1 (1.7)
Oral herpes	1 (1.7)	0	1 (1.7)
Injury, poisoning and procedural complications			
-Total	1 (1.7)	0	1 (1.7)
Procedural pain	1 (1.7)	0	1 (1.7)

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	2 (3.3)	2 (3.3)	0
Aspartate aminotransferase increased	1 (1.7)	1 (1.7)	0
White blood cell count decreased	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	8 (13.3)	2 (3.3)	6 (10.0)
Decreased appetite	5 (8.3)	1 (1.7)	4 (6.7)
Hypomagnesaemia	3 (5.0)	3 (5.0)	0
Hyperglycaemia	1 (1.7)	0	1 (1.7)
Hypocalcaemia	1 (1.7)	0	1 (1.7)
Vitamin d deficiency	1 (1.7)	0	1 (1.7)
Musculoskeletal and connective tissue disorders			
-Total	6 (10.0)	3 (5.0)	3 (5.0)
Pain in extremity	3 (5.0)	2 (3.3)	1 (1.7)
Neck pain	2 (3.3)	1 (1.7)	1 (1.7)
Pain in jaw	1 (1.7)	0	1 (1.7)
Nervous system disorders			

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	3 (5.0)	1 (1.7)	2 (3.3)
Headache	3 (5.0)	1 (1.7)	2 (3.3)
Psychiatric disorders			
-Total	2 (3.3)	1 (1.7)	1 (1.7)
Anxiety	1 (1.7)	0	1 (1.7)
Depression	1 (1.7)	1 (1.7)	0
Skin and subcutaneous tissue disorders			
-Total	2 (3.3)	0	2 (3.3)
Rash erythematous	2 (3.3)	0	2 (3.3)
Vascular disorders			
-Total	2 (3.3)	2 (3.3)	0
Hypertension	2 (3.3)	2 (3.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227c
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (100)	1 (16.7)	5 (83.3)
Gastrointestinal disorders			
-Total	1 (16.7)	1 (16.7)	0
Dry mouth	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
-Total	1 (16.7)	1 (16.7)	0
Oedema peripheral	1 (16.7)	1 (16.7)	0
Pyrexia	1 (16.7)	1 (16.7)	0
Infections and infestations			
-Total	2 (33.3)	0	2 (33.3)

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Conjunctivitis	1 (16.7)	0	1 (16.7)
Oral herpes	1 (16.7)	0	1 (16.7)
Investigations			
-Total	1 (16.7)	0	1 (16.7)
Blood fibrinogen decreased	1 (16.7)	0	1 (16.7)
Blood immunoglobulin m decreased	1 (16.7)	1 (16.7)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (33.3)	0	2 (33.3)
Bone pain	1 (16.7)	0	1 (16.7)
Pain in extremity	1 (16.7)	0	1 (16.7)
Pain in jaw	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	1 (16.7)	1 (16.7)	0
Headache	1 (16.7)	1 (16.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 227c
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (88.9)	1 (11.1)	7 (77.8)
Blood and lymphatic system disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Anaemia	1 (11.1)	0	1 (11.1)
Leukocytosis	1 (11.1)	1 (11.1)	0
Cardiac disorders			
-Total	1 (11.1)	0	1 (11.1)
Pericardial effusion	1 (11.1)	0	1 (11.1)
Tachycardia	1 (11.1)	1 (11.1)	0
Eye disorders			

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (22.2)	0	2 (22.2)
Photophobia	1 (11.1)	0	1 (11.1)
Retinopathy	1 (11.1)	0	1 (11.1)
Gastrointestinal disorders			
-Total	4 (44.4)	1 (11.1)	3 (33.3)
Nausea	3 (33.3)	0	3 (33.3)
Vomiting	3 (33.3)	1 (11.1)	2 (22.2)
Constipation	2 (22.2)	1 (11.1)	1 (11.1)
Abdominal pain	1 (11.1)	0	1 (11.1)
General disorders and administration site conditions			
-Total	4 (44.4)	1 (11.1)	3 (33.3)
Pyrexia	2 (22.2)	1 (11.1)	1 (11.1)
Catheter site bruise	1 (11.1)	1 (11.1)	0
Catheter site pain	1 (11.1)	0	1 (11.1)
Device related thrombosis	1 (11.1)	0	1 (11.1)
Non-cardiac chest pain	1 (11.1)	1 (11.1)	0
Oedema peripheral	1 (11.1)	0	1 (11.1)

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain	1 (11.1)	0	1 (11.1)
Hepatobiliary disorders			
-Total	2 (22.2)	0	2 (22.2)
Hepatic steatosis	1 (11.1)	0	1 (11.1)
Hyperbilirubinaemia	1 (11.1)	0	1 (11.1)
Immune system disorders			
-Total	1 (11.1)	0	1 (11.1)
Drug hypersensitivity	1 (11.1)	0	1 (11.1)
Infections and infestations			
-Total	1 (11.1)	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	1 (11.1)
Rhinovirus infection	1 (11.1)	0	1 (11.1)
Staphylococcal scalded skin syndrome	1 (11.1)	0	1 (11.1)
Injury, poisoning and procedural complications			
-Total	1 (11.1)	0	1 (11.1)
Procedural hypertension	1 (11.1)	0	1 (11.1)
Procedural pain	1 (11.1)	0	1 (11.1)

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	2 (22.2)	0	2 (22.2)
Aspartate aminotransferase increased	1 (11.1)	0	1 (11.1)
White blood cell count decreased	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	3 (33.3)	1 (11.1)	2 (22.2)
Hyperglycaemia	2 (22.2)	0	2 (22.2)
Decreased appetite	1 (11.1)	1 (11.1)	0
Fluid overload	1 (11.1)	0	1 (11.1)
Hypocalcaemia	1 (11.1)	1 (11.1)	0
Hypomagnesaemia	1 (11.1)	1 (11.1)	0
Vitamin d deficiency	1 (11.1)	0	1 (11.1)
Musculoskeletal and connective tissue disorders			
-Total	3 (33.3)	1 (11.1)	2 (22.2)
Arthralgia	1 (11.1)	0	1 (11.1)
Muscle spasms	1 (11.1)	1 (11.1)	0
Neck pain	1 (11.1)	0	1 (11.1)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Synovitis	1 (11.1)	0	1 (11.1)
Nervous system disorders			
-Total	2 (22.2)	0	2 (22.2)
Headache	2 (22.2)	0	2 (22.2)
Product issues			
-Total	1 (11.1)	0	1 (11.1)
Device occlusion	1 (11.1)	0	1 (11.1)
Psychiatric disorders			
-Total	1 (11.1)	0	1 (11.1)
Anxiety	1 (11.1)	0	1 (11.1)
Depression	1 (11.1)	0	1 (11.1)
Renal and urinary disorders			
-Total	1 (11.1)	0	1 (11.1)
Acute kidney injury	1 (11.1)	1 (11.1)	0
Dysuria	1 (11.1)	0	1 (11.1)
Skin and subcutaneous tissue disorders			
-Total	3 (33.3)	2 (22.2)	1 (11.1)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Cold sweat	1 (11.1)	1 (11.1)	0
Night sweats	1 (11.1)	1 (11.1)	0
Rash	1 (11.1)	1 (11.1)	0
Rash erythematous	1 (11.1)	1 (11.1)	0
Urticaria	1 (11.1)	0	1 (11.1)
Vascular disorders			
-Total	2 (22.2)	0	2 (22.2)
Hypertension	2 (22.2)	0	2 (22.2)
Venous thrombosis limb	1 (11.1)	1 (11.1)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227d
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (46.7)	4 (13.3)	10 (33.3)
Gastrointestinal disorders			
-Total	6 (20.0)	2 (6.7)	4 (13.3)
Vomiting	5 (16.7)	2 (6.7)	3 (10.0)
Nausea	4 (13.3)	0	4 (13.3)
General disorders and administration site conditions			
-Total	5 (16.7)	2 (6.7)	3 (10.0)
Pyrexia	5 (16.7)	2 (6.7)	3 (10.0)
Fatigue	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (20.0)	4 (13.3)	2 (6.7)
Decreased appetite	4 (13.3)	2 (6.7)	2 (6.7)
Hypomagnesaemia	4 (13.3)	4 (13.3)	0
Nervous system disorders			
-Total	3 (10.0)	1 (3.3)	2 (6.7)
Headache	3 (10.0)	1 (3.3)	2 (6.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227d
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (28.9)	7 (15.6)	6 (13.3)
Gastrointestinal disorders			
-Total	7 (15.6)	2 (4.4)	5 (11.1)
Nausea	4 (8.9)	0	4 (8.9)
Vomiting	3 (6.7)	2 (4.4)	1 (2.2)
General disorders and administration site conditions			
-Total	9 (20.0)	6 (13.3)	3 (6.7)
Fatigue	5 (11.1)	3 (6.7)	2 (4.4)
Pyrexia	5 (11.1)	4 (8.9)	1 (2.2)
Metabolism and nutrition disorders			

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	2 (4.4)	0	2 (4.4)
Decreased appetite	2 (4.4)	0	2 (4.4)
Nervous system disorders			
-Total	3 (6.7)	1 (2.2)	2 (4.4)
Headache	3 (6.7)	1 (2.2)	2 (4.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227e
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (87.5)	3 (37.5)	4 (50.0)
Gastrointestinal disorders			
-Total	4 (50.0)	2 (25.0)	2 (25.0)
Abdominal pain	2 (25.0)	1 (12.5)	1 (12.5)
Diarrhoea	2 (25.0)	1 (12.5)	1 (12.5)
Vomiting	2 (25.0)	2 (25.0)	0
Dyspepsia	1 (12.5)	0	1 (12.5)
Nausea	1 (12.5)	0	1 (12.5)
Stomatitis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	2 (25.0)	2 (25.0)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Catheter site pain	1 (12.5)	1 (12.5)	0
Chills	1 (12.5)	1 (12.5)	0
Fatigue	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Immune system disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	1 (12.5)	0	1 (12.5)
Clostridium difficile infection	1 (12.5)	0	1 (12.5)
Injury, poisoning and procedural complications			
-Total	1 (12.5)	1 (12.5)	0
Wound	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	2 (25.0)	0	2 (25.0)
Decreased appetite	1 (12.5)	0	1 (12.5)
Dehydration	1 (12.5)	0	1 (12.5)
Hypomagnesaemia	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vitamin d deficiency	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Neck pain	1 (12.5)	0	1 (12.5)
Pain in extremity	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	2 (25.0)	0	2 (25.0)
Headache	2 (25.0)	0	2 (25.0)
Psychiatric disorders			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Anxiety	1 (12.5)	0	1 (12.5)
Confusional state	1 (12.5)	0	1 (12.5)
Depression	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	0	2 (25.0)
Cough	1 (12.5)	1 (12.5)	0
Epistaxis	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoxia	1 (12.5)	0	1 (12.5)
Nasal congestion	1 (12.5)	1 (12.5)	0
Oropharyngeal pain	1 (12.5)	1 (12.5)	0
Pleural effusion	1 (12.5)	0	1 (12.5)
Rhinorrhoea	1 (12.5)	1 (12.5)	0
Skin and subcutaneous tissue disorders			
-Total	2 (25.0)	2 (25.0)	0
Dermatitis diaper	1 (12.5)	1 (12.5)	0
Rash papular	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	1 (12.5)	1 (12.5)	0
Hypertension	1 (12.5)	1 (12.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227e
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	33 (49.3)	10 (14.9)	23 (34.3)
Gastrointestinal disorders			
-Total	12 (17.9)	2 (3.0)	10 (14.9)
Nausea	7 (10.4)	0	7 (10.4)
Vomiting	6 (9.0)	2 (3.0)	4 (6.0)
Abdominal pain	4 (6.0)	0	4 (6.0)
General disorders and administration site conditions			
-Total	14 (20.9)	7 (10.4)	7 (10.4)
Pyrexia	9 (13.4)	5 (7.5)	4 (6.0)
Fatigue	5 (7.5)	3 (4.5)	2 (3.0)
Catheter site pain	3 (4.5)	0	3 (4.5)

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Chills	1 (1.5)	1 (1.5)	0
Immune system disorders			
-Total	2 (3.0)	1 (1.5)	1 (1.5)
Hypogammaglobulinaemia	2 (3.0)	1 (1.5)	1 (1.5)
Metabolism and nutrition disorders			
-Total	8 (11.9)	3 (4.5)	5 (7.5)
Decreased appetite	5 (7.5)	2 (3.0)	3 (4.5)
Hypomagnesaemia	3 (4.5)	3 (4.5)	0
Dehydration	1 (1.5)	0	1 (1.5)
Vitamin d deficiency	1 (1.5)	0	1 (1.5)
Musculoskeletal and connective tissue disorders			
-Total	5 (7.5)	2 (3.0)	3 (4.5)
Pain in extremity	3 (4.5)	1 (1.5)	2 (3.0)
Neck pain	2 (3.0)	1 (1.5)	1 (1.5)
Nervous system disorders			
-Total	4 (6.0)	2 (3.0)	2 (3.0)
Headache	4 (6.0)	2 (3.0)	2 (3.0)
Psychiatric disorders			

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (3.0)	0	2 (3.0)
Anxiety	1 (1.5)	0	1 (1.5)
Confusional state	1 (1.5)	0	1 (1.5)
Depression	1 (1.5)	0	1 (1.5)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (6.0)	0	4 (6.0)
Hypoxia	3 (4.5)	0	3 (4.5)
Pleural effusion	2 (3.0)	1 (1.5)	1 (1.5)
Cough	1 (1.5)	1 (1.5)	0
Epistaxis	1 (1.5)	0	1 (1.5)
Skin and subcutaneous tissue disorders			
-Total	1 (1.5)	1 (1.5)	0
Rash papular	1 (1.5)	1 (1.5)	0
Vascular disorders			
-Total	3 (4.5)	1 (1.5)	2 (3.0)
Hypertension	3 (4.5)	1 (1.5)	2 (3.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227f
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
General disorders and administration site conditions			
-Total	1 (50.0)	0	1 (50.0)
Fatigue	1 (50.0)	1 (50.0)	0
Non-cardiac chest pain	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Blood fibrinogen decreased	1 (50.0)	0	1 (50.0)
Blood immunoglobulin m decreased	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (50.0)	0	1 (50.0)
Decreased appetite	1 (50.0)	0	1 (50.0)
Nervous system disorders			
-Total	2 (100)	2 (100)	0
Headache	2 (100)	2 (100)	0
Reproductive system and breast disorders			
-Total	1 (50.0)	0	1 (50.0)
Scrotal pain	1 (50.0)	0	1 (50.0)
Skin and subcutaneous tissue disorders			
-Total	1 (50.0)	1 (50.0)	0
Skin irritation	1 (50.0)	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227f
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	24 (32.9)	9 (12.3)	15 (20.5)
Gastrointestinal disorders			
-Total	13 (17.8)	4 (5.5)	9 (12.3)
Nausea	8 (11.0)	0	8 (11.0)
Vomiting	8 (11.0)	4 (5.5)	4 (5.5)
General disorders and administration site conditions			
-Total	13 (17.8)	8 (11.0)	5 (6.8)
Pyrexia	9 (12.3)	6 (8.2)	3 (4.1)
Fatigue	5 (6.8)	3 (4.1)	2 (2.7)
Non-cardiac chest pain	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			

Philadelphia chromosome/BCR-ABL: Negative

Group term Preferred term	All patients N=73 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
-Total	5 (6.8)	2 (2.7)	3 (4.1)
Decreased appetite	5 (6.8)	2 (2.7)	3 (4.1)
Nervous system disorders			
-Total	4 (5.5)	0	4 (5.5)
Headache	4 (5.5)	0	4 (5.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227g
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (100)	1 (33.3)	2 (66.7)
Gastrointestinal disorders			
-Total	2 (66.7)	0	2 (66.7)
Abdominal pain	1 (33.3)	1 (33.3)	0
Colitis	1 (33.3)	1 (33.3)	0
Diarrhoea	1 (33.3)	0	1 (33.3)
Dyspepsia	1 (33.3)	0	1 (33.3)
Nausea	1 (33.3)	0	1 (33.3)
Perianal erythema	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	1 (33.3)	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Chills	1 (33.3)	1 (33.3)	0
Fatigue	1 (33.3)	1 (33.3)	0
Pyrexia	1 (33.3)	1 (33.3)	0
Infections and infestations			
-Total	1 (33.3)	1 (33.3)	0
Sinusitis	1 (33.3)	1 (33.3)	0
Investigations			
-Total	1 (33.3)	1 (33.3)	0
Aspartate aminotransferase increased	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Decreased appetite	1 (33.3)	0	1 (33.3)
Hypokalaemia	1 (33.3)	1 (33.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (33.3)	0	1 (33.3)
Neck pain	1 (33.3)	0	1 (33.3)
Nervous system disorders			

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (33.3)	0	1 (33.3)
Headache	1 (33.3)	0	1 (33.3)
Psychiatric disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Anxiety	1 (33.3)	0	1 (33.3)
Irritability	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Cough	1 (33.3)	1 (33.3)	0
Hypoxia	1 (33.3)	0	1 (33.3)
Nasal congestion	1 (33.3)	1 (33.3)	0
Oropharyngeal pain	1 (33.3)	1 (33.3)	0
Rhinorrhoea	1 (33.3)	1 (33.3)	0
Vascular disorders			
-Total	1 (33.3)	1 (33.3)	0
Hypertension	1 (33.3)	1 (33.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227g
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	30 (41.7)	9 (12.5)	21 (29.2)
Gastrointestinal disorders			
-Total	15 (20.8)	4 (5.6)	11 (15.3)
Vomiting	8 (11.1)	4 (5.6)	4 (5.6)
Nausea	7 (9.7)	0	7 (9.7)
Abdominal pain	5 (6.9)	0	5 (6.9)
Diarrhoea	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	13 (18.1)	7 (9.7)	6 (8.3)
Pyrexia	9 (12.5)	5 (6.9)	4 (5.6)
Fatigue	5 (6.9)	3 (4.2)	2 (2.8)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Chills	1 (1.4)	1 (1.4)	0
Investigations			
-Total	1 (1.4)	0	1 (1.4)
Aspartate aminotransferase increased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	6 (8.3)	2 (2.8)	4 (5.6)
Decreased appetite	5 (6.9)	2 (2.8)	3 (4.2)
Hypokalaemia	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	2 (2.8)	1 (1.4)	1 (1.4)
Neck pain	2 (2.8)	1 (1.4)	1 (1.4)
Nervous system disorders			
-Total	5 (6.9)	2 (2.8)	3 (4.2)
Headache	5 (6.9)	2 (2.8)	3 (4.2)
Psychiatric disorders			
-Total	1 (1.4)	0	1 (1.4)
Anxiety	1 (1.4)	0	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	3 (4.2)	0	3 (4.2)
Hypoxia	3 (4.2)	0	3 (4.2)
Cough	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	3 (4.2)	1 (1.4)	2 (2.8)
Hypertension	3 (4.2)	1 (1.4)	2 (2.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227h
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Cardiac disorders			
-Total	1 (100)	0	1 (100)
Tachycardia	1 (100)	0	1 (100)
Gastrointestinal disorders			
-Total	1 (100)	0	1 (100)
Haematemesis	1 (100)	0	1 (100)
Vomiting	1 (100)	0	1 (100)
Psychiatric disorders			
-Total	1 (100)	0	1 (100)
Insomnia	1 (100)	0	1 (100)

Hypodiploidy: Yes

Group term Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Mental status changes	1 (100)	1 (100)	0
Skin and subcutaneous tissue disorders			
-Total	1 (100)	0	1 (100)
Rash erythematous	1 (100)	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227h
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	22 (29.7)	9 (12.2)	13 (17.6)
Cardiac disorders			
-Total	1 (1.4)	1 (1.4)	0
Tachycardia	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	12 (16.2)	4 (5.4)	8 (10.8)
Nausea	8 (10.8)	0	8 (10.8)
Vomiting	7 (9.5)	4 (5.4)	3 (4.1)
General disorders and administration site conditions			
-Total	10 (13.5)	6 (8.1)	4 (5.4)

Hypodiploidy: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pyrexia	10 (13.5)	6 (8.1)	4 (5.4)
Psychiatric disorders			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Insomnia	1 (1.4)	0	1 (1.4)
Mental status changes	1 (1.4)	1 (1.4)	0
Skin and subcutaneous tissue disorders			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Rash erythematous	2 (2.7)	1 (1.4)	1 (1.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227i
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	2 (50.0)	2 (50.0)
Endocrine disorders			
-Total	1 (25.0)	1 (25.0)	0
Cushingoid	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Dry mouth	1 (25.0)	1 (25.0)	0
Immune system disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)
Infections and infestations			

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (25.0)	0	1 (25.0)
Cytomegalovirus viraemia	1 (25.0)	0	1 (25.0)
Investigations			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Blood creatinine increased	1 (25.0)	1 (25.0)	0
Blood fibrinogen decreased	1 (25.0)	0	1 (25.0)
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0
Coronavirus test positive	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	1 (25.0)	1 (25.0)	0
Hyperuricaemia	1 (25.0)	1 (25.0)	0
Nervous system disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Headache	1 (25.0)	1 (25.0)	0
Neuralgia	1 (25.0)	0	1 (25.0)
Psychiatric disorders			
-Total	1 (25.0)	0	1 (25.0)
Insomnia	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227i
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	23 (32.4)	9 (12.7)	14 (19.7)
Gastrointestinal disorders			
-Total	13 (18.3)	4 (5.6)	9 (12.7)
Nausea	8 (11.3)	0	8 (11.3)
Vomiting	8 (11.3)	4 (5.6)	4 (5.6)
General disorders and administration site conditions			
-Total	10 (14.1)	6 (8.5)	4 (5.6)
Pyrexia	10 (14.1)	6 (8.5)	4 (5.6)
Immune system disorders			
-Total	2 (2.8)	1 (1.4)	1 (1.4)

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	2 (2.8)	1 (1.4)	1 (1.4)
Metabolism and nutrition disorders			
-Total	1 (1.4)	1 (1.4)	0
Hyperuricaemia	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	5 (7.0)	1 (1.4)	4 (5.6)
Headache	5 (7.0)	1 (1.4)	4 (5.6)
Psychiatric disorders			
-Total	1 (1.4)	0	1 (1.4)
Insomnia	1 (1.4)	0	1 (1.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227j
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (27.3)	1 (4.5)	5 (22.7)
Gastrointestinal disorders			
-Total	4 (18.2)	1 (4.5)	3 (13.6)
Nausea	3 (13.6)	0	3 (13.6)
Vomiting	2 (9.1)	1 (4.5)	1 (4.5)
General disorders and administration site conditions			
-Total	3 (13.6)	1 (4.5)	2 (9.1)
Pyrexia	3 (13.6)	1 (4.5)	2 (9.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227j
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	17 (32.1)	7 (13.2)	10 (18.9)
Gastrointestinal disorders			
-Total	12 (22.6)	3 (5.7)	9 (17.0)
Abdominal pain	6 (11.3)	1 (1.9)	5 (9.4)
Vomiting	6 (11.3)	3 (5.7)	3 (5.7)
Nausea	5 (9.4)	0	5 (9.4)
General disorders and administration site conditions			
-Total	7 (13.2)	5 (9.4)	2 (3.8)
Pyrexia	7 (13.2)	5 (9.4)	2 (3.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227k
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (26.7)	8 (10.7)	12 (16.0)
Gastrointestinal disorders			
-Total	13 (17.3)	4 (5.3)	9 (12.0)
Nausea	8 (10.7)	0	8 (10.7)
Vomiting	8 (10.7)	4 (5.3)	4 (5.3)
General disorders and administration site conditions			
-Total	10 (13.3)	6 (8.0)	4 (5.3)
Pyrexia	10 (13.3)	6 (8.0)	4 (5.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227l
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (34.4)	5 (15.6)	6 (18.8)
Gastrointestinal disorders			
-Total	5 (15.6)	2 (6.3)	3 (9.4)
Nausea	3 (9.4)	0	3 (9.4)
Vomiting	3 (9.4)	2 (6.3)	1 (3.1)
General disorders and administration site conditions			
-Total	6 (18.8)	3 (9.4)	3 (9.4)
Pyrexia	6 (18.8)	3 (9.4)	3 (9.4)
Nervous system disorders			
-Total	4 (12.5)	2 (6.3)	2 (6.3)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Headache	4 (12.5)	2 (6.3)	2 (6.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227l
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (25.6)	3 (7.0)	8 (18.6)
Gastrointestinal disorders			
-Total	8 (18.6)	2 (4.7)	6 (14.0)
Nausea	5 (11.6)	0	5 (11.6)
Vomiting	5 (11.6)	2 (4.7)	3 (7.0)
General disorders and administration site conditions			
-Total	4 (9.3)	3 (7.0)	1 (2.3)
Pyrexia	4 (9.3)	3 (7.0)	1 (2.3)
Nervous system disorders			
-Total	2 (4.7)	0	2 (4.7)

Prior SCT therapy: No

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Headache	2 (4.7)	0	2 (4.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227m
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (66.7)	1 (5.6)	11 (61.1)
Blood and lymphatic system disorders			
-Total	2 (11.1)	0	2 (11.1)
Anaemia	2 (11.1)	0	2 (11.1)
Gastrointestinal disorders			
-Total	2 (11.1)	0	2 (11.1)
Nausea	2 (11.1)	0	2 (11.1)
Vomiting	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
-Total	3 (16.7)	1 (5.6)	2 (11.1)

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Catheter site pain	2 (11.1)	0	2 (11.1)
Pyrexia	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	2 (11.1)	0	2 (11.1)
Conjunctivitis	2 (11.1)	0	2 (11.1)
Investigations			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
White blood cell count decreased	2 (11.1)	1 (5.6)	1 (5.6)
Metabolism and nutrition disorders			
-Total	2 (11.1)	0	2 (11.1)
Decreased appetite	2 (11.1)	0	2 (11.1)
Musculoskeletal and connective tissue disorders			
-Total	4 (22.2)	1 (5.6)	3 (16.7)
Neck pain	2 (11.1)	1 (5.6)	1 (5.6)
Pain in jaw	2 (11.1)	0	2 (11.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (16.7)	0	3 (16.7)

Eligibility for SCT: Yes

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypoxia	2 (11.1)	0	2 (11.1)
Pleural effusion	2 (11.1)	0	2 (11.1)

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227m
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (33.3)	7 (12.3)	12 (21.1)
Blood and lymphatic system disorders			
-Total	2 (3.5)	0	2 (3.5)
Anaemia	2 (3.5)	0	2 (3.5)
Gastrointestinal disorders			
-Total	11 (19.3)	4 (7.0)	7 (12.3)
Vomiting	7 (12.3)	4 (7.0)	3 (5.3)
Nausea	6 (10.5)	0	6 (10.5)
General disorders and administration site conditions			
-Total	10 (17.5)	6 (10.5)	4 (7.0)

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	9 (15.8)	5 (8.8)	4 (7.0)
Catheter site pain	2 (3.5)	1 (1.8)	1 (1.8)
Metabolism and nutrition disorders			
-Total	4 (7.0)	2 (3.5)	2 (3.5)
Decreased appetite	4 (7.0)	2 (3.5)	2 (3.5)
Musculoskeletal and connective tissue disorders			
-Total	1 (1.8)	0	1 (1.8)
Neck pain	1 (1.8)	0	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (5.3)	1 (1.8)	2 (3.5)
Hypoxia	2 (3.5)	0	2 (3.5)
Pleural effusion	1 (1.8)	1 (1.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227n
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (27.3)	4 (18.2)	2 (9.1)
Gastrointestinal disorders			
-Total	4 (18.2)	2 (9.1)	2 (9.1)
Vomiting	3 (13.6)	2 (9.1)	1 (4.5)
Nausea	1 (4.5)	0	1 (4.5)
General disorders and administration site conditions			
-Total	2 (9.1)	2 (9.1)	0
Pyrexia	2 (9.1)	2 (9.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227n
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (26.4)	4 (7.5)	10 (18.9)
Gastrointestinal disorders			
-Total	9 (17.0)	2 (3.8)	7 (13.2)
Nausea	7 (13.2)	0	7 (13.2)
Vomiting	5 (9.4)	2 (3.8)	3 (5.7)
General disorders and administration site conditions			
-Total	8 (15.1)	4 (7.5)	4 (7.5)
Pyrexia	8 (15.1)	4 (7.5)	4 (7.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227o
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (85.7)	2 (28.6)	4 (57.1)
Gastrointestinal disorders			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Vomiting	2 (28.6)	1 (14.3)	1 (14.3)
Abdominal pain	1 (14.3)	0	1 (14.3)
Colitis	1 (14.3)	1 (14.3)	0
Constipation	1 (14.3)	0	1 (14.3)
Nausea	1 (14.3)	0	1 (14.3)
Perianal erythema	1 (14.3)	0	1 (14.3)
Hepatobiliary disorders			
-Total	1 (14.3)	0	1 (14.3)
Hyperbilirubinaemia	1 (14.3)	0	1 (14.3)

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	1 (14.3)	1 (14.3)	0
Hypogammaglobulinaemia	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	1 (14.3)	1 (14.3)	0
Sinusitis	1 (14.3)	1 (14.3)	0
Injury, poisoning and procedural complications			
-Total	1 (14.3)	0	1 (14.3)
Radiation skin injury	1 (14.3)	0	1 (14.3)
Investigations			
-Total	2 (28.6)	0	2 (28.6)
Aspartate aminotransferase increased	1 (14.3)	0	1 (14.3)
Blood bilirubin increased	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)
Hyperkalaemia	1 (14.3)	0	1 (14.3)

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Malnutrition	1 (14.3)	0	1 (14.3)
Musculoskeletal and connective tissue disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Back pain	1 (14.3)	1 (14.3)	0
Muscle spasms	1 (14.3)	1 (14.3)	0
Musculoskeletal chest pain	1 (14.3)	1 (14.3)	0
Pain in extremity	1 (14.3)	0	1 (14.3)
Pain in jaw	1 (14.3)	0	1 (14.3)
Psychiatric disorders			
-Total	1 (14.3)	1 (14.3)	0
Irritability	1 (14.3)	1 (14.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (14.3)	0	1 (14.3)
Urticaria	1 (14.3)	0	1 (14.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 227o
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	26 (38.2)	8 (11.8)	18 (26.5)
Gastrointestinal disorders			
-Total	15 (22.1)	4 (5.9)	11 (16.2)
Nausea	7 (10.3)	0	7 (10.3)
Vomiting	6 (8.8)	3 (4.4)	3 (4.4)
Abdominal pain	5 (7.4)	1 (1.5)	4 (5.9)
Constipation	4 (5.9)	3 (4.4)	1 (1.5)
General disorders and administration site conditions			
-Total	10 (14.7)	6 (8.8)	4 (5.9)
Pyrexia	10 (14.7)	6 (8.8)	4 (5.9)
Immune system disorders			

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	2 (2.9)	0	2 (2.9)
Hypogammaglobulinaemia	2 (2.9)	0	2 (2.9)
Investigations			
-Total	1 (1.5)	1 (1.5)	0
Aspartate aminotransferase increased	1 (1.5)	1 (1.5)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (5.9)	2 (2.9)	2 (2.9)
Pain in extremity	3 (4.4)	2 (2.9)	1 (1.5)
Pain in jaw	1 (1.5)	0	1 (1.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227p
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	2 (50.0)
Cardiac disorders			
-Total	1 (25.0)	1 (25.0)	0
Bradycardia	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Gastrointestinal haemorrhage	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	2 (50.0)	0	2 (50.0)
Conjunctivitis	1 (25.0)	0	1 (25.0)
Metapneumovirus infection	1 (25.0)	0	1 (25.0)

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypoxia	1 (25.0)	0	1 (25.0)
Skin and subcutaneous tissue disorders			
-Total	2 (50.0)	2 (50.0)	0
Dermatitis diaper	1 (25.0)	1 (25.0)	0
Rash papular	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	1 (25.0)	1 (25.0)	0
Hypertension	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227p
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	23 (32.4)	8 (11.3)	15 (21.1)
Gastrointestinal disorders			
-Total	13 (18.3)	4 (5.6)	9 (12.7)
Nausea	8 (11.3)	0	8 (11.3)
Vomiting	8 (11.3)	4 (5.6)	4 (5.6)
General disorders and administration site conditions			
-Total	10 (14.1)	6 (8.5)	4 (5.6)
Pyrexia	10 (14.1)	6 (8.5)	4 (5.6)
Infections and infestations			
-Total	1 (1.4)	0	1 (1.4)

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Conjunctivitis	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (4.2)	0	3 (4.2)
Hypoxia	3 (4.2)	0	3 (4.2)
Skin and subcutaneous tissue disorders			
-Total	1 (1.4)	1 (1.4)	0
Rash papular	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	3 (4.2)	1 (1.4)	2 (2.8)
Hypertension	3 (4.2)	1 (1.4)	2 (2.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227q
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (40.6)	4 (12.5)	9 (28.1)
Gastrointestinal disorders			
-Total	8 (25.0)	3 (9.4)	5 (15.6)
Nausea	5 (15.6)	0	5 (15.6)
Vomiting	4 (12.5)	3 (9.4)	1 (3.1)
General disorders and administration site conditions			
-Total	6 (18.8)	2 (6.3)	4 (12.5)
Catheter site pain	4 (12.5)	1 (3.1)	3 (9.4)
Fatigue	2 (6.3)	0	2 (6.3)
Pyrexia	2 (6.3)	1 (3.1)	1 (3.1)
Metabolism and nutrition disorders			

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (9.4)	1 (3.1)	2 (6.3)
Decreased appetite	2 (6.3)	1 (3.1)	1 (3.1)
Hyperglycaemia	1 (3.1)	0	1 (3.1)
Musculoskeletal and connective tissue disorders			
-Total	4 (12.5)	2 (6.3)	2 (6.3)
Pain in extremity	4 (12.5)	2 (6.3)	2 (6.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227q
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (34.4)	6 (18.8)	5 (15.6)
Gastrointestinal disorders			
-Total	3 (9.4)	1 (3.1)	2 (6.3)
Vomiting	2 (6.3)	1 (3.1)	1 (3.1)
Nausea	1 (3.1)	0	1 (3.1)
General disorders and administration site conditions			
-Total	9 (28.1)	7 (21.9)	2 (6.3)
Pyrexia	7 (21.9)	5 (15.6)	2 (6.3)
Fatigue	4 (12.5)	4 (12.5)	0
Metabolism and nutrition disorders			
-Total	4 (12.5)	1 (3.1)	3 (9.4)

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All grades n (%)	All patients N=32 Grade 1 n (%)	Grade 2 n (%)
Decreased appetite	4 (12.5)	1 (3.1)	3 (9.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227q
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (27.3)	0	3 (27.3)
Gastrointestinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Nausea	2 (18.2)	0	2 (18.2)
Vomiting	2 (18.2)	0	2 (18.2)
General disorders and administration site conditions			
-Total	1 (9.1)	0	1 (9.1)
Pyrexia	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	2 (18.2)	0	2 (18.2)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperglycaemia	2 (18.2)	0	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227r
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (87.5)	3 (37.5)	4 (50.0)
Gastrointestinal disorders			
-Total	4 (50.0)	2 (25.0)	2 (25.0)
Abdominal pain	2 (25.0)	1 (12.5)	1 (12.5)
Diarrhoea	2 (25.0)	1 (12.5)	1 (12.5)
Vomiting	2 (25.0)	2 (25.0)	0
Dyspepsia	1 (12.5)	0	1 (12.5)
Nausea	1 (12.5)	0	1 (12.5)
Stomatitis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (25.0)	2 (25.0)	0
Catheter site pain	1 (12.5)	1 (12.5)	0
Chills	1 (12.5)	1 (12.5)	0
Fatigue	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Immune system disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	1 (12.5)	0	1 (12.5)
Clostridium difficile infection	1 (12.5)	0	1 (12.5)
Injury, poisoning and procedural complications			
-Total	1 (12.5)	1 (12.5)	0
Wound	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	2 (25.0)	0	2 (25.0)
Decreased appetite	1 (12.5)	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dehydration	1 (12.5)	0	1 (12.5)
Hypomagnesaemia	1 (12.5)	1 (12.5)	0
Vitamin d deficiency	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Neck pain	1 (12.5)	0	1 (12.5)
Pain in extremity	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	2 (25.0)	0	2 (25.0)
Headache	2 (25.0)	0	2 (25.0)
Psychiatric disorders			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Anxiety	1 (12.5)	0	1 (12.5)
Confusional state	1 (12.5)	0	1 (12.5)
Depression	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	0	2 (25.0)

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Cough	1 (12.5)	1 (12.5)	0
Epistaxis	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	0	1 (12.5)
Nasal congestion	1 (12.5)	1 (12.5)	0
Oropharyngeal pain	1 (12.5)	1 (12.5)	0
Pleural effusion	1 (12.5)	0	1 (12.5)
Rhinorrhoea	1 (12.5)	1 (12.5)	0
Skin and subcutaneous tissue disorders			
-Total	2 (25.0)	2 (25.0)	0
Dermatitis diaper	1 (12.5)	1 (12.5)	0
Rash papular	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	1 (12.5)	1 (12.5)	0
Hypertension	1 (12.5)	1 (12.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 227r
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (52.2)	2 (8.7)	10 (43.5)
Gastrointestinal disorders			
-Total	6 (26.1)	0	6 (26.1)
Nausea	4 (17.4)	0	4 (17.4)
Abdominal pain	3 (13.0)	0	3 (13.0)
Constipation	2 (8.7)	2 (8.7)	0
Vomiting	2 (8.7)	0	2 (8.7)
General disorders and administration site conditions			
-Total	3 (13.0)	1 (4.3)	2 (8.7)
Pyrexia	3 (13.0)	1 (4.3)	2 (8.7)

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Catheter site pain	1 (4.3)	0	1 (4.3)
Immune system disorders			
-Total	1 (4.3)	1 (4.3)	0
Hypogammaglobulinaemia	1 (4.3)	1 (4.3)	0
Metabolism and nutrition disorders			
-Total	3 (13.0)	2 (8.7)	1 (4.3)
Decreased appetite	2 (8.7)	2 (8.7)	0
Hypomagnesaemia	1 (4.3)	1 (4.3)	0
Vitamin d deficiency	1 (4.3)	0	1 (4.3)
Musculoskeletal and connective tissue disorders			
-Total	2 (8.7)	0	2 (8.7)
Neck pain	1 (4.3)	0	1 (4.3)
Pain in extremity	1 (4.3)	0	1 (4.3)
Nervous system disorders			
-Total	2 (8.7)	0	2 (8.7)
Headache	2 (8.7)	0	2 (8.7)
Psychiatric disorders			

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (4.3)	0	1 (4.3)
Anxiety	1 (4.3)	0	1 (4.3)
Depression	1 (4.3)	0	1 (4.3)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (8.7)	0	2 (8.7)
Hypoxia	2 (8.7)	0	2 (8.7)
Cough	1 (4.3)	1 (4.3)	0
Pleural effusion	1 (4.3)	0	1 (4.3)
Vascular disorders			
-Total	2 (8.7)	0	2 (8.7)
Hypertension	2 (8.7)	0	2 (8.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227r
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (45.8)	4 (16.7)	7 (29.2)
Gastrointestinal disorders			
-Total	5 (20.8)	1 (4.2)	4 (16.7)
Constipation	3 (12.5)	1 (4.2)	2 (8.3)
Nausea	2 (8.3)	0	2 (8.3)
Abdominal pain	1 (4.2)	0	1 (4.2)
Vomiting	1 (4.2)	0	1 (4.2)
General disorders and administration site conditions			
-Total	7 (29.2)	4 (16.7)	3 (12.5)
Fatigue	4 (16.7)	2 (8.3)	2 (8.3)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Catheter site pain	2 (8.3)	0	2 (8.3)
Pyrexia	2 (8.3)	2 (8.3)	0
Metabolism and nutrition disorders			
-Total	4 (16.7)	1 (4.2)	3 (12.5)
Decreased appetite	2 (8.3)	0	2 (8.3)
Hypomagnesaemia	2 (8.3)	2 (8.3)	0
Dehydration	1 (4.2)	0	1 (4.2)
Musculoskeletal and connective tissue disorders			
-Total	1 (4.2)	1 (4.2)	0
Neck pain	1 (4.2)	1 (4.2)	0
Psychiatric disorders			
-Total	1 (4.2)	0	1 (4.2)
Confusional state	1 (4.2)	0	1 (4.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227r
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (55.0)	4 (20.0)	7 (35.0)
Gastrointestinal disorders			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Vomiting	3 (15.0)	2 (10.0)	1 (5.0)
Nausea	1 (5.0)	0	1 (5.0)
General disorders and administration site conditions			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Pyrexia	4 (20.0)	2 (10.0)	2 (10.0)
Chills	1 (5.0)	1 (5.0)	0
Fatigue	1 (5.0)	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	1 (5.0)	0	1 (5.0)
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)
Metabolism and nutrition disorders			
-Total	1 (5.0)	0	1 (5.0)
Decreased appetite	1 (5.0)	0	1 (5.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Pain in extremity	2 (10.0)	1 (5.0)	1 (5.0)
Nervous system disorders			
-Total	2 (10.0)	2 (10.0)	0
Headache	2 (10.0)	2 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (10.0)	0	2 (10.0)
Epistaxis	1 (5.0)	0	1 (5.0)
Hypoxia	1 (5.0)	0	1 (5.0)
Pleural effusion	1 (5.0)	1 (5.0)	0

Number of previous relapses: >=3

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Skin and subcutaneous tissue disorders			
-Total	1 (5.0)	1 (5.0)	0
Rash papular	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	1 (5.0)	1 (5.0)	0
Hypertension	1 (5.0)	1 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (50.0)	3 (15.0)	7 (35.0)
Gastrointestinal disorders			
-Total	6 (30.0)	3 (15.0)	3 (15.0)
Abdominal pain	2 (10.0)	1 (5.0)	1 (5.0)
Constipation	2 (10.0)	2 (10.0)	0
Diarrhoea	2 (10.0)	1 (5.0)	1 (5.0)
Nausea	2 (10.0)	1 (5.0)	1 (5.0)
General disorders and administration site conditions			
-Total	4 (20.0)	1 (5.0)	3 (15.0)
Pyrexia	3 (15.0)	0	3 (15.0)

Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Catheter site pain	1 (5.0)	1 (5.0)	0
Investigations			
-Total	2 (10.0)	0	2 (10.0)
C-reactive protein increased	2 (10.0)	0	2 (10.0)
Metabolism and nutrition disorders			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Hypophosphataemia	2 (10.0)	2 (10.0)	0
Decreased appetite	1 (5.0)	0	1 (5.0)
Fluid overload	1 (5.0)	0	1 (5.0)
Hypomagnesaemia	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Pain in jaw	2 (10.0)	1 (5.0)	1 (5.0)
Nervous system disorders			
-Total	2 (10.0)	0	2 (10.0)
Headache	2 (10.0)	0	2 (10.0)
Psychiatric disorders			

Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Anxiety	2 (10.0)	1 (5.0)	1 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.0)	1 (5.0)	0
Dyspnoea	1 (5.0)	1 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (30.3)	8 (24.2)	2 (6.1)
Gastrointestinal disorders			
-Total	4 (12.1)	4 (12.1)	0
Nausea	3 (9.1)	3 (9.1)	0
Vomiting	2 (6.1)	2 (6.1)	0
Diarrhoea	1 (3.0)	1 (3.0)	0
General disorders and administration site conditions			
-Total	3 (9.1)	1 (3.0)	2 (6.1)
Pyrexia	3 (9.1)	1 (3.0)	2 (6.1)
Metabolism and nutrition disorders			

Age: >=10 years to <18 years

Group term Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	1 (3.0)	1 (3.0)	0
Decreased appetite	1 (3.0)	1 (3.0)	0
Nervous system disorders			
-Total	3 (9.1)	3 (9.1)	0
Headache	3 (9.1)	3 (9.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (87.5)	1 (12.5)	6 (75.0)
Blood and lymphatic system disorders			
-Total	2 (25.0)	0	2 (25.0)
Anaemia	2 (25.0)	0	2 (25.0)
Febrile neutropenia	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Nausea	3 (37.5)	1 (12.5)	2 (25.0)
Diarrhoea	1 (12.5)	0	1 (12.5)
Vomiting	1 (12.5)	0	1 (12.5)

Age: >=18

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Catheter site pain	1 (12.5)	1 (12.5)	0
Medical device pain	1 (12.5)	0	1 (12.5)
Pain	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	1 (12.5)	0	1 (12.5)
Device related infection	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	2 (25.0)	0	2 (25.0)
Decreased appetite	1 (12.5)	0	1 (12.5)
Fluid overload	1 (12.5)	0	1 (12.5)
Hypomagnesaemia	1 (12.5)	0	1 (12.5)
Hypophosphataemia	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	1 (12.5)	0	1 (12.5)
Insomnia	1 (12.5)	0	1 (12.5)

Age: >=18

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	0	2 (25.0)
Dyspnoea	1 (12.5)	0	1 (12.5)
Epistaxis	1 (12.5)	0	1 (12.5)
Skin and subcutaneous tissue disorders			
-Total	1 (12.5)	1 (12.5)	0
Skin haemorrhage	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Hypertension	1 (12.5)	1 (12.5)	0
Phlebitis	1 (12.5)	0	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 229b
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	9 (31.0)	4 (13.8)	5 (17.2)
Gastrointestinal disorders			
-Total	6 (20.7)	4 (13.8)	2 (6.9)
Nausea	5 (17.2)	3 (10.3)	2 (6.9)
Vomiting	3 (10.3)	2 (6.9)	1 (3.4)
General disorders and administration site conditions			
-Total	3 (10.3)	1 (3.4)	2 (6.9)
Pyrexia	3 (10.3)	1 (3.4)	2 (6.9)
Nervous system disorders			
-Total	1 (3.4)	0	1 (3.4)

Gender: Male

Group term Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Headache	1 (3.4)	0	1 (3.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229b
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (34.4)	4 (12.5)	7 (21.9)
Gastrointestinal disorders			
-Total	6 (18.8)	3 (9.4)	3 (9.4)
Diarrhoea	4 (12.5)	2 (6.3)	2 (6.3)
Nausea	3 (9.4)	2 (6.3)	1 (3.1)
General disorders and administration site conditions			
-Total	3 (9.4)	0	3 (9.4)
Pyrexia	3 (9.4)	0	3 (9.4)
Nervous system disorders			
-Total	4 (12.5)	3 (9.4)	1 (3.1)

Gender: Female

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Headache	4 (12.5)	3 (9.4)	1 (3.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	18 (36.0)	5 (10.0)	13 (26.0)
Gastrointestinal disorders			
-Total	9 (18.0)	4 (8.0)	5 (10.0)
Nausea	6 (12.0)	3 (6.0)	3 (6.0)
Diarrhoea	3 (6.0)	1 (2.0)	2 (4.0)
General disorders and administration site conditions			
-Total	6 (12.0)	2 (4.0)	4 (8.0)
Pyrexia	5 (10.0)	1 (2.0)	4 (8.0)
Catheter site pain	1 (2.0)	1 (2.0)	0
Investigations			

Race: White

Group term Preferred term	All patients N=50 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	3 (6.0)	1 (2.0)	2 (4.0)
Alanine aminotransferase increased	2 (4.0)	1 (2.0)	1 (2.0)
Aspartate aminotransferase increased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	2 (4.0)	0	2 (4.0)
Decreased appetite	2 (4.0)	0	2 (4.0)
Nervous system disorders			
-Total	4 (8.0)	2 (4.0)	2 (4.0)
Headache	4 (8.0)	2 (4.0)	2 (4.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (60.0)	1 (20.0)	2 (40.0)
General disorders and administration site conditions			
-Total	1 (20.0)	0	1 (20.0)
Pyrexia	1 (20.0)	0	1 (20.0)
Investigations			
-Total	1 (20.0)	0	1 (20.0)
Alanine aminotransferase increased	1 (20.0)	0	1 (20.0)
Aspartate aminotransferase increased	1 (20.0)	1 (20.0)	0
Blood uric acid increased	1 (20.0)	1 (20.0)	0

Race: Asian

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Skin and subcutaneous tissue disorders			
-Total	1 (20.0)	1 (20.0)	0
Pruritus generalised	1 (20.0)	1 (20.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (83.3)	3 (50.0)	2 (33.3)
Cardiac disorders			
-Total	1 (16.7)	1 (16.7)	0
Tachycardia	1 (16.7)	1 (16.7)	0
Gastrointestinal disorders			
-Total	2 (33.3)	2 (33.3)	0
Nausea	2 (33.3)	2 (33.3)	0
Abdominal pain lower	1 (16.7)	1 (16.7)	0
Diarrhoea	1 (16.7)	1 (16.7)	0
Haematochezia	1 (16.7)	1 (16.7)	0

Race: Other

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
General disorders and administration site conditions			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Catheter site pain	1 (16.7)	1 (16.7)	0
Chills	1 (16.7)	0	1 (16.7)
Device related thrombosis	1 (16.7)	0	1 (16.7)
Investigations			
-Total	1 (16.7)	1 (16.7)	0
Weight decreased	1 (16.7)	1 (16.7)	0
Metabolism and nutrition disorders			
-Total	1 (16.7)	1 (16.7)	0
Decreased appetite	1 (16.7)	1 (16.7)	0
Nervous system disorders			
-Total	1 (16.7)	1 (16.7)	0
Headache	1 (16.7)	1 (16.7)	0
Product issues			
-Total	1 (16.7)	1 (16.7)	0
Device occlusion	1 (16.7)	1 (16.7)	0

Race: Other

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (16.7)	1 (16.7)	0
Nasal discomfort	1 (16.7)	1 (16.7)	0
Skin and subcutaneous tissue disorders			
-Total	1 (16.7)	1 (16.7)	0
Rash pruritic	1 (16.7)	1 (16.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229d
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (13.0)	1 (4.3)	2 (8.7)
Gastrointestinal disorders			
-Total	3 (13.0)	1 (4.3)	2 (8.7)
Nausea	3 (13.0)	1 (4.3)	2 (8.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All

patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229d
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (26.3)	4 (10.5)	6 (15.8)
Gastrointestinal disorders			
-Total	5 (13.2)	4 (10.5)	1 (2.6)
Nausea	5 (13.2)	4 (10.5)	1 (2.6)
General disorders and administration site conditions			
-Total	6 (15.8)	1 (2.6)	5 (13.2)
Pyrexia	6 (15.8)	1 (2.6)	5 (13.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs

started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229e
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (42.9)	1 (14.3)	2 (28.6)
Blood and lymphatic system disorders			
-Total	1 (14.3)	0	1 (14.3)
Anaemia	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Vomiting	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	1 (14.3)	0	1 (14.3)
Pyrexia	1 (14.3)	0	1 (14.3)

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=7 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Metabolism and nutrition disorders			
-Total	1 (14.3)	1 (14.3)	0
Hypokalaemia	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	1 (14.3)	1 (14.3)	0
Dysgeusia	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	2 (28.6)	0	2 (28.6)
Depression	1 (14.3)	0	1 (14.3)
Insomnia	1 (14.3)	0	1 (14.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229e
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (22.2)	5 (9.3)	7 (13.0)
Blood and lymphatic system disorders			
-Total	1 (1.9)	0	1 (1.9)
Anaemia	1 (1.9)	0	1 (1.9)
Gastrointestinal disorders			
-Total	8 (14.8)	5 (9.3)	3 (5.6)
Nausea	8 (14.8)	5 (9.3)	3 (5.6)
Vomiting	2 (3.7)	1 (1.9)	1 (1.9)
General disorders and administration site conditions			
-Total	5 (9.3)	1 (1.9)	4 (7.4)

Response status at study entry: Relapsed disease

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	5 (9.3)	1 (1.9)	4 (7.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229f
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Alanine aminotransferase increased	1 (50.0)	0	1 (50.0)
Aspartate aminotransferase increased	1 (50.0)	1 (50.0)	0
Blood uric acid increased	1 (50.0)	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229f
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Negative

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (25.4)	5 (8.5)	10 (16.9)
Gastrointestinal disorders			
-Total	8 (13.6)	5 (8.5)	3 (5.1)
Nausea	8 (13.6)	5 (8.5)	3 (5.1)
General disorders and administration site conditions			
-Total	6 (10.2)	1 (1.7)	5 (8.5)
Pyrexia	6 (10.2)	1 (1.7)	5 (8.5)
Investigations			
-Total	3 (5.1)	1 (1.7)	2 (3.4)
Alanine aminotransferase increased	2 (3.4)	1 (1.7)	1 (1.7)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	1 (1.7)	0	1 (1.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229g
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (100)	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders			
-Total	1 (33.3)	0	1 (33.3)
Anaemia	1 (33.3)	0	1 (33.3)
Cardiac disorders			
-Total	1 (33.3)	0	1 (33.3)
Bradycardia	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
-Total	1 (33.3)	1 (33.3)	0
Nausea	1 (33.3)	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	1 (33.3)	0	1 (33.3)
Pyrexia	1 (33.3)	0	1 (33.3)
Infections and infestations			
-Total	1 (33.3)	0	1 (33.3)
Pneumonia	1 (33.3)	0	1 (33.3)
Investigations			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0
Blood lactic acid increased	1 (33.3)	0	1 (33.3)
C-reactive protein increased	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)
Fluid overload	1 (33.3)	0	1 (33.3)
Hypermagnesaemia	1 (33.3)	1 (33.3)	0
Nervous system disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Headache	1 (33.3)	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypotonia	1 (33.3)	0	1 (33.3)
Psychiatric disorders			
-Total	1 (33.3)	0	1 (33.3)
Insomnia	1 (33.3)	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229g
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	17 (29.3)	6 (10.3)	11 (19.0)
Blood and lymphatic system disorders			
-Total	1 (1.7)	0	1 (1.7)
Anaemia	1 (1.7)	0	1 (1.7)
Gastrointestinal disorders			
-Total	7 (12.1)	4 (6.9)	3 (5.2)
Nausea	7 (12.1)	4 (6.9)	3 (5.2)
General disorders and administration site conditions			
-Total	5 (8.6)	1 (1.7)	4 (6.9)
Pyrexia	5 (8.6)	1 (1.7)	4 (6.9)

Mixed-lineage leukemia rearrangement: No

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	3 (5.2)	0	3 (5.2)
Alanine aminotransferase increased	2 (3.4)	0	2 (3.4)
C-reactive protein increased	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	1 (1.7)	0	1 (1.7)
Fluid overload	1 (1.7)	0	1 (1.7)
Nervous system disorders			
-Total	4 (6.9)	2 (3.4)	2 (3.4)
Headache	4 (6.9)	2 (3.4)	2 (3.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229h
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (21.7)	5 (8.3)	8 (13.3)
Gastrointestinal disorders			
-Total	8 (13.3)	5 (8.3)	3 (5.0)
Nausea	8 (13.3)	5 (8.3)	3 (5.0)
General disorders and administration site conditions			
-Total	6 (10.0)	1 (1.7)	5 (8.3)
Pyrexia	6 (10.0)	1 (1.7)	5 (8.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs

started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229i
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	3 (75.0)	1 (25.0)
Eye disorders			
-Total	1 (25.0)	1 (25.0)	0
Eye irritation	1 (25.0)	1 (25.0)	0
Investigations			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Alanine aminotransferase increased	1 (25.0)	0	1 (25.0)
Aspartate aminotransferase increased	1 (25.0)	1 (25.0)	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0
Blood uric acid increased	1 (25.0)	1 (25.0)	0

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Musculoskeletal and connective tissue disorders			
-Total	1 (25.0)	1 (25.0)	0
Pain in jaw	1 (25.0)	1 (25.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (25.0)	1 (25.0)	0
Pruritus generalised	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229i
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (26.3)	5 (8.8)	10 (17.5)
Gastrointestinal disorders			
-Total	8 (14.0)	5 (8.8)	3 (5.3)
Nausea	8 (14.0)	5 (8.8)	3 (5.3)
General disorders and administration site conditions			
-Total	6 (10.5)	1 (1.8)	5 (8.8)
Pyrexia	6 (10.5)	1 (1.8)	5 (8.8)
Investigations			
-Total	3 (5.3)	1 (1.8)	2 (3.5)
Alanine aminotransferase increased	2 (3.5)	1 (1.8)	1 (1.8)

BCR-ABL1-like: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	1 (1.8)	0	1 (1.8)
Musculoskeletal and connective tissue disorders			
-Total	1 (1.8)	0	1 (1.8)
Pain in jaw	1 (1.8)	0	1 (1.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229j
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (38.9)	2 (11.1)	5 (27.8)
Gastrointestinal disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Diarrhoea	2 (11.1)	1 (5.6)	1 (5.6)
Nausea	2 (11.1)	2 (11.1)	0
General disorders and administration site conditions			
-Total	3 (16.7)	0	3 (16.7)
Pyrexia	3 (16.7)	0	3 (16.7)
Nervous system disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	2 (11.1)	1 (5.6)	1 (5.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229j
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=43	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (27.9)	5 (11.6)	7 (16.3)
Gastrointestinal disorders			
-Total	7 (16.3)	3 (7.0)	4 (9.3)
Nausea	6 (14.0)	3 (7.0)	3 (7.0)
Diarrhoea	2 (4.7)	1 (2.3)	1 (2.3)
General disorders and administration site conditions			
-Total	3 (7.0)	1 (2.3)	2 (4.7)
Pyrexia	3 (7.0)	1 (2.3)	2 (4.7)
Nervous system disorders			
-Total	3 (7.0)	2 (4.7)	1 (2.3)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	3 (7.0)	2 (4.7)	1 (2.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229k
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (13.1)	5 (8.2)	3 (4.9)
Gastrointestinal disorders			
-Total	8 (13.1)	5 (8.2)	3 (4.9)
Nausea	8 (13.1)	5 (8.2)	3 (4.9)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All

patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229l
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (17.9)	3 (10.7)	2 (7.1)
Gastrointestinal disorders			
-Total	2 (7.1)	2 (7.1)	0
Nausea	2 (7.1)	2 (7.1)	0
General disorders and administration site conditions			
-Total	3 (10.7)	1 (3.6)	2 (7.1)
Pyrexia	3 (10.7)	1 (3.6)	2 (7.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs

started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229l
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (24.2)	2 (6.1)	6 (18.2)
Gastrointestinal disorders			
-Total	6 (18.2)	3 (9.1)	3 (9.1)
Nausea	6 (18.2)	3 (9.1)	3 (9.1)
General disorders and administration site conditions			
-Total	3 (9.1)	0	3 (9.1)
Pyrexia	3 (9.1)	0	3 (9.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs

started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229m
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	9 (64.3)	3 (21.4)	6 (42.9)
Gastrointestinal disorders			
-Total	5 (35.7)	0	5 (35.7)
Nausea	3 (21.4)	0	3 (21.4)
Diarrhoea	2 (14.3)	0	2 (14.3)
General disorders and administration site conditions			
-Total	1 (7.1)	0	1 (7.1)
Pyrexia	1 (7.1)	0	1 (7.1)
Metabolism and nutrition disorders			
-Total	4 (28.6)	3 (21.4)	1 (7.1)

Eligibility for SCT: Yes

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Decreased appetite	2 (14.3)	1 (7.1)	1 (7.1)
Hyperphosphataemia	2 (14.3)	2 (14.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229m
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (29.8)	7 (14.9)	7 (14.9)
Gastrointestinal disorders			
-Total	6 (12.8)	6 (12.8)	0
Nausea	5 (10.6)	5 (10.6)	0
Diarrhoea	2 (4.3)	2 (4.3)	0
General disorders and administration site conditions			
-Total	5 (10.6)	1 (2.1)	4 (8.5)
Pyrexia	5 (10.6)	1 (2.1)	4 (8.5)
Metabolism and nutrition disorders			
-Total	2 (4.3)	0	2 (4.3)

Eligibility for SCT: No

Group term Preferred term	All patients N=47 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Decreased appetite	1 (2.1)	0	1 (2.1)
Hyperphosphataemia	1 (2.1)	0	1 (2.1)
Nervous system disorders			
-Total	5 (10.6)	3 (6.4)	2 (4.3)
Headache	5 (10.6)	3 (6.4)	2 (4.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229n
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (33.3)	4 (19.0)	3 (14.3)
Gastrointestinal disorders			
-Total	4 (19.0)	3 (14.3)	1 (4.8)
Nausea	3 (14.3)	2 (9.5)	1 (4.8)
Vomiting	3 (14.3)	2 (9.5)	1 (4.8)
General disorders and administration site conditions			
-Total	2 (9.5)	1 (4.8)	1 (4.8)
Pyrexia	2 (9.5)	1 (4.8)	1 (4.8)
Nervous system disorders			
-Total	1 (4.8)	0	1 (4.8)

Baseline bone marrow tumor burden: Low

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	1 (4.8)	0	1 (4.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229n
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (27.5)	4 (10.0)	7 (17.5)
Gastrointestinal disorders			
-Total	5 (12.5)	3 (7.5)	2 (5.0)
Nausea	5 (12.5)	3 (7.5)	2 (5.0)
General disorders and administration site conditions			
-Total	4 (10.0)	0	4 (10.0)
Pyrexia	4 (10.0)	0	4 (10.0)
Nervous system disorders			
-Total	4 (10.0)	3 (7.5)	1 (2.5)
Headache	4 (10.0)	3 (7.5)	1 (2.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229o
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	2 (50.0)
Cardiac disorders			
-Total	1 (25.0)	0	1 (25.0)
Bradycardia	1 (25.0)	0	1 (25.0)
Gastrointestinal disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Nausea	1 (25.0)	1 (25.0)	0
Pancreatic failure	1 (25.0)	0	1 (25.0)
General disorders and administration site conditions			
-Total	1 (25.0)	0	1 (25.0)

Baseline extramedullary disease presence: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	1 (25.0)	0	1 (25.0)
Pneumonia	1 (25.0)	0	1 (25.0)
Investigations			
-Total	1 (25.0)	0	1 (25.0)
Blood lactic acid increased	1 (25.0)	0	1 (25.0)
C-reactive protein increased	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			
-Total	1 (25.0)	0	1 (25.0)
Fluid overload	1 (25.0)	0	1 (25.0)
Hypermagnesaemia	1 (25.0)	1 (25.0)	0
Nervous system disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypotonia	1 (25.0)	0	1 (25.0)
Product issues			
-Total	1 (25.0)	1 (25.0)	0
Device occlusion	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229o
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

		All patients N=57	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (22.8)	5 (8.8)	8 (14.0)
Gastrointestinal disorders			
-Total	7 (12.3)	4 (7.0)	3 (5.3)
Nausea	7 (12.3)	4 (7.0)	3 (5.3)
General disorders and administration site conditions			
-Total	5 (8.8)	1 (1.8)	4 (7.0)
Pyrexia	5 (8.8)	1 (1.8)	4 (7.0)
Investigations			
-Total	1 (1.8)	0	1 (1.8)
C-reactive protein increased	1 (1.8)	0	1 (1.8)

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Metabolism and nutrition disorders			
-Total	1 (1.8)	0	1 (1.8)
Fluid overload	1 (1.8)	0	1 (1.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229p
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (25.0)	0	1 (25.0)
Immune system disorders			
-Total	1 (25.0)	1 (25.0)	0
Hypogammaglobulinaemia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0
Viral upper respiratory tract infection	1 (25.0)	1 (25.0)	0
Injury, poisoning and procedural complications			
-Total	1 (25.0)	0	1 (25.0)
Radiation skin injury	1 (25.0)	0	1 (25.0)

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	1 (25.0)	1 (25.0)	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (25.0)	1 (25.0)	0
Arthralgia	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Cough	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229p
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (26.3)	6 (10.5)	9 (15.8)
Gastrointestinal disorders			
-Total	8 (14.0)	5 (8.8)	3 (5.3)
Nausea	8 (14.0)	5 (8.8)	3 (5.3)
General disorders and administration site conditions			
-Total	6 (10.5)	1 (1.8)	5 (8.8)
Pyrexia	6 (10.5)	1 (1.8)	5 (8.8)
Metabolism and nutrition disorders			
-Total	2 (3.5)	1 (1.8)	1 (1.8)
Hyperphosphataemia	2 (3.5)	1 (1.8)	1 (1.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229q
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (38.7)	5 (16.1)	7 (22.6)
Gastrointestinal disorders			
-Total	5 (16.1)	2 (6.5)	3 (9.7)
Nausea	5 (16.1)	2 (6.5)	3 (9.7)
General disorders and administration site conditions			
-Total	2 (6.5)	0	2 (6.5)
Pyrexia	2 (6.5)	0	2 (6.5)
Investigations			
-Total	2 (6.5)	2 (6.5)	0
International normalised ratio increased	1 (3.2)	1 (3.2)	0

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=31 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Weight increased	1 (3.2)	1 (3.2)	0
Nervous system disorders			
-Total	4 (12.9)	2 (6.5)	2 (6.5)
Headache	4 (12.9)	2 (6.5)	2 (6.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229q
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (17.2)	3 (10.3)	2 (6.9)
Gastrointestinal disorders			
-Total	3 (10.3)	3 (10.3)	0
Nausea	3 (10.3)	3 (10.3)	0
General disorders and administration site conditions			
-Total	3 (10.3)	1 (3.4)	2 (6.9)
Pyrexia	3 (10.3)	1 (3.4)	2 (6.9)
Nervous system disorders			
-Total	1 (3.4)	1 (3.4)	0
Headache	1 (3.4)	1 (3.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229q
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
General disorders and administration site conditions			
-Total	1 (100)	0	1 (100)
Pyrexia	1 (100)	0	1 (100)
Infections and infestations			
-Total	1 (100)	0	1 (100)
Bronchitis	1 (100)	0	1 (100)
Investigations			
-Total	1 (100)	0	1 (100)

Time since enrollment to CTL019 infusion: Missing

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Activated partial thromboplastin time prolonged	1 (100)	0	1 (100)
International normalised ratio increased	1 (100)	0	1 (100)
Weight increased	1 (100)	1 (100)	0
Metabolism and nutrition disorders			
-Total	1 (100)	0	1 (100)
Hypoalbuminaemia	1 (100)	0	1 (100)
Hypoglycaemia	1 (100)	0	1 (100)
Nervous system disorders			
-Total	1 (100)	0	1 (100)
Somnolence	1 (100)	0	1 (100)
Renal and urinary disorders			
-Total	1 (100)	0	1 (100)
Urinary retention	1 (100)	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (42.9)	1 (14.3)	2 (28.6)
Blood and lymphatic system disorders			
-Total	1 (14.3)	0	1 (14.3)
Anaemia	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Vomiting	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	1 (14.3)	0	1 (14.3)
Pyrexia	1 (14.3)	0	1 (14.3)

Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	1 (14.3)	1 (14.3)	0
Hypokalaemia	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	1 (14.3)	1 (14.3)	0
Dysgeusia	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	2 (28.6)	0	2 (28.6)
Depression	1 (14.3)	0	1 (14.3)
Insomnia	1 (14.3)	0	1 (14.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (42.1)	5 (26.3)	3 (15.8)
Gastrointestinal disorders			
-Total	4 (21.1)	3 (15.8)	1 (5.3)
Nausea	4 (21.1)	3 (15.8)	1 (5.3)
Diarrhoea	1 (5.3)	1 (5.3)	0
Vomiting	1 (5.3)	0	1 (5.3)
General disorders and administration site conditions			
-Total	1 (5.3)	0	1 (5.3)
Pyrexia	1 (5.3)	0	1 (5.3)
Metabolism and nutrition disorders			

Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (21.1)	2 (10.5)	2 (10.5)
Decreased appetite	3 (15.8)	1 (5.3)	2 (10.5)
Hyperphosphataemia	1 (5.3)	1 (5.3)	0
Nervous system disorders			
-Total	3 (15.8)	2 (10.5)	1 (5.3)
Headache	3 (15.8)	2 (10.5)	1 (5.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	9 (47.4)	4 (21.1)	5 (26.3)
Blood and lymphatic system disorders			
-Total	1 (5.3)	0	1 (5.3)
Anaemia	1 (5.3)	0	1 (5.3)
Gastrointestinal disorders			
-Total	6 (31.6)	2 (10.5)	4 (21.1)
Nausea	4 (21.1)	2 (10.5)	2 (10.5)
Diarrhoea	2 (10.5)	0	2 (10.5)
Vomiting	1 (5.3)	1 (5.3)	0

Number of previous relapses: 2

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	1 (5.3)	0	1 (5.3)
Pyrexia	1 (5.3)	0	1 (5.3)
Metabolism and nutrition disorders			
-Total	1 (5.3)	1 (5.3)	0
Hypophosphataemia	1 (5.3)	1 (5.3)	0
Nervous system disorders			
-Total	1 (5.3)	1 (5.3)	0
Headache	1 (5.3)	1 (5.3)	0
Skin and subcutaneous tissue disorders			
-Total	2 (10.5)	2 (10.5)	0
Alopecia	2 (10.5)	2 (10.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (50.0)	3 (18.8)	5 (31.3)
Gastrointestinal disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Abdominal pain	2 (12.5)	1 (6.3)	1 (6.3)
Diarrhoea	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
-Total	3 (18.8)	1 (6.3)	2 (12.5)
Pyrexia	3 (18.8)	1 (6.3)	2 (12.5)
Investigations			

Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (12.5)	1 (6.3)	1 (6.3)
International normalised ratio increased	2 (12.5)	1 (6.3)	1 (6.3)
Metabolism and nutrition disorders			
-Total	4 (25.0)	3 (18.8)	1 (6.3)
Hyperphosphataemia	2 (12.5)	1 (6.3)	1 (6.3)
Hypophosphataemia	2 (12.5)	2 (12.5)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Pain in jaw	2 (12.5)	1 (6.3)	1 (6.3)
Nervous system disorders			
-Total	1 (6.3)	0	1 (6.3)
Headache	1 (6.3)	0	1 (6.3)
Psychiatric disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Anxiety	2 (12.5)	1 (6.3)	1 (6.3)
Respiratory, thoracic and mediastinal disorders			

Number of previous relapses: >=3

Group term Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Dyspnoea	2 (12.5)	1 (6.3)	1 (6.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility - Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231a
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: <10 years

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (50.0)	0	1 (50.0)
Pain in jaw	1 (50.0)	0	1 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231a
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=10 years to <18 years

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	3 (60.0)
Endocrine disorders			
-Total	1 (20.0)	0	1 (20.0)
Adrenal insufficiency	1 (20.0)	0	1 (20.0)
General disorders and administration site conditions			
-Total	2 (40.0)	0	2 (40.0)
Pyrexia	2 (40.0)	0	2 (40.0)
Chills	1 (20.0)	1 (20.0)	0
Infections and infestations			
-Total	1 (20.0)	0	1 (20.0)

Age: >=10 years to <18 years

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Bronchitis	1 (20.0)	0	1 (20.0)
Oral herpes	1 (20.0)	0	1 (20.0)
Investigations			
-Total	1 (20.0)	0	1 (20.0)
Activated partial thromboplastin time prolonged	1 (20.0)	0	1 (20.0)
International normalised ratio increased	1 (20.0)	0	1 (20.0)
Weight increased	1 (20.0)	1 (20.0)	0
Metabolism and nutrition disorders			
-Total	2 (40.0)	0	2 (40.0)
Hypernatraemia	1 (20.0)	0	1 (20.0)
Hypoalbuminaemia	1 (20.0)	0	1 (20.0)
Hypoglycaemia	1 (20.0)	0	1 (20.0)
Hypomagnesaemia	1 (20.0)	1 (20.0)	0
Nervous system disorders			
-Total	1 (20.0)	0	1 (20.0)
Somnolence	1 (20.0)	0	1 (20.0)
Renal and urinary disorders			

Age: >=10 years to <18 years

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Haematuria	1 (20.0)	1 (20.0)	0
Urinary retention	1 (20.0)	0	1 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231a
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=18

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	0	4 (100)
Eye disorders			
-Total	1 (25.0)	0	1 (25.0)
Photophobia	1 (25.0)	0	1 (25.0)
Gastrointestinal disorders			
-Total	2 (50.0)	0	2 (50.0)
Nausea	2 (50.0)	0	2 (50.0)
Vomiting	2 (50.0)	0	2 (50.0)
Constipation	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			

Age: >=18

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (25.0)	0	1 (25.0)
Pain	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			
-Total	2 (50.0)	0	2 (50.0)
Hyperglycaemia	2 (50.0)	0	2 (50.0)
Product issues			
-Total	1 (25.0)	0	1 (25.0)
Device occlusion	1 (25.0)	0	1 (25.0)
Psychiatric disorders			
-Total	1 (25.0)	0	1 (25.0)
Confusional state	1 (25.0)	0	1 (25.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Epistaxis	1 (25.0)	0	1 (25.0)
Pleural effusion	1 (25.0)	0	1 (25.0)
Vascular disorders			
-Total	1 (25.0)	0	1 (25.0)

Age: >=18

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypertension	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231b
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Male

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	9 (90.0)	1 (10.0)	8 (80.0)
Endocrine disorders			
-Total	1 (10.0)	0	1 (10.0)
Adrenal insufficiency	1 (10.0)	0	1 (10.0)
Eye disorders			
-Total	1 (10.0)	0	1 (10.0)
Photophobia	1 (10.0)	0	1 (10.0)
Gastrointestinal disorders			
-Total	2 (20.0)	0	2 (20.0)
Nausea	2 (20.0)	0	2 (20.0)
Vomiting	2 (20.0)	0	2 (20.0)

Gender: Male

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Constipation	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			
-Total	3 (30.0)	0	3 (30.0)
Pyrexia	2 (20.0)	0	2 (20.0)
Chills	1 (10.0)	1 (10.0)	0
Pain	1 (10.0)	0	1 (10.0)
Infections and infestations			
-Total	1 (10.0)	0	1 (10.0)
Bronchitis	1 (10.0)	0	1 (10.0)
Oral herpes	1 (10.0)	0	1 (10.0)
Investigations			
-Total	1 (10.0)	0	1 (10.0)
Activated partial thromboplastin time prolonged	1 (10.0)	0	1 (10.0)
International normalised ratio increased	1 (10.0)	0	1 (10.0)
Weight increased	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			

Gender: Male

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (40.0)	0	4 (40.0)
Hyperglycaemia	2 (20.0)	0	2 (20.0)
Hypernatraemia	1 (10.0)	0	1 (10.0)
Hypoalbuminaemia	1 (10.0)	0	1 (10.0)
Hypoglycaemia	1 (10.0)	0	1 (10.0)
Hypomagnesaemia	1 (10.0)	1 (10.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (10.0)	0	1 (10.0)
Pain in jaw	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	1 (10.0)	0	1 (10.0)
Somnolence	1 (10.0)	0	1 (10.0)
Product issues			
-Total	1 (10.0)	0	1 (10.0)
Device occlusion	1 (10.0)	0	1 (10.0)
Psychiatric disorders			
-Total	1 (10.0)	0	1 (10.0)

Gender: Male

Group term Preferred term	All patients N=10 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Confusional state	1 (10.0)	0	1 (10.0)
Renal and urinary disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Haematuria	1 (10.0)	1 (10.0)	0
Urinary retention	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (10.0)	0	1 (10.0)
Epistaxis	1 (10.0)	0	1 (10.0)
Pleural effusion	1 (10.0)	0	1 (10.0)
Vascular disorders			
-Total	1 (10.0)	0	1 (10.0)
Hypertension	1 (10.0)	0	1 (10.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231c
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: White

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (75.0)	1 (12.5)	5 (62.5)
Endocrine disorders			
-Total	1 (12.5)	0	1 (12.5)
Adrenal insufficiency	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Constipation	1 (12.5)	1 (12.5)	0
Nausea	1 (12.5)	0	1 (12.5)
Vomiting	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			

Race: White

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (25.0)	0	2 (25.0)
Pyrexia	2 (25.0)	0	2 (25.0)
Chills	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	1 (12.5)	0	1 (12.5)
Bronchitis	1 (12.5)	0	1 (12.5)
Oral herpes	1 (12.5)	0	1 (12.5)
Investigations			
-Total	1 (12.5)	0	1 (12.5)
Activated partial thromboplastin time prolonged	1 (12.5)	0	1 (12.5)
International normalised ratio increased	1 (12.5)	0	1 (12.5)
Weight increased	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	3 (37.5)	0	3 (37.5)
Hyperglycaemia	1 (12.5)	0	1 (12.5)
Hypernatraemia	1 (12.5)	0	1 (12.5)
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)

Race: White

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoglycaemia	1 (12.5)	0	1 (12.5)
Hypomagnesaemia	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	1 (12.5)	0	1 (12.5)
Somnolence	1 (12.5)	0	1 (12.5)
Psychiatric disorders			
-Total	1 (12.5)	0	1 (12.5)
Confusional state	1 (12.5)	0	1 (12.5)
Renal and urinary disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Haematuria	1 (12.5)	1 (12.5)	0
Urinary retention	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Epistaxis	1 (12.5)	0	1 (12.5)
Pleural effusion	1 (12.5)	0	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231c
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Asian

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Musculoskeletal and connective tissue disorders			
-Total	1 (100)	0	1 (100)
Pain in jaw	1 (100)	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231c
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Other

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Eye disorders			
-Total	1 (50.0)	0	1 (50.0)
Photophobia	1 (50.0)	0	1 (50.0)
Gastrointestinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Nausea	1 (50.0)	0	1 (50.0)
Vomiting	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
-Total	1 (50.0)	0	1 (50.0)

Race: Other

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pain	1 (50.0)	0	1 (50.0)
Metabolism and nutrition disorders			
-Total	1 (50.0)	0	1 (50.0)
Hyperglycaemia	1 (50.0)	0	1 (50.0)
Product issues			
-Total	1 (50.0)	0	1 (50.0)
Device occlusion	1 (50.0)	0	1 (50.0)
Vascular disorders			
-Total	1 (50.0)	0	1 (50.0)
Hypertension	1 (50.0)	0	1 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231d
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Hispanic or Latino

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (80.0)	0	4 (80.0)
Endocrine disorders			
-Total	1 (20.0)	0	1 (20.0)
Adrenal insufficiency	1 (20.0)	0	1 (20.0)
Gastrointestinal disorders			
-Total	2 (40.0)	0	2 (40.0)
Nausea	2 (40.0)	0	2 (40.0)
Vomiting	2 (40.0)	0	2 (40.0)
Constipation	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			

Ethnicity: Hispanic or Latino

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (40.0)	0	2 (40.0)
Chills	1 (20.0)	1 (20.0)	0
Pain	1 (20.0)	0	1 (20.0)
Pyrexia	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	3 (60.0)	0	3 (60.0)
Hyperglycaemia	2 (40.0)	0	2 (40.0)
Hypernatraemia	1 (20.0)	0	1 (20.0)
Hypomagnesaemia	1 (20.0)	1 (20.0)	0
Product issues			
-Total	1 (20.0)	0	1 (20.0)
Device occlusion	1 (20.0)	0	1 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231d
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (83.3)	1 (16.7)	4 (66.7)
Eye disorders			
-Total	1 (16.7)	0	1 (16.7)
Photophobia	1 (16.7)	0	1 (16.7)
General disorders and administration site conditions			
-Total	1 (16.7)	0	1 (16.7)
Pyrexia	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	1 (16.7)	0	1 (16.7)
Bronchitis	1 (16.7)	0	1 (16.7)

Ethnicity: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oral herpes	1 (16.7)	0	1 (16.7)
Investigations			
-Total	1 (16.7)	0	1 (16.7)
Activated partial thromboplastin time prolonged	1 (16.7)	0	1 (16.7)
International normalised ratio increased	1 (16.7)	0	1 (16.7)
Weight increased	1 (16.7)	1 (16.7)	0
Metabolism and nutrition disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)
Hypoglycaemia	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Pain in jaw	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	1 (16.7)	0	1 (16.7)
Somnolence	1 (16.7)	0	1 (16.7)

Ethnicity: Other

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Psychiatric disorders			
-Total	1 (16.7)	0	1 (16.7)
Confusional state	1 (16.7)	0	1 (16.7)
Renal and urinary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Haematuria	1 (16.7)	1 (16.7)	0
Urinary retention	1 (16.7)	0	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (16.7)	0	1 (16.7)
Epistaxis	1 (16.7)	0	1 (16.7)
Pleural effusion	1 (16.7)	0	1 (16.7)
Vascular disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypertension	1 (16.7)	0	1 (16.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231e
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Primary refractory

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Psychiatric disorders			
-Total	1 (100)	0	1 (100)
Confusional state	1 (100)	0	1 (100)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	0	1 (100)
Epistaxis	1 (100)	0	1 (100)
Pleural effusion	1 (100)	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231e
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (80.0)	1 (10.0)	7 (70.0)
Endocrine disorders			
-Total	1 (10.0)	0	1 (10.0)
Adrenal insufficiency	1 (10.0)	0	1 (10.0)
Eye disorders			
-Total	1 (10.0)	0	1 (10.0)
Photophobia	1 (10.0)	0	1 (10.0)
Gastrointestinal disorders			
-Total	2 (20.0)	0	2 (20.0)
Nausea	2 (20.0)	0	2 (20.0)
Vomiting	2 (20.0)	0	2 (20.0)
Constipation	1 (10.0)	1 (10.0)	0

Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	3 (30.0)	0	3 (30.0)
Pyrexia	2 (20.0)	0	2 (20.0)
Chills	1 (10.0)	1 (10.0)	0
Pain	1 (10.0)	0	1 (10.0)
Infections and infestations			
-Total	1 (10.0)	0	1 (10.0)
Bronchitis	1 (10.0)	0	1 (10.0)
Oral herpes	1 (10.0)	0	1 (10.0)
Investigations			
-Total	1 (10.0)	0	1 (10.0)
Activated partial thromboplastin time prolonged	1 (10.0)	0	1 (10.0)
International normalised ratio increased	1 (10.0)	0	1 (10.0)
Weight increased	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			
-Total	4 (40.0)	0	4 (40.0)
Hyperglycaemia	2 (20.0)	0	2 (20.0)

Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypernatraemia	1 (10.0)	0	1 (10.0)
Hypoalbuminaemia	1 (10.0)	0	1 (10.0)
Hypoglycaemia	1 (10.0)	0	1 (10.0)
Hypomagnesaemia	1 (10.0)	1 (10.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (10.0)	0	1 (10.0)
Pain in jaw	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	1 (10.0)	0	1 (10.0)
Somnolence	1 (10.0)	0	1 (10.0)
Product issues			
-Total	1 (10.0)	0	1 (10.0)
Device occlusion	1 (10.0)	0	1 (10.0)
Renal and urinary disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Haematuria	1 (10.0)	1 (10.0)	0
Urinary retention	1 (10.0)	0	1 (10.0)
Vascular disorders			

Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (10.0)	0	1 (10.0)
Hypertension	1 (10.0)	0	1 (10.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231f
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Negative

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (36.4)	0	4 (36.4)
Gastrointestinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Nausea	2 (18.2)	0	2 (18.2)
Vomiting	2 (18.2)	0	2 (18.2)
General disorders and administration site conditions			
-Total	2 (18.2)	0	2 (18.2)
Pyrexia	2 (18.2)	0	2 (18.2)
Metabolism and nutrition disorders			
-Total	2 (18.2)	0	2 (18.2)
Hyperglycaemia	2 (18.2)	0	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231g
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: No

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (36.4)	0	4 (36.4)
Gastrointestinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Nausea	2 (18.2)	0	2 (18.2)
Vomiting	2 (18.2)	0	2 (18.2)
General disorders and administration site conditions			
-Total	2 (18.2)	0	2 (18.2)
Pyrexia	2 (18.2)	0	2 (18.2)
Metabolism and nutrition disorders			
-Total	2 (18.2)	0	2 (18.2)
Hyperglycaemia	2 (18.2)	0	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231h
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (36.4)	0	4 (36.4)
Gastrointestinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Nausea	2 (18.2)	0	2 (18.2)
Vomiting	2 (18.2)	0	2 (18.2)
General disorders and administration site conditions			
-Total	2 (18.2)	0	2 (18.2)
Pyrexia	2 (18.2)	0	2 (18.2)
Metabolism and nutrition disorders			
-Total	2 (18.2)	0	2 (18.2)

Hypodiploidy: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hyperglycaemia	2 (18.2)	0	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231i
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (36.4)	0	4 (36.4)
Gastrointestinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Nausea	2 (18.2)	0	2 (18.2)
Vomiting	2 (18.2)	0	2 (18.2)
General disorders and administration site conditions			
-Total	2 (18.2)	0	2 (18.2)
Pyrexia	2 (18.2)	0	2 (18.2)
Metabolism and nutrition disorders			
-Total	2 (18.2)	0	2 (18.2)

BCR-ABL1-like: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hyperglycaemia	2 (18.2)	0	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231j
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (100)	0	3 (100)
Endocrine disorders			
-Total	1 (33.3)	0	1 (33.3)
Adrenal insufficiency	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Constipation	1 (33.3)	1 (33.3)	0
Nausea	1 (33.3)	0	1 (33.3)
Vomiting	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	1 (33.3)	0	1 (33.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Chills	1 (33.3)	1 (33.3)	0
Pyrexia	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	2 (66.7)	0	2 (66.7)
Hyperglycaemia	1 (33.3)	0	1 (33.3)
Hypernatraemia	1 (33.3)	0	1 (33.3)
Hypomagnesaemia	1 (33.3)	1 (33.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231j
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (75.0)	1 (12.5)	5 (62.5)
Eye disorders			
-Total	1 (12.5)	0	1 (12.5)
Photophobia	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Nausea	1 (12.5)	0	1 (12.5)
Vomiting	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			
-Total	2 (25.0)	0	2 (25.0)
Pain	1 (12.5)	0	1 (12.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	1 (12.5)	0	1 (12.5)
Bronchitis	1 (12.5)	0	1 (12.5)
Oral herpes	1 (12.5)	0	1 (12.5)
Investigations			
-Total	1 (12.5)	0	1 (12.5)
Activated partial thromboplastin time prolonged	1 (12.5)	0	1 (12.5)
International normalised ratio increased	1 (12.5)	0	1 (12.5)
Weight increased	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	2 (25.0)	0	2 (25.0)
Hyperglycaemia	1 (12.5)	0	1 (12.5)
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)
Hypoglycaemia	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	1 (12.5)	0	1 (12.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in jaw	1 (12.5)	0	1 (12.5)
Nervous system disorders			
-Total	1 (12.5)	0	1 (12.5)
Somnolence	1 (12.5)	0	1 (12.5)
Product issues			
-Total	1 (12.5)	0	1 (12.5)
Device occlusion	1 (12.5)	0	1 (12.5)
Psychiatric disorders			
-Total	1 (12.5)	0	1 (12.5)
Confusional state	1 (12.5)	0	1 (12.5)
Renal and urinary disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Haematuria	1 (12.5)	1 (12.5)	0
Urinary retention	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Epistaxis	1 (12.5)	0	1 (12.5)
Pleural effusion	1 (12.5)	0	1 (12.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypertension	1 (12.5)	0	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231k
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: US

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (36.4)	0	4 (36.4)
Gastrointestinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Nausea	2 (18.2)	0	2 (18.2)
Vomiting	2 (18.2)	0	2 (18.2)
General disorders and administration site conditions			
-Total	2 (18.2)	0	2 (18.2)
Pyrexia	2 (18.2)	0	2 (18.2)
Metabolism and nutrition disorders			
-Total	2 (18.2)	0	2 (18.2)

Region: US

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hyperglycaemia	2 (18.2)	0	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231l
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	1 (25.0)	3 (75.0)
Gastrointestinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Nausea	1 (25.0)	0	1 (25.0)
Vomiting	1 (25.0)	0	1 (25.0)
General disorders and administration site conditions			
-Total	3 (75.0)	0	3 (75.0)
Pyrexia	2 (50.0)	0	2 (50.0)
Chills	1 (25.0)	1 (25.0)	0
Pain	1 (25.0)	0	1 (25.0)

Prior SCT therapy: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	1 (25.0)	0	1 (25.0)
Bronchitis	1 (25.0)	0	1 (25.0)
Oral herpes	1 (25.0)	0	1 (25.0)
Investigations			
-Total	1 (25.0)	0	1 (25.0)
Activated partial thromboplastin time prolonged	1 (25.0)	0	1 (25.0)
International normalised ratio increased	1 (25.0)	0	1 (25.0)
Weight increased	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	2 (50.0)	0	2 (50.0)
Hyperglycaemia	1 (25.0)	0	1 (25.0)
Hypoalbuminaemia	1 (25.0)	0	1 (25.0)
Hypoglycaemia	1 (25.0)	0	1 (25.0)
Nervous system disorders			
-Total	1 (25.0)	0	1 (25.0)
Somnolence	1 (25.0)	0	1 (25.0)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Product issues			
-Total	1 (25.0)	0	1 (25.0)
Device occlusion	1 (25.0)	0	1 (25.0)
Renal and urinary disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Haematuria	1 (25.0)	1 (25.0)	0
Urinary retention	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231l
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (71.4)	0	5 (71.4)
Endocrine disorders			
-Total	1 (14.3)	0	1 (14.3)
Adrenal insufficiency	1 (14.3)	0	1 (14.3)
Eye disorders			
-Total	1 (14.3)	0	1 (14.3)
Photophobia	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Constipation	1 (14.3)	1 (14.3)	0
Nausea	1 (14.3)	0	1 (14.3)

Prior SCT therapy: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	2 (28.6)	0	2 (28.6)
Hyperglycaemia	1 (14.3)	0	1 (14.3)
Hypernatraemia	1 (14.3)	0	1 (14.3)
Hypomagnesaemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (14.3)	0	1 (14.3)
Pain in jaw	1 (14.3)	0	1 (14.3)
Psychiatric disorders			
-Total	1 (14.3)	0	1 (14.3)
Confusional state	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Epistaxis	1 (14.3)	0	1 (14.3)
Pleural effusion	1 (14.3)	0	1 (14.3)
Vascular disorders			

Prior SCT therapy: No

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	1 (14.3)	0	1 (14.3)
Hypertension	1 (14.3)	0	1 (14.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231m
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (75.0)	0	3 (75.0)
Gastrointestinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Constipation	1 (25.0)	1 (25.0)	0
Nausea	1 (25.0)	0	1 (25.0)
Vomiting	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			
-Total	1 (25.0)	0	1 (25.0)
Hyperglycaemia	1 (25.0)	0	1 (25.0)
Musculoskeletal and connective tissue disorders			

Eligibility for SCT: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	1 (25.0)	0	1 (25.0)
Pain in jaw	1 (25.0)	0	1 (25.0)
Psychiatric disorders			
-Total	1 (25.0)	0	1 (25.0)
Confusional state	1 (25.0)	0	1 (25.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Epistaxis	1 (25.0)	0	1 (25.0)
Pleural effusion	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231m
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (85.7)	1 (14.3)	5 (71.4)
Endocrine disorders			
-Total	1 (14.3)	0	1 (14.3)
Adrenal insufficiency	1 (14.3)	0	1 (14.3)
Eye disorders			
-Total	1 (14.3)	0	1 (14.3)
Photophobia	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Nausea	1 (14.3)	0	1 (14.3)
Vomiting	1 (14.3)	0	1 (14.3)

Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	3 (42.9)	0	3 (42.9)
Pyrexia	2 (28.6)	0	2 (28.6)
Chills	1 (14.3)	1 (14.3)	0
Pain	1 (14.3)	0	1 (14.3)
Infections and infestations			
-Total	1 (14.3)	0	1 (14.3)
Bronchitis	1 (14.3)	0	1 (14.3)
Oral herpes	1 (14.3)	0	1 (14.3)
Investigations			
-Total	1 (14.3)	0	1 (14.3)
Activated partial thromboplastin time prolonged	1 (14.3)	0	1 (14.3)
International normalised ratio increased	1 (14.3)	0	1 (14.3)
Weight increased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	3 (42.9)	0	3 (42.9)

Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperglycaemia	1 (14.3)	0	1 (14.3)
Hypernatraemia	1 (14.3)	0	1 (14.3)
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)
Hypoglycaemia	1 (14.3)	0	1 (14.3)
Hypomagnesaemia	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	1 (14.3)	0	1 (14.3)
Somnolence	1 (14.3)	0	1 (14.3)
Product issues			
-Total	1 (14.3)	0	1 (14.3)
Device occlusion	1 (14.3)	0	1 (14.3)
Renal and urinary disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Haematuria	1 (14.3)	1 (14.3)	0
Urinary retention	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypertension	1 (14.3)	0	1 (14.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231n
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: Low

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Eye disorders			
-Total	1 (50.0)	0	1 (50.0)
Photophobia	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
-Total	1 (50.0)	0	1 (50.0)
Pyrexia	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Bronchitis	1 (50.0)	0	1 (50.0)
Oral herpes	1 (50.0)	0	1 (50.0)

Baseline bone marrow tumor burden: Low

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Activated partial thromboplastin time prolonged	1 (50.0)	0	1 (50.0)
International normalised ratio increased	1 (50.0)	0	1 (50.0)
Weight increased	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	1 (50.0)	0	1 (50.0)
Hypoalbuminaemia	1 (50.0)	0	1 (50.0)
Hypoglycaemia	1 (50.0)	0	1 (50.0)
Nervous system disorders			
-Total	1 (50.0)	0	1 (50.0)
Somnolence	1 (50.0)	0	1 (50.0)
Renal and urinary disorders			
-Total	1 (50.0)	0	1 (50.0)
Urinary retention	1 (50.0)	0	1 (50.0)
Vascular disorders			
-Total	1 (50.0)	0	1 (50.0)

Baseline bone marrow tumor burden: Low

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	1 (50.0)	0	1 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231n
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: High

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (77.8)	1 (11.1)	6 (66.7)
Endocrine disorders			
-Total	1 (11.1)	0	1 (11.1)
Adrenal insufficiency	1 (11.1)	0	1 (11.1)
Gastrointestinal disorders			
-Total	2 (22.2)	0	2 (22.2)
Nausea	2 (22.2)	0	2 (22.2)
Vomiting	2 (22.2)	0	2 (22.2)
Constipation	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
-Total	2 (22.2)	0	2 (22.2)

Baseline bone marrow tumor burden: High

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Chills	1 (11.1)	1 (11.1)	0
Pain	1 (11.1)	0	1 (11.1)
Pyrexia	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	3 (33.3)	0	3 (33.3)
Hyperglycaemia	2 (22.2)	0	2 (22.2)
Hypernatraemia	1 (11.1)	0	1 (11.1)
Hypomagnesaemia	1 (11.1)	1 (11.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (11.1)	0	1 (11.1)
Pain in jaw	1 (11.1)	0	1 (11.1)
Product issues			
-Total	1 (11.1)	0	1 (11.1)
Device occlusion	1 (11.1)	0	1 (11.1)
Psychiatric disorders			
-Total	1 (11.1)	0	1 (11.1)
Confusional state	1 (11.1)	0	1 (11.1)
Renal and urinary disorders			

Baseline bone marrow tumor burden: High

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (11.1)	1 (11.1)	0
Haematuria	1 (11.1)	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (11.1)	0	1 (11.1)
Epistaxis	1 (11.1)	0	1 (11.1)
Pleural effusion	1 (11.1)	0	1 (11.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231o
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline extramedullary disease presence: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (50.0)	0	1 (50.0)
Pain in jaw	1 (50.0)	0	1 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231o
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (88.9)	1 (11.1)	7 (77.8)
Endocrine disorders			
-Total	1 (11.1)	0	1 (11.1)
Adrenal insufficiency	1 (11.1)	0	1 (11.1)
Eye disorders			
-Total	1 (11.1)	0	1 (11.1)
Photophobia	1 (11.1)	0	1 (11.1)
Gastrointestinal disorders			
-Total	2 (22.2)	0	2 (22.2)
Nausea	2 (22.2)	0	2 (22.2)
Vomiting	2 (22.2)	0	2 (22.2)
Constipation	1 (11.1)	1 (11.1)	0

Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	3 (33.3)	0	3 (33.3)
Pyrexia	2 (22.2)	0	2 (22.2)
Chills	1 (11.1)	1 (11.1)	0
Pain	1 (11.1)	0	1 (11.1)
Infections and infestations			
-Total	1 (11.1)	0	1 (11.1)
Bronchitis	1 (11.1)	0	1 (11.1)
Oral herpes	1 (11.1)	0	1 (11.1)
Investigations			
-Total	1 (11.1)	0	1 (11.1)
Activated partial thromboplastin time prolonged	1 (11.1)	0	1 (11.1)
International normalised ratio increased	1 (11.1)	0	1 (11.1)
Weight increased	1 (11.1)	1 (11.1)	0
Metabolism and nutrition disorders			
-Total	4 (44.4)	0	4 (44.4)
Hyperglycaemia	2 (22.2)	0	2 (22.2)

Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypernatraemia	1 (11.1)	0	1 (11.1)
Hypoalbuminaemia	1 (11.1)	0	1 (11.1)
Hypoglycaemia	1 (11.1)	0	1 (11.1)
Hypomagnesaemia	1 (11.1)	1 (11.1)	0
Nervous system disorders			
-Total	1 (11.1)	0	1 (11.1)
Somnolence	1 (11.1)	0	1 (11.1)
Product issues			
-Total	1 (11.1)	0	1 (11.1)
Device occlusion	1 (11.1)	0	1 (11.1)
Psychiatric disorders			
-Total	1 (11.1)	0	1 (11.1)
Confusional state	1 (11.1)	0	1 (11.1)
Renal and urinary disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Haematuria	1 (11.1)	1 (11.1)	0
Urinary retention	1 (11.1)	0	1 (11.1)
Respiratory, thoracic and mediastinal disorders			

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	1 (11.1)	0	1 (11.1)
Epistaxis	1 (11.1)	0	1 (11.1)
Pleural effusion	1 (11.1)	0	1 (11.1)
Vascular disorders			
-Total	1 (11.1)	0	1 (11.1)
Hypertension	1 (11.1)	0	1 (11.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231p
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (36.4)	0	4 (36.4)
Gastrointestinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Nausea	2 (18.2)	0	2 (18.2)
Vomiting	2 (18.2)	0	2 (18.2)
General disorders and administration site conditions			
-Total	2 (18.2)	0	2 (18.2)
Pyrexia	2 (18.2)	0	2 (18.2)
Metabolism and nutrition disorders			
-Total	2 (18.2)	0	2 (18.2)

Down syndrome: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hyperglycaemia	2 (18.2)	0	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231q
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: Missing

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (36.4)	0	4 (36.4)
Gastrointestinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Nausea	2 (18.2)	0	2 (18.2)
Vomiting	2 (18.2)	0	2 (18.2)
General disorders and administration site conditions			
-Total	2 (18.2)	0	2 (18.2)
Pyrexia	2 (18.2)	0	2 (18.2)
Metabolism and nutrition disorders			
-Total	2 (18.2)	0	2 (18.2)
Hyperglycaemia	2 (18.2)	0	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 0

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Psychiatric disorders			
-Total	1 (100)	0	1 (100)
Confusional state	1 (100)	0	1 (100)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	0	1 (100)
Epistaxis	1 (100)	0	1 (100)
Pleural effusion	1 (100)	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 1

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Eye disorders			
-Total	1 (33.3)	0	1 (33.3)
Photophobia	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Constipation	1 (33.3)	1 (33.3)	0
Nausea	1 (33.3)	0	1 (33.3)
Vomiting	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)

Number of previous relapses: 1

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hyperglycaemia	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypertension	1 (33.3)	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 2

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Endocrine disorders			
-Total	1 (33.3)	0	1 (33.3)
Adrenal insufficiency	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypernatraemia	1 (33.3)	0	1 (33.3)
Hypomagnesaemia	1 (33.3)	1 (33.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (33.3)	0	1 (33.3)

Number of previous relapses: 2

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in jaw	1 (33.3)	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: >=3

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	1 (25.0)	3 (75.0)
Gastrointestinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Nausea	1 (25.0)	0	1 (25.0)
Vomiting	1 (25.0)	0	1 (25.0)
General disorders and administration site conditions			
-Total	3 (75.0)	0	3 (75.0)
Pyrexia	2 (50.0)	0	2 (50.0)
Chills	1 (25.0)	1 (25.0)	0
Pain	1 (25.0)	0	1 (25.0)

Number of previous relapses: >=3

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	1 (25.0)	0	1 (25.0)
Bronchitis	1 (25.0)	0	1 (25.0)
Oral herpes	1 (25.0)	0	1 (25.0)
Investigations			
-Total	1 (25.0)	0	1 (25.0)
Activated partial thromboplastin time prolonged	1 (25.0)	0	1 (25.0)
International normalised ratio increased	1 (25.0)	0	1 (25.0)
Weight increased	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	2 (50.0)	0	2 (50.0)
Hyperglycaemia	1 (25.0)	0	1 (25.0)
Hypoalbuminaemia	1 (25.0)	0	1 (25.0)
Hypoglycaemia	1 (25.0)	0	1 (25.0)
Nervous system disorders			
-Total	1 (25.0)	0	1 (25.0)
Somnolence	1 (25.0)	0	1 (25.0)

Number of previous relapses: >=3

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Product issues			
-Total	1 (25.0)	0	1 (25.0)
Device occlusion	1 (25.0)	0	1 (25.0)
Renal and urinary disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Haematuria	1 (25.0)	1 (25.0)	0
Urinary retention	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233a
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	21 (95.5)	1 (4.5)	20 (90.9)
Blood and lymphatic system disorders			
-Total	2 (9.1)	2 (9.1)	0
Anaemia	2 (9.1)	2 (9.1)	0
Cardiac disorders			
-Total	5 (22.7)	3 (13.6)	2 (9.1)
Sinus tachycardia	3 (13.6)	2 (9.1)	1 (4.5)
Tachycardia	2 (9.1)	1 (4.5)	1 (4.5)
Gastrointestinal disorders			
-Total	15 (68.2)	5 (22.7)	10 (45.5)

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Nausea	10 (45.5)	3 (13.6)	7 (31.8)
Diarrhoea	9 (40.9)	5 (22.7)	4 (18.2)
Vomiting	9 (40.9)	5 (22.7)	4 (18.2)
Constipation	5 (22.7)	5 (22.7)	0
Abdominal pain	4 (18.2)	2 (9.1)	2 (9.1)
General disorders and administration site conditions			
-Total	12 (54.5)	6 (27.3)	6 (27.3)
Pyrexia	8 (36.4)	3 (13.6)	5 (22.7)
Fatigue	4 (18.2)	4 (18.2)	0
Catheter site pain	3 (13.6)	1 (4.5)	2 (9.1)
Chills	1 (4.5)	1 (4.5)	0
Immune system disorders			
-Total	17 (77.3)	2 (9.1)	15 (68.2)
Cytokine release syndrome	13 (59.1)	2 (9.1)	11 (50.0)
Hypogammaglobulinaemia	9 (40.9)	2 (9.1)	7 (31.8)
Infections and infestations			
-Total	10 (45.5)	4 (18.2)	6 (27.3)

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Upper respiratory tract infection	5 (22.7)	3 (13.6)	2 (9.1)
Clostridium difficile infection	3 (13.6)	0	3 (13.6)
Gastroenteritis	3 (13.6)	1 (4.5)	2 (9.1)
Rhinovirus infection	3 (13.6)	3 (13.6)	0
Sinusitis	3 (13.6)	1 (4.5)	2 (9.1)
Injury, poisoning and procedural complications			
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Procedural pain	3 (13.6)	2 (9.1)	1 (4.5)
Investigations			
-Total	11 (50.0)	2 (9.1)	9 (40.9)
White blood cell count decreased	5 (22.7)	2 (9.1)	3 (13.6)
Aspartate aminotransferase increased	4 (18.2)	2 (9.1)	2 (9.1)
Alanine aminotransferase increased	3 (13.6)	0	3 (13.6)
Blood bilirubin increased	2 (9.1)	0	2 (9.1)
International normalised ratio increased	2 (9.1)	2 (9.1)	0
Lymphocyte count decreased	2 (9.1)	1 (4.5)	1 (4.5)

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Prothrombin time prolonged	2 (9.1)	2 (9.1)	0
Activated partial thromboplastin time prolonged	1 (4.5)	1 (4.5)	0
Blood fibrinogen decreased	1 (4.5)	0	1 (4.5)
Neutrophil count decreased	1 (4.5)	0	1 (4.5)
Platelet count decreased	1 (4.5)	0	1 (4.5)
Weight decreased	1 (4.5)	0	1 (4.5)
Metabolism and nutrition disorders			
-Total	12 (54.5)	4 (18.2)	8 (36.4)
Decreased appetite	6 (27.3)	3 (13.6)	3 (13.6)
Hypocalcaemia	4 (18.2)	2 (9.1)	2 (9.1)
Hypophosphataemia	4 (18.2)	3 (13.6)	1 (4.5)
Hypokalaemia	3 (13.6)	0	3 (13.6)
Fluid overload	2 (9.1)	1 (4.5)	1 (4.5)
Hypoalbuminaemia	2 (9.1)	0	2 (9.1)
Hyperglycaemia	1 (4.5)	0	1 (4.5)
Hypernatraemia	1 (4.5)	0	1 (4.5)
Hyperphosphataemia	1 (4.5)	1 (4.5)	0

Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	9 (40.9)	5 (22.7)	4 (18.2)
Pain in extremity	7 (31.8)	4 (18.2)	3 (13.6)
Pain in jaw	3 (13.6)	1 (4.5)	2 (9.1)
Nervous system disorders			
-Total	9 (40.9)	6 (27.3)	3 (13.6)
Headache	8 (36.4)	5 (22.7)	3 (13.6)
Dizziness	2 (9.1)	2 (9.1)	0
Psychiatric disorders			
-Total	4 (18.2)	2 (9.1)	2 (9.1)
Anxiety	2 (9.1)	1 (4.5)	1 (4.5)
Confusional state	2 (9.1)	1 (4.5)	1 (4.5)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (45.5)	4 (18.2)	6 (27.3)
Cough	5 (22.7)	5 (22.7)	0
Hypoxia	3 (13.6)	0	3 (13.6)
Rhinorrhoea	3 (13.6)	2 (9.1)	1 (4.5)

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Oropharyngeal pain	2 (9.1)	2 (9.1)	0
Pleural effusion	2 (9.1)	0	2 (9.1)
Epistaxis	1 (4.5)	0	1 (4.5)
Nasal congestion	1 (4.5)	1 (4.5)	0
Skin and subcutaneous tissue disorders			
-Total	4 (18.2)	3 (13.6)	1 (4.5)
Rash	4 (18.2)	3 (13.6)	1 (4.5)
Vascular disorders			
-Total	5 (22.7)	2 (9.1)	3 (13.6)
Hypertension	5 (22.7)	2 (9.1)	3 (13.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233a
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	37 (94.9)	0	37 (94.9)
Blood and lymphatic system disorders			
-Total	9 (23.1)	2 (5.1)	7 (17.9)
Anaemia	9 (23.1)	2 (5.1)	7 (17.9)
Cardiac disorders			
-Total	12 (30.8)	6 (15.4)	6 (15.4)
Tachycardia	10 (25.6)	6 (15.4)	4 (10.3)
Sinus tachycardia	3 (7.7)	1 (2.6)	2 (5.1)
Gastrointestinal disorders			
-Total	24 (61.5)	10 (25.6)	14 (35.9)

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	14 (35.9)	11 (28.2)	3 (7.7)
Nausea	13 (33.3)	5 (12.8)	8 (20.5)
Diarrhoea	11 (28.2)	7 (17.9)	4 (10.3)
Abdominal pain	8 (20.5)	4 (10.3)	4 (10.3)
Constipation	4 (10.3)	3 (7.7)	1 (2.6)
General disorders and administration site conditions			
-Total	24 (61.5)	10 (25.6)	14 (35.9)
Pyrexia	14 (35.9)	4 (10.3)	10 (25.6)
Fatigue	10 (25.6)	9 (23.1)	1 (2.6)
Chills	7 (17.9)	5 (12.8)	2 (5.1)
Catheter site pain	2 (5.1)	1 (2.6)	1 (2.6)
Pain	2 (5.1)	1 (2.6)	1 (2.6)
Immune system disorders			
-Total	29 (74.4)	5 (12.8)	24 (61.5)
Cytokine release syndrome	24 (61.5)	5 (12.8)	19 (48.7)
Hypogammaglobulinaemia	16 (41.0)	2 (5.1)	14 (35.9)
Infections and infestations			

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	12 (30.8)	5 (12.8)	7 (17.9)
Upper respiratory tract infection	4 (10.3)	2 (5.1)	2 (5.1)
Clostridium difficile infection	2 (5.1)	0	2 (5.1)
Influenza	2 (5.1)	1 (2.6)	1 (2.6)
Rhinovirus infection	2 (5.1)	2 (5.1)	0
Gastroenteritis	1 (2.6)	0	1 (2.6)
Sinusitis	1 (2.6)	0	1 (2.6)
Injury, poisoning and procedural complications			
-Total	2 (5.1)	0	2 (5.1)
Procedural pain	2 (5.1)	0	2 (5.1)
Investigations			
-Total	25 (64.1)	2 (5.1)	23 (59.0)
Aspartate aminotransferase increased	11 (28.2)	5 (12.8)	6 (15.4)
Alanine aminotransferase increased	10 (25.6)	4 (10.3)	6 (15.4)
White blood cell count decreased	10 (25.6)	4 (10.3)	6 (15.4)
Blood creatinine increased	7 (17.9)	5 (12.8)	2 (5.1)

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
International normalised ratio increased	7 (17.9)	6 (15.4)	1 (2.6)
Activated partial thromboplastin time prolonged	5 (12.8)	2 (5.1)	3 (7.7)
Blood bilirubin increased	5 (12.8)	2 (5.1)	3 (7.7)
Lymphocyte count decreased	5 (12.8)	1 (2.6)	4 (10.3)
Neutrophil count decreased	5 (12.8)	2 (5.1)	3 (7.7)
Prothrombin time prolonged	4 (10.3)	3 (7.7)	1 (2.6)
Platelet count decreased	3 (7.7)	2 (5.1)	1 (2.6)
Weight decreased	2 (5.1)	2 (5.1)	0
Metabolism and nutrition disorders			
-Total	20 (51.3)	9 (23.1)	11 (28.2)
Decreased appetite	10 (25.6)	8 (20.5)	2 (5.1)
Hyperphosphataemia	7 (17.9)	6 (15.4)	1 (2.6)
Hypokalaemia	6 (15.4)	3 (7.7)	3 (7.7)
Hypernatraemia	4 (10.3)	1 (2.6)	3 (7.7)
Hypoalbuminaemia	4 (10.3)	1 (2.6)	3 (7.7)
Fluid overload	1 (2.6)	0	1 (2.6)
Hyperglycaemia	1 (2.6)	0	1 (2.6)

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypophosphataemia	1 (2.6)	1 (2.6)	0
Musculoskeletal and connective tissue disorders			
-Total	10 (25.6)	9 (23.1)	1 (2.6)
Arthralgia	5 (12.8)	5 (12.8)	0
Myalgia	5 (12.8)	4 (10.3)	1 (2.6)
Pain in extremity	3 (7.7)	3 (7.7)	0
Pain in jaw	1 (2.6)	1 (2.6)	0
Nervous system disorders			
-Total	17 (43.6)	10 (25.6)	7 (17.9)
Headache	17 (43.6)	10 (25.6)	7 (17.9)
Dizziness	1 (2.6)	1 (2.6)	0
Peroneal nerve palsy	1 (2.6)	1 (2.6)	0
Psychiatric disorders			
-Total	7 (17.9)	3 (7.7)	4 (10.3)
Anxiety	5 (12.8)	2 (5.1)	3 (7.7)
Confusional state	3 (7.7)	1 (2.6)	2 (5.1)
Respiratory, thoracic and mediastinal disorders			

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	18 (46.2)	9 (23.1)	9 (23.1)
Cough	9 (23.1)	7 (17.9)	2 (5.1)
Nasal congestion	5 (12.8)	5 (12.8)	0
Epistaxis	4 (10.3)	3 (7.7)	1 (2.6)
Hypoxia	4 (10.3)	0	4 (10.3)
Oropharyngeal pain	4 (10.3)	2 (5.1)	2 (5.1)
Rhinorrhoea	3 (7.7)	3 (7.7)	0
Pleural effusion	2 (5.1)	1 (2.6)	1 (2.6)
Skin and subcutaneous tissue disorders			
-Total	8 (20.5)	6 (15.4)	2 (5.1)
Dry skin	5 (12.8)	5 (12.8)	0
Rash	4 (10.3)	2 (5.1)	2 (5.1)
Vascular disorders			
-Total	4 (10.3)	2 (5.1)	2 (5.1)
Hypertension	4 (10.3)	2 (5.1)	2 (5.1)

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- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233a
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (92.9)	0	13 (92.9)
Blood and lymphatic system disorders			
-Total	3 (21.4)	0	3 (21.4)
Anaemia	3 (21.4)	0	3 (21.4)
Cardiac disorders			
-Total	4 (28.6)	2 (14.3)	2 (14.3)
Tachycardia	4 (28.6)	2 (14.3)	2 (14.3)
Gastrointestinal disorders			
-Total	8 (57.1)	1 (7.1)	7 (50.0)
Nausea	7 (50.0)	1 (7.1)	6 (42.9)

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Diarrhoea	5 (35.7)	2 (14.3)	3 (21.4)
Vomiting	4 (28.6)	1 (7.1)	3 (21.4)
Abdominal pain	2 (14.3)	1 (7.1)	1 (7.1)
Constipation	2 (14.3)	1 (7.1)	1 (7.1)
General disorders and administration site conditions			
-Total	9 (64.3)	1 (7.1)	8 (57.1)
Pyrexia	7 (50.0)	2 (14.3)	5 (35.7)
Chills	3 (21.4)	3 (21.4)	0
Fatigue	3 (21.4)	0	3 (21.4)
Catheter site pain	2 (14.3)	1 (7.1)	1 (7.1)
Pain	2 (14.3)	0	2 (14.3)
Immune system disorders			
-Total	8 (57.1)	0	8 (57.1)
Cytokine release syndrome	8 (57.1)	0	8 (57.1)
Hypogammaglobulinaemia	3 (21.4)	0	3 (21.4)
Infections and infestations			
-Total	4 (28.6)	0	4 (28.6)

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Influenza	2 (14.3)	0	2 (14.3)
Rhinovirus infection	1 (7.1)	0	1 (7.1)
Sinusitis	1 (7.1)	0	1 (7.1)
Upper respiratory tract infection	1 (7.1)	0	1 (7.1)
Investigations			
-Total	5 (35.7)	0	5 (35.7)
Prothrombin time prolonged	3 (21.4)	0	3 (21.4)
Blood fibrinogen decreased	2 (14.3)	0	2 (14.3)
Platelet count decreased	2 (14.3)	1 (7.1)	1 (7.1)
Weight decreased	2 (14.3)	0	2 (14.3)
White blood cell count decreased	2 (14.3)	0	2 (14.3)
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0
Aspartate aminotransferase increased	1 (7.1)	1 (7.1)	0
International normalised ratio increased	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			
-Total	9 (64.3)	1 (7.1)	8 (57.1)
Decreased appetite	3 (21.4)	0	3 (21.4)

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypokalaemia	3 (21.4)	2 (14.3)	1 (7.1)
Fluid overload	2 (14.3)	0	2 (14.3)
Hyperglycaemia	2 (14.3)	0	2 (14.3)
Hyperphosphataemia	1 (7.1)	1 (7.1)	0
Hypocalcaemia	1 (7.1)	1 (7.1)	0
Hypophosphataemia	1 (7.1)	1 (7.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (7.1)	0	1 (7.1)
Arthralgia	1 (7.1)	0	1 (7.1)
Pain in extremity	1 (7.1)	0	1 (7.1)
Nervous system disorders			
-Total	7 (50.0)	4 (28.6)	3 (21.4)
Dizziness	3 (21.4)	3 (21.4)	0
Headache	3 (21.4)	1 (7.1)	2 (14.3)
Peroneal nerve palsy	2 (14.3)	1 (7.1)	1 (7.1)
Psychiatric disorders			
-Total	3 (21.4)	1 (7.1)	2 (14.3)

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Confusional state	2 (14.3)	1 (7.1)	1 (7.1)
Anxiety	1 (7.1)	0	1 (7.1)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (35.7)	1 (7.1)	4 (28.6)
Epistaxis	4 (28.6)	1 (7.1)	3 (21.4)
Pleural effusion	3 (21.4)	0	3 (21.4)
Cough	1 (7.1)	1 (7.1)	0
Hypoxia	1 (7.1)	0	1 (7.1)
Skin and subcutaneous tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Rash	1 (7.1)	1 (7.1)	0
Vascular disorders			
-Total	5 (35.7)	0	5 (35.7)
Hypertension	5 (35.7)	0	5 (35.7)

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- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233b
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	34 (85.0)	2 (5.0)	32 (80.0)
Blood and lymphatic system disorders			
-Total	8 (20.0)	3 (7.5)	5 (12.5)
Anaemia	8 (20.0)	3 (7.5)	5 (12.5)
Cardiac disorders			
-Total	8 (20.0)	3 (7.5)	5 (12.5)
Tachycardia	7 (17.5)	3 (7.5)	4 (10.0)
Sinus tachycardia	1 (2.5)	0	1 (2.5)
Gastrointestinal disorders			
-Total	19 (47.5)	8 (20.0)	11 (27.5)

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	12 (30.0)	9 (22.5)	3 (7.5)
Nausea	10 (25.0)	4 (10.0)	6 (15.0)
Diarrhoea	7 (17.5)	3 (7.5)	4 (10.0)
Abdominal pain	5 (12.5)	3 (7.5)	2 (5.0)
Constipation	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	17 (42.5)	5 (12.5)	12 (30.0)
Pyrexia	12 (30.0)	2 (5.0)	10 (25.0)
Chills	5 (12.5)	5 (12.5)	0
Fatigue	4 (10.0)	3 (7.5)	1 (2.5)
Catheter site pain	2 (5.0)	0	2 (5.0)
Immune system disorders			
-Total	27 (67.5)	5 (12.5)	22 (55.0)
Cytokine release syndrome	23 (57.5)	5 (12.5)	18 (45.0)
Hypogammaglobulinaemia	15 (37.5)	2 (5.0)	13 (32.5)
Infections and infestations			
-Total	8 (20.0)	3 (7.5)	5 (12.5)

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	6 (15.0)	2 (5.0)	4 (10.0)
Clostridium difficile infection	1 (2.5)	0	1 (2.5)
Rhinovirus infection	1 (2.5)	1 (2.5)	0
Investigations			
-Total	18 (45.0)	1 (2.5)	17 (42.5)
White blood cell count decreased	8 (20.0)	3 (7.5)	5 (12.5)
Aspartate aminotransferase increased	7 (17.5)	2 (5.0)	5 (12.5)
International normalised ratio increased	5 (12.5)	4 (10.0)	1 (2.5)
Activated partial thromboplastin time prolonged	4 (10.0)	2 (5.0)	2 (5.0)
Alanine aminotransferase increased	4 (10.0)	1 (2.5)	3 (7.5)
Blood bilirubin increased	4 (10.0)	2 (5.0)	2 (5.0)
Lymphocyte count decreased	4 (10.0)	1 (2.5)	3 (7.5)
Platelet count decreased	4 (10.0)	2 (5.0)	2 (5.0)
Blood creatinine increased	2 (5.0)	2 (5.0)	0
Prothrombin time prolonged	2 (5.0)	1 (2.5)	1 (2.5)
Weight decreased	1 (2.5)	1 (2.5)	0

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	13 (32.5)	8 (20.0)	5 (12.5)
Decreased appetite	6 (15.0)	3 (7.5)	3 (7.5)
Hypokalaemia	6 (15.0)	4 (10.0)	2 (5.0)
Hyperphosphataemia	3 (7.5)	2 (5.0)	1 (2.5)
Hypophosphataemia	2 (5.0)	2 (5.0)	0
Hypocalcaemia	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Pain in extremity	2 (5.0)	1 (2.5)	1 (2.5)
Nervous system disorders			
-Total	12 (30.0)	8 (20.0)	4 (10.0)
Headache	11 (27.5)	7 (17.5)	4 (10.0)
Dizziness	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	7 (17.5)	4 (10.0)	3 (7.5)
Confusional state	5 (12.5)	3 (7.5)	2 (5.0)

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Anxiety	3 (7.5)	1 (2.5)	2 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (32.5)	2 (5.0)	11 (27.5)
Cough	6 (15.0)	4 (10.0)	2 (5.0)
Pleural effusion	5 (12.5)	1 (2.5)	4 (10.0)
Epistaxis	4 (10.0)	1 (2.5)	3 (7.5)
Hypoxia	3 (7.5)	0	3 (7.5)
Rhinorrhoea	2 (5.0)	1 (2.5)	1 (2.5)
Oropharyngeal pain	1 (2.5)	0	1 (2.5)
Rhinitis allergic	1 (2.5)	1 (2.5)	0
Skin and subcutaneous tissue disorders			
-Total	9 (22.5)	8 (20.0)	1 (2.5)
Erythema	4 (10.0)	4 (10.0)	0
Rash	3 (7.5)	2 (5.0)	1 (2.5)
Dry skin	1 (2.5)	1 (2.5)	0
Pruritus	1 (2.5)	1 (2.5)	0
Vascular disorders			

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	9 (22.5)	3 (7.5)	6 (15.0)
Hypertension	9 (22.5)	3 (7.5)	6 (15.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233b
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	34 (97.1)	1 (2.9)	33 (94.3)
Blood and lymphatic system disorders			
-Total	6 (17.1)	1 (2.9)	5 (14.3)
Anaemia	6 (17.1)	1 (2.9)	5 (14.3)
Cardiac disorders			
-Total	13 (37.1)	8 (22.9)	5 (14.3)
Tachycardia	9 (25.7)	6 (17.1)	3 (8.6)
Sinus tachycardia	5 (14.3)	3 (8.6)	2 (5.7)
Gastrointestinal disorders			
-Total	28 (80.0)	8 (22.9)	20 (57.1)

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Nausea	20 (57.1)	5 (14.3)	15 (42.9)
Diarrhoea	18 (51.4)	11 (31.4)	7 (20.0)
Vomiting	15 (42.9)	8 (22.9)	7 (20.0)
Constipation	10 (28.6)	8 (22.9)	2 (5.7)
Abdominal pain	9 (25.7)	4 (11.4)	5 (14.3)
General disorders and administration site conditions			
-Total	27 (77.1)	14 (40.0)	13 (37.1)
Pyrexia	17 (48.6)	7 (20.0)	10 (28.6)
Fatigue	13 (37.1)	10 (28.6)	3 (8.6)
Chills	6 (17.1)	4 (11.4)	2 (5.7)
Catheter site pain	5 (14.3)	3 (8.6)	2 (5.7)
Oedema peripheral	4 (11.4)	3 (8.6)	1 (2.9)
Immune system disorders			
-Total	27 (77.1)	2 (5.7)	25 (71.4)
Cytokine release syndrome	22 (62.9)	2 (5.7)	20 (57.1)
Hypogammaglobulinaemia	13 (37.1)	2 (5.7)	11 (31.4)
Infections and infestations			

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (31.4)	5 (14.3)	6 (17.1)
Rhinovirus infection	5 (14.3)	4 (11.4)	1 (2.9)
Clostridium difficile infection	4 (11.4)	0	4 (11.4)
Upper respiratory tract infection	4 (11.4)	3 (8.6)	1 (2.9)
Injury, poisoning and procedural complications			
-Total	8 (22.9)	3 (8.6)	5 (14.3)
Procedural pain	5 (14.3)	2 (5.7)	3 (8.6)
Transfusion reaction	4 (11.4)	2 (5.7)	2 (5.7)
Investigations			
-Total	22 (62.9)	3 (8.6)	19 (54.3)
Alanine aminotransferase increased	10 (28.6)	4 (11.4)	6 (17.1)
Aspartate aminotransferase increased	9 (25.7)	6 (17.1)	3 (8.6)
White blood cell count decreased	9 (25.7)	3 (8.6)	6 (17.1)
Prothrombin time prolonged	7 (20.0)	4 (11.4)	3 (8.6)
Blood creatinine increased	5 (14.3)	3 (8.6)	2 (5.7)
International normalised ratio increased	5 (14.3)	5 (14.3)	0

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Weight decreased	4 (11.4)	1 (2.9)	3 (8.6)
Blood bilirubin increased	3 (8.6)	0	3 (8.6)
Lymphocyte count decreased	3 (8.6)	1 (2.9)	2 (5.7)
Activated partial thromboplastin time prolonged	2 (5.7)	1 (2.9)	1 (2.9)
Platelet count decreased	2 (5.7)	1 (2.9)	1 (2.9)
Metabolism and nutrition disorders			
-Total	23 (65.7)	12 (34.3)	11 (31.4)
Decreased appetite	13 (37.1)	8 (22.9)	5 (14.3)
Hyperphosphataemia	6 (17.1)	6 (17.1)	0
Hypokalaemia	6 (17.1)	1 (2.9)	5 (14.3)
Hypocalcaemia	4 (11.4)	2 (5.7)	2 (5.7)
Hypophosphataemia	4 (11.4)	3 (8.6)	1 (2.9)
Musculoskeletal and connective tissue disorders			
-Total	9 (25.7)	6 (17.1)	3 (8.6)
Pain in extremity	9 (25.7)	6 (17.1)	3 (8.6)
Nervous system disorders			
-Total	19 (54.3)	11 (31.4)	8 (22.9)

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	17 (48.6)	9 (25.7)	8 (22.9)
Dizziness	5 (14.3)	5 (14.3)	0
Psychiatric disorders			
-Total	7 (20.0)	2 (5.7)	5 (14.3)
Anxiety	5 (14.3)	2 (5.7)	3 (8.6)
Confusional state	2 (5.7)	0	2 (5.7)
Respiratory, thoracic and mediastinal disorders			
-Total	20 (57.1)	11 (31.4)	9 (25.7)
Cough	9 (25.7)	9 (25.7)	0
Epistaxis	5 (14.3)	3 (8.6)	2 (5.7)
Hypoxia	5 (14.3)	0	5 (14.3)
Oropharyngeal pain	5 (14.3)	4 (11.4)	1 (2.9)
Rhinitis allergic	4 (11.4)	3 (8.6)	1 (2.9)
Rhinorrhoea	4 (11.4)	4 (11.4)	0
Pleural effusion	2 (5.7)	0	2 (5.7)
Skin and subcutaneous tissue disorders			
-Total	12 (34.3)	9 (25.7)	3 (8.6)

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Rash	6 (17.1)	4 (11.4)	2 (5.7)
Dry skin	4 (11.4)	4 (11.4)	0
Petechiae	4 (11.4)	3 (8.6)	1 (2.9)
Pruritus	4 (11.4)	4 (11.4)	0
Erythema	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	5 (14.3)	1 (2.9)	4 (11.4)
Hypertension	5 (14.3)	1 (2.9)	4 (11.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233c
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	56 (93.3)	1 (1.7)	55 (91.7)
Blood and lymphatic system disorders			
-Total	14 (23.3)	4 (6.7)	10 (16.7)
Anaemia	12 (20.0)	4 (6.7)	8 (13.3)
Disseminated intravascular coagulation	2 (3.3)	0	2 (3.3)
Lymphopenia	1 (1.7)	0	1 (1.7)
Cardiac disorders			
-Total	18 (30.0)	7 (11.7)	11 (18.3)
Tachycardia	12 (20.0)	5 (8.3)	7 (11.7)
Sinus tachycardia	6 (10.0)	3 (5.0)	3 (5.0)

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pericardial effusion	2 (3.3)	1 (1.7)	1 (1.7)
Endocrine disorders			
-Total	2 (3.3)	1 (1.7)	1 (1.7)
Adrenal insufficiency	2 (3.3)	1 (1.7)	1 (1.7)
Eye disorders			
-Total	9 (15.0)	5 (8.3)	4 (6.7)
Periorbital oedema	3 (5.0)	2 (3.3)	1 (1.7)
Vision blurred	3 (5.0)	2 (3.3)	1 (1.7)
Conjunctival haemorrhage	2 (3.3)	2 (3.3)	0
Photophobia	2 (3.3)	1 (1.7)	1 (1.7)
Dry eye	1 (1.7)	0	1 (1.7)
Uveitis	1 (1.7)	0	1 (1.7)
Gastrointestinal disorders			
-Total	40 (66.7)	15 (25.0)	25 (41.7)
Nausea	22 (36.7)	5 (8.3)	17 (28.3)
Vomiting	22 (36.7)	12 (20.0)	10 (16.7)
Diarrhoea	21 (35.0)	12 (20.0)	9 (15.0)
Abdominal pain	12 (20.0)	6 (10.0)	6 (10.0)

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Constipation	9 (15.0)	7 (11.7)	2 (3.3)
Abdominal pain upper	2 (3.3)	1 (1.7)	1 (1.7)
Abdominal pain lower	1 (1.7)	0	1 (1.7)
General disorders and administration site conditions			
-Total	34 (56.7)	12 (20.0)	22 (36.7)
Pyrexia	23 (38.3)	6 (10.0)	17 (28.3)
Fatigue	13 (21.7)	9 (15.0)	4 (6.7)
Chills	9 (15.0)	9 (15.0)	0
Catheter site pain	5 (8.3)	1 (1.7)	4 (6.7)
Malaise	3 (5.0)	1 (1.7)	2 (3.3)
Oedema peripheral	2 (3.3)	2 (3.3)	0
Pain	2 (3.3)	1 (1.7)	1 (1.7)
Hepatobiliary disorders			
-Total	2 (3.3)	0	2 (3.3)
Hyperbilirubinaemia	2 (3.3)	0	2 (3.3)
Immune system disorders			
-Total	43 (71.7)	5 (8.3)	38 (63.3)

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Cytokine release syndrome	36 (60.0)	5 (8.3)	31 (51.7)
Hypogammaglobulinaemia	22 (36.7)	2 (3.3)	20 (33.3)
Seasonal allergy	1 (1.7)	1 (1.7)	0
Infections and infestations			
-Total	22 (36.7)	6 (10.0)	16 (26.7)
Upper respiratory tract infection	9 (15.0)	4 (6.7)	5 (8.3)
Rhinovirus infection	5 (8.3)	5 (8.3)	0
Clostridium difficile infection	4 (6.7)	0	4 (6.7)
Otitis media	3 (5.0)	0	3 (5.0)
Urinary tract infection	3 (5.0)	0	3 (5.0)
Clostridium difficile colitis	2 (3.3)	1 (1.7)	1 (1.7)
Viral infection	2 (3.3)	1 (1.7)	1 (1.7)
Viral upper respiratory tract infection	2 (3.3)	2 (3.3)	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0
Injury, poisoning and procedural complications			
-Total	5 (8.3)	2 (3.3)	3 (5.0)
Procedural pain	3 (5.0)	2 (3.3)	1 (1.7)

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Transfusion reaction	3 (5.0)	1 (1.7)	2 (3.3)
Investigations			
-Total	34 (56.7)	2 (3.3)	32 (53.3)
White blood cell count decreased	14 (23.3)	5 (8.3)	9 (15.0)
Alanine aminotransferase increased	11 (18.3)	4 (6.7)	7 (11.7)
Aspartate aminotransferase increased	11 (18.3)	6 (10.0)	5 (8.3)
International normalised ratio increased	8 (13.3)	7 (11.7)	1 (1.7)
Blood bilirubin increased	7 (11.7)	2 (3.3)	5 (8.3)
Prothrombin time prolonged	7 (11.7)	4 (6.7)	3 (5.0)
Platelet count decreased	6 (10.0)	3 (5.0)	3 (5.0)
Activated partial thromboplastin time prolonged	5 (8.3)	2 (3.3)	3 (5.0)
Blood creatinine increased	5 (8.3)	4 (6.7)	1 (1.7)
Lymphocyte count decreased	5 (8.3)	1 (1.7)	4 (6.7)
Neutrophil count decreased	4 (6.7)	2 (3.3)	2 (3.3)
Weight decreased	4 (6.7)	1 (1.7)	3 (5.0)
Blood immunoglobulin m decreased	3 (5.0)	3 (5.0)	0

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
C-reactive protein increased	2 (3.3)	0	2 (3.3)
Blood immunoglobulin a decreased	1 (1.7)	1 (1.7)	0
Blood uric acid increased	1 (1.7)	1 (1.7)	0
Haemoglobin decreased	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	33 (55.0)	10 (16.7)	23 (38.3)
Decreased appetite	14 (23.3)	6 (10.0)	8 (13.3)
Hypokalaemia	11 (18.3)	4 (6.7)	7 (11.7)
Hyperphosphataemia	7 (11.7)	6 (10.0)	1 (1.7)
Hypoalbuminaemia	6 (10.0)	1 (1.7)	5 (8.3)
Hypophosphataemia	6 (10.0)	5 (8.3)	1 (1.7)
Hypernatraemia	4 (6.7)	0	4 (6.7)
Hypocalcaemia	4 (6.7)	2 (3.3)	2 (3.3)
Hyperglycaemia	2 (3.3)	0	2 (3.3)
Hyperuricaemia	2 (3.3)	2 (3.3)	0
Vitamin d deficiency	2 (3.3)	2 (3.3)	0
Musculoskeletal and connective tissue disorders			

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	15 (25.0)	10 (16.7)	5 (8.3)
Pain in extremity	6 (10.0)	3 (5.0)	3 (5.0)
Arthralgia	5 (8.3)	4 (6.7)	1 (1.7)
Myalgia	3 (5.0)	2 (3.3)	1 (1.7)
Pain in jaw	3 (5.0)	2 (3.3)	1 (1.7)
Muscle spasms	2 (3.3)	2 (3.3)	0
Muscular weakness	2 (3.3)	1 (1.7)	1 (1.7)
Musculoskeletal chest pain	2 (3.3)	2 (3.3)	0
Joint range of motion decreased	1 (1.7)	1 (1.7)	0
Nervous system disorders			
-Total	29 (48.3)	17 (28.3)	12 (20.0)
Headache	22 (36.7)	14 (23.3)	8 (13.3)
Dizziness	6 (10.0)	6 (10.0)	0
Encephalopathy	2 (3.3)	0	2 (3.3)
Dysarthria	1 (1.7)	0	1 (1.7)
Neuropathy peripheral	1 (1.7)	1 (1.7)	0
Seizure	1 (1.7)	0	1 (1.7)
Tremor	1 (1.7)	1 (1.7)	0

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Product issues			
-Total	1 (1.7)	1 (1.7)	0
Device occlusion	1 (1.7)	1 (1.7)	0
Psychiatric disorders			
-Total	15 (25.0)	8 (13.3)	7 (11.7)
Confusional state	7 (11.7)	3 (5.0)	4 (6.7)
Anxiety	6 (10.0)	3 (5.0)	3 (5.0)
Delirium	3 (5.0)	2 (3.3)	1 (1.7)
Depression	3 (5.0)	2 (3.3)	1 (1.7)
Agitation	1 (1.7)	0	1 (1.7)
Renal and urinary disorders			
-Total	3 (5.0)	1 (1.7)	2 (3.3)
Acute kidney injury	2 (3.3)	0	2 (3.3)
Dysuria	1 (1.7)	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	30 (50.0)	12 (20.0)	18 (30.0)
Cough	12 (20.0)	10 (16.7)	2 (3.3)

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypoxia	8 (13.3)	0	8 (13.3)
Epistaxis	7 (11.7)	3 (5.0)	4 (6.7)
Pleural effusion	7 (11.7)	1 (1.7)	6 (10.0)
Nasal congestion	5 (8.3)	5 (8.3)	0
Oropharyngeal pain	5 (8.3)	4 (6.7)	1 (1.7)
Rhinorrhoea	5 (8.3)	4 (6.7)	1 (1.7)
Rhinitis allergic	4 (6.7)	3 (5.0)	1 (1.7)
Skin and subcutaneous tissue disorders			
-Total	17 (28.3)	12 (20.0)	5 (8.3)
Rash	6 (10.0)	5 (8.3)	1 (1.7)
Erythema	4 (6.7)	4 (6.7)	0
Rash erythematous	4 (6.7)	1 (1.7)	3 (5.0)
Hyperhidrosis	3 (5.0)	3 (5.0)	0
Pruritus	3 (5.0)	3 (5.0)	0
Dry skin	2 (3.3)	2 (3.3)	0
Night sweats	1 (1.7)	0	1 (1.7)
Rash pruritic	1 (1.7)	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Vascular disorders			
-Total	12 (20.0)	5 (8.3)	7 (11.7)
Hypertension	11 (18.3)	4 (6.7)	7 (11.7)
Orthostatic hypotension	1 (1.7)	1 (1.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233c
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (100)	0	6 (100)
Blood and lymphatic system disorders			
-Total	1 (16.7)	0	1 (16.7)
Anaemia	1 (16.7)	0	1 (16.7)
Lymphopenia	1 (16.7)	0	1 (16.7)
Cardiac disorders			
-Total	1 (16.7)	1 (16.7)	0
Atrioventricular block second degree	1 (16.7)	1 (16.7)	0
Gastrointestinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)

Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	1 (16.7)	0	1 (16.7)
Dry mouth	1 (16.7)	1 (16.7)	0
Nausea	1 (16.7)	1 (16.7)	0
Vomiting	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
-Total	5 (83.3)	3 (50.0)	2 (33.3)
Fatigue	3 (50.0)	3 (50.0)	0
Pyrexia	2 (33.3)	1 (16.7)	1 (16.7)
Oedema peripheral	1 (16.7)	1 (16.7)	0
Pain	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	5 (83.3)	0	5 (83.3)
Cytokine release syndrome	4 (66.7)	0	4 (66.7)
Hypogammaglobulinaemia	3 (50.0)	1 (16.7)	2 (33.3)
Infections and infestations			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Gingivitis	1 (16.7)	1 (16.7)	0

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Molluscum contagiosum	1 (16.7)	1 (16.7)	0
Pharyngitis	1 (16.7)	0	1 (16.7)
Streptococcal infection	1 (16.7)	0	1 (16.7)
Viral infection	1 (16.7)	1 (16.7)	0
Viral upper respiratory tract infection	1 (16.7)	0	1 (16.7)
Investigations			
-Total	1 (16.7)	0	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	0	1 (16.7)
Aspartate aminotransferase increased	1 (16.7)	1 (16.7)	0
Blood immunoglobulin a decreased	1 (16.7)	1 (16.7)	0
Blood uric acid increased	1 (16.7)	1 (16.7)	0
International normalised ratio increased	1 (16.7)	1 (16.7)	0
Lymphocyte count decreased	1 (16.7)	0	1 (16.7)
Neutrophil count decreased	1 (16.7)	0	1 (16.7)
White blood cell count decreased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	2 (33.3)	2 (33.3)	0

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Decreased appetite	1 (16.7)	1 (16.7)	0
Hyperphosphataemia	1 (16.7)	1 (16.7)	0
Hyperuricaemia	1 (16.7)	1 (16.7)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (83.3)	2 (33.3)	3 (50.0)
Pain in extremity	3 (50.0)	2 (33.3)	1 (16.7)
Arthralgia	1 (16.7)	1 (16.7)	0
Joint range of motion decreased	1 (16.7)	1 (16.7)	0
Myalgia	1 (16.7)	1 (16.7)	0
Osteonecrosis	1 (16.7)	0	1 (16.7)
Pain in jaw	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	2 (33.3)	2 (33.3)	0
Headache	2 (33.3)	2 (33.3)	0
Renal and urinary disorders			
-Total	1 (16.7)	0	1 (16.7)
Dysuria	1 (16.7)	0	1 (16.7)

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pollakiuria	1 (16.7)	1 (16.7)	0
Skin and subcutaneous tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Pruritus generalised	1 (16.7)	1 (16.7)	0
Rash	1 (16.7)	0	1 (16.7)
Vascular disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypertension	1 (16.7)	0	1 (16.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233c
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	9 (100)	0	9 (100)
Blood and lymphatic system disorders			
-Total	4 (44.4)	1 (11.1)	3 (33.3)
Anaemia	1 (11.1)	0	1 (11.1)
Disseminated intravascular coagulation	1 (11.1)	0	1 (11.1)
Leukocytosis	1 (11.1)	1 (11.1)	0
Lymphadenopathy	1 (11.1)	0	1 (11.1)
Cardiac disorders			
-Total	4 (44.4)	2 (22.2)	2 (22.2)

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Tachycardia	4 (44.4)	4 (44.4)	0
Pericardial effusion	1 (11.1)	0	1 (11.1)
Ventricular tachycardia	1 (11.1)	0	1 (11.1)
Endocrine disorders			
-Total	1 (11.1)	0	1 (11.1)
Adrenal insufficiency	1 (11.1)	0	1 (11.1)
Eye disorders			
-Total	4 (44.4)	1 (11.1)	3 (33.3)
Conjunctival haemorrhage	1 (11.1)	1 (11.1)	0
Dry eye	1 (11.1)	1 (11.1)	0
Periorbital oedema	1 (11.1)	1 (11.1)	0
Photophobia	1 (11.1)	0	1 (11.1)
Retinopathy	1 (11.1)	0	1 (11.1)
Uveitis	1 (11.1)	0	1 (11.1)
Vision blurred	1 (11.1)	0	1 (11.1)
Gastrointestinal disorders			
-Total	7 (77.8)	1 (11.1)	6 (66.7)
Nausea	7 (77.8)	3 (33.3)	4 (44.4)

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	4 (44.4)	4 (44.4)	0
Diarrhoea	3 (33.3)	2 (22.2)	1 (11.1)
Abdominal pain	2 (22.2)	1 (11.1)	1 (11.1)
Constipation	2 (22.2)	2 (22.2)	0
Abdominal pain lower	1 (11.1)	1 (11.1)	0
Abdominal pain upper	1 (11.1)	0	1 (11.1)
Dysphagia	1 (11.1)	0	1 (11.1)
Flatulence	1 (11.1)	1 (11.1)	0
Haematochezia	1 (11.1)	1 (11.1)	0
Lip pain	1 (11.1)	0	1 (11.1)
General disorders and administration site conditions			
-Total	7 (77.8)	1 (11.1)	6 (66.7)
Pyrexia	4 (44.4)	2 (22.2)	2 (22.2)
Catheter site pain	2 (22.2)	2 (22.2)	0
Chills	2 (22.2)	0	2 (22.2)
Catheter site haemorrhage	1 (11.1)	1 (11.1)	0
Device related thrombosis	1 (11.1)	0	1 (11.1)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Fatigue	1 (11.1)	1 (11.1)	0
Injection site haematoma	1 (11.1)	1 (11.1)	0
Malaise	1 (11.1)	0	1 (11.1)
Oedema peripheral	1 (11.1)	0	1 (11.1)
Pain	1 (11.1)	0	1 (11.1)
Hepatobiliary disorders			
-Total	3 (33.3)	1 (11.1)	2 (22.2)
Gallbladder enlargement	1 (11.1)	1 (11.1)	0
Hepatic steatosis	1 (11.1)	0	1 (11.1)
Hyperbilirubinaemia	1 (11.1)	0	1 (11.1)
Immune system disorders			
-Total	6 (66.7)	2 (22.2)	4 (44.4)
Cytokine release syndrome	5 (55.6)	2 (22.2)	3 (33.3)
Hypogammaglobulinaemia	3 (33.3)	1 (11.1)	2 (22.2)
Immunodeficiency common variable	2 (22.2)	0	2 (22.2)
Immunodeficiency	1 (11.1)	0	1 (11.1)
Seasonal allergy	1 (11.1)	1 (11.1)	0
Infections and infestations			

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	5 (55.6)	0	5 (55.6)
Catheter site cellulitis	1 (11.1)	1 (11.1)	0
Clostridium difficile colitis	1 (11.1)	0	1 (11.1)
Clostridium difficile infection	1 (11.1)	0	1 (11.1)
Cytomegalovirus infection	1 (11.1)	1 (11.1)	0
Herpes simplex	1 (11.1)	1 (11.1)	0
Meningitis aseptic	1 (11.1)	0	1 (11.1)
Oral herpes	1 (11.1)	0	1 (11.1)
Otitis media	1 (11.1)	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	1 (11.1)
Rhinitis	1 (11.1)	1 (11.1)	0
Rhinovirus infection	1 (11.1)	0	1 (11.1)
Staphylococcal scalded skin syndrome	1 (11.1)	0	1 (11.1)
Upper respiratory tract infection	1 (11.1)	1 (11.1)	0
Urinary tract infection	1 (11.1)	0	1 (11.1)
Vulvovaginal mycotic infection	1 (11.1)	0	1 (11.1)
Injury, poisoning and procedural complications			

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	4 (44.4)	2 (22.2)	2 (22.2)
Procedural pain	2 (22.2)	0	2 (22.2)
Arthropod bite	1 (11.1)	1 (11.1)	0
Post procedural haemorrhage	1 (11.1)	1 (11.1)	0
Transfusion reaction	1 (11.1)	1 (11.1)	0
Investigations			
-Total	6 (66.7)	1 (11.1)	5 (55.6)
Aspartate aminotransferase increased	4 (44.4)	1 (11.1)	3 (33.3)
Alanine aminotransferase increased	2 (22.2)	1 (11.1)	1 (11.1)
Blood creatinine increased	2 (22.2)	1 (11.1)	1 (11.1)
Prothrombin time prolonged	2 (22.2)	1 (11.1)	1 (11.1)
White blood cell count decreased	2 (22.2)	1 (11.1)	1 (11.1)
Activated partial thromboplastin time prolonged	1 (11.1)	1 (11.1)	0
Blood alkaline phosphatase increased	1 (11.1)	1 (11.1)	0
Blood immunoglobulin a decreased	1 (11.1)	1 (11.1)	0
Blood immunoglobulin m decreased	1 (11.1)	1 (11.1)	0

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood lactate dehydrogenase increased	1 (11.1)	1 (11.1)	0
C-reactive protein increased	1 (11.1)	1 (11.1)	0
Culture stool positive	1 (11.1)	1 (11.1)	0
Haemoglobin decreased	1 (11.1)	1 (11.1)	0
Hepatic enzyme increased	1 (11.1)	0	1 (11.1)
International normalised ratio increased	1 (11.1)	1 (11.1)	0
Lymphocyte count decreased	1 (11.1)	1 (11.1)	0
Neutrophil count decreased	1 (11.1)	0	1 (11.1)
Weight decreased	1 (11.1)	1 (11.1)	0
Metabolism and nutrition disorders			
-Total	6 (66.7)	4 (44.4)	2 (22.2)
Decreased appetite	4 (44.4)	4 (44.4)	0
Hyperglycaemia	2 (22.2)	0	2 (22.2)
Acidosis	1 (11.1)	1 (11.1)	0
Hypernatraemia	1 (11.1)	1 (11.1)	0
Hyperphosphataemia	1 (11.1)	1 (11.1)	0
Hypocalcaemia	1 (11.1)	1 (11.1)	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypokalaemia	1 (11.1)	1 (11.1)	0
Vitamin d deficiency	1 (11.1)	0	1 (11.1)
Musculoskeletal and connective tissue disorders			
-Total	5 (55.6)	4 (44.4)	1 (11.1)
Pain in extremity	2 (22.2)	2 (22.2)	0
Coccydynia	1 (11.1)	1 (11.1)	0
Muscle spasms	1 (11.1)	1 (11.1)	0
Muscular weakness	1 (11.1)	1 (11.1)	0
Musculoskeletal chest pain	1 (11.1)	1 (11.1)	0
Myalgia	1 (11.1)	1 (11.1)	0
Synovitis	1 (11.1)	0	1 (11.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (11.1)	0	1 (11.1)
Myelodysplastic syndrome	1 (11.1)	0	1 (11.1)
Nervous system disorders			
-Total	5 (55.6)	1 (11.1)	4 (44.4)
Headache	4 (44.4)	0	4 (44.4)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Asterixis	1 (11.1)	1 (11.1)	0
Ataxia	1 (11.1)	0	1 (11.1)
Dysarthria	1 (11.1)	1 (11.1)	0
Encephalopathy	1 (11.1)	1 (11.1)	0
Myoclonus	1 (11.1)	1 (11.1)	0
Neuropathy peripheral	1 (11.1)	0	1 (11.1)
Pleocytosis	1 (11.1)	1 (11.1)	0
Seizure	1 (11.1)	0	1 (11.1)
Tremor	1 (11.1)	1 (11.1)	0
Product issues			
-Total	1 (11.1)	1 (11.1)	0
Device occlusion	1 (11.1)	1 (11.1)	0
Psychiatric disorders			
-Total	2 (22.2)	0	2 (22.2)
Anxiety	2 (22.2)	0	2 (22.2)
Adjustment disorder	1 (11.1)	0	1 (11.1)
Agitation	1 (11.1)	0	1 (11.1)
Delirium	1 (11.1)	0	1 (11.1)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Depression	1 (11.1)	0	1 (11.1)
Suicidal ideation	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Acute kidney injury	2 (22.2)	2 (22.2)	0
Dysuria	1 (11.1)	0	1 (11.1)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (55.6)	3 (33.3)	2 (22.2)
Cough	3 (33.3)	3 (33.3)	0
Epistaxis	2 (22.2)	1 (11.1)	1 (11.1)
Haemoptysis	1 (11.1)	1 (11.1)	0
Nasal congestion	1 (11.1)	1 (11.1)	0
Nasal discomfort	1 (11.1)	1 (11.1)	0
Oropharyngeal pain	1 (11.1)	0	1 (11.1)
Rhinitis allergic	1 (11.1)	1 (11.1)	0
Rhinorrhoea	1 (11.1)	1 (11.1)	0
Skin and subcutaneous tissue disorders			

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	5 (55.6)	4 (44.4)	1 (11.1)
Dry skin	3 (33.3)	3 (33.3)	0
Pruritus	2 (22.2)	2 (22.2)	0
Rash	2 (22.2)	1 (11.1)	1 (11.1)
Cold sweat	1 (11.1)	1 (11.1)	0
Dermatitis	1 (11.1)	1 (11.1)	0
Dermatitis atopic	1 (11.1)	1 (11.1)	0
Eczema	1 (11.1)	1 (11.1)	0
Erythema	1 (11.1)	1 (11.1)	0
Hyperhidrosis	1 (11.1)	1 (11.1)	0
Night sweats	1 (11.1)	1 (11.1)	0
Rash erythematous	1 (11.1)	1 (11.1)	0
Rash pruritic	1 (11.1)	1 (11.1)	0
Rash vesicular	1 (11.1)	1 (11.1)	0
Skin exfoliation	1 (11.1)	1 (11.1)	0
Skin fissures	1 (11.1)	1 (11.1)	0
Vascular disorders			
-Total	4 (44.4)	0	4 (44.4)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypertension	2 (22.2)	0	2 (22.2)
Orthostatic hypotension	1 (11.1)	0	1 (11.1)
Secondary hypertension	1 (11.1)	0	1 (11.1)
Venous thrombosis limb	1 (11.1)	1 (11.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233d
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	28 (93.3)	0	28 (93.3)
Blood and lymphatic system disorders			
-Total	7 (23.3)	3 (10.0)	4 (13.3)
Anaemia	7 (23.3)	3 (10.0)	4 (13.3)
Cardiac disorders			
-Total	7 (23.3)	6 (20.0)	1 (3.3)
Tachycardia	7 (23.3)	6 (20.0)	1 (3.3)
Gastrointestinal disorders			
-Total	19 (63.3)	6 (20.0)	13 (43.3)
Nausea	12 (40.0)	1 (3.3)	11 (36.7)

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	12 (40.0)	8 (26.7)	4 (13.3)
Diarrhoea	9 (30.0)	5 (16.7)	4 (13.3)
Abdominal pain	4 (13.3)	3 (10.0)	1 (3.3)
Constipation	3 (10.0)	3 (10.0)	0
General disorders and administration site conditions			
-Total	14 (46.7)	5 (16.7)	9 (30.0)
Pyrexia	8 (26.7)	3 (10.0)	5 (16.7)
Chills	5 (16.7)	3 (10.0)	2 (6.7)
Fatigue	3 (10.0)	3 (10.0)	0
Pain	3 (10.0)	1 (3.3)	2 (6.7)
Catheter site pain	1 (3.3)	0	1 (3.3)
Immune system disorders			
-Total	22 (73.3)	1 (3.3)	21 (70.0)
Cytokine release syndrome	18 (60.0)	2 (6.7)	16 (53.3)
Hypogammaglobulinaemia	14 (46.7)	0	14 (46.7)
Infections and infestations			
-Total	14 (46.7)	3 (10.0)	11 (36.7)

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Influenza	4 (13.3)	1 (3.3)	3 (10.0)
Upper respiratory tract infection	4 (13.3)	2 (6.7)	2 (6.7)
Otitis media	3 (10.0)	0	3 (10.0)
Parainfluenzae virus infection	3 (10.0)	2 (6.7)	1 (3.3)
Urinary tract infection	3 (10.0)	0	3 (10.0)
Rhinovirus infection	1 (3.3)	1 (3.3)	0
Injury, poisoning and procedural complications			
-Total	3 (10.0)	1 (3.3)	2 (6.7)
Procedural pain	3 (10.0)	1 (3.3)	2 (6.7)
Investigations			
-Total	13 (43.3)	0	13 (43.3)
Platelet count decreased	5 (16.7)	3 (10.0)	2 (6.7)
White blood cell count decreased	5 (16.7)	1 (3.3)	4 (13.3)
Alanine aminotransferase increased	4 (13.3)	1 (3.3)	3 (10.0)
Aspartate aminotransferase increased	4 (13.3)	2 (6.7)	2 (6.7)
Blood creatinine increased	4 (13.3)	4 (13.3)	0

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Activated partial thromboplastin time prolonged	3 (10.0)	2 (6.7)	1 (3.3)
Blood bilirubin increased	3 (10.0)	1 (3.3)	2 (6.7)
Lymphocyte count decreased	2 (6.7)	1 (3.3)	1 (3.3)
Prothrombin time prolonged	2 (6.7)	1 (3.3)	1 (3.3)
International normalised ratio increased	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			
-Total	17 (56.7)	7 (23.3)	10 (33.3)
Decreased appetite	10 (33.3)	5 (16.7)	5 (16.7)
Hypokalaemia	6 (20.0)	3 (10.0)	3 (10.0)
Hyperphosphataemia	5 (16.7)	4 (13.3)	1 (3.3)
Hypernatraemia	3 (10.0)	1 (3.3)	2 (6.7)
Hypoalbuminaemia	1 (3.3)	0	1 (3.3)
Musculoskeletal and connective tissue disorders			
-Total	6 (20.0)	6 (20.0)	0
Arthralgia	3 (10.0)	3 (10.0)	0
Pain in extremity	3 (10.0)	3 (10.0)	0

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nervous system disorders			
-Total	11 (36.7)	7 (23.3)	4 (13.3)
Headache	11 (36.7)	7 (23.3)	4 (13.3)
Psychiatric disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Anxiety	1 (3.3)	0	1 (3.3)
Confusional state	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	16 (53.3)	10 (33.3)	6 (20.0)
Cough	6 (20.0)	4 (13.3)	2 (6.7)
Nasal congestion	5 (16.7)	5 (16.7)	0
Rhinorrhoea	5 (16.7)	4 (13.3)	1 (3.3)
Epistaxis	4 (13.3)	3 (10.0)	1 (3.3)
Oropharyngeal pain	3 (10.0)	2 (6.7)	1 (3.3)
Tachypnoea	3 (10.0)	3 (10.0)	0
Hypoxia	2 (6.7)	0	2 (6.7)
Skin and subcutaneous tissue disorders			

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	7 (23.3)	6 (20.0)	1 (3.3)
Dry skin	3 (10.0)	3 (10.0)	0
Pruritus	3 (10.0)	3 (10.0)	0
Rash	2 (6.7)	1 (3.3)	1 (3.3)
Vascular disorders			
-Total	4 (13.3)	1 (3.3)	3 (10.0)
Hypertension	4 (13.3)	1 (3.3)	3 (10.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233d
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	42 (93.3)	3 (6.7)	39 (86.7)
Blood and lymphatic system disorders			
-Total	7 (15.6)	1 (2.2)	6 (13.3)
Anaemia	7 (15.6)	1 (2.2)	6 (13.3)
Cardiac disorders			
-Total	9 (20.0)	3 (6.7)	6 (13.3)
Tachycardia	9 (20.0)	3 (6.7)	6 (13.3)
Gastrointestinal disorders			
-Total	28 (62.2)	10 (22.2)	18 (40.0)
Nausea	18 (40.0)	8 (17.8)	10 (22.2)

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	16 (35.6)	9 (20.0)	7 (15.6)
Vomiting	15 (33.3)	9 (20.0)	6 (13.3)
Abdominal pain	10 (22.2)	4 (8.9)	6 (13.3)
Constipation	8 (17.8)	6 (13.3)	2 (4.4)
General disorders and administration site conditions			
-Total	31 (68.9)	12 (26.7)	19 (42.2)
Pyrexia	21 (46.7)	6 (13.3)	15 (33.3)
Fatigue	14 (31.1)	10 (22.2)	4 (8.9)
Catheter site pain	6 (13.3)	3 (6.7)	3 (6.7)
Chills	6 (13.3)	6 (13.3)	0
Pain	1 (2.2)	0	1 (2.2)
Immune system disorders			
-Total	32 (71.1)	6 (13.3)	26 (57.8)
Cytokine release syndrome	27 (60.0)	5 (11.1)	22 (48.9)
Hypogammaglobulinaemia	14 (31.1)	4 (8.9)	10 (22.2)
Infections and infestations			
-Total	12 (26.7)	6 (13.3)	6 (13.3)

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	6 (13.3)	3 (6.7)	3 (6.7)
Rhinovirus infection	5 (11.1)	4 (8.9)	1 (2.2)
Otitis media	1 (2.2)	0	1 (2.2)
Urinary tract infection	1 (2.2)	0	1 (2.2)
Injury, poisoning and procedural complications			
-Total	2 (4.4)	1 (2.2)	1 (2.2)
Procedural pain	2 (4.4)	1 (2.2)	1 (2.2)
Investigations			
-Total	24 (53.3)	2 (4.4)	22 (48.9)
Aspartate aminotransferase increased	12 (26.7)	6 (13.3)	6 (13.3)
White blood cell count decreased	12 (26.7)	5 (11.1)	7 (15.6)
Alanine aminotransferase increased	10 (22.2)	4 (8.9)	6 (13.3)
International normalised ratio increased	9 (20.0)	8 (17.8)	1 (2.2)
Prothrombin time prolonged	7 (15.6)	4 (8.9)	3 (6.7)
Lymphocyte count decreased	5 (11.1)	1 (2.2)	4 (8.9)
Blood bilirubin increased	4 (8.9)	1 (2.2)	3 (6.7)

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Activated partial thromboplastin time prolonged	3 (6.7)	1 (2.2)	2 (4.4)
Blood creatinine increased	3 (6.7)	1 (2.2)	2 (4.4)
Platelet count decreased	1 (2.2)	0	1 (2.2)
Metabolism and nutrition disorders			
-Total	19 (42.2)	8 (17.8)	11 (24.4)
Decreased appetite	9 (20.0)	6 (13.3)	3 (6.7)
Hypokalaemia	6 (13.3)	2 (4.4)	4 (8.9)
Hypoalbuminaemia	5 (11.1)	1 (2.2)	4 (8.9)
Hyperphosphataemia	4 (8.9)	4 (8.9)	0
Hypernatraemia	2 (4.4)	0	2 (4.4)
Musculoskeletal and connective tissue disorders			
-Total	12 (26.7)	7 (15.6)	5 (11.1)
Pain in extremity	8 (17.8)	4 (8.9)	4 (8.9)
Myalgia	5 (11.1)	4 (8.9)	1 (2.2)
Arthralgia	3 (6.7)	2 (4.4)	1 (2.2)
Nervous system disorders			
-Total	17 (37.8)	9 (20.0)	8 (17.8)

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	17 (37.8)	9 (20.0)	8 (17.8)
Psychiatric disorders			
-Total	12 (26.7)	5 (11.1)	7 (15.6)
Anxiety	7 (15.6)	3 (6.7)	4 (8.9)
Confusional state	6 (13.3)	2 (4.4)	4 (8.9)
Respiratory, thoracic and mediastinal disorders			
-Total	18 (40.0)	5 (11.1)	13 (28.9)
Cough	9 (20.0)	9 (20.0)	0
Pleural effusion	7 (15.6)	1 (2.2)	6 (13.3)
Hypoxia	6 (13.3)	0	6 (13.3)
Epistaxis	5 (11.1)	1 (2.2)	4 (8.9)
Oropharyngeal pain	3 (6.7)	2 (4.4)	1 (2.2)
Tachypnoea	2 (4.4)	0	2 (4.4)
Nasal congestion	1 (2.2)	1 (2.2)	0
Rhinorrhoea	1 (2.2)	1 (2.2)	0
Skin and subcutaneous tissue disorders			
-Total	8 (17.8)	6 (13.3)	2 (4.4)

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Rash	7 (15.6)	5 (11.1)	2 (4.4)
Dry skin	2 (4.4)	2 (4.4)	0
Pruritus	2 (4.4)	2 (4.4)	0
Vascular disorders			
-Total	10 (22.2)	3 (6.7)	7 (15.6)
Hypertension	10 (22.2)	3 (6.7)	7 (15.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233e
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (100)	0	8 (100)
Blood and lymphatic system disorders			
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Anaemia	3 (37.5)	2 (25.0)	1 (12.5)
Cardiac disorders			
-Total	2 (25.0)	2 (25.0)	0
Palpitations	1 (12.5)	1 (12.5)	0
Pericardial effusion	1 (12.5)	1 (12.5)	0
Tachycardia	1 (12.5)	1 (12.5)	0
Endocrine disorders			
-Total	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Adrenal insufficiency	1 (12.5)	1 (12.5)	0
Eye disorders			
-Total	1 (12.5)	1 (12.5)	0
Eye pain	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	7 (87.5)	3 (37.5)	4 (50.0)
Vomiting	5 (62.5)	3 (37.5)	2 (25.0)
Diarrhoea	4 (50.0)	3 (37.5)	1 (12.5)
Nausea	4 (50.0)	1 (12.5)	3 (37.5)
Abdominal pain	3 (37.5)	2 (25.0)	1 (12.5)
Constipation	1 (12.5)	1 (12.5)	0
Oral pain	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	5 (62.5)	1 (12.5)	4 (50.0)
Pyrexia	4 (50.0)	1 (12.5)	3 (37.5)
Asthenia	1 (12.5)	1 (12.5)	0
Catheter site pain	1 (12.5)	0	1 (12.5)
Chills	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fatigue	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
-Total	1 (12.5)	0	1 (12.5)
Hepatomegaly	1 (12.5)	0	1 (12.5)
Immune system disorders			
-Total	7 (87.5)	0	7 (87.5)
Cytokine release syndrome	5 (62.5)	0	5 (62.5)
Hypogammaglobulinaemia	4 (50.0)	0	4 (50.0)
Graft versus host disease	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	5 (62.5)	1 (12.5)	4 (50.0)
Upper respiratory tract infection	2 (25.0)	0	2 (25.0)
Viral infection	2 (25.0)	1 (12.5)	1 (12.5)
Clostridium difficile infection	1 (12.5)	0	1 (12.5)
Ear infection	1 (12.5)	1 (12.5)	0
Gastroenteritis	1 (12.5)	0	1 (12.5)
Rhinovirus infection	1 (12.5)	1 (12.5)	0
Skin infection	1 (12.5)	0	1 (12.5)
Tinea capitis	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Contusion	1 (12.5)	1 (12.5)	0
Infusion related reaction	1 (12.5)	0	1 (12.5)
Procedural nausea	1 (12.5)	0	1 (12.5)
Sunburn	1 (12.5)	1 (12.5)	0
Tracheal haemorrhage	1 (12.5)	0	1 (12.5)
Wound	1 (12.5)	1 (12.5)	0
Investigations			
-Total	6 (75.0)	2 (25.0)	4 (50.0)
Lymphocyte count decreased	2 (25.0)	1 (12.5)	1 (12.5)
White blood cell count decreased	2 (25.0)	1 (12.5)	1 (12.5)
Activated partial thromboplastin time prolonged	1 (12.5)	1 (12.5)	0
Blood creatinine increased	1 (12.5)	0	1 (12.5)
Blood fibrinogen decreased	1 (12.5)	0	1 (12.5)
Blood immunoglobulin m decreased	1 (12.5)	1 (12.5)	0
Blood magnesium decreased	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood phosphorus increased	1 (12.5)	1 (12.5)	0
Blood uric acid increased	1 (12.5)	1 (12.5)	0
Cardiac murmur	1 (12.5)	1 (12.5)	0
Fibrin d dimer increased	1 (12.5)	1 (12.5)	0
International normalised ratio increased	1 (12.5)	1 (12.5)	0
Neutrophil count decreased	1 (12.5)	0	1 (12.5)
Prothrombin time prolonged	1 (12.5)	0	1 (12.5)
Weight decreased	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	5 (62.5)	3 (37.5)	2 (25.0)
Hypokalaemia	3 (37.5)	2 (25.0)	1 (12.5)
Decreased appetite	2 (25.0)	1 (12.5)	1 (12.5)
Hypernatraemia	1 (12.5)	0	1 (12.5)
Hypoalbuminaemia	1 (12.5)	1 (12.5)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Pain in extremity	2 (25.0)	2 (25.0)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	1 (12.5)	1 (12.5)	0
Muscular weakness	1 (12.5)	1 (12.5)	0
Neck pain	1 (12.5)	0	1 (12.5)
Pain in jaw	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	5 (62.5)	5 (62.5)	0
Headache	3 (37.5)	3 (37.5)	0
Dizziness	1 (12.5)	1 (12.5)	0
Dysgeusia	1 (12.5)	1 (12.5)	0
Peroneal nerve palsy	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	4 (50.0)	0	4 (50.0)
Confusional state	3 (37.5)	1 (12.5)	2 (25.0)
Depression	2 (25.0)	1 (12.5)	1 (12.5)
Anxiety	1 (12.5)	1 (12.5)	0
Delirium	1 (12.5)	1 (12.5)	0
Insomnia	1 (12.5)	0	1 (12.5)
Sleep disorder	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	7 (87.5)	2 (25.0)	5 (62.5)
Cough	3 (37.5)	3 (37.5)	0
Hypoxia	2 (25.0)	0	2 (25.0)
Pleural effusion	2 (25.0)	0	2 (25.0)
Rhinorrhoea	2 (25.0)	1 (12.5)	1 (12.5)
Epistaxis	1 (12.5)	0	1 (12.5)
Nasal congestion	1 (12.5)	1 (12.5)	0
Oropharyngeal pain	1 (12.5)	0	1 (12.5)
Pharyngeal erythema	1 (12.5)	1 (12.5)	0
Skin and subcutaneous tissue disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Erythema	2 (25.0)	2 (25.0)	0
Alopecia	1 (12.5)	0	1 (12.5)
Dermatitis diaper	1 (12.5)	1 (12.5)	0
Dry skin	1 (12.5)	1 (12.5)	0
Livedo reticularis	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=8 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Rash erythematous	1 (12.5)	0	1 (12.5)
Rash maculo-papular	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Hypertension	3 (37.5)	1 (12.5)	2 (25.0)
Haematoma	1 (12.5)	0	1 (12.5)
Hot flush	1 (12.5)	1 (12.5)	0

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- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233e
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	62 (92.5)	3 (4.5)	59 (88.1)
Blood and lymphatic system disorders			
-Total	11 (16.4)	2 (3.0)	9 (13.4)
Anaemia	11 (16.4)	2 (3.0)	9 (13.4)
Cardiac disorders			
-Total	16 (23.9)	7 (10.4)	9 (13.4)
Tachycardia	15 (22.4)	8 (11.9)	7 (10.4)
Pericardial effusion	2 (3.0)	0	2 (3.0)
Palpitations	1 (1.5)	1 (1.5)	0
Endocrine disorders			
-Total	2 (3.0)	0	2 (3.0)

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Adrenal insufficiency	2 (3.0)	0	2 (3.0)
Eye disorders			
-Total	2 (3.0)	0	2 (3.0)
Eye pain	2 (3.0)	0	2 (3.0)
Gastrointestinal disorders			
-Total	40 (59.7)	13 (19.4)	27 (40.3)
Nausea	26 (38.8)	8 (11.9)	18 (26.9)
Vomiting	22 (32.8)	14 (20.9)	8 (11.9)
Diarrhoea	21 (31.3)	11 (16.4)	10 (14.9)
Abdominal pain	11 (16.4)	5 (7.5)	6 (9.0)
Constipation	10 (14.9)	8 (11.9)	2 (3.0)
Oral pain	1 (1.5)	0	1 (1.5)
General disorders and administration site conditions			
-Total	39 (58.2)	18 (26.9)	21 (31.3)
Pyrexia	25 (37.3)	8 (11.9)	17 (25.4)
Fatigue	16 (23.9)	12 (17.9)	4 (6.0)
Chills	10 (14.9)	8 (11.9)	2 (3.0)
Catheter site pain	6 (9.0)	3 (4.5)	3 (4.5)

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatobiliary disorders			
-Total	2 (3.0)	1 (1.5)	1 (1.5)
Hepatomegaly	2 (3.0)	1 (1.5)	1 (1.5)
Immune system disorders			
-Total	48 (71.6)	8 (11.9)	40 (59.7)
Cytokine release syndrome	40 (59.7)	7 (10.4)	33 (49.3)
Hypogammaglobulinaemia	24 (35.8)	4 (6.0)	20 (29.9)
Graft versus host disease	1 (1.5)	1 (1.5)	0
Infections and infestations			
-Total	18 (26.9)	7 (10.4)	11 (16.4)
Upper respiratory tract infection	8 (11.9)	5 (7.5)	3 (4.5)
Rhinovirus infection	5 (7.5)	4 (6.0)	1 (1.5)
Clostridium difficile infection	4 (6.0)	0	4 (6.0)
Gastroenteritis	3 (4.5)	1 (1.5)	2 (3.0)
Ear infection	1 (1.5)	0	1 (1.5)
Skin infection	1 (1.5)	0	1 (1.5)
Viral infection	1 (1.5)	1 (1.5)	0
Injury, poisoning and procedural complications			

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (9.0)	4 (6.0)	2 (3.0)
Infusion related reaction	4 (6.0)	2 (3.0)	2 (3.0)
Contusion	2 (3.0)	2 (3.0)	0
Investigations			
-Total	36 (53.7)	3 (4.5)	33 (49.3)
Aspartate aminotransferase increased	16 (23.9)	8 (11.9)	8 (11.9)
White blood cell count decreased	15 (22.4)	5 (7.5)	10 (14.9)
Alanine aminotransferase increased	14 (20.9)	5 (7.5)	9 (13.4)
International normalised ratio increased	9 (13.4)	8 (11.9)	1 (1.5)
Prothrombin time prolonged	8 (11.9)	5 (7.5)	3 (4.5)
Blood bilirubin increased	7 (10.4)	2 (3.0)	5 (7.5)
Blood creatinine increased	6 (9.0)	5 (7.5)	1 (1.5)
Activated partial thromboplastin time prolonged	5 (7.5)	2 (3.0)	3 (4.5)
Lymphocyte count decreased	5 (7.5)	1 (1.5)	4 (6.0)
Neutrophil count decreased	5 (7.5)	2 (3.0)	3 (4.5)
Weight decreased	4 (6.0)	1 (1.5)	3 (4.5)
Blood immunoglobulin m decreased	3 (4.5)	3 (4.5)	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood fibrinogen decreased	2 (3.0)	0	2 (3.0)
Blood phosphorus increased	1 (1.5)	1 (1.5)	0
Blood uric acid increased	1 (1.5)	1 (1.5)	0
Metabolism and nutrition disorders			
-Total	31 (46.3)	12 (17.9)	19 (28.4)
Decreased appetite	17 (25.4)	10 (14.9)	7 (10.4)
Hyperphosphataemia	9 (13.4)	8 (11.9)	1 (1.5)
Hypokalaemia	9 (13.4)	3 (4.5)	6 (9.0)
Hypoalbuminaemia	5 (7.5)	0	5 (7.5)
Hypernatraemia	4 (6.0)	1 (1.5)	3 (4.5)
Musculoskeletal and connective tissue disorders			
-Total	16 (23.9)	9 (13.4)	7 (10.4)
Pain in extremity	9 (13.4)	5 (7.5)	4 (6.0)
Arthralgia	5 (7.5)	4 (6.0)	1 (1.5)
Pain in jaw	3 (4.5)	1 (1.5)	2 (3.0)
Muscular weakness	2 (3.0)	1 (1.5)	1 (1.5)
Neck pain	1 (1.5)	0	1 (1.5)
Nervous system disorders			

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	29 (43.3)	16 (23.9)	13 (19.4)
Headache	25 (37.3)	13 (19.4)	12 (17.9)
Dizziness	5 (7.5)	5 (7.5)	0
Peroneal nerve palsy	2 (3.0)	1 (1.5)	1 (1.5)
Psychiatric disorders			
-Total	15 (22.4)	6 (9.0)	9 (13.4)
Anxiety	7 (10.4)	2 (3.0)	5 (7.5)
Confusional state	4 (6.0)	2 (3.0)	2 (3.0)
Delirium	3 (4.5)	1 (1.5)	2 (3.0)
Insomnia	3 (4.5)	0	3 (4.5)
Depression	2 (3.0)	1 (1.5)	1 (1.5)
Respiratory, thoracic and mediastinal disorders			
-Total	26 (38.8)	12 (17.9)	14 (20.9)
Cough	12 (17.9)	10 (14.9)	2 (3.0)
Epistaxis	8 (11.9)	4 (6.0)	4 (6.0)
Hypoxia	6 (9.0)	0	6 (9.0)
Nasal congestion	5 (7.5)	5 (7.5)	0
Oropharyngeal pain	5 (7.5)	4 (6.0)	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pleural effusion	5 (7.5)	1 (1.5)	4 (6.0)
Rhinorrhoea	4 (6.0)	4 (6.0)	0
Skin and subcutaneous tissue disorders			
-Total	21 (31.3)	14 (20.9)	7 (10.4)
Rash	9 (13.4)	6 (9.0)	3 (4.5)
Dry skin	4 (6.0)	4 (6.0)	0
Rash erythematous	4 (6.0)	2 (3.0)	2 (3.0)
Alopecia	3 (4.5)	2 (3.0)	1 (1.5)
Erythema	3 (4.5)	3 (4.5)	0
Rash maculo-papular	3 (4.5)	2 (3.0)	1 (1.5)
Vascular disorders			
-Total	11 (16.4)	3 (4.5)	8 (11.9)
Hypertension	11 (16.4)	3 (4.5)	8 (11.9)

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- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233f
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	2 (100)	0	2 (100)
Anaemia	1 (50.0)	0	1 (50.0)
Eosinophilia	1 (50.0)	0	1 (50.0)
Lymphopenia	1 (50.0)	0	1 (50.0)
Cardiac disorders			
-Total	1 (50.0)	0	1 (50.0)
Sinus tachycardia	1 (50.0)	0	1 (50.0)
Gastrointestinal disorders			
-Total	1 (50.0)	0	1 (50.0)

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	1 (50.0)	0	1 (50.0)
Pigmentation lip	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	2 (100)	1 (50.0)	1 (50.0)
Chills	1 (50.0)	1 (50.0)	0
Fatigue	1 (50.0)	1 (50.0)	0
Pain	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	0	1 (50.0)
Immune system disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Graft versus host disease	1 (50.0)	1 (50.0)	0
Graft versus host disease in skin	1 (50.0)	1 (50.0)	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Cellulitis of male external genital organ	1 (50.0)	0	1 (50.0)
Otitis media	1 (50.0)	0	1 (50.0)

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Urinary tract infection	1 (50.0)	0	1 (50.0)
Injury, poisoning and procedural complications			
-Total	1 (50.0)	1 (50.0)	0
Skin abrasion	1 (50.0)	1 (50.0)	0
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Alanine aminotransferase increased	1 (50.0)	0	1 (50.0)
Aspartate aminotransferase increased	1 (50.0)	1 (50.0)	0
Blood immunoglobulin a decreased	1 (50.0)	1 (50.0)	0
Blood uric acid increased	1 (50.0)	1 (50.0)	0
International normalised ratio increased	1 (50.0)	1 (50.0)	0
Lymphocyte count decreased	1 (50.0)	0	1 (50.0)
Neutrophil count decreased	1 (50.0)	0	1 (50.0)
White blood cell count decreased	1 (50.0)	0	1 (50.0)
Metabolism and nutrition disorders			
-Total	2 (100)	2 (100)	0
Hyperphosphataemia	1 (50.0)	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperuricaemia	1 (50.0)	1 (50.0)	0
Vitamin d deficiency	1 (50.0)	1 (50.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (100)	2 (100)	0
Joint range of motion decreased	2 (100)	2 (100)	0
Arthralgia	1 (50.0)	1 (50.0)	0
Back pain	1 (50.0)	1 (50.0)	0
Muscle spasms	1 (50.0)	1 (50.0)	0
Myalgia	1 (50.0)	1 (50.0)	0
Pain in extremity	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	2 (100)	2 (100)	0
Headache	2 (100)	2 (100)	0
Reproductive system and breast disorders			
-Total	1 (50.0)	0	1 (50.0)
Scrotal pain	1 (50.0)	0	1 (50.0)
Respiratory, thoracic and mediastinal disorders			

Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
-Total	1 (50.0)	1 (50.0)	0
Cough	1 (50.0)	1 (50.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (50.0)	1 (50.0)	0
Macule	1 (50.0)	1 (50.0)	0
Rash maculo-papular	1 (50.0)	1 (50.0)	0
Skin irritation	1 (50.0)	1 (50.0)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233f
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

		All patients N=73	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	67 (91.8)	2 (2.7)	65 (89.0)
Blood and lymphatic system disorders			
-Total	14 (19.2)	4 (5.5)	10 (13.7)
Anaemia	13 (17.8)	4 (5.5)	9 (12.3)
Lymphopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	20 (27.4)	11 (15.1)	9 (12.3)
Tachycardia	16 (21.9)	9 (12.3)	7 (9.6)
Sinus tachycardia	5 (6.8)	3 (4.1)	2 (2.7)
Gastrointestinal disorders			
-Total	46 (63.0)	16 (21.9)	30 (41.1)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	30 (41.1)	9 (12.3)	21 (28.8)
Vomiting	27 (37.0)	17 (23.3)	10 (13.7)
Diarrhoea	24 (32.9)	14 (19.2)	10 (13.7)
Abdominal pain	14 (19.2)	7 (9.6)	7 (9.6)
Constipation	11 (15.1)	9 (12.3)	2 (2.7)
General disorders and administration site conditions			
-Total	40 (54.8)	15 (20.5)	25 (34.2)
Pyrexia	28 (38.4)	9 (12.3)	19 (26.0)
Fatigue	16 (21.9)	12 (16.4)	4 (5.5)
Chills	10 (13.7)	8 (11.0)	2 (2.7)
Pain	3 (4.1)	0	3 (4.1)
Immune system disorders			
-Total	53 (72.6)	7 (9.6)	46 (63.0)
Cytokine release syndrome	45 (61.6)	7 (9.6)	38 (52.1)
Hypogammaglobulinaemia	27 (37.0)	4 (5.5)	23 (31.5)
Graft versus host disease	1 (1.4)	0	1 (1.4)
Infections and infestations			
-Total	14 (19.2)	3 (4.1)	11 (15.1)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	10 (13.7)	5 (6.8)	5 (6.8)
Otitis media	3 (4.1)	0	3 (4.1)
Urinary tract infection	3 (4.1)	0	3 (4.1)
Injury, poisoning and procedural complications			
-Total	1 (1.4)	1 (1.4)	0
Skin abrasion	1 (1.4)	1 (1.4)	0
Investigations			
-Total	34 (46.6)	4 (5.5)	30 (41.1)
White blood cell count decreased	16 (21.9)	6 (8.2)	10 (13.7)
Aspartate aminotransferase increased	15 (20.5)	7 (9.6)	8 (11.0)
Alanine aminotransferase increased	13 (17.8)	5 (6.8)	8 (11.0)
International normalised ratio increased	9 (12.3)	8 (11.0)	1 (1.4)
Prothrombin time prolonged	9 (12.3)	5 (6.8)	4 (5.5)
Lymphocyte count decreased	6 (8.2)	2 (2.7)	4 (5.5)
Neutrophil count decreased	5 (6.8)	2 (2.7)	3 (4.1)
Blood immunoglobulin a decreased	2 (2.7)	2 (2.7)	0
Blood uric acid increased	1 (1.4)	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	31 (42.5)	16 (21.9)	15 (20.5)
Decreased appetite	19 (26.0)	11 (15.1)	8 (11.0)
Hypokalaemia	12 (16.4)	5 (6.8)	7 (9.6)
Hyperphosphataemia	8 (11.0)	7 (9.6)	1 (1.4)
Hyperuricaemia	2 (2.7)	2 (2.7)	0
Vitamin d deficiency	2 (2.7)	1 (1.4)	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	18 (24.7)	13 (17.8)	5 (6.8)
Pain in extremity	10 (13.7)	6 (8.2)	4 (5.5)
Arthralgia	5 (6.8)	4 (5.5)	1 (1.4)
Myalgia	4 (5.5)	3 (4.1)	1 (1.4)
Muscle spasms	2 (2.7)	2 (2.7)	0
Nervous system disorders			
-Total	26 (35.6)	14 (19.2)	12 (16.4)
Headache	26 (35.6)	14 (19.2)	12 (16.4)
Psychiatric disorders			
-Total	8 (11.0)	3 (4.1)	5 (6.8)

Philadelphia chromosome/BCR-ABL: Negative			
		All patients N=73	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Anxiety	8 (11.0)	3 (4.1)	5 (6.8)
Respiratory, thoracic and mediastinal disorders			
-Total	23 (31.5)	9 (12.3)	14 (19.2)
Cough	14 (19.2)	12 (16.4)	2 (2.7)
Epistaxis	9 (12.3)	4 (5.5)	5 (6.8)
Hypoxia	8 (11.0)	0	8 (11.0)
Skin and subcutaneous tissue disorders			
-Total	13 (17.8)	9 (12.3)	4 (5.5)
Rash	9 (12.3)	6 (8.2)	3 (4.1)
Rash maculo-papular	3 (4.1)	2 (2.7)	1 (1.4)
Macule	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	14 (19.2)	4 (5.5)	10 (13.7)
Hypertension	14 (19.2)	4 (5.5)	10 (13.7)

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Table 233g
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (100)	0	3 (100)
Blood and lymphatic system disorders			
-Total	1 (33.3)	0	1 (33.3)
Anaemia	1 (33.3)	0	1 (33.3)
Cardiac disorders			
-Total	1 (33.3)	0	1 (33.3)
Bradycardia	1 (33.3)	0	1 (33.3)
Pericardial effusion	1 (33.3)	0	1 (33.3)
Eye disorders			
-Total	1 (33.3)	1 (33.3)	0
Conjunctival haemorrhage	1 (33.3)	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Periorbital oedema	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	2 (66.7)	0	2 (66.7)
Nausea	2 (66.7)	1 (33.3)	1 (33.3)
Abdominal pain	1 (33.3)	1 (33.3)	0
Colitis	1 (33.3)	1 (33.3)	0
Diarrhoea	1 (33.3)	0	1 (33.3)
Perianal erythema	1 (33.3)	0	1 (33.3)
Vomiting	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	2 (66.7)	0	2 (66.7)
Pyrexia	2 (66.7)	0	2 (66.7)
Asthenia	1 (33.3)	1 (33.3)	0
Chills	1 (33.3)	1 (33.3)	0
Mucosal haemorrhage	1 (33.3)	0	1 (33.3)
Hepatobiliary disorders			
-Total	1 (33.3)	0	1 (33.3)
Hepatomegaly	1 (33.3)	0	1 (33.3)

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	2 (66.7)	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	2 (66.7)
Infections and infestations			
-Total	1 (33.3)	0	1 (33.3)
Pneumonia	1 (33.3)	0	1 (33.3)
Sinusitis	1 (33.3)	1 (33.3)	0
Upper respiratory tract infection	1 (33.3)	1 (33.3)	0
Injury, poisoning and procedural complications			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Procedural complication	1 (33.3)	1 (33.3)	0
Tracheal haemorrhage	1 (33.3)	0	1 (33.3)
Investigations			
-Total	3 (100)	0	3 (100)
Aspartate aminotransferase increased	2 (66.7)	1 (33.3)	1 (33.3)
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0
Blood fibrinogen decreased	1 (33.3)	0	1 (33.3)

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood lactic acid increased	1 (33.3)	0	1 (33.3)
Blood phosphorus decreased	1 (33.3)	1 (33.3)	0
Blood urea increased	1 (33.3)	1 (33.3)	0
C-reactive protein increased	1 (33.3)	0	1 (33.3)
International normalised ratio increased	1 (33.3)	1 (33.3)	0
Prothrombin time prolonged	1 (33.3)	0	1 (33.3)
White blood cell count decreased	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Fluid overload	1 (33.3)	0	1 (33.3)
Hyperalbuminaemia	1 (33.3)	1 (33.3)	0
Hypercalcaemia	1 (33.3)	1 (33.3)	0
Hyperchloraemia	1 (33.3)	1 (33.3)	0
Hypermagnesaemia	1 (33.3)	1 (33.3)	0
Hypernatraemia	1 (33.3)	0	1 (33.3)
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)
Hypokalaemia	1 (33.3)	1 (33.3)	0
Hypophosphataemia	1 (33.3)	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolic alkalosis	1 (33.3)	1 (33.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (33.3)	0	1 (33.3)
Neck pain	1 (33.3)	0	1 (33.3)
Nervous system disorders			
-Total	3 (100)	2 (66.7)	1 (33.3)
Dizziness	1 (33.3)	1 (33.3)	0
Headache	1 (33.3)	1 (33.3)	0
Hypotonia	1 (33.3)	0	1 (33.3)
Psychiatric disorders			
-Total	2 (66.7)	0	2 (66.7)
Insomnia	2 (66.7)	0	2 (66.7)
Confusional state	1 (33.3)	1 (33.3)	0
Delirium	1 (33.3)	0	1 (33.3)
Irritability	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (66.7)	0	2 (66.7)

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	1 (33.3)	1 (33.3)	0
Epistaxis	1 (33.3)	0	1 (33.3)
Hypoxia	1 (33.3)	0	1 (33.3)
Pleural effusion	1 (33.3)	0	1 (33.3)
Skin and subcutaneous tissue disorders			
-Total	1 (33.3)	1 (33.3)	0
Hyperhidrosis	1 (33.3)	1 (33.3)	0
Papule	1 (33.3)	1 (33.3)	0
Rash papular	1 (33.3)	1 (33.3)	0
Vascular disorders			
-Total	2 (66.7)	0	2 (66.7)
Hypertension	2 (66.7)	0	2 (66.7)
Flushing	1 (33.3)	1 (33.3)	0

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Table 233g
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

		All patients N=72	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	66 (91.7)	2 (2.8)	64 (88.9)
Blood and lymphatic system disorders			
-Total	13 (18.1)	4 (5.6)	9 (12.5)
Anaemia	13 (18.1)	4 (5.6)	9 (12.5)
Cardiac disorders			
-Total	17 (23.6)	9 (12.5)	8 (11.1)
Tachycardia	16 (22.2)	9 (12.5)	7 (9.7)
Pericardial effusion	2 (2.8)	1 (1.4)	1 (1.4)
Bradycardia	1 (1.4)	1 (1.4)	0
Eye disorders			
-Total	3 (4.2)	2 (2.8)	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Periorbital oedema	3 (4.2)	2 (2.8)	1 (1.4)
Conjunctival haemorrhage	2 (2.8)	2 (2.8)	0
Gastrointestinal disorders			
-Total	45 (62.5)	15 (20.8)	30 (41.7)
Nausea	28 (38.9)	8 (11.1)	20 (27.8)
Vomiting	26 (36.1)	17 (23.6)	9 (12.5)
Diarrhoea	24 (33.3)	14 (19.4)	10 (13.9)
Abdominal pain	13 (18.1)	6 (8.3)	7 (9.7)
Constipation	11 (15.3)	9 (12.5)	2 (2.8)
General disorders and administration site conditions			
-Total	39 (54.2)	18 (25.0)	21 (29.2)
Pyrexia	27 (37.5)	9 (12.5)	18 (25.0)
Fatigue	17 (23.6)	13 (18.1)	4 (5.6)
Chills	10 (13.9)	8 (11.1)	2 (2.8)
Hepatobiliary disorders			
-Total	2 (2.8)	1 (1.4)	1 (1.4)
Hepatomegaly	2 (2.8)	1 (1.4)	1 (1.4)
Immune system disorders			

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	52 (72.2)	7 (9.7)	45 (62.5)
Cytokine release syndrome	43 (59.7)	7 (9.7)	36 (50.0)
Hypogammaglobulinaemia	28 (38.9)	4 (5.6)	24 (33.3)
Infections and infestations			
-Total	13 (18.1)	3 (4.2)	10 (13.9)
Upper respiratory tract infection	9 (12.5)	4 (5.6)	5 (6.9)
Pneumonia	4 (5.6)	0	4 (5.6)
Sinusitis	4 (5.6)	0	4 (5.6)
Investigations			
-Total	31 (43.1)	5 (6.9)	26 (36.1)
White blood cell count decreased	16 (22.2)	6 (8.3)	10 (13.9)
Aspartate aminotransferase increased	14 (19.4)	7 (9.7)	7 (9.7)
Alanine aminotransferase increased	13 (18.1)	4 (5.6)	9 (12.5)
International normalised ratio increased	9 (12.5)	8 (11.1)	1 (1.4)
Prothrombin time prolonged	8 (11.1)	5 (6.9)	3 (4.2)
Blood fibrinogen decreased	2 (2.8)	0	2 (2.8)
Blood urea increased	2 (2.8)	1 (1.4)	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
C-reactive protein increased	2 (2.8)	1 (1.4)	1 (1.4)
Metabolism and nutrition disorders			
-Total	37 (51.4)	15 (20.8)	22 (30.6)
Decreased appetite	19 (26.4)	11 (15.3)	8 (11.1)
Hypokalaemia	11 (15.3)	4 (5.6)	7 (9.7)
Hyperphosphataemia	9 (12.5)	8 (11.1)	1 (1.4)
Hypoalbuminaemia	5 (6.9)	1 (1.4)	4 (5.6)
Hypophosphataemia	5 (6.9)	4 (5.6)	1 (1.4)
Fluid overload	4 (5.6)	1 (1.4)	3 (4.2)
Hypernatraemia	4 (5.6)	1 (1.4)	3 (4.2)
Musculoskeletal and connective tissue disorders			
-Total	12 (16.7)	7 (9.7)	5 (6.9)
Pain in extremity	11 (15.3)	7 (9.7)	4 (5.6)
Neck pain	1 (1.4)	0	1 (1.4)
Nervous system disorders			
-Total	29 (40.3)	17 (23.6)	12 (16.7)
Headache	27 (37.5)	15 (20.8)	12 (16.7)
Dizziness	5 (6.9)	5 (6.9)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Psychiatric disorders			
-Total	16 (22.2)	6 (8.3)	10 (13.9)
Anxiety	8 (11.1)	3 (4.2)	5 (6.9)
Confusional state	6 (8.3)	2 (2.8)	4 (5.6)
Delirium	3 (4.2)	2 (2.8)	1 (1.4)
Insomnia	2 (2.8)	0	2 (2.8)
Irritability	2 (2.8)	2 (2.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	24 (33.3)	10 (13.9)	14 (19.4)
Cough	14 (19.4)	12 (16.7)	2 (2.8)
Epistaxis	8 (11.1)	4 (5.6)	4 (5.6)
Hypoxia	7 (9.7)	0	7 (9.7)
Pleural effusion	6 (8.3)	1 (1.4)	5 (6.9)
Skin and subcutaneous tissue disorders			
-Total	14 (19.4)	11 (15.3)	3 (4.2)
Rash	9 (12.5)	6 (8.3)	3 (4.2)
Hyperhidrosis	3 (4.2)	3 (4.2)	0

Mixed-lineage leukemia rearrangement: No

Group term Preferred term	All patients N=72 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Rash papular	2 (2.8)	2 (2.8)	0
Papule	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	13 (18.1)	5 (6.9)	8 (11.1)
Hypertension	12 (16.7)	4 (5.6)	8 (11.1)
Flushing	1 (1.4)	1 (1.4)	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233h
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Cardiac disorders			
-Total	1 (100)	0	1 (100)
Tachycardia	1 (100)	0	1 (100)
Gastrointestinal disorders			
-Total	1 (100)	0	1 (100)
Haematemesis	1 (100)	0	1 (100)
Nausea	1 (100)	0	1 (100)
Vomiting	1 (100)	0	1 (100)
Immune system disorders			

Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (100)	0	1 (100)
Cytokine release syndrome	1 (100)	0	1 (100)
Investigations			
-Total	1 (100)	0	1 (100)
Activated partial thromboplastin time prolonged	1 (100)	0	1 (100)
Aspartate aminotransferase increased	1 (100)	0	1 (100)
Blood phosphorus increased	1 (100)	1 (100)	0
International normalised ratio increased	1 (100)	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0
Nervous system disorders			
-Total	1 (100)	0	1 (100)
Encephalopathy	1 (100)	0	1 (100)
Psychiatric disorders			
-Total	1 (100)	0	1 (100)
Insomnia	1 (100)	0	1 (100)
Mental status changes	1 (100)	1 (100)	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Skin and subcutaneous tissue disorders			
-Total	1 (100)	0	1 (100)
Rash erythematous	1 (100)	0	1 (100)

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- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233h
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	67 (90.5)	4 (5.4)	63 (85.1)
Blood and lymphatic system disorders			
-Total	14 (18.9)	4 (5.4)	10 (13.5)
Anaemia	14 (18.9)	4 (5.4)	10 (13.5)
Cardiac disorders			
-Total	15 (20.3)	9 (12.2)	6 (8.1)
Tachycardia	15 (20.3)	9 (12.2)	6 (8.1)
Gastrointestinal disorders			
-Total	46 (62.2)	16 (21.6)	30 (40.5)
Nausea	29 (39.2)	9 (12.2)	20 (27.0)

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	26 (35.1)	17 (23.0)	9 (12.2)
Diarrhoea	25 (33.8)	14 (18.9)	11 (14.9)
Abdominal pain	14 (18.9)	7 (9.5)	7 (9.5)
Constipation	11 (14.9)	9 (12.2)	2 (2.7)
Haematemesis	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	41 (55.4)	18 (24.3)	23 (31.1)
Pyrexia	29 (39.2)	9 (12.2)	20 (27.0)
Fatigue	17 (23.0)	13 (17.6)	4 (5.4)
Chills	11 (14.9)	9 (12.2)	2 (2.7)
Immune system disorders			
-Total	53 (71.6)	7 (9.5)	46 (62.2)
Cytokine release syndrome	44 (59.5)	7 (9.5)	37 (50.0)
Hypogammaglobulinaemia	28 (37.8)	4 (5.4)	24 (32.4)
Infections and infestations			
-Total	10 (13.5)	5 (6.8)	5 (6.8)
Upper respiratory tract infection	10 (13.5)	5 (6.8)	5 (6.8)

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	34 (45.9)	6 (8.1)	28 (37.8)
White blood cell count decreased	16 (21.6)	5 (6.8)	11 (14.9)
Aspartate aminotransferase increased	15 (20.3)	8 (10.8)	7 (9.5)
Alanine aminotransferase increased	14 (18.9)	5 (6.8)	9 (12.2)
International normalised ratio increased	9 (12.2)	8 (10.8)	1 (1.4)
Prothrombin time prolonged	9 (12.2)	5 (6.8)	4 (5.4)
Activated partial thromboplastin time prolonged	5 (6.8)	3 (4.1)	2 (2.7)
Blood phosphorus increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	31 (41.9)	17 (23.0)	14 (18.9)
Decreased appetite	19 (25.7)	11 (14.9)	8 (10.8)
Hypokalaemia	12 (16.2)	5 (6.8)	7 (9.5)
Hyperphosphataemia	9 (12.2)	8 (10.8)	1 (1.4)
Musculoskeletal and connective tissue disorders			

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (14.9)	7 (9.5)	4 (5.4)
Pain in extremity	11 (14.9)	7 (9.5)	4 (5.4)
Nervous system disorders			
-Total	29 (39.2)	16 (21.6)	13 (17.6)
Headache	28 (37.8)	16 (21.6)	12 (16.2)
Encephalopathy	2 (2.7)	1 (1.4)	1 (1.4)
Psychiatric disorders			
-Total	12 (16.2)	4 (5.4)	8 (10.8)
Anxiety	8 (10.8)	3 (4.1)	5 (6.8)
Insomnia	3 (4.1)	0	3 (4.1)
Mental status changes	2 (2.7)	2 (2.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	24 (32.4)	10 (13.5)	14 (18.9)
Cough	15 (20.3)	13 (17.6)	2 (2.7)
Epistaxis	9 (12.2)	4 (5.4)	5 (6.8)
Hypoxia	8 (10.8)	0	8 (10.8)
Skin and subcutaneous tissue disorders			

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	12 (16.2)	7 (9.5)	5 (6.8)
Rash	9 (12.2)	6 (8.1)	3 (4.1)
Rash erythematous	4 (5.4)	2 (2.7)	2 (2.7)
Vascular disorders			
-Total	14 (18.9)	4 (5.4)	10 (13.5)
Hypertension	14 (18.9)	4 (5.4)	10 (13.5)

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Table 233i
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	0	4 (100)
Blood and lymphatic system disorders			
-Total	2 (50.0)	0	2 (50.0)
Anaemia	2 (50.0)	0	2 (50.0)
Lymphopenia	1 (25.0)	0	1 (25.0)
Cardiac disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Cardiac dysfunction	1 (25.0)	1 (25.0)	0
Sinus tachycardia	1 (25.0)	0	1 (25.0)
Tachycardia	1 (25.0)	1 (25.0)	0

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Endocrine disorders			
-Total	1 (25.0)	1 (25.0)	0
Cushingoid	1 (25.0)	1 (25.0)	0
Eye disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Dry eye	1 (25.0)	0	1 (25.0)
Eye irritation	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	3 (75.0)	1 (25.0)	2 (50.0)
Diarrhoea	3 (75.0)	2 (50.0)	1 (25.0)
Abdominal pain	2 (50.0)	2 (50.0)	0
Nausea	2 (50.0)	1 (25.0)	1 (25.0)
Vomiting	2 (50.0)	1 (25.0)	1 (25.0)
Abdominal distension	1 (25.0)	0	1 (25.0)
Abdominal tenderness	1 (25.0)	1 (25.0)	0
Constipation	1 (25.0)	1 (25.0)	0
Dry mouth	1 (25.0)	1 (25.0)	0
Gastrooesophageal reflux disease	1 (25.0)	1 (25.0)	0

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	4 (100)	3 (75.0)	1 (25.0)
Fatigue	4 (100)	4 (100)	0
Pain	1 (25.0)	0	1 (25.0)
Pyrexia	1 (25.0)	1 (25.0)	0
Immune system disorders			
-Total	4 (100)	0	4 (100)
Hypogammaglobulinaemia	4 (100)	0	4 (100)
Cytokine release syndrome	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	3 (75.0)	1 (25.0)	2 (50.0)
Clostridium difficile infection	1 (25.0)	0	1 (25.0)
Cytomegalovirus infection	1 (25.0)	1 (25.0)	0
Gingivitis	1 (25.0)	1 (25.0)	0
Otitis media acute	1 (25.0)	0	1 (25.0)
Parainfluenzae virus infection	1 (25.0)	1 (25.0)	0
Pharyngitis	1 (25.0)	0	1 (25.0)

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sinusitis	1 (25.0)	0	1 (25.0)
Streptococcal infection	1 (25.0)	0	1 (25.0)
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0
Viral infection	1 (25.0)	1 (25.0)	0
Injury, poisoning and procedural complications			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Contusion	1 (25.0)	1 (25.0)	0
Infusion related reaction	1 (25.0)	0	1 (25.0)
Procedural pain	1 (25.0)	0	1 (25.0)
Procedural site reaction	1 (25.0)	1 (25.0)	0
Investigations			
-Total	3 (75.0)	0	3 (75.0)
International normalised ratio increased	2 (50.0)	2 (50.0)	0
White blood cell count decreased	2 (50.0)	0	2 (50.0)
Activated partial thromboplastin time prolonged	1 (25.0)	1 (25.0)	0
Alanine aminotransferase increased	1 (25.0)	0	1 (25.0)

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	1 (25.0)	1 (25.0)	0
Blood bilirubin increased	1 (25.0)	0	1 (25.0)
Blood creatinine increased	1 (25.0)	1 (25.0)	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0
Blood uric acid increased	1 (25.0)	1 (25.0)	0
Coronavirus test positive	1 (25.0)	1 (25.0)	0
Lymphocyte count decreased	1 (25.0)	0	1 (25.0)
Neutrophil count decreased	1 (25.0)	0	1 (25.0)
Platelet count decreased	1 (25.0)	0	1 (25.0)
Pulmonary function test decreased	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Decreased appetite	2 (50.0)	1 (25.0)	1 (25.0)
Hyperphosphataemia	2 (50.0)	2 (50.0)	0
Hyperuricaemia	1 (25.0)	1 (25.0)	0
Hypokalaemia	1 (25.0)	0	1 (25.0)
Musculoskeletal and connective tissue disorders			

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (100)	2 (50.0)	2 (50.0)
Arthralgia	2 (50.0)	2 (50.0)	0
Joint range of motion decreased	1 (25.0)	1 (25.0)	0
Musculoskeletal chest pain	1 (25.0)	1 (25.0)	0
Musculoskeletal pain	1 (25.0)	0	1 (25.0)
Myalgia	1 (25.0)	1 (25.0)	0
Osteonecrosis	1 (25.0)	0	1 (25.0)
Pain in extremity	1 (25.0)	1 (25.0)	0
Pain in jaw	1 (25.0)	1 (25.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (25.0)	0	1 (25.0)
Skin papilloma	1 (25.0)	0	1 (25.0)
Nervous system disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Headache	3 (75.0)	3 (75.0)	0
Dizziness	1 (25.0)	1 (25.0)	0
Neuralgia	1 (25.0)	0	1 (25.0)

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Psychiatric disorders			
-Total	1 (25.0)	0	1 (25.0)
Insomnia	1 (25.0)	0	1 (25.0)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Rhinorrhoea	1 (25.0)	1 (25.0)	0
Tachypnoea	1 (25.0)	1 (25.0)	0
Wheezing	1 (25.0)	0	1 (25.0)
Skin and subcutaneous tissue disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Petechiae	1 (25.0)	1 (25.0)	0
Pruritus generalised	1 (25.0)	1 (25.0)	0
Rash	1 (25.0)	0	1 (25.0)
Rash follicular	1 (25.0)	1 (25.0)	0
Rash papular	1 (25.0)	1 (25.0)	0

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Table 233i
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	66 (93.0)	2 (2.8)	64 (90.1)
Blood and lymphatic system disorders			
-Total	13 (18.3)	4 (5.6)	9 (12.7)
Anaemia	12 (16.9)	4 (5.6)	8 (11.3)
Lymphopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	19 (26.8)	10 (14.1)	9 (12.7)
Tachycardia	15 (21.1)	8 (11.3)	7 (9.9)
Sinus tachycardia	5 (7.0)	3 (4.2)	2 (2.8)
Eye disorders			

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (1.4)	1 (1.4)	0
Dry eye	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	44 (62.0)	15 (21.1)	29 (40.8)
Nausea	28 (39.4)	8 (11.3)	20 (28.2)
Vomiting	25 (35.2)	16 (22.5)	9 (12.7)
Diarrhoea	22 (31.0)	12 (16.9)	10 (14.1)
Abdominal pain	12 (16.9)	5 (7.0)	7 (9.9)
Constipation	10 (14.1)	8 (11.3)	2 (2.8)
Abdominal distension	1 (1.4)	0	1 (1.4)
General disorders and administration site conditions			
-Total	38 (53.5)	13 (18.3)	25 (35.2)
Pyrexia	28 (39.4)	8 (11.3)	20 (28.2)
Fatigue	13 (18.3)	9 (12.7)	4 (5.6)
Chills	11 (15.5)	9 (12.7)	2 (2.8)
Pain	3 (4.2)	1 (1.4)	2 (2.8)
Immune system disorders			

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	50 (70.4)	7 (9.9)	43 (60.6)
Cytokine release syndrome	44 (62.0)	7 (9.9)	37 (52.1)
Hypogammaglobulinaemia	24 (33.8)	4 (5.6)	20 (28.2)
Infections and infestations			
-Total	18 (25.4)	5 (7.0)	13 (18.3)
Upper respiratory tract infection	9 (12.7)	4 (5.6)	5 (7.0)
Clostridium difficile infection	4 (5.6)	0	4 (5.6)
Sinusitis	4 (5.6)	1 (1.4)	3 (4.2)
Parainfluenzae virus infection	2 (2.8)	1 (1.4)	1 (1.4)
Viral infection	2 (2.8)	1 (1.4)	1 (1.4)
Cytomegalovirus infection	1 (1.4)	1 (1.4)	0
Otitis media acute	1 (1.4)	0	1 (1.4)
Injury, poisoning and procedural complications			
-Total	8 (11.3)	4 (5.6)	4 (5.6)
Infusion related reaction	4 (5.6)	2 (2.8)	2 (2.8)
Procedural pain	4 (5.6)	2 (2.8)	2 (2.8)
Contusion	2 (2.8)	2 (2.8)	0

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	36 (50.7)	2 (2.8)	34 (47.9)
Aspartate aminotransferase increased	15 (21.1)	7 (9.9)	8 (11.3)
White blood cell count decreased	15 (21.1)	6 (8.5)	9 (12.7)
Alanine aminotransferase increased	13 (18.3)	5 (7.0)	8 (11.3)
Prothrombin time prolonged	9 (12.7)	5 (7.0)	4 (5.6)
International normalised ratio increased	8 (11.3)	7 (9.9)	1 (1.4)
Blood bilirubin increased	6 (8.5)	2 (2.8)	4 (5.6)
Blood creatinine increased	6 (8.5)	4 (5.6)	2 (2.8)
Lymphocyte count decreased	6 (8.5)	2 (2.8)	4 (5.6)
Activated partial thromboplastin time prolonged	5 (7.0)	2 (2.8)	3 (4.2)
Neutrophil count decreased	5 (7.0)	2 (2.8)	3 (4.2)
Platelet count decreased	5 (7.0)	3 (4.2)	2 (2.8)
Blood immunoglobulin a decreased	2 (2.8)	2 (2.8)	0
Blood uric acid increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	28 (39.4)	15 (21.1)	13 (18.3)
Decreased appetite	17 (23.9)	10 (14.1)	7 (9.9)
Hypokalaemia	11 (15.5)	5 (7.0)	6 (8.5)
Hyperphosphataemia	7 (9.9)	6 (8.5)	1 (1.4)
Hyperuricaemia	2 (2.8)	2 (2.8)	0
Musculoskeletal and connective tissue disorders			
-Total	20 (28.2)	14 (19.7)	6 (8.5)
Pain in extremity	10 (14.1)	6 (8.5)	4 (5.6)
Arthralgia	4 (5.6)	3 (4.2)	1 (1.4)
Myalgia	4 (5.6)	3 (4.2)	1 (1.4)
Pain in jaw	3 (4.2)	1 (1.4)	2 (2.8)
Musculoskeletal chest pain	2 (2.8)	2 (2.8)	0
Musculoskeletal pain	2 (2.8)	2 (2.8)	0
Joint range of motion decreased	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	28 (39.4)	16 (22.5)	12 (16.9)
Headache	25 (35.2)	13 (18.3)	12 (16.9)

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dizziness	5 (7.0)	5 (7.0)	0
Psychiatric disorders			
-Total	11 (15.5)	3 (4.2)	8 (11.3)
Anxiety	8 (11.3)	3 (4.2)	5 (7.0)
Insomnia	3 (4.2)	0	3 (4.2)
Respiratory, thoracic and mediastinal disorders			
-Total	27 (38.0)	11 (15.5)	16 (22.5)
Cough	15 (21.1)	13 (18.3)	2 (2.8)
Epistaxis	9 (12.7)	4 (5.6)	5 (7.0)
Hypoxia	8 (11.3)	0	8 (11.3)
Rhinorrhoea	5 (7.0)	4 (5.6)	1 (1.4)
Tachypnoea	4 (5.6)	2 (2.8)	2 (2.8)
Skin and subcutaneous tissue disorders			
-Total	12 (16.9)	9 (12.7)	3 (4.2)
Rash	8 (11.3)	6 (8.5)	2 (2.8)
Petechiae	3 (4.2)	2 (2.8)	1 (1.4)
Rash papular	2 (2.8)	2 (2.8)	0

BCR-ABL1-like: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Vascular disorders			
-Total	14 (19.7)	4 (5.6)	10 (14.1)
Hypertension	14 (19.7)	4 (5.6)	10 (14.1)

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233j
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	21 (95.5)	0	21 (95.5)
Blood and lymphatic system disorders			
-Total	3 (13.6)	1 (4.5)	2 (9.1)
Anaemia	3 (13.6)	1 (4.5)	2 (9.1)
Cardiac disorders			
-Total	7 (31.8)	3 (13.6)	4 (18.2)
Tachycardia	4 (18.2)	2 (9.1)	2 (9.1)
Sinus tachycardia	3 (13.6)	1 (4.5)	2 (9.1)
Eye disorders			
-Total	6 (27.3)	4 (18.2)	2 (9.1)
Periorbital oedema	3 (13.6)	2 (9.1)	1 (4.5)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vision blurred	3 (13.6)	2 (9.1)	1 (4.5)
Gastrointestinal disorders			
-Total	16 (72.7)	6 (27.3)	10 (45.5)
Diarrhoea	11 (50.0)	5 (22.7)	6 (27.3)
Vomiting	10 (45.5)	7 (31.8)	3 (13.6)
Nausea	9 (40.9)	4 (18.2)	5 (22.7)
Abdominal pain	4 (18.2)	2 (9.1)	2 (9.1)
Constipation	4 (18.2)	3 (13.6)	1 (4.5)
General disorders and administration site conditions			
-Total	16 (72.7)	5 (22.7)	11 (50.0)
Pyrexia	13 (59.1)	3 (13.6)	10 (45.5)
Fatigue	6 (27.3)	3 (13.6)	3 (13.6)
Catheter site pain	3 (13.6)	2 (9.1)	1 (4.5)
Chills	3 (13.6)	3 (13.6)	0
Immune system disorders			
-Total	17 (77.3)	2 (9.1)	15 (68.2)
Cytokine release syndrome	16 (72.7)	2 (9.1)	14 (63.6)
Hypogammaglobulinaemia	9 (40.9)	2 (9.1)	7 (31.8)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	9 (40.9)	6 (27.3)	3 (13.6)
Upper respiratory tract infection	6 (27.3)	3 (13.6)	3 (13.6)
Gastroenteritis	3 (13.6)	1 (4.5)	2 (9.1)
Rhinovirus infection	3 (13.6)	3 (13.6)	0
Investigations			
-Total	10 (45.5)	2 (9.1)	8 (36.4)
Aspartate aminotransferase increased	5 (22.7)	3 (13.6)	2 (9.1)
Alanine aminotransferase increased	4 (18.2)	2 (9.1)	2 (9.1)
Prothrombin time prolonged	4 (18.2)	2 (9.1)	2 (9.1)
White blood cell count decreased	4 (18.2)	2 (9.1)	2 (9.1)
Blood creatinine increased	3 (13.6)	2 (9.1)	1 (4.5)
Lymphocyte count decreased	3 (13.6)	1 (4.5)	2 (9.1)
International normalised ratio increased	2 (9.1)	2 (9.1)	0
Metabolism and nutrition disorders			
-Total	13 (59.1)	3 (13.6)	10 (45.5)
Decreased appetite	7 (31.8)	3 (13.6)	4 (18.2)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fluid overload	3 (13.6)	0	3 (13.6)
Hypernatraemia	3 (13.6)	0	3 (13.6)
Hyperphosphataemia	2 (9.1)	2 (9.1)	0
Hypokalaemia	2 (9.1)	1 (4.5)	1 (4.5)
Musculoskeletal and connective tissue disorders			
-Total	7 (31.8)	4 (18.2)	3 (13.6)
Pain in extremity	7 (31.8)	4 (18.2)	3 (13.6)
Nervous system disorders			
-Total	8 (36.4)	4 (18.2)	4 (18.2)
Headache	8 (36.4)	4 (18.2)	4 (18.2)
Psychiatric disorders			
-Total	4 (18.2)	2 (9.1)	2 (9.1)
Anxiety	3 (13.6)	1 (4.5)	2 (9.1)
Irritability	3 (13.6)	3 (13.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	11 (50.0)	6 (27.3)	5 (22.7)
Cough	8 (36.4)	7 (31.8)	1 (4.5)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	3 (13.6)	1 (4.5)	2 (9.1)
Hypoxia	2 (9.1)	0	2 (9.1)
Pleural effusion	1 (4.5)	0	1 (4.5)
Skin and subcutaneous tissue disorders			
-Total	7 (31.8)	4 (18.2)	3 (13.6)
Rash	4 (18.2)	2 (9.1)	2 (9.1)
Rash maculo-papular	3 (13.6)	2 (9.1)	1 (4.5)
Vascular disorders			
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Hypertension	3 (13.6)	2 (9.1)	1 (4.5)

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233j
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	48 (90.6)	3 (5.7)	45 (84.9)
Blood and lymphatic system disorders			
-Total	11 (20.8)	3 (5.7)	8 (15.1)
Anaemia	11 (20.8)	3 (5.7)	8 (15.1)
Cardiac disorders			
-Total	14 (26.4)	8 (15.1)	6 (11.3)
Tachycardia	12 (22.6)	7 (13.2)	5 (9.4)
Sinus tachycardia	3 (5.7)	2 (3.8)	1 (1.9)
Eye disorders			
-Total	1 (1.9)	0	1 (1.9)
Periorbital oedema	1 (1.9)	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vision blurred	1 (1.9)	0	1 (1.9)
Gastrointestinal disorders			
-Total	31 (58.5)	10 (18.9)	21 (39.6)
Nausea	21 (39.6)	5 (9.4)	16 (30.2)
Vomiting	17 (32.1)	10 (18.9)	7 (13.2)
Diarrhoea	14 (26.4)	9 (17.0)	5 (9.4)
Abdominal pain	10 (18.9)	5 (9.4)	5 (9.4)
Constipation	7 (13.2)	6 (11.3)	1 (1.9)
General disorders and administration site conditions			
-Total	28 (52.8)	14 (26.4)	14 (26.4)
Pyrexia	16 (30.2)	6 (11.3)	10 (18.9)
Fatigue	11 (20.8)	10 (18.9)	1 (1.9)
Chills	8 (15.1)	6 (11.3)	2 (3.8)
Catheter site pain	4 (7.5)	1 (1.9)	3 (5.7)
Immune system disorders			
-Total	37 (69.8)	5 (9.4)	32 (60.4)
Cytokine release syndrome	29 (54.7)	5 (9.4)	24 (45.3)
Hypogammaglobulinaemia	19 (35.8)	2 (3.8)	17 (32.1)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	8 (15.1)	4 (7.5)	4 (7.5)
Upper respiratory tract infection	4 (7.5)	2 (3.8)	2 (3.8)
Rhinovirus infection	3 (5.7)	2 (3.8)	1 (1.9)
Gastroenteritis	1 (1.9)	0	1 (1.9)
Investigations			
-Total	25 (47.2)	1 (1.9)	24 (45.3)
White blood cell count decreased	13 (24.5)	4 (7.5)	9 (17.0)
Aspartate aminotransferase increased	11 (20.8)	5 (9.4)	6 (11.3)
Alanine aminotransferase increased	10 (18.9)	3 (5.7)	7 (13.2)
International normalised ratio increased	8 (15.1)	7 (13.2)	1 (1.9)
Prothrombin time prolonged	5 (9.4)	3 (5.7)	2 (3.8)
Blood creatinine increased	4 (7.5)	3 (5.7)	1 (1.9)
Lymphocyte count decreased	4 (7.5)	1 (1.9)	3 (5.7)
Metabolism and nutrition disorders			
-Total	23 (43.4)	13 (24.5)	10 (18.9)
Decreased appetite	12 (22.6)	8 (15.1)	4 (7.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	10 (18.9)	4 (7.5)	6 (11.3)
Hyperphosphataemia	7 (13.2)	6 (11.3)	1 (1.9)
Fluid overload	2 (3.8)	1 (1.9)	1 (1.9)
Hypernatraemia	2 (3.8)	1 (1.9)	1 (1.9)
Musculoskeletal and connective tissue disorders			
-Total	4 (7.5)	3 (5.7)	1 (1.9)
Pain in extremity	4 (7.5)	3 (5.7)	1 (1.9)
Nervous system disorders			
-Total	20 (37.7)	12 (22.6)	8 (15.1)
Headache	20 (37.7)	12 (22.6)	8 (15.1)
Psychiatric disorders			
-Total	5 (9.4)	2 (3.8)	3 (5.7)
Anxiety	5 (9.4)	2 (3.8)	3 (5.7)
Respiratory, thoracic and mediastinal disorders			
-Total	15 (28.3)	4 (7.5)	11 (20.8)
Cough	7 (13.2)	6 (11.3)	1 (1.9)
Epistaxis	6 (11.3)	3 (5.7)	3 (5.7)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoxia	6 (11.3)	0	6 (11.3)
Pleural effusion	6 (11.3)	1 (1.9)	5 (9.4)
Skin and subcutaneous tissue disorders			
-Total	6 (11.3)	5 (9.4)	1 (1.9)
Rash	5 (9.4)	4 (7.5)	1 (1.9)
Rash maculo-papular	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	11 (20.8)	2 (3.8)	9 (17.0)
Hypertension	11 (20.8)	2 (3.8)	9 (17.0)

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233k
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	68 (90.7)	4 (5.3)	64 (85.3)
Blood and lymphatic system disorders			
-Total	14 (18.7)	4 (5.3)	10 (13.3)
Anaemia	14 (18.7)	4 (5.3)	10 (13.3)
Cardiac disorders			
-Total	16 (21.3)	9 (12.0)	7 (9.3)
Tachycardia	16 (21.3)	9 (12.0)	7 (9.3)
Gastrointestinal disorders			
-Total	47 (62.7)	16 (21.3)	31 (41.3)
Nausea	30 (40.0)	9 (12.0)	21 (28.0)

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Vomiting	27 (36.0)	17 (22.7)	10 (13.3)
Diarrhoea	25 (33.3)	14 (18.7)	11 (14.7)
Abdominal pain	14 (18.7)	7 (9.3)	7 (9.3)
Constipation	11 (14.7)	9 (12.0)	2 (2.7)
General disorders and administration site conditions			
-Total	41 (54.7)	18 (24.0)	23 (30.7)
Pyrexia	29 (38.7)	9 (12.0)	20 (26.7)
Fatigue	17 (22.7)	13 (17.3)	4 (5.3)
Chills	11 (14.7)	9 (12.0)	2 (2.7)
Immune system disorders			
-Total	54 (72.0)	7 (9.3)	47 (62.7)
Cytokine release syndrome	45 (60.0)	7 (9.3)	38 (50.7)
Hypogammaglobulinaemia	28 (37.3)	4 (5.3)	24 (32.0)
Infections and infestations			
-Total	10 (13.3)	5 (6.7)	5 (6.7)
Upper respiratory tract infection	10 (13.3)	5 (6.7)	5 (6.7)
Investigations			

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	34 (45.3)	6 (8.0)	28 (37.3)
White blood cell count decreased	17 (22.7)	6 (8.0)	11 (14.7)
Aspartate aminotransferase increased	16 (21.3)	8 (10.7)	8 (10.7)
Alanine aminotransferase increased	14 (18.7)	5 (6.7)	9 (12.0)
International normalised ratio increased	10 (13.3)	9 (12.0)	1 (1.3)
Prothrombin time prolonged	9 (12.0)	5 (6.7)	4 (5.3)
Metabolism and nutrition disorders			
-Total	31 (41.3)	17 (22.7)	14 (18.7)
Decreased appetite	19 (25.3)	11 (14.7)	8 (10.7)
Hypokalaemia	12 (16.0)	5 (6.7)	7 (9.3)
Hyperphosphataemia	9 (12.0)	8 (10.7)	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	11 (14.7)	7 (9.3)	4 (5.3)
Pain in extremity	11 (14.7)	7 (9.3)	4 (5.3)
Nervous system disorders			
-Total	28 (37.3)	16 (21.3)	12 (16.0)

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Headache	28 (37.3)	16 (21.3)	12 (16.0)
Psychiatric disorders			
-Total	8 (10.7)	3 (4.0)	5 (6.7)
Anxiety	8 (10.7)	3 (4.0)	5 (6.7)
Respiratory, thoracic and mediastinal disorders			
-Total	24 (32.0)	10 (13.3)	14 (18.7)
Cough	15 (20.0)	13 (17.3)	2 (2.7)
Epistaxis	9 (12.0)	4 (5.3)	5 (6.7)
Hypoxia	8 (10.7)	0	8 (10.7)
Skin and subcutaneous tissue disorders			
-Total	9 (12.0)	6 (8.0)	3 (4.0)
Rash	9 (12.0)	6 (8.0)	3 (4.0)
Vascular disorders			
-Total	14 (18.7)	4 (5.3)	10 (13.3)
Hypertension	14 (18.7)	4 (5.3)	10 (13.3)

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accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233l
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	30 (93.8)	1 (3.1)	29 (90.6)
Blood and lymphatic system disorders			
-Total	7 (21.9)	2 (6.3)	5 (15.6)
Anaemia	7 (21.9)	2 (6.3)	5 (15.6)
Cardiac disorders			
-Total	12 (37.5)	5 (15.6)	7 (21.9)
Tachycardia	8 (25.0)	4 (12.5)	4 (12.5)
Sinus tachycardia	5 (15.6)	2 (6.3)	3 (9.4)
Gastrointestinal disorders			
-Total	19 (59.4)	5 (15.6)	14 (43.8)

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	14 (43.8)	6 (18.8)	8 (25.0)
Diarrhoea	12 (37.5)	6 (18.8)	6 (18.8)
Vomiting	12 (37.5)	9 (28.1)	3 (9.4)
Abdominal pain	10 (31.3)	4 (12.5)	6 (18.8)
Constipation	4 (12.5)	4 (12.5)	0
General disorders and administration site conditions			
-Total	21 (65.6)	12 (37.5)	9 (28.1)
Pyrexia	15 (46.9)	8 (25.0)	7 (21.9)
Fatigue	9 (28.1)	7 (21.9)	2 (6.3)
Chills	4 (12.5)	4 (12.5)	0
Oedema peripheral	4 (12.5)	3 (9.4)	1 (3.1)
Catheter site pain	2 (6.3)	2 (6.3)	0
Immune system disorders			
-Total	24 (75.0)	6 (18.8)	18 (56.3)
Cytokine release syndrome	18 (56.3)	4 (12.5)	14 (43.8)
Hypogammaglobulinaemia	13 (40.6)	3 (9.4)	10 (31.3)
Infections and infestations			

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	5 (15.6)	4 (12.5)	1 (3.1)
Upper respiratory tract infection	5 (15.6)	4 (12.5)	1 (3.1)
Investigations			
-Total	20 (62.5)	2 (6.3)	18 (56.3)
Aspartate aminotransferase increased	11 (34.4)	7 (21.9)	4 (12.5)
Alanine aminotransferase increased	10 (31.3)	5 (15.6)	5 (15.6)
White blood cell count decreased	9 (28.1)	3 (9.4)	6 (18.8)
International normalised ratio increased	7 (21.9)	6 (18.8)	1 (3.1)
Prothrombin time prolonged	6 (18.8)	4 (12.5)	2 (6.3)
Blood bilirubin increased	5 (15.6)	2 (6.3)	3 (9.4)
Blood creatinine increased	5 (15.6)	4 (12.5)	1 (3.1)
Lymphocyte count decreased	4 (12.5)	1 (3.1)	3 (9.4)
Neutrophil count decreased	4 (12.5)	2 (6.3)	2 (6.3)
Metabolism and nutrition disorders			
-Total	15 (46.9)	10 (31.3)	5 (15.6)
Decreased appetite	10 (31.3)	7 (21.9)	3 (9.4)
Hyperphosphataemia	8 (25.0)	7 (21.9)	1 (3.1)

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	5 (15.6)	2 (6.3)	3 (9.4)
Musculoskeletal and connective tissue disorders			
-Total	8 (25.0)	5 (15.6)	3 (9.4)
Myalgia	5 (15.6)	4 (12.5)	1 (3.1)
Pain in extremity	5 (15.6)	3 (9.4)	2 (6.3)
Nervous system disorders			
-Total	16 (50.0)	7 (21.9)	9 (28.1)
Headache	15 (46.9)	6 (18.8)	9 (28.1)
Dizziness	4 (12.5)	4 (12.5)	0
Psychiatric disorders			
-Total	5 (15.6)	1 (3.1)	4 (12.5)
Anxiety	4 (12.5)	1 (3.1)	3 (9.4)
Confusional state	2 (6.3)	0	2 (6.3)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (43.8)	7 (21.9)	7 (21.9)
Cough	8 (25.0)	7 (21.9)	1 (3.1)
Epistaxis	5 (15.6)	3 (9.4)	2 (6.3)

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoxia	5 (15.6)	0	5 (15.6)
Rhinitis allergic	4 (12.5)	4 (12.5)	0
Skin and subcutaneous tissue disorders			
-Total	5 (15.6)	4 (12.5)	1 (3.1)
Rash	5 (15.6)	4 (12.5)	1 (3.1)
Vascular disorders			
-Total	6 (18.8)	2 (6.3)	4 (12.5)
Hypertension	6 (18.8)	2 (6.3)	4 (12.5)

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233l
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	39 (90.7)	3 (7.0)	36 (83.7)
Blood and lymphatic system disorders			
-Total	7 (16.3)	2 (4.7)	5 (11.6)
Anaemia	7 (16.3)	2 (4.7)	5 (11.6)
Cardiac disorders			
-Total	9 (20.9)	6 (14.0)	3 (7.0)
Tachycardia	8 (18.6)	5 (11.6)	3 (7.0)
Sinus tachycardia	1 (2.3)	1 (2.3)	0
Gastrointestinal disorders			
-Total	28 (65.1)	11 (25.6)	17 (39.5)

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	16 (37.2)	3 (7.0)	13 (30.2)
Vomiting	15 (34.9)	8 (18.6)	7 (16.3)
Diarrhoea	13 (30.2)	8 (18.6)	5 (11.6)
Constipation	7 (16.3)	5 (11.6)	2 (4.7)
Abdominal pain	4 (9.3)	3 (7.0)	1 (2.3)
General disorders and administration site conditions			
-Total	23 (53.5)	7 (16.3)	16 (37.2)
Pyrexia	14 (32.6)	1 (2.3)	13 (30.2)
Fatigue	8 (18.6)	6 (14.0)	2 (4.7)
Chills	7 (16.3)	5 (11.6)	2 (4.7)
Catheter site pain	5 (11.6)	1 (2.3)	4 (9.3)
Immune system disorders			
-Total	30 (69.8)	1 (2.3)	29 (67.4)
Cytokine release syndrome	27 (62.8)	3 (7.0)	24 (55.8)
Hypogammaglobulinaemia	15 (34.9)	1 (2.3)	14 (32.6)
Infections and infestations			
-Total	5 (11.6)	1 (2.3)	4 (9.3)

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	5 (11.6)	1 (2.3)	4 (9.3)
Investigations			
-Total	17 (39.5)	0	17 (39.5)
White blood cell count decreased	8 (18.6)	3 (7.0)	5 (11.6)
Aspartate aminotransferase increased	5 (11.6)	1 (2.3)	4 (9.3)
Alanine aminotransferase increased	4 (9.3)	0	4 (9.3)
International normalised ratio increased	3 (7.0)	3 (7.0)	0
Lymphocyte count decreased	3 (7.0)	1 (2.3)	2 (4.7)
Prothrombin time prolonged	3 (7.0)	1 (2.3)	2 (4.7)
Blood bilirubin increased	2 (4.7)	0	2 (4.7)
Blood creatinine increased	2 (4.7)	1 (2.3)	1 (2.3)
Neutrophil count decreased	2 (4.7)	0	2 (4.7)
Metabolism and nutrition disorders			
-Total	19 (44.2)	7 (16.3)	12 (27.9)
Decreased appetite	9 (20.9)	4 (9.3)	5 (11.6)
Hypokalaemia	7 (16.3)	3 (7.0)	4 (9.3)
Hypernatraemia	5 (11.6)	1 (2.3)	4 (9.3)

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	1 (2.3)	1 (2.3)	0
Musculoskeletal and connective tissue disorders			
-Total	6 (14.0)	4 (9.3)	2 (4.7)
Pain in extremity	6 (14.0)	4 (9.3)	2 (4.7)
Nervous system disorders			
-Total	15 (34.9)	12 (27.9)	3 (7.0)
Headache	13 (30.2)	10 (23.3)	3 (7.0)
Dizziness	2 (4.7)	2 (4.7)	0
Psychiatric disorders			
-Total	9 (20.9)	5 (11.6)	4 (9.3)
Confusional state	5 (11.6)	3 (7.0)	2 (4.7)
Anxiety	4 (9.3)	2 (4.7)	2 (4.7)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (30.2)	5 (11.6)	8 (18.6)
Cough	7 (16.3)	6 (14.0)	1 (2.3)
Epistaxis	4 (9.3)	1 (2.3)	3 (7.0)
Hypoxia	3 (7.0)	0	3 (7.0)

Prior SCT therapy: No

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Rhinitis allergic	1 (2.3)	0	1 (2.3)
Skin and subcutaneous tissue disorders			
-Total	4 (9.3)	2 (4.7)	2 (4.7)
Rash	4 (9.3)	2 (4.7)	2 (4.7)
Vascular disorders			
-Total	8 (18.6)	2 (4.7)	6 (14.0)
Hypertension	8 (18.6)	2 (4.7)	6 (14.0)

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233m
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (83.3)	0	15 (83.3)
Blood and lymphatic system disorders			
-Total	6 (33.3)	2 (11.1)	4 (22.2)
Anaemia	4 (22.2)	2 (11.1)	2 (11.1)
Thrombocytopenia	2 (11.1)	0	2 (11.1)
Cardiac disorders			
-Total	2 (11.1)	2 (11.1)	0
Tachycardia	2 (11.1)	2 (11.1)	0
Gastrointestinal disorders			
-Total	11 (61.1)	3 (16.7)	8 (44.4)

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	7 (38.9)	0	7 (38.9)
Diarrhoea	4 (22.2)	2 (11.1)	2 (11.1)
Vomiting	4 (22.2)	2 (11.1)	2 (11.1)
Constipation	3 (16.7)	2 (11.1)	1 (5.6)
Abdominal pain	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	4 (22.2)	1 (5.6)	3 (16.7)
Catheter site pain	2 (11.1)	0	2 (11.1)
Fatigue	2 (11.1)	1 (5.6)	1 (5.6)
Pyrexia	2 (11.1)	0	2 (11.1)
Chills	1 (5.6)	1 (5.6)	0
Immune system disorders			
-Total	12 (66.7)	0	12 (66.7)
Cytokine release syndrome	11 (61.1)	0	11 (61.1)
Hypogammaglobulinaemia	7 (38.9)	1 (5.6)	6 (33.3)
Infections and infestations			
-Total	6 (33.3)	2 (11.1)	4 (22.2)

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Influenza	2 (11.1)	0	2 (11.1)
Urinary tract infection	2 (11.1)	0	2 (11.1)
Viral upper respiratory tract infection	2 (11.1)	2 (11.1)	0
Injury, poisoning and procedural complications			
-Total	4 (22.2)	2 (11.1)	2 (11.1)
Procedural pain	2 (11.1)	2 (11.1)	0
Radiation skin injury	2 (11.1)	0	2 (11.1)
Investigations			
-Total	7 (38.9)	0	7 (38.9)
White blood cell count decreased	4 (22.2)	2 (11.1)	2 (11.1)
Blood bilirubin increased	3 (16.7)	1 (5.6)	2 (11.1)
Alanine aminotransferase increased	2 (11.1)	0	2 (11.1)
Lymphocyte count decreased	2 (11.1)	1 (5.6)	1 (5.6)
Neutrophil count decreased	2 (11.1)	1 (5.6)	1 (5.6)
Aspartate aminotransferase increased	1 (5.6)	0	1 (5.6)
Blood creatinine increased	1 (5.6)	1 (5.6)	0

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
International normalised ratio increased	1 (5.6)	1 (5.6)	0
Prothrombin time prolonged	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	9 (50.0)	3 (16.7)	6 (33.3)
Decreased appetite	5 (27.8)	2 (11.1)	3 (16.7)
Hypokalaemia	3 (16.7)	2 (11.1)	1 (5.6)
Hyperphosphataemia	2 (11.1)	2 (11.1)	0
Hypomagnesaemia	2 (11.1)	1 (5.6)	1 (5.6)
Hypophosphataemia	2 (11.1)	1 (5.6)	1 (5.6)
Musculoskeletal and connective tissue disorders			
-Total	7 (38.9)	5 (27.8)	2 (11.1)
Pain in extremity	4 (22.2)	3 (16.7)	1 (5.6)
Arthralgia	3 (16.7)	2 (11.1)	1 (5.6)
Muscular weakness	2 (11.1)	1 (5.6)	1 (5.6)
Nervous system disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Headache	3 (16.7)	2 (11.1)	1 (5.6)

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Psychiatric disorders			
-Total	1 (5.6)	0	1 (5.6)
Confusional state	1 (5.6)	0	1 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (50.0)	3 (16.7)	6 (33.3)
Cough	3 (16.7)	1 (5.6)	2 (11.1)
Epistaxis	3 (16.7)	1 (5.6)	2 (11.1)
Nasal congestion	3 (16.7)	3 (16.7)	0
Hypoxia	2 (11.1)	0	2 (11.1)
Pleural effusion	2 (11.1)	0	2 (11.1)
Rhinorrhoea	2 (11.1)	1 (5.6)	1 (5.6)
Skin and subcutaneous tissue disorders			
-Total	3 (16.7)	3 (16.7)	0
Rash erythematous	2 (11.1)	2 (11.1)	0
Rash	1 (5.6)	1 (5.6)	0
Vascular disorders			
-Total	3 (16.7)	1 (5.6)	2 (11.1)

Eligibility for SCT: Yes

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)

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- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233m
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	53 (93.0)	4 (7.0)	49 (86.0)
Blood and lymphatic system disorders			
-Total	11 (19.3)	3 (5.3)	8 (14.0)
Anaemia	10 (17.5)	2 (3.5)	8 (14.0)
Thrombocytopenia	3 (5.3)	1 (1.8)	2 (3.5)
Cardiac disorders			
-Total	14 (24.6)	7 (12.3)	7 (12.3)
Tachycardia	14 (24.6)	7 (12.3)	7 (12.3)
Gastrointestinal disorders			
-Total	36 (63.2)	13 (22.8)	23 (40.4)

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	23 (40.4)	9 (15.8)	14 (24.6)
Vomiting	23 (40.4)	15 (26.3)	8 (14.0)
Diarrhoea	21 (36.8)	12 (21.1)	9 (15.8)
Abdominal pain	13 (22.8)	6 (10.5)	7 (12.3)
Constipation	8 (14.0)	7 (12.3)	1 (1.8)
General disorders and administration site conditions			
-Total	40 (70.2)	18 (31.6)	22 (38.6)
Pyrexia	27 (47.4)	9 (15.8)	18 (31.6)
Fatigue	15 (26.3)	12 (21.1)	3 (5.3)
Chills	10 (17.5)	8 (14.0)	2 (3.5)
Catheter site pain	5 (8.8)	3 (5.3)	2 (3.5)
Immune system disorders			
-Total	42 (73.7)	7 (12.3)	35 (61.4)
Cytokine release syndrome	34 (59.6)	7 (12.3)	27 (47.4)
Hypogammaglobulinaemia	21 (36.8)	3 (5.3)	18 (31.6)
Infections and infestations			
-Total	14 (24.6)	5 (8.8)	9 (15.8)

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	10 (17.5)	5 (8.8)	5 (8.8)
Influenza	2 (3.5)	1 (1.8)	1 (1.8)
Urinary tract infection	2 (3.5)	0	2 (3.5)
Viral upper respiratory tract infection	1 (1.8)	0	1 (1.8)
Injury, poisoning and procedural complications			
-Total	3 (5.3)	0	3 (5.3)
Procedural pain	3 (5.3)	0	3 (5.3)
Investigations			
-Total	31 (54.4)	2 (3.5)	29 (50.9)
Aspartate aminotransferase increased	15 (26.3)	8 (14.0)	7 (12.3)
White blood cell count decreased	13 (22.8)	4 (7.0)	9 (15.8)
Alanine aminotransferase increased	12 (21.1)	5 (8.8)	7 (12.3)
International normalised ratio increased	9 (15.8)	8 (14.0)	1 (1.8)
Prothrombin time prolonged	8 (14.0)	4 (7.0)	4 (7.0)
Activated partial thromboplastin time prolonged	6 (10.5)	3 (5.3)	3 (5.3)

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood creatinine increased	6 (10.5)	4 (7.0)	2 (3.5)
Lymphocyte count decreased	5 (8.8)	1 (1.8)	4 (7.0)
Blood bilirubin increased	4 (7.0)	1 (1.8)	3 (5.3)
Neutrophil count decreased	4 (7.0)	1 (1.8)	3 (5.3)
Metabolism and nutrition disorders			
-Total	26 (45.6)	16 (28.1)	10 (17.5)
Decreased appetite	14 (24.6)	9 (15.8)	5 (8.8)
Hypokalaemia	9 (15.8)	3 (5.3)	6 (10.5)
Hyperphosphataemia	7 (12.3)	6 (10.5)	1 (1.8)
Hypophosphataemia	4 (7.0)	4 (7.0)	0
Hypomagnesaemia	1 (1.8)	1 (1.8)	0
Musculoskeletal and connective tissue disorders			
-Total	9 (15.8)	6 (10.5)	3 (5.3)
Pain in extremity	7 (12.3)	4 (7.0)	3 (5.3)
Arthralgia	3 (5.3)	3 (5.3)	0
Muscular weakness	1 (1.8)	1 (1.8)	0
Nervous system disorders			

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	25 (43.9)	14 (24.6)	11 (19.3)
Headache	25 (43.9)	14 (24.6)	11 (19.3)
Psychiatric disorders			
-Total	13 (22.8)	6 (10.5)	7 (12.3)
Anxiety	8 (14.0)	3 (5.3)	5 (8.8)
Confusional state	6 (10.5)	3 (5.3)	3 (5.3)
Respiratory, thoracic and mediastinal disorders			
-Total	24 (42.1)	13 (22.8)	11 (19.3)
Cough	12 (21.1)	12 (21.1)	0
Epistaxis	6 (10.5)	3 (5.3)	3 (5.3)
Hypoxia	6 (10.5)	0	6 (10.5)
Pleural effusion	5 (8.8)	1 (1.8)	4 (7.0)
Rhinorrhoea	4 (7.0)	4 (7.0)	0
Nasal congestion	3 (5.3)	3 (5.3)	0
Skin and subcutaneous tissue disorders			
-Total	10 (17.5)	4 (7.0)	6 (10.5)
Rash	8 (14.0)	5 (8.8)	3 (5.3)

Eligibility for SCT: No

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Rash erythematous	3 (5.3)	0	3 (5.3)
Vascular disorders			
-Total	11 (19.3)	3 (5.3)	8 (14.0)
Hypertension	11 (19.3)	3 (5.3)	8 (14.0)

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233n
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	22 (100)	1 (4.5)	21 (95.5)
Blood and lymphatic system disorders			
-Total	4 (18.2)	2 (9.1)	2 (9.1)
Anaemia	4 (18.2)	2 (9.1)	2 (9.1)
Cardiac disorders			
-Total	3 (13.6)	1 (4.5)	2 (9.1)
Tachycardia	3 (13.6)	1 (4.5)	2 (9.1)
Gastrointestinal disorders			
-Total	16 (72.7)	7 (31.8)	9 (40.9)
Vomiting	11 (50.0)	8 (36.4)	3 (13.6)
Nausea	10 (45.5)	4 (18.2)	6 (27.3)

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	5 (22.7)	2 (9.1)	3 (13.6)
Abdominal pain	4 (18.2)	2 (9.1)	2 (9.1)
Constipation	4 (18.2)	3 (13.6)	1 (4.5)
General disorders and administration site conditions			
-Total	13 (59.1)	9 (40.9)	4 (18.2)
Pyrexia	8 (36.4)	5 (22.7)	3 (13.6)
Fatigue	6 (27.3)	5 (22.7)	1 (4.5)
Catheter site pain	3 (13.6)	1 (4.5)	2 (9.1)
Chills	2 (9.1)	2 (9.1)	0
Immune system disorders			
-Total	18 (81.8)	2 (9.1)	16 (72.7)
Cytokine release syndrome	15 (68.2)	0	15 (68.2)
Hypogammaglobulinaemia	12 (54.5)	2 (9.1)	10 (45.5)
Infections and infestations			
-Total	8 (36.4)	3 (13.6)	5 (22.7)
Upper respiratory tract infection	5 (22.7)	1 (4.5)	4 (18.2)
Viral infection	3 (13.6)	2 (9.1)	1 (4.5)
Investigations			

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (50.0)	1 (4.5)	10 (45.5)
International normalised ratio increased	5 (22.7)	4 (18.2)	1 (4.5)
White blood cell count decreased	5 (22.7)	3 (13.6)	2 (9.1)
Aspartate aminotransferase increased	4 (18.2)	0	4 (18.2)
Lymphocyte count decreased	4 (18.2)	2 (9.1)	2 (9.1)
Alanine aminotransferase increased	3 (13.6)	1 (4.5)	2 (9.1)
Blood bilirubin increased	3 (13.6)	2 (9.1)	1 (4.5)
Blood creatinine increased	3 (13.6)	3 (13.6)	0
Neutrophil count decreased	3 (13.6)	1 (4.5)	2 (9.1)
Prothrombin time prolonged	2 (9.1)	1 (4.5)	1 (4.5)
Metabolism and nutrition disorders			
-Total	7 (31.8)	4 (18.2)	3 (13.6)
Decreased appetite	5 (22.7)	2 (9.1)	3 (13.6)
Hyperphosphataemia	2 (9.1)	2 (9.1)	0
Hypokalaemia	1 (4.5)	1 (4.5)	0
Musculoskeletal and connective tissue disorders			
-Total	7 (31.8)	5 (22.7)	2 (9.1)

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	5 (22.7)	3 (13.6)	2 (9.1)
Arthralgia	3 (13.6)	2 (9.1)	1 (4.5)
Nervous system disorders			
-Total	9 (40.9)	5 (22.7)	4 (18.2)
Headache	7 (31.8)	4 (18.2)	3 (13.6)
Peroneal nerve palsy	3 (13.6)	2 (9.1)	1 (4.5)
Psychiatric disorders			
-Total	4 (18.2)	2 (9.1)	2 (9.1)
Anxiety	3 (13.6)	1 (4.5)	2 (9.1)
Confusional state	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	8 (36.4)	5 (22.7)	3 (13.6)
Cough	5 (22.7)	4 (18.2)	1 (4.5)
Hypoxia	3 (13.6)	0	3 (13.6)
Nasal congestion	3 (13.6)	3 (13.6)	0
Pleural effusion	1 (4.5)	1 (4.5)	0
Skin and subcutaneous tissue disorders			

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=22 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
-Total	8 (36.4)	5 (22.7)	3 (13.6)
Erythema	4 (18.2)	4 (18.2)	0
Alopecia	3 (13.6)	1 (4.5)	2 (9.1)
Rash	2 (9.1)	1 (4.5)	1 (4.5)
Vascular disorders			
-Total	6 (27.3)	2 (9.1)	4 (18.2)
Hypertension	6 (27.3)	2 (9.1)	4 (18.2)

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233n
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

		All patients N=53	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	46 (86.8)	3 (5.7)	43 (81.1)
Blood and lymphatic system disorders			
-Total	10 (18.9)	2 (3.8)	8 (15.1)
Anaemia	10 (18.9)	2 (3.8)	8 (15.1)
Cardiac disorders			
-Total	18 (34.0)	10 (18.9)	8 (15.1)
Tachycardia	13 (24.5)	8 (15.1)	5 (9.4)
Sinus tachycardia	6 (11.3)	3 (5.7)	3 (5.7)
Gastrointestinal disorders			
-Total	31 (58.5)	9 (17.0)	22 (41.5)
Diarrhoea	20 (37.7)	12 (22.6)	8 (15.1)

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	20 (37.7)	5 (9.4)	15 (28.3)
Vomiting	16 (30.2)	9 (17.0)	7 (13.2)
Abdominal pain	10 (18.9)	5 (9.4)	5 (9.4)
Constipation	7 (13.2)	6 (11.3)	1 (1.9)
General disorders and administration site conditions			
-Total	31 (58.5)	10 (18.9)	21 (39.6)
Pyrexia	21 (39.6)	4 (7.5)	17 (32.1)
Fatigue	11 (20.8)	8 (15.1)	3 (5.7)
Chills	9 (17.0)	7 (13.2)	2 (3.8)
Catheter site pain	4 (7.5)	2 (3.8)	2 (3.8)
Immune system disorders			
-Total	36 (67.9)	5 (9.4)	31 (58.5)
Cytokine release syndrome	30 (56.6)	7 (13.2)	23 (43.4)
Hypogammaglobulinaemia	16 (30.2)	2 (3.8)	14 (26.4)
Infections and infestations			
-Total	5 (9.4)	4 (7.5)	1 (1.9)
Upper respiratory tract infection	5 (9.4)	4 (7.5)	1 (1.9)
Investigations			

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	26 (49.1)	1 (1.9)	25 (47.2)
Aspartate aminotransferase increased	12 (22.6)	8 (15.1)	4 (7.5)
White blood cell count decreased	12 (22.6)	3 (5.7)	9 (17.0)
Alanine aminotransferase increased	11 (20.8)	4 (7.5)	7 (13.2)
Prothrombin time prolonged	7 (13.2)	4 (7.5)	3 (5.7)
International normalised ratio increased	5 (9.4)	5 (9.4)	0
Blood bilirubin increased	4 (7.5)	0	4 (7.5)
Blood creatinine increased	4 (7.5)	2 (3.8)	2 (3.8)
Lymphocyte count decreased	3 (5.7)	0	3 (5.7)
Neutrophil count decreased	3 (5.7)	1 (1.9)	2 (3.8)
Metabolism and nutrition disorders			
-Total	24 (45.3)	13 (24.5)	11 (20.8)
Decreased appetite	14 (26.4)	9 (17.0)	5 (9.4)
Hypokalaemia	11 (20.8)	4 (7.5)	7 (13.2)
Hyperphosphataemia	7 (13.2)	6 (11.3)	1 (1.9)
Musculoskeletal and connective tissue disorders			
-Total	8 (15.1)	6 (11.3)	2 (3.8)

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	6 (11.3)	4 (7.5)	2 (3.8)
Arthralgia	3 (5.7)	3 (5.7)	0
Nervous system disorders			
-Total	24 (45.3)	15 (28.3)	9 (17.0)
Headache	21 (39.6)	12 (22.6)	9 (17.0)
Dizziness	6 (11.3)	6 (11.3)	0
Psychiatric disorders			
-Total	10 (18.9)	4 (7.5)	6 (11.3)
Confusional state	6 (11.3)	2 (3.8)	4 (7.5)
Anxiety	5 (9.4)	2 (3.8)	3 (5.7)
Respiratory, thoracic and mediastinal disorders			
-Total	23 (43.4)	10 (18.9)	13 (24.5)
Cough	10 (18.9)	9 (17.0)	1 (1.9)
Epistaxis	9 (17.0)	4 (7.5)	5 (9.4)
Pleural effusion	6 (11.3)	0	6 (11.3)
Hypoxia	5 (9.4)	0	5 (9.4)
Nasal congestion	3 (5.7)	3 (5.7)	0

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	8 (15.1)	6 (11.3)	2 (3.8)
Rash	7 (13.2)	5 (9.4)	2 (3.8)
Alopecia	1 (1.9)	1 (1.9)	0
Erythema	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	8 (15.1)	2 (3.8)	6 (11.3)
Hypertension	8 (15.1)	2 (3.8)	6 (11.3)

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233o
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (85.7)	0	6 (85.7)
Blood and lymphatic system disorders			
-Total	1 (14.3)	0	1 (14.3)
Lymphadenopathy	1 (14.3)	0	1 (14.3)
Cardiac disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Bradycardia	1 (14.3)	0	1 (14.3)
Pericardial effusion	1 (14.3)	0	1 (14.3)
Tachycardia	1 (14.3)	1 (14.3)	0
Ear and labyrinth disorders			
-Total	1 (14.3)	0	1 (14.3)

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Tympanic membrane perforation	1 (14.3)	0	1 (14.3)
Eye disorders			
-Total	1 (14.3)	1 (14.3)	0
Conjunctival haemorrhage	1 (14.3)	1 (14.3)	0
Periorbital oedema	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	4 (57.1)	0	4 (57.1)
Nausea	3 (42.9)	1 (14.3)	2 (28.6)
Abdominal pain	1 (14.3)	1 (14.3)	0
Colitis	1 (14.3)	1 (14.3)	0
Pancreatic failure	1 (14.3)	0	1 (14.3)
Perianal erythema	1 (14.3)	0	1 (14.3)
Vomiting	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Pyrexia	2 (28.6)	0	2 (28.6)
Acquired gene mutation	1 (14.3)	1 (14.3)	0
Chills	1 (14.3)	0	1 (14.3)

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Malaise	1 (14.3)	0	1 (14.3)
Mucosal haemorrhage	1 (14.3)	0	1 (14.3)
Hepatobiliary disorders			
-Total	1 (14.3)	0	1 (14.3)
Hyperbilirubinaemia	1 (14.3)	0	1 (14.3)
Immune system disorders			
-Total	5 (71.4)	2 (28.6)	3 (42.9)
Cytokine release syndrome	4 (57.1)	2 (28.6)	2 (28.6)
Hypogammaglobulinaemia	3 (42.9)	1 (14.3)	2 (28.6)
Immunodeficiency	1 (14.3)	0	1 (14.3)
Seasonal allergy	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	3 (42.9)	0	3 (42.9)
Pneumonia	2 (28.6)	0	2 (28.6)
Sinusitis	2 (28.6)	1 (14.3)	1 (14.3)
Gastroenteritis	1 (14.3)	0	1 (14.3)
Haemophilus infection	1 (14.3)	0	1 (14.3)
Otitis media	1 (14.3)	0	1 (14.3)
Otitis media acute	1 (14.3)	0	1 (14.3)

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Subcutaneous abscess	1 (14.3)	0	1 (14.3)
Upper respiratory tract infection	1 (14.3)	1 (14.3)	0
Injury, poisoning and procedural complications			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Arthropod bite	1 (14.3)	1 (14.3)	0
Procedural complication	1 (14.3)	1 (14.3)	0
Procedural pain	1 (14.3)	0	1 (14.3)
Radiation skin injury	1 (14.3)	0	1 (14.3)
Investigations			
-Total	4 (57.1)	0	4 (57.1)
Aspartate aminotransferase increased	3 (42.9)	0	3 (42.9)
C-reactive protein increased	2 (28.6)	1 (14.3)	1 (14.3)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0
Blood alkaline phosphatase increased	1 (14.3)	1 (14.3)	0
Blood bilirubin increased	1 (14.3)	0	1 (14.3)

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood lactate dehydrogenase increased	1 (14.3)	1 (14.3)	0
Blood lactic acid increased	1 (14.3)	0	1 (14.3)
Blood phosphorus decreased	1 (14.3)	1 (14.3)	0
Blood urea increased	1 (14.3)	1 (14.3)	0
Serum ferritin increased	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	2 (28.6)	0	2 (28.6)
Decreased appetite	1 (14.3)	0	1 (14.3)
Fluid overload	1 (14.3)	0	1 (14.3)
Hyperalbuminaemia	1 (14.3)	1 (14.3)	0
Hypercalcaemia	1 (14.3)	1 (14.3)	0
Hyperchloraemia	1 (14.3)	1 (14.3)	0
Hyperkalaemia	1 (14.3)	0	1 (14.3)
Hypermagnesaemia	1 (14.3)	1 (14.3)	0
Hypernatraemia	1 (14.3)	0	1 (14.3)
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)
Hypophosphataemia	1 (14.3)	1 (14.3)	0
Malnutrition	1 (14.3)	0	1 (14.3)

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolic alkalosis	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Arthralgia	1 (14.3)	1 (14.3)	0
Muscle spasms	1 (14.3)	1 (14.3)	0
Muscular weakness	1 (14.3)	0	1 (14.3)
Musculoskeletal chest pain	1 (14.3)	1 (14.3)	0
Pain in jaw	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	3 (42.9)	0	3 (42.9)
Dysarthria	1 (14.3)	0	1 (14.3)
Headache	1 (14.3)	0	1 (14.3)
Hypotonia	1 (14.3)	0	1 (14.3)
Somnolence	1 (14.3)	1 (14.3)	0
Product issues			
-Total	1 (14.3)	1 (14.3)	0
Device occlusion	1 (14.3)	1 (14.3)	0
Psychiatric disorders			

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (14.3)	0	1 (14.3)
Delirium	1 (14.3)	0	1 (14.3)
Insomnia	1 (14.3)	0	1 (14.3)
Irritability	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Cough	1 (14.3)	1 (14.3)	0
Epistaxis	1 (14.3)	0	1 (14.3)
Oropharyngeal plaque	1 (14.3)	1 (14.3)	0
Rhinorrhoea	1 (14.3)	1 (14.3)	0
Skin and subcutaneous tissue disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Dermatitis	1 (14.3)	1 (14.3)	0
Hyperhidrosis	1 (14.3)	1 (14.3)	0
Papule	1 (14.3)	1 (14.3)	0
Pruritus	1 (14.3)	1 (14.3)	0
Rash	1 (14.3)	0	1 (14.3)

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=7 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Rash papular	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	1 (14.3)	0	1 (14.3)
Flushing	1 (14.3)	1 (14.3)	0
Hypertension	1 (14.3)	0	1 (14.3)

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Table 233o
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

		All patients N=68	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	64 (94.1)	2 (2.9)	62 (91.2)
Blood and lymphatic system disorders			
-Total	14 (20.6)	4 (5.9)	10 (14.7)
Anaemia	14 (20.6)	4 (5.9)	10 (14.7)
Cardiac disorders			
-Total	16 (23.5)	8 (11.8)	8 (11.8)
Tachycardia	15 (22.1)	8 (11.8)	7 (10.3)
Pericardial effusion	2 (2.9)	1 (1.5)	1 (1.5)
Bradycardia	1 (1.5)	1 (1.5)	0
Eye disorders			
-Total	3 (4.4)	2 (2.9)	1 (1.5)

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Periorbital oedema	3 (4.4)	2 (2.9)	1 (1.5)
Conjunctival haemorrhage	2 (2.9)	2 (2.9)	0
Gastrointestinal disorders			
-Total	43 (63.2)	14 (20.6)	29 (42.6)
Nausea	27 (39.7)	8 (11.8)	19 (27.9)
Vomiting	26 (38.2)	16 (23.5)	10 (14.7)
Diarrhoea	25 (36.8)	14 (20.6)	11 (16.2)
Abdominal pain	13 (19.1)	6 (8.8)	7 (10.3)
Constipation	11 (16.2)	9 (13.2)	2 (2.9)
General disorders and administration site conditions			
-Total	42 (61.8)	19 (27.9)	23 (33.8)
Pyrexia	27 (39.7)	9 (13.2)	18 (26.5)
Fatigue	17 (25.0)	13 (19.1)	4 (5.9)
Chills	10 (14.7)	9 (13.2)	1 (1.5)
Catheter site pain	7 (10.3)	3 (4.4)	4 (5.9)
Malaise	3 (4.4)	1 (1.5)	2 (2.9)
Hepatobiliary disorders			
-Total	2 (2.9)	0	2 (2.9)

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperbilirubinaemia	2 (2.9)	0	2 (2.9)
Immune system disorders			
-Total	49 (72.1)	5 (7.4)	44 (64.7)
Cytokine release syndrome	41 (60.3)	5 (7.4)	36 (52.9)
Hypogammaglobulinaemia	25 (36.8)	3 (4.4)	22 (32.4)
Seasonal allergy	1 (1.5)	1 (1.5)	0
Infections and infestations			
-Total	15 (22.1)	3 (4.4)	12 (17.6)
Upper respiratory tract infection	9 (13.2)	4 (5.9)	5 (7.4)
Gastroenteritis	3 (4.4)	1 (1.5)	2 (2.9)
Otitis media	3 (4.4)	0	3 (4.4)
Pneumonia	3 (4.4)	0	3 (4.4)
Sinusitis	3 (4.4)	0	3 (4.4)
Otitis media acute	1 (1.5)	0	1 (1.5)
Injury, poisoning and procedural complications			
-Total	5 (7.4)	2 (2.9)	3 (4.4)
Procedural pain	4 (5.9)	2 (2.9)	2 (2.9)
Radiation skin injury	1 (1.5)	0	1 (1.5)

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	33 (48.5)	1 (1.5)	32 (47.1)
White blood cell count decreased	17 (25.0)	6 (8.8)	11 (16.2)
Alanine aminotransferase increased	14 (20.6)	5 (7.4)	9 (13.2)
Aspartate aminotransferase increased	13 (19.1)	8 (11.8)	5 (7.4)
International normalised ratio increased	10 (14.7)	9 (13.2)	1 (1.5)
Prothrombin time prolonged	9 (13.2)	5 (7.4)	4 (5.9)
Blood creatinine increased	7 (10.3)	5 (7.4)	2 (2.9)
Lymphocyte count decreased	7 (10.3)	2 (2.9)	5 (7.4)
Blood bilirubin increased	6 (8.8)	2 (2.9)	4 (5.9)
Activated partial thromboplastin time prolonged	5 (7.4)	2 (2.9)	3 (4.4)
Blood urea increased	2 (2.9)	1 (1.5)	1 (1.5)
C-reactive protein increased	1 (1.5)	0	1 (1.5)
Serum ferritin increased	1 (1.5)	0	1 (1.5)
Metabolism and nutrition disorders			
-Total	37 (54.4)	16 (23.5)	21 (30.9)
Decreased appetite	18 (26.5)	11 (16.2)	7 (10.3)

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	12 (17.6)	5 (7.4)	7 (10.3)
Hyperphosphataemia	9 (13.2)	8 (11.8)	1 (1.5)
Hypoalbuminaemia	5 (7.4)	1 (1.5)	4 (5.9)
Hypophosphataemia	5 (7.4)	4 (5.9)	1 (1.5)
Fluid overload	4 (5.9)	1 (1.5)	3 (4.4)
Hypernatraemia	4 (5.9)	1 (1.5)	3 (4.4)
Hyperkalaemia	1 (1.5)	1 (1.5)	0
Musculoskeletal and connective tissue disorders			
-Total	18 (26.5)	14 (20.6)	4 (5.9)
Pain in extremity	11 (16.2)	7 (10.3)	4 (5.9)
Arthralgia	5 (7.4)	4 (5.9)	1 (1.5)
Pain in jaw	3 (4.4)	2 (2.9)	1 (1.5)
Muscle spasms	2 (2.9)	2 (2.9)	0
Muscular weakness	2 (2.9)	2 (2.9)	0
Musculoskeletal chest pain	2 (2.9)	2 (2.9)	0
Nervous system disorders			
-Total	28 (41.2)	16 (23.5)	12 (17.6)
Headache	27 (39.7)	16 (23.5)	11 (16.2)

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dysarthria	1 (1.5)	1 (1.5)	0
Somnolence	1 (1.5)	0	1 (1.5)
Product issues			
-Total	1 (1.5)	1 (1.5)	0
Device occlusion	1 (1.5)	1 (1.5)	0
Psychiatric disorders			
-Total	17 (25.0)	6 (8.8)	11 (16.2)
Anxiety	8 (11.8)	3 (4.4)	5 (7.4)
Confusional state	7 (10.3)	3 (4.4)	4 (5.9)
Delirium	3 (4.4)	2 (2.9)	1 (1.5)
Insomnia	3 (4.4)	0	3 (4.4)
Irritability	2 (2.9)	2 (2.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	26 (38.2)	10 (14.7)	16 (23.5)
Cough	14 (20.6)	12 (17.6)	2 (2.9)
Epistaxis	8 (11.8)	4 (5.9)	4 (5.9)
Hypoxia	8 (11.8)	0	8 (11.8)
Pleural effusion	7 (10.3)	1 (1.5)	6 (8.8)

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinorrhoea	5 (7.4)	4 (5.9)	1 (1.5)
Skin and subcutaneous tissue disorders			
-Total	15 (22.1)	13 (19.1)	2 (2.9)
Rash	8 (11.8)	6 (8.8)	2 (2.9)
Pruritus	4 (5.9)	4 (5.9)	0
Hyperhidrosis	3 (4.4)	3 (4.4)	0
Rash papular	2 (2.9)	2 (2.9)	0
Papule	1 (1.5)	1 (1.5)	0
Vascular disorders			
-Total	14 (20.6)	5 (7.4)	9 (13.2)
Hypertension	13 (19.1)	4 (5.9)	9 (13.2)
Flushing	1 (1.5)	1 (1.5)	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233p
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (100)	0	4 (100)
Blood and lymphatic system disorders			
-Total	2 (50.0)	2 (50.0)	0
Anaemia	2 (50.0)	2 (50.0)	0
Cardiac disorders			
-Total	1 (25.0)	1 (25.0)	0
Bradycardia	1 (25.0)	1 (25.0)	0
Eye disorders			
-Total	1 (25.0)	1 (25.0)	0
Ocular hyperaemia	1 (25.0)	1 (25.0)	0

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Vomiting	2 (50.0)	2 (50.0)	0
Constipation	1 (25.0)	1 (25.0)	0
Gastrointestinal haemorrhage	1 (25.0)	1 (25.0)	0
Nausea	1 (25.0)	0	1 (25.0)
General disorders and administration site conditions			
-Total	2 (50.0)	2 (50.0)	0
Fatigue	1 (25.0)	1 (25.0)	0
Influenza like illness	1 (25.0)	1 (25.0)	0
Immune system disorders			
-Total	3 (75.0)	1 (25.0)	2 (50.0)
Cytokine release syndrome	3 (75.0)	1 (25.0)	2 (50.0)
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	3 (75.0)	0	3 (75.0)
Conjunctivitis	1 (25.0)	0	1 (25.0)

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fungal skin infection	1 (25.0)	1 (25.0)	0
Metapneumovirus infection	1 (25.0)	0	1 (25.0)
Rash pustular	1 (25.0)	0	1 (25.0)
Viral infection	1 (25.0)	0	1 (25.0)
Viral upper respiratory tract infection	1 (25.0)	1 (25.0)	0
Injury, poisoning and procedural complications			
-Total	1 (25.0)	0	1 (25.0)
Radiation skin injury	1 (25.0)	0	1 (25.0)
Skin laceration	1 (25.0)	0	1 (25.0)
Investigations			
-Total	2 (50.0)	0	2 (50.0)
Lymphocyte count decreased	2 (50.0)	1 (25.0)	1 (25.0)
White blood cell count decreased	2 (50.0)	1 (25.0)	1 (25.0)
Blood bilirubin increased	1 (25.0)	1 (25.0)	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fibrin d dimer increased	1 (25.0)	1 (25.0)	0
Neutrophil count decreased	1 (25.0)	1 (25.0)	0
Platelet count decreased	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	1 (25.0)	1 (25.0)	0
Decreased appetite	1 (25.0)	1 (25.0)	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (50.0)	2 (50.0)	0
Arthralgia	1 (25.0)	1 (25.0)	0
Pain in extremity	1 (25.0)	1 (25.0)	0
Nervous system disorders			
-Total	1 (25.0)	0	1 (25.0)
Headache	1 (25.0)	0	1 (25.0)
Tremor	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (50.0)	0	2 (50.0)

Down syndrome: Yes			
	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	1 (25.0)	0	1 (25.0)
Hypoxia	1 (25.0)	0	1 (25.0)
Nasal congestion	1 (25.0)	1 (25.0)	0
Rhinorrhoea	1 (25.0)	0	1 (25.0)
Skin and subcutaneous tissue disorders			
-Total	3 (75.0)	3 (75.0)	0
Dermatitis diaper	1 (25.0)	1 (25.0)	0
Dry skin	1 (25.0)	1 (25.0)	0
Erythema	1 (25.0)	1 (25.0)	0
Rash maculo-papular	1 (25.0)	1 (25.0)	0
Rash papular	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	1 (25.0)	1 (25.0)	0
Hypertension	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 233p
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	64 (90.1)	2 (2.8)	62 (87.3)
Blood and lymphatic system disorders			
-Total	12 (16.9)	2 (2.8)	10 (14.1)
Anaemia	12 (16.9)	2 (2.8)	10 (14.1)
Cardiac disorders			
-Total	17 (23.9)	9 (12.7)	8 (11.3)
Tachycardia	16 (22.5)	9 (12.7)	7 (9.9)
Bradycardia	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	44 (62.0)	14 (19.7)	30 (42.3)

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	29 (40.8)	9 (12.7)	20 (28.2)
Diarrhoea	25 (35.2)	14 (19.7)	11 (15.5)
Vomiting	25 (35.2)	15 (21.1)	10 (14.1)
Abdominal pain	14 (19.7)	7 (9.9)	7 (9.9)
Constipation	10 (14.1)	8 (11.3)	2 (2.8)
Gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	40 (56.3)	17 (23.9)	23 (32.4)
Pyrexia	29 (40.8)	9 (12.7)	20 (28.2)
Fatigue	16 (22.5)	12 (16.9)	4 (5.6)
Chills	11 (15.5)	9 (12.7)	2 (2.8)
Influenza like illness	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	51 (71.8)	6 (8.5)	45 (63.4)
Cytokine release syndrome	42 (59.2)	6 (8.5)	36 (50.7)
Hypogammaglobulinaemia	27 (38.0)	4 (5.6)	23 (32.4)
Infections and infestations			

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	15 (21.1)	8 (11.3)	7 (9.9)
Upper respiratory tract infection	10 (14.1)	5 (7.0)	5 (7.0)
Viral infection	2 (2.8)	2 (2.8)	0
Viral upper respiratory tract infection	2 (2.8)	1 (1.4)	1 (1.4)
Fungal skin infection	1 (1.4)	0	1 (1.4)
Injury, poisoning and procedural complications			
-Total	1 (1.4)	0	1 (1.4)
Radiation skin injury	1 (1.4)	0	1 (1.4)
Investigations			
-Total	35 (49.3)	2 (2.8)	33 (46.5)
Aspartate aminotransferase increased	16 (22.5)	8 (11.3)	8 (11.3)
White blood cell count decreased	15 (21.1)	5 (7.0)	10 (14.1)
Alanine aminotransferase increased	14 (19.7)	5 (7.0)	9 (12.7)
International normalised ratio increased	10 (14.1)	9 (12.7)	1 (1.4)
Prothrombin time prolonged	9 (12.7)	5 (7.0)	4 (5.6)
Blood bilirubin increased	6 (8.5)	1 (1.4)	5 (7.0)

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood creatinine increased	6 (8.5)	4 (5.6)	2 (2.8)
Lymphocyte count decreased	5 (7.0)	1 (1.4)	4 (5.6)
Neutrophil count decreased	5 (7.0)	1 (1.4)	4 (5.6)
Platelet count decreased	5 (7.0)	2 (2.8)	3 (4.2)
Blood immunoglobulin m decreased	3 (4.2)	3 (4.2)	0
Blood immunoglobulin a decreased	2 (2.8)	2 (2.8)	0
Metabolism and nutrition disorders			
-Total	30 (42.3)	16 (22.5)	14 (19.7)
Decreased appetite	18 (25.4)	10 (14.1)	8 (11.3)
Hypokalaemia	12 (16.9)	5 (7.0)	7 (9.9)
Hyperphosphataemia	8 (11.3)	7 (9.9)	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	13 (18.3)	9 (12.7)	4 (5.6)
Pain in extremity	10 (14.1)	6 (8.5)	4 (5.6)
Arthralgia	5 (7.0)	4 (5.6)	1 (1.4)
Nervous system disorders			
-Total	27 (38.0)	16 (22.5)	11 (15.5)

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	27 (38.0)	16 (22.5)	11 (15.5)
Tremor	1 (1.4)	1 (1.4)	0
Psychiatric disorders			
-Total	8 (11.3)	3 (4.2)	5 (7.0)
Anxiety	8 (11.3)	3 (4.2)	5 (7.0)
Respiratory, thoracic and mediastinal disorders			
-Total	29 (40.8)	16 (22.5)	13 (18.3)
Cough	14 (19.7)	13 (18.3)	1 (1.4)
Epistaxis	9 (12.7)	4 (5.6)	5 (7.0)
Hypoxia	7 (9.9)	0	7 (9.9)
Nasal congestion	5 (7.0)	5 (7.0)	0
Rhinorrhoea	5 (7.0)	5 (7.0)	0
Skin and subcutaneous tissue disorders			
-Total	20 (28.2)	16 (22.5)	4 (5.6)
Rash	9 (12.7)	6 (8.5)	3 (4.2)
Dry skin	4 (5.6)	4 (5.6)	0
Erythema	4 (5.6)	4 (5.6)	0

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Rash maculo-papular	3 (4.2)	2 (2.8)	1 (1.4)
Rash papular	2 (2.8)	2 (2.8)	0
Vascular disorders			
-Total	13 (18.3)	3 (4.2)	10 (14.1)
Hypertension	13 (18.3)	3 (4.2)	10 (14.1)

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233q
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	32 (100)	0	32 (100)
Blood and lymphatic system disorders			
-Total	5 (15.6)	2 (6.3)	3 (9.4)
Anaemia	4 (12.5)	2 (6.3)	2 (6.3)
Thrombocytopenia	1 (3.1)	0	1 (3.1)
Cardiac disorders			
-Total	8 (25.0)	6 (18.8)	2 (6.3)
Tachycardia	6 (18.8)	5 (15.6)	1 (3.1)
Sinus tachycardia	2 (6.3)	1 (3.1)	1 (3.1)
Gastrointestinal disorders			
-Total	26 (81.3)	10 (31.3)	16 (50.0)

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	17 (53.1)	4 (12.5)	13 (40.6)
Vomiting	14 (43.8)	9 (28.1)	5 (15.6)
Diarrhoea	11 (34.4)	6 (18.8)	5 (15.6)
Abdominal pain	8 (25.0)	4 (12.5)	4 (12.5)
Constipation	8 (25.0)	7 (21.9)	1 (3.1)
General disorders and administration site conditions			
-Total	18 (56.3)	6 (18.8)	12 (37.5)
Pyrexia	14 (43.8)	4 (12.5)	10 (31.3)
Fatigue	6 (18.8)	5 (15.6)	1 (3.1)
Catheter site pain	5 (15.6)	1 (3.1)	4 (12.5)
Oedema peripheral	4 (12.5)	3 (9.4)	1 (3.1)
Chills	1 (3.1)	0	1 (3.1)
Immune system disorders			
-Total	28 (87.5)	1 (3.1)	27 (84.4)
Cytokine release syndrome	25 (78.1)	3 (9.4)	22 (68.8)
Hypogammaglobulinaemia	16 (50.0)	1 (3.1)	15 (46.9)
Infections and infestations			
-Total	13 (40.6)	4 (12.5)	9 (28.1)

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	6 (18.8)	2 (6.3)	4 (12.5)
Rhinovirus infection	5 (15.6)	4 (12.5)	1 (3.1)
Clostridium difficile infection	4 (12.5)	0	4 (12.5)
Investigations			
-Total	17 (53.1)	2 (6.3)	15 (46.9)
White blood cell count decreased	8 (25.0)	1 (3.1)	7 (21.9)
Aspartate aminotransferase increased	7 (21.9)	5 (15.6)	2 (6.3)
Alanine aminotransferase increased	5 (15.6)	3 (9.4)	2 (6.3)
Blood bilirubin increased	3 (9.4)	1 (3.1)	2 (6.3)
Blood creatinine increased	3 (9.4)	2 (6.3)	1 (3.1)
Prothrombin time prolonged	3 (9.4)	3 (9.4)	0
Lymphocyte count decreased	2 (6.3)	0	2 (6.3)
Neutrophil count decreased	2 (6.3)	1 (3.1)	1 (3.1)
Platelet count decreased	2 (6.3)	1 (3.1)	1 (3.1)
International normalised ratio increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	18 (56.3)	8 (25.0)	10 (31.3)

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	12 (37.5)	5 (15.6)	7 (21.9)
Hypokalaemia	6 (18.8)	3 (9.4)	3 (9.4)
Hypocalcaemia	4 (12.5)	3 (9.4)	1 (3.1)
Hyperphosphataemia	3 (9.4)	3 (9.4)	0
Musculoskeletal and connective tissue disorders			
-Total	10 (31.3)	6 (18.8)	4 (12.5)
Pain in extremity	7 (21.9)	3 (9.4)	4 (12.5)
Arthralgia	4 (12.5)	3 (9.4)	1 (3.1)
Nervous system disorders			
-Total	18 (56.3)	10 (31.3)	8 (25.0)
Headache	17 (53.1)	9 (28.1)	8 (25.0)
Dizziness	2 (6.3)	2 (6.3)	0
Psychiatric disorders			
-Total	7 (21.9)	3 (9.4)	4 (12.5)
Anxiety	5 (15.6)	2 (6.3)	3 (9.4)
Confusional state	2 (6.3)	1 (3.1)	1 (3.1)
Renal and urinary disorders			
-Total	4 (12.5)	2 (6.3)	2 (6.3)

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Acute kidney injury	4 (12.5)	2 (6.3)	2 (6.3)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (43.8)	6 (18.8)	8 (25.0)
Cough	8 (25.0)	7 (21.9)	1 (3.1)
Epistaxis	5 (15.6)	3 (9.4)	2 (6.3)
Hypoxia	4 (12.5)	0	4 (12.5)
Pleural effusion	1 (3.1)	0	1 (3.1)
Rhinitis allergic	1 (3.1)	0	1 (3.1)
Skin and subcutaneous tissue disorders			
-Total	10 (31.3)	8 (25.0)	2 (6.3)
Pruritus	5 (15.6)	5 (15.6)	0
Rash	5 (15.6)	3 (9.4)	2 (6.3)
Dry skin	4 (12.5)	4 (12.5)	0
Vascular disorders			
-Total	8 (25.0)	4 (12.5)	4 (12.5)
Hypertension	8 (25.0)	4 (12.5)	4 (12.5)

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- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233q
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	32 (100)	2 (6.3)	30 (93.8)
Blood and lymphatic system disorders			
-Total	12 (37.5)	3 (9.4)	9 (28.1)
Anaemia	10 (31.3)	2 (6.3)	8 (25.0)
Thrombocytopenia	4 (12.5)	1 (3.1)	3 (9.4)
Cardiac disorders			
-Total	13 (40.6)	5 (15.6)	8 (25.0)
Tachycardia	10 (31.3)	4 (12.5)	6 (18.8)
Sinus tachycardia	4 (12.5)	2 (6.3)	2 (6.3)
Eye disorders			
-Total	4 (12.5)	3 (9.4)	1 (3.1)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Periorbital oedema	4 (12.5)	3 (9.4)	1 (3.1)
Gastrointestinal disorders			
-Total	21 (65.6)	6 (18.8)	15 (46.9)
Diarrhoea	14 (43.8)	8 (25.0)	6 (18.8)
Nausea	13 (40.6)	5 (15.6)	8 (25.0)
Vomiting	13 (40.6)	8 (25.0)	5 (15.6)
Abdominal pain	6 (18.8)	3 (9.4)	3 (9.4)
Constipation	3 (9.4)	2 (6.3)	1 (3.1)
General disorders and administration site conditions			
-Total	24 (75.0)	13 (40.6)	11 (34.4)
Pyrexia	13 (40.6)	5 (15.6)	8 (25.0)
Fatigue	11 (34.4)	8 (25.0)	3 (9.4)
Chills	10 (31.3)	9 (28.1)	1 (3.1)
Catheter site pain	2 (6.3)	2 (6.3)	0
Immune system disorders			
-Total	26 (81.3)	6 (18.8)	20 (62.5)
Cytokine release syndrome	20 (62.5)	4 (12.5)	16 (50.0)
Hypogammaglobulinaemia	12 (37.5)	3 (9.4)	9 (28.1)

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Infections and infestations			
-Total	9 (28.1)	3 (9.4)	6 (18.8)
Otitis media	4 (12.5)	0	4 (12.5)
Upper respiratory tract infection	4 (12.5)	3 (9.4)	1 (3.1)
Clostridium difficile infection	1 (3.1)	0	1 (3.1)
Rhinovirus infection	1 (3.1)	1 (3.1)	0
Investigations			
-Total	19 (59.4)	0	19 (59.4)
Alanine aminotransferase increased	9 (28.1)	2 (6.3)	7 (21.9)
Aspartate aminotransferase increased	9 (28.1)	3 (9.4)	6 (18.8)
White blood cell count decreased	9 (28.1)	5 (15.6)	4 (12.5)
International normalised ratio increased	8 (25.0)	8 (25.0)	0
Prothrombin time prolonged	6 (18.8)	2 (6.3)	4 (12.5)
Lymphocyte count decreased	5 (15.6)	2 (6.3)	3 (9.4)
Blood bilirubin increased	4 (12.5)	1 (3.1)	3 (9.4)
Blood creatinine increased	4 (12.5)	3 (9.4)	1 (3.1)
Neutrophil count decreased	4 (12.5)	1 (3.1)	3 (9.4)

Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Platelet count decreased	4 (12.5)	2 (6.3)	2 (6.3)
Metabolism and nutrition disorders			
-Total	18 (56.3)	9 (28.1)	9 (28.1)
Decreased appetite	7 (21.9)	6 (18.8)	1 (3.1)
Hyperphosphataemia	6 (18.8)	5 (15.6)	1 (3.1)
Hypokalaemia	6 (18.8)	2 (6.3)	4 (12.5)
Hypoalbuminaemia	5 (15.6)	1 (3.1)	4 (12.5)
Hypocalcaemia	1 (3.1)	0	1 (3.1)
Musculoskeletal and connective tissue disorders			
-Total	8 (25.0)	7 (21.9)	1 (3.1)
Myalgia	5 (15.6)	4 (12.5)	1 (3.1)
Pain in extremity	4 (12.5)	4 (12.5)	0
Arthralgia	2 (6.3)	2 (6.3)	0
Nervous system disorders			
-Total	13 (40.6)	9 (28.1)	4 (12.5)
Headache	11 (34.4)	7 (21.9)	4 (12.5)
Dizziness	4 (12.5)	4 (12.5)	0
Psychiatric disorders			

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (18.8)	3 (9.4)	3 (9.4)
Confusional state	4 (12.5)	2 (6.3)	2 (6.3)
Anxiety	3 (9.4)	1 (3.1)	2 (6.3)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (43.8)	6 (18.8)	8 (25.0)
Cough	7 (21.9)	6 (18.8)	1 (3.1)
Pleural effusion	5 (15.6)	1 (3.1)	4 (12.5)
Hypoxia	4 (12.5)	0	4 (12.5)
Rhinitis allergic	4 (12.5)	4 (12.5)	0
Epistaxis	3 (9.4)	1 (3.1)	2 (6.3)
Skin and subcutaneous tissue disorders			
-Total	5 (15.6)	4 (12.5)	1 (3.1)
Rash	4 (12.5)	3 (9.4)	1 (3.1)
Dry skin	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	5 (15.6)	0	5 (15.6)
Hypertension	5 (15.6)	0	5 (15.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233q
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (36.4)	0	4 (36.4)
General disorders and administration site conditions			
-Total	2 (18.2)	0	2 (18.2)
Pyrexia	2 (18.2)	0	2 (18.2)
Investigations			
-Total	1 (9.1)	0	1 (9.1)
International normalised ratio increased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing			
		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoalbuminaemia	1 (9.1)	0	1 (9.1)
Psychiatric disorders			
-Total	1 (9.1)	0	1 (9.1)
Confusional state	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (9.1)	0	1 (9.1)
Epistaxis	1 (9.1)	0	1 (9.1)
Pleural effusion	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypertension	1 (9.1)	0	1 (9.1)

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (100)	0	8 (100)
Blood and lymphatic system disorders			
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Anaemia	3 (37.5)	2 (25.0)	1 (12.5)
Cardiac disorders			
-Total	2 (25.0)	2 (25.0)	0
Palpitations	1 (12.5)	1 (12.5)	0
Pericardial effusion	1 (12.5)	1 (12.5)	0
Tachycardia	1 (12.5)	1 (12.5)	0
Endocrine disorders			

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (12.5)	1 (12.5)	0
Adrenal insufficiency	1 (12.5)	1 (12.5)	0
Eye disorders			
-Total	1 (12.5)	1 (12.5)	0
Eye pain	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	7 (87.5)	3 (37.5)	4 (50.0)
Vomiting	5 (62.5)	3 (37.5)	2 (25.0)
Diarrhoea	4 (50.0)	3 (37.5)	1 (12.5)
Nausea	4 (50.0)	1 (12.5)	3 (37.5)
Abdominal pain	3 (37.5)	2 (25.0)	1 (12.5)
Constipation	1 (12.5)	1 (12.5)	0
Oral pain	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	5 (62.5)	1 (12.5)	4 (50.0)
Pyrexia	4 (50.0)	1 (12.5)	3 (37.5)
Asthenia	1 (12.5)	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Catheter site pain	1 (12.5)	0	1 (12.5)
Chills	1 (12.5)	1 (12.5)	0
Fatigue	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
-Total	1 (12.5)	0	1 (12.5)
Hepatomegaly	1 (12.5)	0	1 (12.5)
Immune system disorders			
-Total	7 (87.5)	0	7 (87.5)
Cytokine release syndrome	5 (62.5)	0	5 (62.5)
Hypogammaglobulinaemia	4 (50.0)	0	4 (50.0)
Graft versus host disease	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	5 (62.5)	1 (12.5)	4 (50.0)
Upper respiratory tract infection	2 (25.0)	0	2 (25.0)
Viral infection	2 (25.0)	1 (12.5)	1 (12.5)
Clostridium difficile infection	1 (12.5)	0	1 (12.5)
Ear infection	1 (12.5)	1 (12.5)	0
Gastroenteritis	1 (12.5)	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinovirus infection	1 (12.5)	1 (12.5)	0
Skin infection	1 (12.5)	0	1 (12.5)
Tinea capitis	1 (12.5)	1 (12.5)	0
Injury, poisoning and procedural complications			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Contusion	1 (12.5)	1 (12.5)	0
Infusion related reaction	1 (12.5)	0	1 (12.5)
Procedural nausea	1 (12.5)	0	1 (12.5)
Sunburn	1 (12.5)	1 (12.5)	0
Tracheal haemorrhage	1 (12.5)	0	1 (12.5)
Wound	1 (12.5)	1 (12.5)	0
Investigations			
-Total	6 (75.0)	2 (25.0)	4 (50.0)
Lymphocyte count decreased	2 (25.0)	1 (12.5)	1 (12.5)
White blood cell count decreased	2 (25.0)	1 (12.5)	1 (12.5)
Activated partial thromboplastin time prolonged	1 (12.5)	1 (12.5)	0
Blood creatinine increased	1 (12.5)	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood fibrinogen decreased	1 (12.5)	0	1 (12.5)
Blood immunoglobulin m decreased	1 (12.5)	1 (12.5)	0
Blood magnesium decreased	1 (12.5)	1 (12.5)	0
Blood phosphorus increased	1 (12.5)	1 (12.5)	0
Blood uric acid increased	1 (12.5)	1 (12.5)	0
Cardiac murmur	1 (12.5)	1 (12.5)	0
Fibrin d dimer increased	1 (12.5)	1 (12.5)	0
International normalised ratio increased	1 (12.5)	1 (12.5)	0
Neutrophil count decreased	1 (12.5)	0	1 (12.5)
Prothrombin time prolonged	1 (12.5)	0	1 (12.5)
Weight decreased	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	5 (62.5)	3 (37.5)	2 (25.0)
Hypokalaemia	3 (37.5)	2 (25.0)	1 (12.5)
Decreased appetite	2 (25.0)	1 (12.5)	1 (12.5)
Hypernatraemia	1 (12.5)	0	1 (12.5)
Hypoalbuminaemia	1 (12.5)	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Pain in extremity	2 (25.0)	2 (25.0)	0
Arthralgia	1 (12.5)	1 (12.5)	0
Muscular weakness	1 (12.5)	1 (12.5)	0
Neck pain	1 (12.5)	0	1 (12.5)
Pain in jaw	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	5 (62.5)	5 (62.5)	0
Headache	3 (37.5)	3 (37.5)	0
Dizziness	1 (12.5)	1 (12.5)	0
Dysgeusia	1 (12.5)	1 (12.5)	0
Peroneal nerve palsy	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	4 (50.0)	0	4 (50.0)
Confusional state	3 (37.5)	1 (12.5)	2 (25.0)
Depression	2 (25.0)	1 (12.5)	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Anxiety	1 (12.5)	1 (12.5)	0
Delirium	1 (12.5)	1 (12.5)	0
Insomnia	1 (12.5)	0	1 (12.5)
Sleep disorder	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (87.5)	2 (25.0)	5 (62.5)
Cough	3 (37.5)	3 (37.5)	0
Hypoxia	2 (25.0)	0	2 (25.0)
Pleural effusion	2 (25.0)	0	2 (25.0)
Rhinorrhoea	2 (25.0)	1 (12.5)	1 (12.5)
Epistaxis	1 (12.5)	0	1 (12.5)
Nasal congestion	1 (12.5)	1 (12.5)	0
Oropharyngeal pain	1 (12.5)	0	1 (12.5)
Pharyngeal erythema	1 (12.5)	1 (12.5)	0
Skin and subcutaneous tissue disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Erythema	2 (25.0)	2 (25.0)	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Alopecia	1 (12.5)	0	1 (12.5)
Dermatitis diaper	1 (12.5)	1 (12.5)	0
Dry skin	1 (12.5)	1 (12.5)	0
Livedo reticularis	1 (12.5)	1 (12.5)	0
Rash erythematous	1 (12.5)	0	1 (12.5)
Rash maculo-papular	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Hypertension	3 (37.5)	1 (12.5)	2 (25.0)
Haematoma	1 (12.5)	0	1 (12.5)
Hot flush	1 (12.5)	1 (12.5)	0

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- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	21 (91.3)	1 (4.3)	20 (87.0)
Blood and lymphatic system disorders			
-Total	3 (13.0)	1 (4.3)	2 (8.7)
Anaemia	3 (13.0)	1 (4.3)	2 (8.7)
Cardiac disorders			
-Total	8 (34.8)	3 (13.0)	5 (21.7)
Tachycardia	5 (21.7)	3 (13.0)	2 (8.7)
Pericardial effusion	2 (8.7)	0	2 (8.7)
Sinus tachycardia	2 (8.7)	1 (4.3)	1 (4.3)
Endocrine disorders			

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (4.3)	0	1 (4.3)
Adrenal insufficiency	1 (4.3)	0	1 (4.3)
Gastrointestinal disorders			
-Total	14 (60.9)	5 (21.7)	9 (39.1)
Nausea	10 (43.5)	4 (17.4)	6 (26.1)
Vomiting	8 (34.8)	4 (17.4)	4 (17.4)
Diarrhoea	7 (30.4)	4 (17.4)	3 (13.0)
Constipation	6 (26.1)	6 (26.1)	0
Abdominal pain	4 (17.4)	2 (8.7)	2 (8.7)
General disorders and administration site conditions			
-Total	13 (56.5)	5 (21.7)	8 (34.8)
Pyrexia	7 (30.4)	1 (4.3)	6 (26.1)
Fatigue	5 (21.7)	5 (21.7)	0
Catheter site pain	2 (8.7)	1 (4.3)	1 (4.3)
Chills	2 (8.7)	1 (4.3)	1 (4.3)
Generalised oedema	2 (8.7)	1 (4.3)	1 (4.3)
Oedema peripheral	2 (8.7)	1 (4.3)	1 (4.3)

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain	1 (4.3)	0	1 (4.3)
Immune system disorders			
-Total	16 (69.6)	2 (8.7)	14 (60.9)
Cytokine release syndrome	14 (60.9)	2 (8.7)	12 (52.2)
Hypogammaglobulinaemia	8 (34.8)	1 (4.3)	7 (30.4)
Infections and infestations			
-Total	13 (56.5)	2 (8.7)	11 (47.8)
Influenza	3 (13.0)	1 (4.3)	2 (8.7)
Pneumonia	3 (13.0)	0	3 (13.0)
Clostridium difficile infection	2 (8.7)	0	2 (8.7)
Gastroenteritis	2 (8.7)	0	2 (8.7)
Otitis media	2 (8.7)	0	2 (8.7)
Rhinovirus infection	2 (8.7)	1 (4.3)	1 (4.3)
Upper respiratory tract infection	2 (8.7)	1 (4.3)	1 (4.3)
Urinary tract infection	1 (4.3)	0	1 (4.3)
Viral infection	1 (4.3)	1 (4.3)	0
Injury, poisoning and procedural complications			

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (4.3)	1 (4.3)	0
Contusion	1 (4.3)	1 (4.3)	0
Investigations			
-Total	13 (56.5)	1 (4.3)	12 (52.2)
Aspartate aminotransferase increased	6 (26.1)	3 (13.0)	3 (13.0)
White blood cell count decreased	6 (26.1)	2 (8.7)	4 (17.4)
Alanine aminotransferase increased	4 (17.4)	1 (4.3)	3 (13.0)
Activated partial thromboplastin time prolonged	3 (13.0)	1 (4.3)	2 (8.7)
Blood bilirubin increased	3 (13.0)	0	3 (13.0)
Blood creatinine increased	3 (13.0)	2 (8.7)	1 (4.3)
International normalised ratio increased	3 (13.0)	3 (13.0)	0
Platelet count decreased	3 (13.0)	0	3 (13.0)
Prothrombin time prolonged	3 (13.0)	3 (13.0)	0
Blood immunoglobulin a decreased	1 (4.3)	1 (4.3)	0
Blood immunoglobulin m decreased	1 (4.3)	1 (4.3)	0
Blood phosphorus increased	1 (4.3)	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Neutrophil count decreased	1 (4.3)	0	1 (4.3)
Weight decreased	1 (4.3)	1 (4.3)	0
Weight increased	1 (4.3)	1 (4.3)	0
Metabolism and nutrition disorders			
-Total	13 (56.5)	5 (21.7)	8 (34.8)
Decreased appetite	9 (39.1)	6 (26.1)	3 (13.0)
Hyperphosphataemia	4 (17.4)	4 (17.4)	0
Hyperglycaemia	3 (13.0)	0	3 (13.0)
Hypernatraemia	3 (13.0)	1 (4.3)	2 (8.7)
Hypocalcaemia	2 (8.7)	2 (8.7)	0
Hypokalaemia	2 (8.7)	1 (4.3)	1 (4.3)
Fluid overload	1 (4.3)	0	1 (4.3)
Hyperuricaemia	1 (4.3)	1 (4.3)	0
Hypoalbuminaemia	1 (4.3)	0	1 (4.3)
Hypophosphataemia	1 (4.3)	1 (4.3)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (21.7)	3 (13.0)	2 (8.7)

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal chest pain	3 (13.0)	3 (13.0)	0
Arthralgia	2 (8.7)	2 (8.7)	0
Muscular weakness	2 (8.7)	1 (4.3)	1 (4.3)
Pain in extremity	2 (8.7)	1 (4.3)	1 (4.3)
Nervous system disorders			
-Total	11 (47.8)	6 (26.1)	5 (21.7)
Headache	11 (47.8)	6 (26.1)	5 (21.7)
Dizziness	1 (4.3)	1 (4.3)	0
Psychiatric disorders			
-Total	6 (26.1)	2 (8.7)	4 (17.4)
Anxiety	2 (8.7)	0	2 (8.7)
Delirium	2 (8.7)	0	2 (8.7)
Depression	2 (8.7)	1 (4.3)	1 (4.3)
Insomnia	2 (8.7)	0	2 (8.7)
Confusional state	1 (4.3)	1 (4.3)	0
Irritability	1 (4.3)	1 (4.3)	0
Renal and urinary disorders			
-Total	3 (13.0)	2 (8.7)	1 (4.3)

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Acute kidney injury	3 (13.0)	2 (8.7)	1 (4.3)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (43.5)	4 (17.4)	6 (26.1)
Epistaxis	4 (17.4)	2 (8.7)	2 (8.7)
Cough	3 (13.0)	3 (13.0)	0
Tachypnoea	3 (13.0)	2 (8.7)	1 (4.3)
Hypoxia	2 (8.7)	0	2 (8.7)
Nasal congestion	2 (8.7)	2 (8.7)	0
Oropharyngeal pain	2 (8.7)	1 (4.3)	1 (4.3)
Pleural effusion	2 (8.7)	0	2 (8.7)
Rhinorrhoea	1 (4.3)	1 (4.3)	0
Skin and subcutaneous tissue disorders			
-Total	11 (47.8)	9 (39.1)	2 (8.7)
Dry skin	4 (17.4)	4 (17.4)	0
Hyperhidrosis	3 (13.0)	3 (13.0)	0
Petechiae	3 (13.0)	3 (13.0)	0
Rash	3 (13.0)	2 (8.7)	1 (4.3)

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash erythematous	3 (13.0)	2 (8.7)	1 (4.3)
Erythema	1 (4.3)	1 (4.3)	0
Rash papular	1 (4.3)	1 (4.3)	0
Vascular disorders			
-Total	4 (17.4)	1 (4.3)	3 (13.0)
Hypertension	4 (17.4)	1 (4.3)	3 (13.0)

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- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	23 (95.8)	0	23 (95.8)
Blood and lymphatic system disorders			
-Total	7 (29.2)	0	7 (29.2)
Anaemia	5 (20.8)	0	5 (20.8)
Thrombocytopenia	3 (12.5)	0	3 (12.5)
Cardiac disorders			
-Total	6 (25.0)	2 (8.3)	4 (16.7)
Tachycardia	5 (20.8)	2 (8.3)	3 (12.5)
Palpitations	1 (4.2)	1 (4.2)	0
Sinus tachycardia	1 (4.2)	0	1 (4.2)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Endocrine disorders			
-Total	1 (4.2)	0	1 (4.2)
Adrenal insufficiency	1 (4.2)	0	1 (4.2)
Eye disorders			
-Total	2 (8.3)	0	2 (8.3)
Eye pain	2 (8.3)	0	2 (8.3)
Gastrointestinal disorders			
-Total	16 (66.7)	5 (20.8)	11 (45.8)
Nausea	10 (41.7)	2 (8.3)	8 (33.3)
Diarrhoea	8 (33.3)	4 (16.7)	4 (16.7)
Vomiting	7 (29.2)	5 (20.8)	2 (8.3)
Constipation	3 (12.5)	1 (4.2)	2 (8.3)
Abdominal pain	2 (8.3)	1 (4.2)	1 (4.2)
Oral pain	1 (4.2)	0	1 (4.2)
General disorders and administration site conditions			
-Total	13 (54.2)	5 (20.8)	8 (33.3)
Pyrexia	8 (33.3)	2 (8.3)	6 (25.0)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Chills	6 (25.0)	5 (20.8)	1 (4.2)
Fatigue	5 (20.8)	3 (12.5)	2 (8.3)
Catheter site pain	3 (12.5)	1 (4.2)	2 (8.3)
Malaise	3 (12.5)	1 (4.2)	2 (8.3)
Pain	1 (4.2)	0	1 (4.2)
Hepatobiliary disorders			
-Total	1 (4.2)	1 (4.2)	0
Hepatomegaly	1 (4.2)	1 (4.2)	0
Immune system disorders			
-Total	17 (70.8)	0	17 (70.8)
Cytokine release syndrome	16 (66.7)	1 (4.2)	15 (62.5)
Hypogammaglobulinaemia	9 (37.5)	1 (4.2)	8 (33.3)
Infections and infestations			
-Total	9 (37.5)	2 (8.3)	7 (29.2)
Rhinovirus infection	3 (12.5)	3 (12.5)	0
Pneumonia	2 (8.3)	0	2 (8.3)
Upper respiratory tract infection	2 (8.3)	0	2 (8.3)
Clostridium difficile infection	1 (4.2)	0	1 (4.2)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastroenteritis	1 (4.2)	1 (4.2)	0
Influenza	1 (4.2)	0	1 (4.2)
Urinary tract infection	1 (4.2)	0	1 (4.2)
Injury, poisoning and procedural complications			
-Total	4 (16.7)	3 (12.5)	1 (4.2)
Procedural pain	3 (12.5)	2 (8.3)	1 (4.2)
Infusion related reaction	2 (8.3)	2 (8.3)	0
Investigations			
-Total	14 (58.3)	2 (8.3)	12 (50.0)
Alanine aminotransferase increased	5 (20.8)	3 (12.5)	2 (8.3)
Aspartate aminotransferase increased	4 (16.7)	2 (8.3)	2 (8.3)
Prothrombin time prolonged	4 (16.7)	2 (8.3)	2 (8.3)
White blood cell count decreased	4 (16.7)	0	4 (16.7)
Transaminases increased	3 (12.5)	3 (12.5)	0
Weight decreased	3 (12.5)	0	3 (12.5)
Blood bilirubin increased	2 (8.3)	0	2 (8.3)
Blood fibrinogen decreased	2 (8.3)	0	2 (8.3)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Platelet count decreased	2 (8.3)	2 (8.3)	0
Blood creatinine increased	1 (4.2)	1 (4.2)	0
Blood immunoglobulin m decreased	1 (4.2)	1 (4.2)	0
International normalised ratio increased	1 (4.2)	1 (4.2)	0
Lymphocyte count decreased	1 (4.2)	0	1 (4.2)
Metabolism and nutrition disorders			
-Total	11 (45.8)	2 (8.3)	9 (37.5)
Decreased appetite	4 (16.7)	1 (4.2)	3 (12.5)
Hypokalaemia	3 (12.5)	1 (4.2)	2 (8.3)
Fluid overload	2 (8.3)	0	2 (8.3)
Hyperphosphataemia	2 (8.3)	2 (8.3)	0
Hypophosphataemia	2 (8.3)	1 (4.2)	1 (4.2)
Hypernatraemia	1 (4.2)	0	1 (4.2)
Hypoalbuminaemia	1 (4.2)	0	1 (4.2)
Hypocalcaemia	1 (4.2)	0	1 (4.2)
Musculoskeletal and connective tissue disorders			
-Total	5 (20.8)	3 (12.5)	2 (8.3)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	3 (12.5)	2 (8.3)	1 (4.2)
Arthralgia	1 (4.2)	0	1 (4.2)
Myalgia	1 (4.2)	1 (4.2)	0
Pain in jaw	1 (4.2)	0	1 (4.2)
Nervous system disorders			
-Total	10 (41.7)	6 (25.0)	4 (16.7)
Headache	7 (29.2)	4 (16.7)	3 (12.5)
Dizziness	2 (8.3)	2 (8.3)	0
Peroneal nerve palsy	2 (8.3)	1 (4.2)	1 (4.2)
Psychiatric disorders			
-Total	5 (20.8)	3 (12.5)	2 (8.3)
Anxiety	2 (8.3)	1 (4.2)	1 (4.2)
Confusional state	2 (8.3)	1 (4.2)	1 (4.2)
Delirium	1 (4.2)	1 (4.2)	0
Renal and urinary disorders			
-Total	1 (4.2)	0	1 (4.2)
Acute kidney injury	1 (4.2)	0	1 (4.2)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	10 (41.7)	5 (20.8)	5 (20.8)
Cough	5 (20.8)	4 (16.7)	1 (4.2)
Rhinitis allergic	3 (12.5)	2 (8.3)	1 (4.2)
Epistaxis	2 (8.3)	1 (4.2)	1 (4.2)
Hypoxia	2 (8.3)	0	2 (8.3)
Rhinorrhoea	2 (8.3)	2 (8.3)	0
Nasal congestion	1 (4.2)	1 (4.2)	0
Oropharyngeal pain	1 (4.2)	1 (4.2)	0
Pleural effusion	1 (4.2)	1 (4.2)	0
Tachypnoea	1 (4.2)	1 (4.2)	0
Skin and subcutaneous tissue disorders			
-Total	7 (29.2)	4 (16.7)	3 (12.5)
Alopecia	3 (12.5)	2 (8.3)	1 (4.2)
Erythema	2 (8.3)	2 (8.3)	0
Rash	2 (8.3)	1 (4.2)	1 (4.2)
Hyperhidrosis	1 (4.2)	1 (4.2)	0

Number of previous relapses: 2

Group term Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Rash maculo-papular	1 (4.2)	0	1 (4.2)
Vascular disorders			
-Total	4 (16.7)	1 (4.2)	3 (12.5)
Hypertension	4 (16.7)	1 (4.2)	3 (12.5)

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- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (95.0)	0	19 (95.0)
Blood and lymphatic system disorders			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Anaemia	3 (15.0)	1 (5.0)	2 (10.0)
Thrombocytopenia	2 (10.0)	1 (5.0)	1 (5.0)
Cardiac disorders			
-Total	7 (35.0)	4 (20.0)	3 (15.0)
Tachycardia	5 (25.0)	3 (15.0)	2 (10.0)
Sinus tachycardia	3 (15.0)	2 (10.0)	1 (5.0)
Ear and labyrinth disorders			

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (10.0)	2 (10.0)	0
Ear pain	2 (10.0)	2 (10.0)	0
Gastrointestinal disorders			
-Total	10 (50.0)	3 (15.0)	7 (35.0)
Vomiting	7 (35.0)	5 (25.0)	2 (10.0)
Diarrhoea	6 (30.0)	3 (15.0)	3 (15.0)
Nausea	6 (30.0)	2 (10.0)	4 (20.0)
Abdominal pain	5 (25.0)	2 (10.0)	3 (15.0)
Abdominal distension	2 (10.0)	0	2 (10.0)
Constipation	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	15 (75.0)	6 (30.0)	9 (45.0)
Pyrexia	10 (50.0)	5 (25.0)	5 (25.0)
Fatigue	6 (30.0)	4 (20.0)	2 (10.0)
Chills	2 (10.0)	2 (10.0)	0
Generalised oedema	2 (10.0)	1 (5.0)	1 (5.0)
Oedema peripheral	2 (10.0)	2 (10.0)	0

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain	2 (10.0)	1 (5.0)	1 (5.0)
Catheter site pain	1 (5.0)	1 (5.0)	0
Malaise	1 (5.0)	0	1 (5.0)
Hepatobiliary disorders			
-Total	1 (5.0)	0	1 (5.0)
Hepatomegaly	1 (5.0)	0	1 (5.0)
Immune system disorders			
-Total	15 (75.0)	6 (30.0)	9 (45.0)
Cytokine release syndrome	10 (50.0)	4 (20.0)	6 (30.0)
Hypogammaglobulinaemia	7 (35.0)	2 (10.0)	5 (25.0)
Graft versus host disease	1 (5.0)	1 (5.0)	0
Infections and infestations			
-Total	9 (45.0)	3 (15.0)	6 (30.0)
Upper respiratory tract infection	4 (20.0)	4 (20.0)	0
Fungal skin infection	2 (10.0)	1 (5.0)	1 (5.0)
Otitis media	2 (10.0)	0	2 (10.0)
Urinary tract infection	2 (10.0)	0	2 (10.0)
Vulvovaginal candidiasis	2 (10.0)	1 (5.0)	1 (5.0)

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Clostridium difficile infection	1 (5.0)	0	1 (5.0)
Ear infection	1 (5.0)	0	1 (5.0)
Skin infection	1 (5.0)	0	1 (5.0)
Injury, poisoning and procedural complications			
-Total	4 (20.0)	1 (5.0)	3 (15.0)
Infusion related reaction	2 (10.0)	0	2 (10.0)
Procedural pain	2 (10.0)	0	2 (10.0)
Contusion	1 (5.0)	1 (5.0)	0
Investigations			
-Total	11 (55.0)	1 (5.0)	10 (50.0)
Aspartate aminotransferase increased	6 (30.0)	3 (15.0)	3 (15.0)
Alanine aminotransferase increased	5 (25.0)	1 (5.0)	4 (20.0)
International normalised ratio increased	5 (25.0)	4 (20.0)	1 (5.0)
White blood cell count decreased	5 (25.0)	3 (15.0)	2 (10.0)
Lymphocyte count decreased	4 (20.0)	1 (5.0)	3 (15.0)
Neutrophil count decreased	4 (20.0)	2 (10.0)	2 (10.0)

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Activated partial thromboplastin time prolonged	2 (10.0)	1 (5.0)	1 (5.0)
Blood bilirubin increased	2 (10.0)	2 (10.0)	0
Blood creatinine increased	2 (10.0)	2 (10.0)	0
Blood immunoglobulin a decreased	2 (10.0)	2 (10.0)	0
Weight increased	2 (10.0)	1 (5.0)	1 (5.0)
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0
Blood uric acid increased	1 (5.0)	1 (5.0)	0
Platelet count decreased	1 (5.0)	1 (5.0)	0
Prothrombin time prolonged	1 (5.0)	0	1 (5.0)
Metabolism and nutrition disorders			
-Total	12 (60.0)	4 (20.0)	8 (40.0)
Decreased appetite	4 (20.0)	3 (15.0)	1 (5.0)
Hypokalaemia	4 (20.0)	1 (5.0)	3 (15.0)
Hyperphosphataemia	3 (15.0)	2 (10.0)	1 (5.0)
Hypoalbuminaemia	3 (15.0)	0	3 (15.0)
Hypophosphataemia	3 (15.0)	3 (15.0)	0
Fluid overload	2 (10.0)	1 (5.0)	1 (5.0)

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperuricaemia	2 (10.0)	2 (10.0)	0
Hypocalcaemia	2 (10.0)	1 (5.0)	1 (5.0)
Hyperglycaemia	1 (5.0)	0	1 (5.0)
Musculoskeletal and connective tissue disorders			
-Total	10 (50.0)	7 (35.0)	3 (15.0)
Myalgia	4 (20.0)	3 (15.0)	1 (5.0)
Pain in extremity	4 (20.0)	2 (10.0)	2 (10.0)
Muscle spasms	3 (15.0)	3 (15.0)	0
Arthralgia	2 (10.0)	2 (10.0)	0
Joint range of motion decreased	2 (10.0)	2 (10.0)	0
Pain in jaw	2 (10.0)	1 (5.0)	1 (5.0)
Neck pain	1 (5.0)	0	1 (5.0)
Nervous system disorders			
-Total	8 (40.0)	4 (20.0)	4 (20.0)
Headache	7 (35.0)	3 (15.0)	4 (20.0)
Dizziness	2 (10.0)	2 (10.0)	0
Psychiatric disorders			

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (20.0)	1 (5.0)	3 (15.0)
Anxiety	3 (15.0)	1 (5.0)	2 (10.0)
Irritability	2 (10.0)	2 (10.0)	0
Confusional state	1 (5.0)	0	1 (5.0)
Insomnia	1 (5.0)	0	1 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (45.0)	5 (25.0)	4 (20.0)
Cough	4 (20.0)	3 (15.0)	1 (5.0)
Dyspnoea	3 (15.0)	1 (5.0)	2 (10.0)
Epistaxis	2 (10.0)	1 (5.0)	1 (5.0)
Hypoxia	2 (10.0)	0	2 (10.0)
Nasal congestion	2 (10.0)	2 (10.0)	0
Oropharyngeal pain	2 (10.0)	2 (10.0)	0
Pleural effusion	2 (10.0)	0	2 (10.0)
Rhinitis allergic	2 (10.0)	2 (10.0)	0
Rhinorrhoea	1 (5.0)	1 (5.0)	0
Tachypnoea	1 (5.0)	0	1 (5.0)

Number of previous relapses: >=3

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Skin and subcutaneous tissue disorders			
-Total	7 (35.0)	5 (25.0)	2 (10.0)
Rash	4 (20.0)	3 (15.0)	1 (5.0)
Rash maculo-papular	2 (10.0)	2 (10.0)	0
Rash papular	2 (10.0)	2 (10.0)	0
Petechiae	1 (5.0)	0	1 (5.0)
Rash erythematous	1 (5.0)	0	1 (5.0)
Vascular disorders			
-Total	5 (25.0)	2 (10.0)	3 (15.0)
Hypertension	3 (15.0)	1 (5.0)	2 (10.0)
Hypotension	2 (10.0)	1 (5.0)	1 (5.0)

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grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 234a
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Age
Full analysis set

Age: <10 years

	Local assessment N=14	**IRC assessment N=14**
Events/Responders (%)	6/14 (42.9)	6/14 (42.9)
Maximum follow-up (months)	30.8	30.8
Median follow-up (months)	5.34	5.36
Percentiles (95% CI) [1]		
25th	5.3 (3.4, 13.6)	5.3 (3.4, 13.6)
50th	13.6 (4.7, NE)	13.6 (4.7, NE)
75th	NE (13.6, NE)	NE (13.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	58.4 (26.2, 80.6)	58.4 (26.2, 80.6)
Month 9	58.4 (26.2, 80.6)	58.4 (26.2, 80.6)
Month 12	58.4 (26.2, 80.6)	58.4 (26.2, 80.6)
Month 15	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 18	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 21	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)

Age: <10 years

	Local assessment N=14	IRC assessment N=14
Month 24	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 27	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 30	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234a
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=10 years to <18 years

	Local assessment N=25	**IRC assessment N=25**
Events/Responders (%)	4/25 (16.0)	4/25 (16.0)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	13.73	13.73
Percentiles (95% CI) [1]		
25th	NE (1.7, NE)	NE (1.7, NE)
50th	NE (14.8, NE)	NE (14.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	96.0 (74.8, 99.4)	96.0 (74.8, 99.4)
Month 6	96.0 (74.8, 99.4)	96.0 (74.8, 99.4)
Month 9	85.3 (60.7, 95.1)	85.3 (60.7, 95.1)
Month 12	85.3 (60.7, 95.1)	85.3 (60.7, 95.1)
Month 15	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 18	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 21	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)

Age: >=10 years to <18 years

	Local assessment N=25	IRC assessment N=25
Month 24	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 27	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 30	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 33	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 36	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 39	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 42	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 45	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234a
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=18

	Local assessment N=6	**IRC assessment N=6**
Events/Responders (%)	3/6 (50.0)	3/6 (50.0)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	8.28	8.28
Percentiles (95% CI) [1]		
25th	5.9 (1.9, 10.9)	5.9 (1.9, 10.9)
50th	10.9 (1.9, NE)	10.9 (1.9, NE)
75th	NE (5.9, NE)	NE (5.9, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	83.3 (27.3, 97.5)	83.3 (27.3, 97.5)
Month 6	62.5 (14.2, 89.3)	62.5 (14.2, 89.3)
Month 9	62.5 (14.2, 89.3)	62.5 (14.2, 89.3)
Month 12	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 15	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 18	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)

Age: >=18

	Local assessment N=6	IRC assessment N=6
Month 21	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 24	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 27	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 30	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 33	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 36	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 39	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 42	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 45	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234b
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Male

	Local assessment N=23	**IRC assessment N=23**
Events/Responders (%)	4/23 (17.4)	4/23 (17.4)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	10.87	10.87
Percentiles (95% CI) [1]		
25th	NE (1.7, NE)	NE (1.7, NE)
50th	NE (10.9, NE)	NE (10.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.7 (72.9, 99.4)	95.7 (72.9, 99.4)
Month 6	90.6 (67.3, 97.6)	90.9 (68.1, 97.6)
Month 9	83.6 (56.3, 94.6)	83.9 (56.7, 94.7)
Month 12	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 15	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 18	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 21	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)

Gender: Male		
	Local assessment N=23	**IRC assessment N=23**
Month 24	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 27	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 30	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 33	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 36	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 39	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 42	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 45	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234b
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Female	**Local assessment N=22**	**IRC assessment N=22**
Events/Responders (%)	9/22 (40.9)	9/22 (40.9)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.20	11.20
Percentiles (95% CI) [1]		
25th	5.9 (1.9, 14.8)	5.9 (1.9, 14.8)
50th	NE (5.9, NE)	NE (5.9, NE)
75th	NE (14.8, NE)	NE (14.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	95.5 (71.9, 99.3)	95.5 (71.9, 99.3)
Month 6	70.5 (45.7, 85.6)	70.5 (45.7, 85.6)
Month 9	65.5 (40.9, 81.9)	65.5 (40.9, 81.9)
Month 12	65.5 (40.9, 81.9)	65.5 (40.9, 81.9)
Month 15	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 18	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 21	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)

Gender: Female

	Local assessment N=22	IRC assessment N=22
Month 24	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 27	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 30	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 33	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 36	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 39	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 42	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 45	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234c
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Race
Full analysis set

Race: White

	Local assessment N=36	**IRC assessment N=36**
Events/Responders (%)	10/36 (27.8)	10/36 (27.8)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	10.78	10.78
Percentiles (95% CI) [1]		
25th	7.6 (3.5, NE)	7.6 (3.5, NE)
50th	NE (10.9, NE)	NE (10.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.4 (79.6, 98.6)	94.4 (79.6, 98.6)
Month 6	77.4 (58.0, 88.7)	77.6 (58.2, 88.8)
Month 9	73.5 (53.5, 86.0)	73.7 (53.7, 86.1)
Month 12	69.4 (48.9, 83.0)	69.6 (49.1, 83.1)
Month 15	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 18	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 21	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)

Race: White		
	Local assessment N=36	**IRC assessment N=36**
Month 24	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 27	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 30	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 33	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 36	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 39	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 42	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 45	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234c
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Asian

	Local assessment N=3	**IRC assessment N=3**
Events/Responders (%)	1/3 (33.3)	1/3 (33.3)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	10.97	10.97
Percentiles (95% CI) [1]		
25th	5.3 (5.3, NE)	5.3 (5.3, NE)
50th	NE (5.3, NE)	NE (5.3, NE)
75th	NE (5.3, NE)	NE (5.3, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 9	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 12	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 15	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 18	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 21	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)

Race: Asian

	Local assessment N=3	IRC assessment N=3
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234c
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Other

	Local assessment N=6	**IRC assessment N=6**
Events/Responders (%)	2/6 (33.3)	2/6 (33.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	14.24	14.24
Percentiles (95% CI) [1]		
25th	14.8 (6.9, NE)	14.8 (6.9, NE)
50th	NE (6.9, NE)	NE (6.9, NE)
75th	NE (6.9, NE)	NE (6.9, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 12	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 15	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 18	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)

Race: Other

	Local assessment N=6	IRC assessment N=6
Month 21	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 24	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 27	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 30	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 33	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 36	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 39	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 42	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 45	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234d
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Hispanic or Latino

	Local assessment N=23	**IRC assessment N=23**
Events/Responders (%)	4/23 (17.4)	4/23 (17.4)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	13.63	13.63
Percentiles (95% CI) [1]		
25th	14.8 (3.5, NE)	14.8 (3.5, NE)
50th	NE (14.8, NE)	NE (14.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	95.0 (69.5, 99.3)	95.0 (69.5, 99.3)
Month 9	95.0 (69.5, 99.3)	95.0 (69.5, 99.3)
Month 12	88.7 (61.4, 97.1)	88.7 (61.4, 97.1)
Month 15	71.1 (38.1, 88.7)	71.1 (38.1, 88.7)
Month 18	71.1 (38.1, 88.7)	71.1 (38.1, 88.7)
Month 21	71.1 (38.1, 88.7)	71.1 (38.1, 88.7)

Ethnicity: Hispanic or Latino	Local assessment N=23	IRC assessment N=23
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234d
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Other

	Local assessment N=22	**IRC assessment N=22**
Events/Responders (%)	9/22 (40.9)	9/22 (40.9)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	6.41	6.41
Percentiles (95% CI) [1]		
25th	5.4 (1.7, 7.6)	5.4 (1.7, 7.6)
50th	NE (5.4, NE)	NE (5.4, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	90.9 (68.3, 97.6)	90.9 (68.3, 97.6)
Month 6	64.4 (39.1, 81.4)	64.6 (39.3, 81.5)
Month 9	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 12	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 15	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 18	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 21	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)

Ethnicity: Other		
	Local assessment N=22	**IRC assessment N=22**
Month 24	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 27	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 30	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 33	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 36	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 39	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 42	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 45	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234e
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Primary refractory	**Local assessment N=4**	**IRC assessment N=4**
Events/Responders (%)	0/4 (0.0)	0/4 (0.0)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	5.31	5.31
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Response status at study entry: Primary refractory		
	Local assessment N=4	**IRC assessment N=4**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234e
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Relapsed disease	**Local assessment N=41**	**IRC assessment N=41**
Events/Responders (%)	13/41 (31.7)	13/41 (31.7)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.43	11.43
Percentiles (95% CI) [1]		
25th	6.9 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.1 (81.9, 98.8)	95.1 (81.9, 98.8)
Month 6	77.9 (60.5, 88.4)	78.1 (60.7, 88.4)
Month 9	71.9 (53.9, 83.9)	72.1 (54.1, 84.0)
Month 12	68.8 (50.6, 81.5)	68.9 (50.7, 81.6)
Month 15	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 18	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 21	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)

Response status at study entry: Relapsed disease

	Local assessment N=41	IRC assessment N=41
Month 24	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 27	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 30	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 33	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 36	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 39	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 42	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 45	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234f
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Positive

	Local assessment N=2	**IRC assessment N=2**
Events/Responders (%)	0/2 (0.0)	0/2 (0.0)
Maximum follow-up (months)	22.6	22.6
Median follow-up (months)	16.80	16.80
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Philadelphia chromosome/BCR-ABL: Positive

	Local assessment N=2	IRC assessment N=2
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234f
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Negative	**Local assessment N=43**	**IRC assessment N=43**
Events/Responders (%)	13/43 (30.2)	13/43 (30.2)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.87	10.87
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.3 (82.7, 98.8)	95.3 (82.7, 98.8)
Month 6	78.2 (60.9, 88.6)	78.3 (61.0, 88.6)
Month 9	72.0 (53.8, 84.0)	72.1 (54.0, 84.0)
Month 12	68.7 (50.3, 81.5)	68.8 (50.4, 81.5)
Month 15	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 18	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 21	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)

Philadelphia chromosome/BCR-ABL: Negative		
	Local assessment N=43	**IRC assessment N=43**
Month 24	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 27	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 30	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 33	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 36	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 39	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 42	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 45	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234g
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: Yes

	Local assessment N=1	**IRC assessment N=1**
Events/Responders (%)	1/1 (100.0)	1/1 (100.0)
Maximum follow-up (months)	3.4	3.4
Median follow-up (months)	3.35	3.35
Percentiles (95% CI) [1]		
25th	3.4 (NE, NE)	3.4 (NE, NE)
50th	3.4 (NE, NE)	3.4 (NE, NE)
75th	3.4 (NE, NE)	3.4 (NE, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	NE	NE
Month 9	NE	NE
Month 12	NE	NE
Month 15	NE	NE
Month 18	NE	NE
Month 21	NE	NE

Mixed-lineage leukemia rearrangement: Yes		
	Local assessment N=1	**IRC assessment N=1**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234g
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: No

	Local assessment N=44	**IRC assessment N=44**
Events/Responders (%)	12/44 (27.3)	12/44 (27.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.20	11.20
Percentiles (95% CI) [1]		
25th	10.9 (5.3, NE)	10.9 (5.3, NE)
50th	NE (14.8, NE)	NE (14.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.5 (83.0, 98.8)	95.5 (83.0, 98.8)
Month 6	81.4 (64.6, 90.7)	81.4 (64.7, 90.8)
Month 9	75.3 (57.7, 86.4)	75.4 (57.8, 86.5)
Month 12	72.2 (54.2, 84.1)	72.3 (54.3, 84.1)
Month 15	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 18	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 21	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)

Mixed-lineage leukemia rearrangement: No

	Local assessment N=44	IRC assessment N=44
Month 24	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 27	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 30	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 33	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 36	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 39	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 42	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 45	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234h
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: No	**Local assessment N=45**	**IRC assessment N=45**
Events/Responders (%)	13/45 (28.9)	13/45 (28.9)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.97	10.97
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.6 (83.4, 98.9)	95.6 (83.4, 98.9)
Month 6	79.4 (62.7, 89.2)	79.5 (62.9, 89.3)
Month 9	73.5 (56.1, 84.9)	73.6 (56.2, 84.9)
Month 12	70.4 (52.7, 82.5)	70.5 (52.8, 82.6)
Month 15	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 18	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 21	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)

Hypodiploidy: No

	Local assessment N=45	IRC assessment N=45
Month 24	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 27	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 30	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 33	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 36	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 39	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 42	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 45	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234i
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: Yes

	Local assessment N=4	IRC assessment N=4
Events/Responders (%)	1/4 (25.0)	1/4 (25.0)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	12.30	12.30
Percentiles (95% CI) [1]		
25th	13.6 (13.6, NE)	13.6 (13.6, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE (13.6, NE)	NE (13.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)
Month 18	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)
Month 21	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)

BCR-ABL1-like: Yes

	Local assessment N=4	IRC assessment N=4
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234i
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: No

	Local assessment N=41	IRC assessment N=41
Events/Responders (%)	12/41 (29.3)	12/41 (29.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.87	10.87
Percentiles (95% CI) [1]		
25th	6.9 (3.5, NE)	6.9 (4.7, NE)
50th	NE (10.9, NE)	NE (10.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.1 (81.9, 98.8)	95.1 (81.9, 98.8)
Month 6	77.4 (59.6, 88.1)	77.5 (59.7, 88.2)
Month 9	70.9 (52.4, 83.3)	71.0 (52.6, 83.4)
Month 12	67.5 (48.8, 80.7)	67.7 (48.9, 80.8)
Month 15	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 18	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 21	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)

BCR-ABL1-like: No

	Local assessment N=41	IRC assessment N=41
Month 24	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 27	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 30	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 33	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 36	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 39	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 42	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 45	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234j
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	Local assessment N=17	**IRC assessment N=17**
Events/Responders (%)	7/17 (41.2)	7/17 (41.2)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	7.56	7.56
Percentiles (95% CI) [1]		
25th	5.3 (1.9, 7.6)	5.3 (1.9, 7.6)
50th	NE (5.3, NE)	NE (5.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.1 (65.0, 99.1)	94.1 (65.0, 99.1)
Month 6	67.6 (38.6, 85.1)	67.6 (38.6, 85.1)
Month 9	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 12	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 15	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 18	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 21	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	Local assessment N=17	IRC assessment N=17
Month 24	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 27	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 30	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 33	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 36	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 39	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 42	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 45	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234j
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	Local assessment N=28	IRC assessment N=28
Events/Responders (%)	6/28 (21.4)	6/28 (21.4)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	11.20	11.20
Percentiles (95% CI) [1]		
25th	14.8 (3.5, NE)	14.8 (3.5, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	96.4 (77.2, 99.5)	96.4 (77.2, 99.5)
Month 6	87.5 (65.8, 95.9)	87.7 (66.1, 95.9)
Month 9	87.5 (65.8, 95.9)	87.7 (66.1, 95.9)
Month 12	82.1 (58.3, 93.0)	82.2 (58.6, 93.1)
Month 15	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 18	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 21	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	Local assessment N=28	IRC assessment N=28
Month 24	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 27	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 30	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 33	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 36	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 39	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 42	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 45	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234k
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Region
Full analysis set

Region: US

	Local assessment N=45	**IRC assessment N=45**
Events/Responders (%)	13/45 (28.9)	13/45 (28.9)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.97	10.97
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.6 (83.4, 98.9)	95.6 (83.4, 98.9)
Month 6	79.4 (62.7, 89.2)	79.5 (62.9, 89.3)
Month 9	73.5 (56.1, 84.9)	73.6 (56.2, 84.9)
Month 12	70.4 (52.7, 82.5)	70.5 (52.8, 82.6)
Month 15	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 18	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 21	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)

Region: US

	Local assessment N=45	IRC assessment N=45
Month 24	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 27	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 30	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 33	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 36	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 39	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 42	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 45	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234l
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: Yes

	Local assessment N=19	**IRC assessment N=19**
Events/Responders (%)	5/19 (26.3)	5/19 (26.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.43	11.43
Percentiles (95% CI) [1]		
25th	13.6 (1.7, NE)	13.6 (1.7, NE)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.7 (68.1, 99.2)	94.7 (68.1, 99.2)
Month 6	88.4 (60.8, 97.0)	88.4 (60.8, 97.0)
Month 9	75.8 (47.4, 90.2)	75.8 (47.4, 90.2)
Month 12	75.8 (47.4, 90.2)	75.8 (47.4, 90.2)
Month 15	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 18	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 21	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)

Prior SCT therapy: Yes

	Local assessment N=19	IRC assessment N=19
Month 24	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 27	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 30	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 33	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 36	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 39	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 42	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 45	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234l
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: No

	Local assessment N=26	**IRC assessment N=26**
Events/Responders (%)	8/26 (30.8)	8/26 (30.8)
Maximum follow-up (months)	29.4	23.4
Median follow-up (months)	8.38	8.38
Percentiles (95% CI) [1]		
25th	5.9 (3.4, NE)	5.9 (3.4, NE)
50th	NE (5.9, NE)	NE (5.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	96.2 (75.7, 99.4)	96.2 (75.7, 99.4)
Month 6	72.4 (48.0, 86.7)	72.4 (48.0, 86.7)
Month 9	72.4 (48.0, 86.7)	72.4 (48.0, 86.7)
Month 12	66.8 (42.1, 82.9)	66.8 (42.1, 82.9)
Month 15	59.4 (33.6, 78.0)	59.4 (33.6, 78.0)
Month 18	59.4 (33.6, 78.0)	59.4 (33.6, 78.0)
Month 21	59.4 (33.6, 78.0)	59.4 (33.6, 78.0)

Prior SCT therapy: No		
	Local assessment N=26	**IRC assessment N=26**
Month 24	59.4 (33.6, 78.0)	NE
Month 27	59.4 (33.6, 78.0)	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234m
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: Yes

	Local assessment N=12	**IRC assessment N=12**
Events/Responders (%)	4/12 (33.3)	4/12 (33.3)
Maximum follow-up (months)	23.4	23.4
Median follow-up (months)	13.95	13.95
Percentiles (95% CI) [1]		
25th	5.9 (3.5, NE)	5.9 (3.5, NE)
50th	NE (5.3, NE)	NE (5.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	73.3 (37.9, 90.6)	73.3 (37.9, 90.6)
Month 9	73.3 (37.9, 90.6)	73.3 (37.9, 90.6)
Month 12	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 15	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 18	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 21	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)

Eligibility for SCT: Yes

	Local assessment N=12	IRC assessment N=12
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234m
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: No

	Local assessment N=33	**IRC assessment N=33**
Events/Responders (%)	9/33 (27.3)	9/33 (27.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.68	10.68
Percentiles (95% CI) [1]		
25th	7.6 (3.4, NE)	7.6 (3.4, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.9 (77.9, 98.4)	93.9 (77.9, 98.4)
Month 6	82.4 (62.4, 92.4)	82.5 (62.6, 92.4)
Month 9	73.7 (52.2, 86.7)	73.8 (52.3, 86.8)
Month 12	73.7 (52.2, 86.7)	73.8 (52.3, 86.8)
Month 15	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 18	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 21	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)

Eligibility for SCT: No

	Local assessment N=33	IRC assessment N=33
Month 24	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 27	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 30	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 33	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 36	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 39	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 42	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 45	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234n
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: Low	**Local assessment N=16**	**IRC assessment N=16**
Events/Responders (%)	3/16 (18.8)	3/16 (18.8)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	15.95	15.95
Percentiles (95% CI) [1]		
25th	NE (5.4, NE)	NE (5.4, NE)
50th	NE (5.9, NE)	NE (5.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	83.9 (49.4, 95.7)	83.9 (49.4, 95.7)
Month 9	83.9 (49.4, 95.7)	83.9 (49.4, 95.7)
Month 12	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 15	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 18	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 21	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)

Baseline bone marrow tumor burden: Low

	Local assessment N=16	IRC assessment N=16
Month 24	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 27	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 30	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 33	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 36	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 39	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 42	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 45	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234n
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: High	**Local assessment N=29**	**IRC assessment N=29**
Events/Responders (%)	10/29 (34.5)	10/29 (34.5)
Maximum follow-up (months)	24.2	24.2
Median follow-up (months)	10.68	10.68
Percentiles (95% CI) [1]		
25th	6.9 (3.4, 14.8)	6.9 (3.4, 14.8)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.1 (75.1, 98.2)	93.1 (75.1, 98.2)
Month 6	76.9 (55.2, 89.0)	76.9 (55.2, 89.0)
Month 9	67.8 (45.4, 82.6)	67.8 (45.4, 82.6)
Month 12	67.8 (45.4, 82.6)	67.8 (45.4, 82.6)
Month 15	54.4 (29.9, 73.5)	54.4 (29.9, 73.5)
Month 18	54.4 (29.9, 73.5)	54.4 (29.9, 73.5)
Month 21	54.4 (29.9, 73.5)	54.4 (29.9, 73.5)

Baseline bone marrow tumor burden: High		
	Local assessment N=29	**IRC assessment N=29**
Month 24	54.4 (29.9, 73.5)	54.4 (29.9, 73.5)
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234o
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: Yes

	Local assessment N=5	**IRC assessment N=5**
Events/Responders (%)	2/5 (40.0)	2/5 (40.0)
Maximum follow-up (months)	30.8	30.8
Median follow-up (months)	14.75	14.75
Percentiles (95% CI) [1]		
25th	9.1 (3.4, NE)	9.1 (3.4, NE)
50th	NE (3.4, NE)	NE (3.4, NE)
75th	NE (3.4, NE)	NE (3.4, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Month 9	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Month 12	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Month 15	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 18	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 21	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)

Baseline extramedullary disease presence: Yes		
	Local assessment N=5	**IRC assessment N=5**
Month 24	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 27	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 30	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234o
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: No

	Local assessment N=40	**IRC assessment N=40**
Events/Responders (%)	11/40 (27.5)	11/40 (27.5)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.92	10.92
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.0 (81.5, 98.7)	95.0 (81.5, 98.7)
Month 6	79.6 (61.7, 89.8)	79.7 (61.8, 89.8)
Month 9	73.0 (54.2, 85.0)	73.0 (54.3, 85.1)
Month 12	69.5 (50.4, 82.4)	69.6 (50.5, 82.5)
Month 15	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 18	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 21	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)

Baseline extramedullary disease presence: No		
	Local assessment N=40	**IRC assessment N=40**
Month 24	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 27	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 30	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 33	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 36	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 39	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 42	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 45	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234p
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: Yes

	Local assessment N=3	**IRC assessment N=3**
Events/Responders (%)	0/3 (0.0)	0/3 (0.0)
Maximum follow-up (months)	20.4	20.4
Median follow-up (months)	4.90	4.90
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	NE	NE

Down syndrome: Yes		
	Local assessment N=3	**IRC assessment N=3**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234p
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: No

	Local assessment N=42	**IRC assessment N=42**
Events/Responders (%)	13/42 (31.0)	13/42 (31.0)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.20	11.20
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.2 (82.3, 98.8)	95.2 (82.3, 98.8)
Month 6	78.2 (61.0, 88.5)	78.4 (61.2, 88.6)
Month 9	72.2 (54.3, 84.1)	72.3 (54.5, 84.1)
Month 12	69.1 (50.9, 81.6)	69.2 (51.0, 81.7)
Month 15	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 18	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 21	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)

Down syndrome: No		
	Local assessment N=42	**IRC assessment N=42**
Month 24	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 27	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 30	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 33	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 36	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 39	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 42	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 45	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234q
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: > Median

	Local assessment N=23	**IRC assessment N=23**
Events/Responders (%)	7/23 (30.4)	7/23 (30.4)
Maximum follow-up (months)	29.4	24.2
Median follow-up (months)	13.63	13.63
Percentiles (95% CI) [1]		
25th	10.9 (5.3, NE)	10.9 (5.3, NE)
50th	NE (10.9, NE)	NE (10.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	83.9 (57.9, 94.5)	83.9 (57.9, 94.5)
Month 9	78.3 (51.9, 91.3)	78.3 (51.9, 91.3)
Month 12	72.7 (46.3, 87.6)	72.7 (46.3, 87.6)
Month 15	59.2 (32.4, 78.4)	59.2 (32.4, 78.4)
Month 18	59.2 (32.4, 78.4)	59.2 (32.4, 78.4)
Month 21	59.2 (32.4, 78.4)	59.2 (32.4, 78.4)

Time since enrollment to CTL019 infusion: > Median	Local assessment N=23	IRC assessment N=23
Month 24	59.2 (32.4, 78.4)	59.2 (32.4, 78.4)
Month 27	59.2 (32.4, 78.4)	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234q
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: <=Median

	Local assessment N=22	**IRC assessment N=22**
Events/Responders (%)	6/22 (27.3)	6/22 (27.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	9.12	9.12
Percentiles (95% CI) [1]		
25th	7.6 (1.7, NE)	7.6 (1.7, NE)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	90.9 (68.3, 97.6)	90.9 (68.3, 97.6)
Month 6	75.9 (51.3, 89.3)	76.4 (52.0, 89.5)
Month 9	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 12	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 15	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 18	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 21	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)

Time since enrollment to CTL019 infusion: <=Median	Local assessment N=22	IRC assessment N=22
Month 24	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 27	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 30	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 33	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 36	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 39	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 42	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 45	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234r
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 0	**Local assessment N=4**	**IRC assessment N=4**
Events/Responders (%)	0/4 (0.0)	0/4 (0.0)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	5.31	5.31
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Number of previous relapses: 0

	Local assessment N=4	IRC assessment N=4
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234r
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 1	**Local assessment N=15**	**IRC assessment N=15**
Events/Responders (%)	3/15 (20.0)	3/15 (20.0)
Maximum follow-up (months)	30.8	30.8
Median follow-up (months)	10.87	10.87
Percentiles (95% CI) [1]		
25th	10.9 (3.4, NE)	10.9 (3.4, NE)
50th	NE (6.9, NE)	NE (6.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	92.9 (59.1, 99.0)	92.9 (59.1, 99.0)
Month 9	82.5 (45.1, 95.5)	82.5 (45.1, 95.5)
Month 12	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 15	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 18	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 21	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)

Number of previous relapses: 1		
	Local assessment N=15	**IRC assessment N=15**
Month 24	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 27	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 30	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234r
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 2

	Local assessment N=14	**IRC assessment N=14**
Events/Responders (%)	6/14 (42.9)	6/14 (42.9)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	12.85	12.85
Percentiles (95% CI) [1]		
25th	5.3 (1.9, NE)	5.3 (1.9, NE)
50th	NE (4.7, NE)	NE (4.7, NE)
75th	NE (14.8, NE)	NE (14.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	92.9 (59.1, 99.0)	92.9 (59.1, 99.0)
Month 6	64.3 (34.3, 83.3)	64.3 (34.3, 83.3)
Month 9	64.3 (34.3, 83.3)	64.3 (34.3, 83.3)
Month 12	64.3 (34.3, 83.3)	64.3 (34.3, 83.3)
Month 15	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 18	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)

Number of previous relapses: 2

	Local assessment N=14	IRC assessment N=14
Month 21	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 24	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 27	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 30	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 33	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 36	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 39	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 42	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 45	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 234r
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: >=3

	Local assessment N=12	**IRC assessment N=12**
Events/Responders (%)	4/12 (33.3)	4/12 (33.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	12.30	12.30
Percentiles (95% CI) [1]		
25th	7.6 (1.7, NE)	7.6 (1.7, NE)
50th	NE (5.4, NE)	NE (5.4, NE)
75th	NE (13.6, NE)	NE (13.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	91.7 (53.9, 98.8)	91.7 (53.9, 98.8)
Month 6	81.5 (43.5, 95.1)	81.5 (43.5, 95.1)
Month 9	71.3 (34.4, 89.8)	71.3 (34.4, 89.8)
Month 12	71.3 (34.4, 89.8)	71.3 (34.4, 89.8)
Month 15	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 18	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)

Number of previous relapses: >=3

	Local assessment N=12	IRC assessment N=12
Month 21	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 24	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 27	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 30	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 33	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 36	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 39	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 42	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 45	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243a
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Age
Full analysis set

Age: <10 years	**Local assessment N=14**	**IRC assessment N=14**
Events/Responders (%)	6/14 (42.9)	6/14 (42.9)
Maximum follow-up (months)	30.8	30.8
Median follow-up (months)	5.36	5.36
Percentiles (95% CI) [1]		
25th	5.3 (3.4, 13.6)	5.3 (3.4, 13.6)
50th	13.6 (4.7, NE)	13.6 (4.7, NE)
75th	NE (13.6, NE)	NE (13.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	58.4 (26.2, 80.6)	58.4 (26.2, 80.6)
Month 9	58.4 (26.2, 80.6)	58.4 (26.2, 80.6)
Month 12	58.4 (26.2, 80.6)	58.4 (26.2, 80.6)
Month 15	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 18	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 21	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)

Age: <10 years

	Local assessment N=14	IRC assessment N=14
Month 24	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 27	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 30	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243a
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=10 years to <18 years

	Local assessment N=25	**IRC assessment N=25**
Events/Responders (%)	4/25 (16.0)	4/25 (16.0)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	13.73	13.73
Percentiles (95% CI) [1]		
25th	NE (1.7, NE)	NE (1.7, NE)
50th	NE (14.8, NE)	NE (14.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	96.0 (74.8, 99.4)	96.0 (74.8, 99.4)
Month 6	96.0 (74.8, 99.4)	96.0 (74.8, 99.4)
Month 9	85.3 (60.7, 95.1)	85.3 (60.7, 95.1)
Month 12	85.3 (60.7, 95.1)	85.3 (60.7, 95.1)
Month 15	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 18	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 21	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)

Age: >=10 years to <18 years		
	Local assessment N=25	**IRC assessment N=25**
Month 24	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 27	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 30	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 33	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 36	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 39	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 42	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 45	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243a
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=18	**Local assessment N=6**	**IRC assessment N=6**
Events/Responders (%)	3/6 (50.0)	3/6 (50.0)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	8.28	8.28
Percentiles (95% CI) [1]		
25th	5.9 (1.9, 10.9)	5.9 (1.9, 10.9)
50th	10.9 (1.9, NE)	10.9 (1.9, NE)
75th	NE (5.9, NE)	NE (5.9, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	83.3 (27.3, 97.5)	83.3 (27.3, 97.5)
Month 6	62.5 (14.2, 89.3)	62.5 (14.2, 89.3)
Month 9	62.5 (14.2, 89.3)	62.5 (14.2, 89.3)
Month 12	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 15	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 18	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 21	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)

Age: >=18

	Local assessment N=6	IRC assessment N=6
Month 24	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 27	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 30	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 33	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 36	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 39	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 42	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 45	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243b
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Male	**Local assessment N=23**	**IRC assessment N=23**
Events/Responders (%)	4/23 (17.4)	4/23 (17.4)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	10.87	10.87
Percentiles (95% CI) [1]		
25th	NE (1.7, NE)	NE (1.7, NE)
50th	NE (10.9, NE)	NE (10.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.7 (72.9, 99.4)	95.7 (72.9, 99.4)
Month 6	90.6 (67.3, 97.6)	90.9 (68.1, 97.6)
Month 9	83.6 (56.3, 94.6)	83.9 (56.7, 94.7)
Month 12	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 15	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 18	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 21	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)

Gender: Male		
	Local assessment N=23	**IRC assessment N=23**
Month 24	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 27	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 30	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 33	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 36	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 39	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 42	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 45	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243b
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Female	**Local assessment N=22**	**IRC assessment N=22**
Events/Responders (%)	9/22 (40.9)	9/22 (40.9)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.20	11.20
Percentiles (95% CI) [1]		
25th	5.9 (1.9, 14.8)	5.9 (1.9, 14.8)
50th	NE (5.9, NE)	NE (5.9, NE)
75th	NE (14.8, NE)	NE (14.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	95.5 (71.9, 99.3)	95.5 (71.9, 99.3)
Month 6	70.5 (45.7, 85.6)	70.5 (45.7, 85.6)
Month 9	65.5 (40.9, 81.9)	65.5 (40.9, 81.9)
Month 12	65.5 (40.9, 81.9)	65.5 (40.9, 81.9)
Month 15	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 18	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 21	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)

Gender: Female		
	Local assessment N=22	**IRC assessment N=22**
Month 24	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 27	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 30	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 33	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 36	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 39	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 42	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 45	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243c
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Race
Full analysis set

Race: White	**Local assessment N=36**	**IRC assessment N=36**
Events/Responders (%)	10/36 (27.8)	10/36 (27.8)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	10.78	10.78
Percentiles (95% CI) [1]		
25th	7.6 (3.5, NE)	7.6 (3.5, NE)
50th	NE (10.9, NE)	NE (10.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.4 (79.6, 98.6)	94.4 (79.6, 98.6)
Month 6	77.4 (58.0, 88.7)	77.6 (58.2, 88.8)
Month 9	73.5 (53.5, 86.0)	73.7 (53.7, 86.1)
Month 12	69.4 (48.9, 83.0)	69.6 (49.1, 83.1)
Month 15	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 18	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 21	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)

Race: White		
	Local assessment N=36	**IRC assessment N=36**
Month 24	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 27	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 30	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 33	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 36	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 39	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 42	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 45	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243c
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Asian	**Local assessment N=3**	**IRC assessment N=3**
Events/Responders (%)	1/3 (33.3)	1/3 (33.3)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	10.97	10.97
Percentiles (95% CI) [1]		
25th	5.3 (5.3, NE)	5.3 (5.3, NE)
50th	NE (5.3, NE)	NE (5.3, NE)
75th	NE (5.3, NE)	NE (5.3, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 9	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 12	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 15	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 18	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 21	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)

Race: Asian		
	Local assessment N=3	**IRC assessment N=3**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243c
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Other

	Local assessment N=6	**IRC assessment N=6**
Events/Responders (%)	2/6 (33.3)	2/6 (33.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	14.24	14.24
Percentiles (95% CI) [1]		
25th	14.8 (6.9, NE)	14.8 (6.9, NE)
50th	NE (6.9, NE)	NE (6.9, NE)
75th	NE (6.9, NE)	NE (6.9, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 12	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 15	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 18	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 21	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)

Race: Other		
	Local assessment N=6	**IRC assessment N=6**
Month 24	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 27	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 30	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 33	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 36	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 39	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 42	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 45	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243d
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Hispanic or Latino	**Local assessment N=23**	**IRC assessment N=23**
Events/Responders (%)	4/23 (17.4)	4/23 (17.4)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	13.63	13.63
Percentiles (95% CI) [1]		
25th	14.8 (3.5, NE)	14.8 (3.5, NE)
50th	NE (14.8, NE)	NE (14.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	95.0 (69.5, 99.3)	95.0 (69.5, 99.3)
Month 9	95.0 (69.5, 99.3)	95.0 (69.5, 99.3)
Month 12	88.7 (61.4, 97.1)	88.7 (61.4, 97.1)
Month 15	71.1 (38.1, 88.7)	71.1 (38.1, 88.7)
Month 18	71.1 (38.1, 88.7)	71.1 (38.1, 88.7)
Month 21	71.1 (38.1, 88.7)	71.1 (38.1, 88.7)

Ethnicity: Hispanic or Latino		
	Local assessment N=23	**IRC assessment N=23**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243d
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Other	**Local assessment N=22**	**IRC assessment N=22**
Events/Responders (%)	9/22 (40.9)	9/22 (40.9)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	6.41	6.41
Percentiles (95% CI) [1]		
25th	5.4 (1.7, 7.6)	5.4 (1.7, 7.6)
50th	NE (5.4, NE)	NE (5.4, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	90.9 (68.3, 97.6)	90.9 (68.3, 97.6)
Month 6	64.4 (39.1, 81.4)	64.6 (39.3, 81.5)
Month 9	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 12	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 15	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 18	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 21	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)

Ethnicity: Other		
	Local assessment N=22	**IRC assessment N=22**
Month 24	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 27	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 30	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 33	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 36	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 39	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 42	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 45	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243e
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Primary refractory	**Local assessment N=4**	**IRC assessment N=4**
Events/Responders (%)	0/4 (0.0)	0/4 (0.0)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	5.31	5.31
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Response status at study entry: Primary refractory		
	Local assessment N=4	**IRC assessment N=4**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243e
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Relapsed disease		
	Local assessment N=41	**IRC assessment N=41**
Events/Responders (%)	13/41 (31.7)	13/41 (31.7)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.43	11.43
Percentiles (95% CI) [1]		
25th	6.9 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.1 (81.9, 98.8)	95.1 (81.9, 98.8)
Month 6	77.9 (60.5, 88.4)	78.1 (60.7, 88.4)
Month 9	71.9 (53.9, 83.9)	72.1 (54.1, 84.0)
Month 12	68.8 (50.6, 81.5)	68.9 (50.7, 81.6)
Month 15	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 18	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 21	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)

Response status at study entry: Relapsed disease		
	Local assessment N=41	**IRC assessment N=41**
Month 24	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 27	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 30	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 33	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 36	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 39	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 42	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 45	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243f
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Positive	**Local assessment N=2**	**IRC assessment N=2**
Events/Responders (%)	0/2 (0.0)	0/2 (0.0)
Maximum follow-up (months)	22.6	22.6
Median follow-up (months)	16.80	16.80
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Philadelphia chromosome/BCR-ABL: Positive		
	Local assessment N=2	**IRC assessment N=2**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243f
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Negative	**Local assessment N=43**	**IRC assessment N=43**
Events/Responders (%)	13/43 (30.2)	13/43 (30.2)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.87	10.87
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.3 (82.7, 98.8)	95.3 (82.7, 98.8)
Month 6	78.2 (60.9, 88.6)	78.3 (61.0, 88.6)
Month 9	72.0 (53.8, 84.0)	72.1 (54.0, 84.0)
Month 12	68.7 (50.3, 81.5)	68.8 (50.4, 81.5)
Month 15	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 18	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 21	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)

Philadelphia chromosome/BCR-ABL: Negative		
	Local assessment N=43	**IRC assessment N=43**
Month 24	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 27	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 30	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 33	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 36	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 39	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 42	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 45	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243g
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: Yes	**Local assessment N=1**	**IRC assessment N=1**
Events/Responders (%)	1/1 (100.0)	1/1 (100.0)
Maximum follow-up (months)	3.4	3.4
Median follow-up (months)	3.35	3.35
Percentiles (95% CI) [1]		
25th	3.4 (NE, NE)	3.4 (NE, NE)
50th	3.4 (NE, NE)	3.4 (NE, NE)
75th	3.4 (NE, NE)	3.4 (NE, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	0.0 (NE, NE)	0.0 (NE, NE)
Month 9	0.0 (NE, NE)	0.0 (NE, NE)
Month 12	0.0 (NE, NE)	0.0 (NE, NE)
Month 15	0.0 (NE, NE)	0.0 (NE, NE)
Month 18	0.0 (NE, NE)	0.0 (NE, NE)
Month 21	0.0 (NE, NE)	0.0 (NE, NE)

Mixed-lineage leukemia rearrangement: Yes		
	Local assessment N=1	**IRC assessment N=1**
Month 24	0.0 (NE, NE)	0.0 (NE, NE)
Month 27	0.0 (NE, NE)	0.0 (NE, NE)
Month 30	0.0 (NE, NE)	0.0 (NE, NE)
Month 33	0.0 (NE, NE)	0.0 (NE, NE)
Month 36	0.0 (NE, NE)	0.0 (NE, NE)
Month 39	0.0 (NE, NE)	0.0 (NE, NE)
Month 42	0.0 (NE, NE)	0.0 (NE, NE)
Month 45	0.0 (NE, NE)	0.0 (NE, NE)
Month 48	0.0 (NE, NE)	0.0 (NE, NE)

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243g
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: No	**Local assessment N=44**	**IRC assessment N=44**
Events/Responders (%)	12/44 (27.3)	12/44 (27.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.20	11.20
Percentiles (95% CI) [1]		
25th	10.9 (5.3, NE)	10.9 (5.3, NE)
50th	NE (14.8, NE)	NE (14.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.5 (83.0, 98.8)	95.5 (83.0, 98.8)
Month 6	81.4 (64.6, 90.7)	81.4 (64.7, 90.8)
Month 9	75.3 (57.7, 86.4)	75.4 (57.8, 86.5)
Month 12	72.2 (54.2, 84.1)	72.3 (54.3, 84.1)
Month 15	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 18	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 21	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)

Mixed-lineage leukemia rearrangement: No		
	Local assessment N=44	**IRC assessment N=44**
Month 24	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 27	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 30	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 33	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 36	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 39	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 42	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 45	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243h
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: No	**Local assessment N=45**	**IRC assessment N=45**
Events/Responders (%)	13/45 (28.9)	13/45 (28.9)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.97	10.97
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.6 (83.4, 98.9)	95.6 (83.4, 98.9)
Month 6	79.4 (62.7, 89.2)	79.5 (62.9, 89.3)
Month 9	73.5 (56.1, 84.9)	73.6 (56.2, 84.9)
Month 12	70.4 (52.7, 82.5)	70.5 (52.8, 82.6)
Month 15	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 18	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 21	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)

Hypodiploidy: No

	Local assessment N=45	IRC assessment N=45
Month 24	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 27	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 30	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 33	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 36	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 39	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 42	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 45	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243i
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: Yes	**Local assessment N=4**	**IRC assessment N=4**
Events/Responders (%)	1/4 (25.0)	1/4 (25.0)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	12.30	12.30
Percentiles (95% CI) [1]		
25th	13.6 (13.6, NE)	13.6 (13.6, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE (13.6, NE)	NE (13.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)
Month 18	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)
Month 21	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)

BCR-ABL1-like: Yes

	Local assessment N=4	IRC assessment N=4
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243i
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: No

	Local assessment N=41	IRC assessment N=41
Events/Responders (%)	12/41 (29.3)	12/41 (29.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.87	10.87
Percentiles (95% CI) [1]		
25th	6.9 (3.5, NE)	6.9 (4.7, NE)
50th	NE (10.9, NE)	NE (10.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.1 (81.9, 98.8)	95.1 (81.9, 98.8)
Month 6	77.4 (59.6, 88.1)	77.5 (59.7, 88.2)
Month 9	70.9 (52.4, 83.3)	71.0 (52.6, 83.4)
Month 12	67.5 (48.8, 80.7)	67.7 (48.9, 80.8)
Month 15	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 18	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 21	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)

BCR-ABL1-like: No

	Local assessment N=41	IRC assessment N=41
Month 24	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 27	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 30	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 33	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 36	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 39	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 42	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 45	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243j
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes	**Local assessment N=17**	**IRC assessment N=17**
Events/Responders (%)	7/17 (41.2)	7/17 (41.2)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	7.56	7.56
Percentiles (95% CI) [1]		
25th	5.3 (1.9, 7.6)	5.3 (1.9, 7.6)
50th	NE (5.3, NE)	NE (5.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.1 (65.0, 99.1)	94.1 (65.0, 99.1)
Month 6	67.6 (38.6, 85.1)	67.6 (38.6, 85.1)
Month 9	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 12	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 15	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 18	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 21	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	Local assessment N=17	IRC assessment N=17
Month 24	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 27	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 30	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 33	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 36	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 39	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 42	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 45	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243j
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : No	**Local assessment N=28**	**IRC assessment N=28**
Events/Responders (%)	6/28 (21.4)	6/28 (21.4)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	11.20	11.20
Percentiles (95% CI) [1]		
25th	14.8 (3.5, NE)	14.8 (3.5, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	96.4 (77.2, 99.5)	96.4 (77.2, 99.5)
Month 6	87.5 (65.8, 95.9)	87.7 (66.1, 95.9)
Month 9	87.5 (65.8, 95.9)	87.7 (66.1, 95.9)
Month 12	82.1 (58.3, 93.0)	82.2 (58.6, 93.1)
Month 15	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 18	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 21	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	Local assessment N=28	IRC assessment N=28
Month 24	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 27	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 30	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 33	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 36	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 39	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 42	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 45	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243k
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Region
Full analysis set

Region: US	**Local assessment N=45**	**IRC assessment N=45**
Events/Responders (%)	13/45 (28.9)	13/45 (28.9)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.97	10.97
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.6 (83.4, 98.9)	95.6 (83.4, 98.9)
Month 6	79.4 (62.7, 89.2)	79.5 (62.9, 89.3)
Month 9	73.5 (56.1, 84.9)	73.6 (56.2, 84.9)
Month 12	70.4 (52.7, 82.5)	70.5 (52.8, 82.6)
Month 15	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 18	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 21	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)

Region: US

	Local assessment N=45	IRC assessment N=45
Month 24	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 27	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 30	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 33	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 36	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 39	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 42	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 45	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243l
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: Yes	**Local assessment N=19**	**IRC assessment N=19**
Events/Responders (%)	5/19 (26.3)	5/19 (26.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.43	11.43
Percentiles (95% CI) [1]		
25th	13.6 (1.7, NE)	13.6 (1.7, NE)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.7 (68.1, 99.2)	94.7 (68.1, 99.2)
Month 6	88.4 (60.8, 97.0)	88.4 (60.8, 97.0)
Month 9	75.8 (47.4, 90.2)	75.8 (47.4, 90.2)
Month 12	75.8 (47.4, 90.2)	75.8 (47.4, 90.2)
Month 15	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 18	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 21	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)

Prior SCT therapy: Yes		
	Local assessment N=19	**IRC assessment N=19**
Month 24	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 27	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 30	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 33	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 36	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 39	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 42	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 45	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243l
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: No	**Local assessment N=26**	**IRC assessment N=26**
Events/Responders (%)	8/26 (30.8)	8/26 (30.8)
Maximum follow-up (months)	29.4	29.4
Median follow-up (months)	8.38	8.38
Percentiles (95% CI) [1]		
25th	5.9 (3.4, NE)	5.9 (3.4, NE)
50th	NE (5.9, NE)	NE (5.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	96.2 (75.7, 99.4)	96.2 (75.7, 99.4)
Month 6	72.4 (48.0, 86.7)	72.4 (48.0, 86.7)
Month 9	72.4 (48.0, 86.7)	72.4 (48.0, 86.7)
Month 12	66.8 (42.1, 82.9)	66.8 (42.1, 82.9)
Month 15	59.4 (33.6, 78.0)	59.4 (33.6, 78.0)
Month 18	59.4 (33.6, 78.0)	59.4 (33.6, 78.0)
Month 21	59.4 (33.6, 78.0)	59.4 (33.6, 78.0)

Prior SCT therapy: No

	Local assessment N=26	IRC assessment N=26
Month 24	59.4 (33.6, 78.0)	NE
Month 27	59.4 (33.6, 78.0)	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243m
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: Yes	**Local assessment N=12**	**IRC assessment N=12**
Events/Responders (%)	4/12 (33.3)	4/12 (33.3)
Maximum follow-up (months)	23.4	23.4
Median follow-up (months)	13.95	13.95
Percentiles (95% CI) [1]		
25th	5.9 (3.5, NE)	5.9 (3.5, NE)
50th	NE (5.3, NE)	NE (5.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	73.3 (37.9, 90.6)	73.3 (37.9, 90.6)
Month 9	73.3 (37.9, 90.6)	73.3 (37.9, 90.6)
Month 12	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 15	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 18	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 21	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)

Eligibility for SCT: Yes

	Local assessment N=12	IRC assessment N=12
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243m
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: No	**Local assessment N=33**	**IRC assessment N=33**
Events/Responders (%)	9/33 (27.3)	9/33 (27.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.68	10.68
Percentiles (95% CI) [1]		
25th	7.6 (3.4, NE)	7.6 (3.4, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.9 (77.9, 98.4)	93.9 (77.9, 98.4)
Month 6	82.4 (62.4, 92.4)	82.5 (62.6, 92.4)
Month 9	73.7 (52.2, 86.7)	73.8 (52.3, 86.8)
Month 12	73.7 (52.2, 86.7)	73.8 (52.3, 86.8)
Month 15	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 18	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 21	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)

Eligibility for SCT: No		
	Local assessment N=33	**IRC assessment N=33**
Month 24	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 27	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 30	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 33	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 36	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 39	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 42	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 45	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243n
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: Low	**Local assessment N=16**	**IRC assessment N=16**
Events/Responders (%)	3/16 (18.8)	3/16 (18.8)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	15.95	15.95
Percentiles (95% CI) [1]		
25th	NE (5.4, NE)	NE (5.4, NE)
50th	NE (5.9, NE)	NE (5.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	83.9 (49.4, 95.7)	83.9 (49.4, 95.7)
Month 9	83.9 (49.4, 95.7)	83.9 (49.4, 95.7)
Month 12	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 15	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 18	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 21	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)

Baseline bone marrow tumor burden: Low		
	Local assessment N=16	**IRC assessment N=16**
Month 24	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 27	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 30	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 33	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 36	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 39	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 42	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 45	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243n
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: High	**Local assessment N=29**	**IRC assessment N=29**
Events/Responders (%)	10/29 (34.5)	10/29 (34.5)
Maximum follow-up (months)	24.2	24.2
Median follow-up (months)	10.68	10.68
Percentiles (95% CI) [1]		
25th	6.9 (3.4, 14.8)	6.9 (3.4, 14.8)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.1 (75.1, 98.2)	93.1 (75.1, 98.2)
Month 6	76.9 (55.2, 89.0)	76.9 (55.2, 89.0)
Month 9	67.8 (45.4, 82.6)	67.8 (45.4, 82.6)
Month 12	67.8 (45.4, 82.6)	67.8 (45.4, 82.6)
Month 15	54.4 (29.9, 73.5)	54.4 (29.9, 73.5)
Month 18	54.4 (29.9, 73.5)	54.4 (29.9, 73.5)
Month 21	54.4 (29.9, 73.5)	54.4 (29.9, 73.5)

Baseline bone marrow tumor burden: High		
	Local assessment N=29	**IRC assessment N=29**
Month 24	54.4 (29.9, 73.5)	54.4 (29.9, 73.5)
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243o
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: Yes	**Local assessment N=5**	**IRC assessment N=5**
Events/Responders (%)	2/5 (40.0)	2/5 (40.0)
Maximum follow-up (months)	30.8	30.8
Median follow-up (months)	14.75	14.75
Percentiles (95% CI) [1]		
25th	9.1 (3.4, NE)	9.1 (3.4, NE)
50th	NE (3.4, NE)	NE (3.4, NE)
75th	NE (3.4, NE)	NE (3.4, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Month 9	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Month 12	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Month 15	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 18	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 21	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)

Baseline extramedullary disease presence: Yes		
	Local assessment N=5	**IRC assessment N=5**
Month 24	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 27	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 30	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243o
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: No		
	Local assessment N=40	**IRC assessment N=40**
Events/Responders (%)	11/40 (27.5)	11/40 (27.5)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.92	10.92
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.0 (81.5, 98.7)	95.0 (81.5, 98.7)
Month 6	79.6 (61.7, 89.8)	79.7 (61.8, 89.8)
Month 9	73.0 (54.2, 85.0)	73.0 (54.3, 85.1)
Month 12	69.5 (50.4, 82.4)	69.6 (50.5, 82.5)
Month 15	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 18	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 21	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)

Baseline extramedullary disease presence: No		
	Local assessment N=40	**IRC assessment N=40**
Month 24	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 27	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 30	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 33	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 36	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 39	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 42	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 45	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243p
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: Yes	**Local assessment N=3**	**IRC assessment N=3**
Events/Responders (%)	0/3 (0.0)	0/3 (0.0)
Maximum follow-up (months)	20.4	20.4
Median follow-up (months)	4.90	4.90
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	NE	NE

Down syndrome: Yes		
	Local assessment N=3	**IRC assessment N=3**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243p
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: No	**Local assessment N=42**	**IRC assessment N=42**
Events/Responders (%)	13/42 (31.0)	13/42 (31.0)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.20	11.20
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.2 (82.3, 98.8)	95.2 (82.3, 98.8)
Month 6	78.2 (61.0, 88.5)	78.4 (61.2, 88.6)
Month 9	72.2 (54.3, 84.1)	72.3 (54.5, 84.1)
Month 12	69.1 (50.9, 81.6)	69.2 (51.0, 81.7)
Month 15	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 18	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 21	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)

Down syndrome: No		
	Local assessment N=42	**IRC assessment N=42**
Month 24	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 27	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 30	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 33	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 36	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 39	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 42	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 45	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243q
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: > Median	**Local assessment N=23**	**IRC assessment N=23**
Events/Responders (%)	7/23 (30.4)	7/23 (30.4)
Maximum follow-up (months)	29.4	29.4
Median follow-up (months)	13.63	13.63
Percentiles (95% CI) [1]		
25th	10.9 (5.3, NE)	10.9 (5.3, NE)
50th	NE (10.9, NE)	NE (10.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	83.9 (57.9, 94.5)	83.9 (57.9, 94.5)
Month 9	78.3 (51.9, 91.3)	78.3 (51.9, 91.3)
Month 12	72.7 (46.3, 87.6)	72.7 (46.3, 87.6)
Month 15	59.2 (32.4, 78.4)	59.2 (32.4, 78.4)
Month 18	59.2 (32.4, 78.4)	59.2 (32.4, 78.4)
Month 21	59.2 (32.4, 78.4)	59.2 (32.4, 78.4)

Time since enrollment to CTL019 infusion: > Median		
	Local assessment N=23	**IRC assessment N=23**
Month 24	59.2 (32.4, 78.4)	59.2 (32.4, 78.4)
Month 27	59.2 (32.4, 78.4)	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243q
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: <=Median	**Local assessment N=22**	**IRC assessment N=22**
Events/Responders (%)	6/22 (27.3)	6/22 (27.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	9.12	9.12
Percentiles (95% CI) [1]		
25th	7.6 (1.7, NE)	7.6 (1.7, NE)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	90.9 (68.3, 97.6)	90.9 (68.3, 97.6)
Month 6	75.9 (51.3, 89.3)	76.4 (52.0, 89.5)
Month 9	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 12	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 15	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 18	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 21	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)

Time since enrollment to CTL019 infusion: <=Median		
	Local assessment N=22	**IRC assessment N=22**
Month 24	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 27	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 30	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 33	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 36	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 39	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 42	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 45	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 0	**Local assessment N=4**	**IRC assessment N=4**
Events/Responders (%)	0/4 (0.0)	0/4 (0.0)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	5.31	5.31
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Number of previous relapses: 0		
	Local assessment N=4	**IRC assessment N=4**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 1	**Local assessment N=15**	**IRC assessment N=15**
Events/Responders (%)	3/15 (20.0)	3/15 (20.0)
Maximum follow-up (months)	30.8	30.8
Median follow-up (months)	10.87	10.87
Percentiles (95% CI) [1]		
25th	10.9 (3.4, NE)	10.9 (3.4, NE)
50th	NE (6.9, NE)	NE (6.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	92.9 (59.1, 99.0)	92.9 (59.1, 99.0)
Month 9	82.5 (45.1, 95.5)	82.5 (45.1, 95.5)
Month 12	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 15	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 18	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 21	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)

Number of previous relapses: 1		
	Local assessment N=15	**IRC assessment N=15**
Month 24	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 27	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 30	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 2	**Local assessment N=14**	**IRC assessment N=14**
Events/Responders (%)	6/14 (42.9)	6/14 (42.9)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	12.85	12.85
Percentiles (95% CI) [1]		
25th	5.3 (1.9, NE)	5.3 (1.9, NE)
50th	NE (4.7, NE)	NE (4.7, NE)
75th	NE (14.8, NE)	NE (14.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	92.9 (59.1, 99.0)	92.9 (59.1, 99.0)
Month 6	64.3 (34.3, 83.3)	64.3 (34.3, 83.3)
Month 9	64.3 (34.3, 83.3)	64.3 (34.3, 83.3)
Month 12	64.3 (34.3, 83.3)	64.3 (34.3, 83.3)
Month 15	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 18	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)

Number of previous relapses: 2		
	Local assessment N=14	**IRC assessment N=14**
Month 21	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 24	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 27	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 30	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 33	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 36	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 39	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 42	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 45	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 243r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: >=3	**Local assessment N=12**	**IRC assessment N=12**
Events/Responders (%)	4/12 (33.3)	4/12 (33.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	12.30	12.30
Percentiles (95% CI) [1]		
25th	7.6 (1.7, NE)	7.6 (1.7, NE)
50th	NE (5.4, NE)	NE (5.4, NE)
75th	NE (13.6, NE)	NE (13.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	91.7 (53.9, 98.8)	91.7 (53.9, 98.8)
Month 6	81.5 (43.5, 95.1)	81.5 (43.5, 95.1)
Month 9	71.3 (34.4, 89.8)	71.3 (34.4, 89.8)
Month 12	71.3 (34.4, 89.8)	71.3 (34.4, 89.8)
Month 15	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 18	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)

Number of previous relapses: >=3

	Local assessment N=12	IRC assessment N=12
Month 21	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 24	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 27	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 30	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 33	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 36	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 39	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 42	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 45	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244a
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Age
Enrolled set

Age: <10 years	**Local assessment N=14**	**IRC assessment N=14**
Events/Responders (%)	6/14 (42.9)	6/14 (42.9)
Maximum follow-up (months)	30.8	30.8
Median follow-up (months)	5.36	5.36
Percentiles (95% CI) [1]		
25th	5.3 (3.4, 13.6)	5.3 (3.4, 13.6)
50th	13.6 (4.7, NE)	13.6 (4.7, NE)
75th	NE (13.6, NE)	NE (13.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	58.4 (26.2, 80.6)	58.4 (26.2, 80.6)
Month 9	58.4 (26.2, 80.6)	58.4 (26.2, 80.6)
Month 12	58.4 (26.2, 80.6)	58.4 (26.2, 80.6)
Month 15	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 18	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 21	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)

Age: <10 years

	Local assessment N=14	IRC assessment N=14
Month 24	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 27	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 30	48.7 (18.8, 73.4)	48.7 (18.8, 73.4)
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244a
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Age
Enrolled set

Age: >=10 years to <18 years

	Local assessment N=25	**IRC assessment N=25**
Events/Responders (%)	4/25 (16.0)	4/25 (16.0)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	13.73	13.73
Percentiles (95% CI) [1]		
25th	NE (1.7, NE)	NE (1.7, NE)
50th	NE (14.8, NE)	NE (14.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	96.0 (74.8, 99.4)	96.0 (74.8, 99.4)
Month 6	96.0 (74.8, 99.4)	96.0 (74.8, 99.4)
Month 9	85.3 (60.7, 95.1)	85.3 (60.7, 95.1)
Month 12	85.3 (60.7, 95.1)	85.3 (60.7, 95.1)
Month 15	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 18	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 21	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)

Age: >=10 years to <18 years		
	Local assessment N=25	**IRC assessment N=25**
Month 24	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 27	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 30	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 33	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 36	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 39	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 42	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 45	77.6 (49.2, 91.3)	77.6 (49.2, 91.3)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244a
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Age
Enrolled set

Age: >=18	**Local assessment N=6**	**IRC assessment N=6**
Events/Responders (%)	3/6 (50.0)	3/6 (50.0)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	8.28	8.28
Percentiles (95% CI) [1]		
25th	5.9 (1.9, 10.9)	5.9 (1.9, 10.9)
50th	10.9 (1.9, NE)	10.9 (1.9, NE)
75th	NE (5.9, NE)	NE (5.9, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	83.3 (27.3, 97.5)	83.3 (27.3, 97.5)
Month 6	62.5 (14.2, 89.3)	62.5 (14.2, 89.3)
Month 9	62.5 (14.2, 89.3)	62.5 (14.2, 89.3)
Month 12	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 15	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 18	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 21	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)

Age: >=18

	Local assessment N=6	IRC assessment N=6
Month 24	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 27	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 30	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 33	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 36	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 39	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 42	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 45	31.3 (1.3, 73.4)	31.3 (1.3, 73.4)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244b
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Gender
Enrolled set

Gender: Male	**Local assessment N=23**	**IRC assessment N=23**
Events/Responders (%)	4/23 (17.4)	4/23 (17.4)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	10.87	10.87
Percentiles (95% CI) [1]		
25th	NE (1.7, NE)	NE (1.7, NE)
50th	NE (10.9, NE)	NE (10.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.7 (72.9, 99.4)	95.7 (72.9, 99.4)
Month 6	90.6 (67.3, 97.6)	90.9 (68.1, 97.6)
Month 9	83.6 (56.3, 94.6)	83.9 (56.7, 94.7)
Month 12	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 15	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 18	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 21	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)

Gender: Male

	Local assessment N=23	IRC assessment N=23
Month 24	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 27	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 30	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 33	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 36	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 39	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 42	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 45	76.7 (48.1, 90.8)	76.9 (48.4, 90.9)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244b
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Gender
Enrolled set

Gender: Female	**Local assessment N=22**	**IRC assessment N=22**
Events/Responders (%)	9/22 (40.9)	9/22 (40.9)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.20	11.20
Percentiles (95% CI) [1]		
25th	5.9 (1.9, 14.8)	5.9 (1.9, 14.8)
50th	NE (5.9, NE)	NE (5.9, NE)
75th	NE (14.8, NE)	NE (14.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	95.5 (71.9, 99.3)	95.5 (71.9, 99.3)
Month 6	70.5 (45.7, 85.6)	70.5 (45.7, 85.6)
Month 9	65.5 (40.9, 81.9)	65.5 (40.9, 81.9)
Month 12	65.5 (40.9, 81.9)	65.5 (40.9, 81.9)
Month 15	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 18	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 21	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)

Gender: Female		
	Local assessment N=22	**IRC assessment N=22**
Month 24	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 27	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 30	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 33	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 36	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 39	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 42	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 45	50.5 (25.0, 71.5)	50.5 (25.0, 71.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244c
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Race
Enrolled set

Race: White	**Local assessment N=36**	**IRC assessment N=36**
Events/Responders (%)	10/36 (27.8)	10/36 (27.8)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	10.78	10.78
Percentiles (95% CI) [1]		
25th	7.6 (3.5, NE)	7.6 (3.5, NE)
50th	NE (10.9, NE)	NE (10.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.4 (79.6, 98.6)	94.4 (79.6, 98.6)
Month 6	77.4 (58.0, 88.7)	77.6 (58.2, 88.8)
Month 9	73.5 (53.5, 86.0)	73.7 (53.7, 86.1)
Month 12	69.4 (48.9, 83.0)	69.6 (49.1, 83.1)
Month 15	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 18	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 21	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)

Race: White		
	Local assessment N=36	**IRC assessment N=36**
Month 24	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 27	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 30	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 33	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 36	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 39	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 42	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 45	64.8 (43.7, 79.7)	64.9 (43.9, 79.8)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244c
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Race
Enrolled set

Race: Asian

	Local assessment N=3	**IRC assessment N=3**
Events/Responders (%)	1/3 (33.3)	1/3 (33.3)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	10.97	10.97
Percentiles (95% CI) [1]		
25th	5.3 (5.3, NE)	5.3 (5.3, NE)
50th	NE (5.3, NE)	NE (5.3, NE)
75th	NE (5.3, NE)	NE (5.3, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 9	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 12	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 15	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 18	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 21	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)

Race: Asian		
	Local assessment N=3	**IRC assessment N=3**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244c
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Race
Enrolled set

Race: Other	**Local assessment N=6**	**IRC assessment N=6**
Events/Responders (%)	2/6 (33.3)	2/6 (33.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	14.24	14.24
Percentiles (95% CI) [1]		
25th	14.8 (6.9, NE)	14.8 (6.9, NE)
50th	NE (6.9, NE)	NE (6.9, NE)
75th	NE (6.9, NE)	NE (6.9, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 12	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 15	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 18	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 21	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)

Race: Other

	Local assessment N=6	IRC assessment N=6
Month 24	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 27	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 30	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 33	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 36	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 39	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 42	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 45	53.3 (6.8, 86.3)	53.3 (6.8, 86.3)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244d
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino	**Local assessment N=23**	**IRC assessment N=23**
Events/Responders (%)	4/23 (17.4)	4/23 (17.4)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	13.63	13.63
Percentiles (95% CI) [1]		
25th	14.8 (3.5, NE)	14.8 (3.5, NE)
50th	NE (14.8, NE)	NE (14.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	95.0 (69.5, 99.3)	95.0 (69.5, 99.3)
Month 9	95.0 (69.5, 99.3)	95.0 (69.5, 99.3)
Month 12	88.7 (61.4, 97.1)	88.7 (61.4, 97.1)
Month 15	71.1 (38.1, 88.7)	71.1 (38.1, 88.7)
Month 18	71.1 (38.1, 88.7)	71.1 (38.1, 88.7)
Month 21	71.1 (38.1, 88.7)	71.1 (38.1, 88.7)

Ethnicity: Hispanic or Latino

	Local assessment N=23	IRC assessment N=23
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244d
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Ethnicity
Enrolled set

Ethnicity: Other	**Local assessment N=22**	**IRC assessment N=22**
Events/Responders (%)	9/22 (40.9)	9/22 (40.9)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	6.41	6.41
Percentiles (95% CI) [1]		
25th	5.4 (1.7, 7.6)	5.4 (1.7, 7.6)
50th	NE (5.4, NE)	NE (5.4, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	90.9 (68.3, 97.6)	90.9 (68.3, 97.6)
Month 6	64.4 (39.1, 81.4)	64.6 (39.3, 81.5)
Month 9	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 12	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 15	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 18	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 21	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)

Ethnicity: Other		
	Local assessment N=22	**IRC assessment N=22**
Month 24	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 27	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 30	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 33	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 36	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 39	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 42	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 45	52.7 (28.3, 72.2)	52.8 (28.4, 72.4)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244e
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Response status at study entry
Enrolled set

Response status at study entry: Primary refractory	**Local assessment N=4**	**IRC assessment N=4**
Events/Responders (%)	0/4 (0.0)	0/4 (0.0)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	5.31	5.31
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Response status at study entry: Primary refractory		
	Local assessment N=4	**IRC assessment N=4**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244e
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease		
	Local assessment N=41	**IRC assessment N=41**
Events/Responders (%)	13/41 (31.7)	13/41 (31.7)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.43	11.43
Percentiles (95% CI) [1]		
25th	6.9 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.1 (81.9, 98.8)	95.1 (81.9, 98.8)
Month 6	77.9 (60.5, 88.4)	78.1 (60.7, 88.4)
Month 9	71.9 (53.9, 83.9)	72.1 (54.1, 84.0)
Month 12	68.8 (50.6, 81.5)	68.9 (50.7, 81.6)
Month 15	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 18	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 21	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)

Response status at study entry: Relapsed disease		
	Local assessment N=41	**IRC assessment N=41**
Month 24	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 27	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 30	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 33	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 36	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 39	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 42	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 45	60.9 (41.6, 75.5)	60.9 (41.7, 75.6)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244f
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive	**Local assessment N=2**	**IRC assessment N=2**
Events/Responders (%)	0/2 (0.0)	0/2 (0.0)
Maximum follow-up (months)	22.6	22.6
Median follow-up (months)	16.80	16.80
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Philadelphia chromosome/BCR-ABL: Positive		
	Local assessment N=2	**IRC assessment N=2**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244f
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative	**Local assessment N=43**	**IRC assessment N=43**
Events/Responders (%)	13/43 (30.2)	13/43 (30.2)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.87	10.87
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.3 (82.7, 98.8)	95.3 (82.7, 98.8)
Month 6	78.2 (60.9, 88.6)	78.3 (61.0, 88.6)
Month 9	72.0 (53.8, 84.0)	72.1 (54.0, 84.0)
Month 12	68.7 (50.3, 81.5)	68.8 (50.4, 81.5)
Month 15	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 18	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 21	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)

Philadelphia chromosome/BCR-ABL: Negative		
	Local assessment N=43	**IRC assessment N=43**
Month 24	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 27	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 30	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 33	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 36	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 39	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 42	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 45	60.7 (41.4, 75.5)	60.8 (41.5, 75.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244g
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes	**Local assessment N=1**	**IRC assessment N=1**
Events/Responders (%)	1/1 (100.0)	1/1 (100.0)
Maximum follow-up (months)	3.4	3.4
Median follow-up (months)	3.35	3.35
Percentiles (95% CI) [1]		
25th	3.4 (NE, NE)	3.4 (NE, NE)
50th	3.4 (NE, NE)	3.4 (NE, NE)
75th	3.4 (NE, NE)	3.4 (NE, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	0.0 (NE, NE)	0.0 (NE, NE)
Month 9	0.0 (NE, NE)	0.0 (NE, NE)
Month 12	0.0 (NE, NE)	0.0 (NE, NE)
Month 15	0.0 (NE, NE)	0.0 (NE, NE)
Month 18	0.0 (NE, NE)	0.0 (NE, NE)
Month 21	0.0 (NE, NE)	0.0 (NE, NE)

Mixed-lineage leukemia rearrangement: Yes		
	Local assessment N=1	**IRC assessment N=1**
Month 24	0.0 (NE, NE)	0.0 (NE, NE)
Month 27	0.0 (NE, NE)	0.0 (NE, NE)
Month 30	0.0 (NE, NE)	0.0 (NE, NE)
Month 33	0.0 (NE, NE)	0.0 (NE, NE)
Month 36	0.0 (NE, NE)	0.0 (NE, NE)
Month 39	0.0 (NE, NE)	0.0 (NE, NE)
Month 42	0.0 (NE, NE)	0.0 (NE, NE)
Month 45	0.0 (NE, NE)	0.0 (NE, NE)
Month 48	0.0 (NE, NE)	0.0 (NE, NE)

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244g
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No	**Local assessment N=44**	**IRC assessment N=44**
Events/Responders (%)	12/44 (27.3)	12/44 (27.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.20	11.20
Percentiles (95% CI) [1]		
25th	10.9 (5.3, NE)	10.9 (5.3, NE)
50th	NE (14.8, NE)	NE (14.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.5 (83.0, 98.8)	95.5 (83.0, 98.8)
Month 6	81.4 (64.6, 90.7)	81.4 (64.7, 90.8)
Month 9	75.3 (57.7, 86.4)	75.4 (57.8, 86.5)
Month 12	72.2 (54.2, 84.1)	72.3 (54.3, 84.1)
Month 15	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 18	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 21	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)

Mixed-lineage leukemia rearrangement: No		
	Local assessment N=44	**IRC assessment N=44**
Month 24	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 27	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 30	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 33	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 36	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 39	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 42	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 45	64.3 (45.0, 78.3)	64.4 (45.1, 78.4)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244h
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Hypodiploidy
Enrolled set

Hypodiploidy: No	**Local assessment N=45**	**IRC assessment N=45**
Events/Responders (%)	13/45 (28.9)	13/45 (28.9)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.97	10.97
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.6 (83.4, 98.9)	95.6 (83.4, 98.9)
Month 6	79.4 (62.7, 89.2)	79.5 (62.9, 89.3)
Month 9	73.5 (56.1, 84.9)	73.6 (56.2, 84.9)
Month 12	70.4 (52.7, 82.5)	70.5 (52.8, 82.6)
Month 15	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 18	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 21	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)

Hypodiploidy: No

	Local assessment N=45	IRC assessment N=45
Month 24	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 27	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 30	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 33	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 36	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 39	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 42	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 45	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244i
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes	**Local assessment N=4**	**IRC assessment N=4**
Events/Responders (%)	1/4 (25.0)	1/4 (25.0)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	12.30	12.30
Percentiles (95% CI) [1]		
25th	13.6 (13.6, NE)	13.6 (13.6, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE (13.6, NE)	NE (13.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)
Month 18	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)
Month 21	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)

BCR-ABL1-like: Yes

	Local assessment N=4	IRC assessment N=4
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244i
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	Local assessment N=41	IRC assessment N=41
Events/Responders (%)	12/41 (29.3)	12/41 (29.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.87	10.87
Percentiles (95% CI) [1]		
25th	6.9 (3.5, NE)	6.9 (4.7, NE)
50th	NE (10.9, NE)	NE (10.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.1 (81.9, 98.8)	95.1 (81.9, 98.8)
Month 6	77.4 (59.6, 88.1)	77.5 (59.7, 88.2)
Month 9	70.9 (52.4, 83.3)	71.0 (52.6, 83.4)
Month 12	67.5 (48.8, 80.7)	67.7 (48.9, 80.8)
Month 15	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 18	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 21	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)

BCR-ABL1-like: No		
	Local assessment N=41	**IRC assessment N=41**
Month 24	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 27	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 30	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 33	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 36	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 39	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 42	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 45	63.0 (43.4, 77.5)	63.1 (43.5, 77.6)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244j
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes	**Local assessment N=17**	**IRC assessment N=17**
Events/Responders (%)	7/17 (41.2)	7/17 (41.2)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	7.56	7.56
Percentiles (95% CI) [1]		
25th	5.3 (1.9, 7.6)	5.3 (1.9, 7.6)
50th	NE (5.3, NE)	NE (5.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.1 (65.0, 99.1)	94.1 (65.0, 99.1)
Month 6	67.6 (38.6, 85.1)	67.6 (38.6, 85.1)
Month 9	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 12	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 15	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 18	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 21	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	Local assessment N=17	IRC assessment N=17
Month 24	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 27	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 30	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 33	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 36	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 39	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 42	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 45	54.1 (26.9, 74.9)	54.1 (26.9, 74.9)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244j
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	Local assessment N=28	IRC assessment N=28
Events/Responders (%)	6/28 (21.4)	6/28 (21.4)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	11.20	11.20
Percentiles (95% CI) [1]		
25th	14.8 (3.5, NE)	14.8 (3.5, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	96.4 (77.2, 99.5)	96.4 (77.2, 99.5)
Month 6	87.5 (65.8, 95.9)	87.7 (66.1, 95.9)
Month 9	87.5 (65.8, 95.9)	87.7 (66.1, 95.9)
Month 12	82.1 (58.3, 93.0)	82.2 (58.6, 93.1)
Month 15	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 18	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 21	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No		
	Local assessment N=28	**IRC assessment N=28**
Month 24	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 27	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 30	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 33	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 36	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 39	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 42	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 45	66.9 (38.4, 84.4)	67.0 (38.5, 84.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244k
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Region
Enrolled set

Region: US	**Local assessment N=45**	**IRC assessment N=45**
Events/Responders (%)	13/45 (28.9)	13/45 (28.9)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.97	10.97
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.6 (83.4, 98.9)	95.6 (83.4, 98.9)
Month 6	79.4 (62.7, 89.2)	79.5 (62.9, 89.3)
Month 9	73.5 (56.1, 84.9)	73.6 (56.2, 84.9)
Month 12	70.4 (52.7, 82.5)	70.5 (52.8, 82.6)
Month 15	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 18	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 21	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)

Region: US

	Local assessment N=45	IRC assessment N=45
Month 24	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 27	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 30	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 33	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 36	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 39	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 42	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 45	62.7 (43.8, 76.8)	62.8 (43.9, 76.9)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244l
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes	**Local assessment N=19**	**IRC assessment N=19**
Events/Responders (%)	5/19 (26.3)	5/19 (26.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.43	11.43
Percentiles (95% CI) [1]		
25th	13.6 (1.7, NE)	13.6 (1.7, NE)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.7 (68.1, 99.2)	94.7 (68.1, 99.2)
Month 6	88.4 (60.8, 97.0)	88.4 (60.8, 97.0)
Month 9	75.8 (47.4, 90.2)	75.8 (47.4, 90.2)
Month 12	75.8 (47.4, 90.2)	75.8 (47.4, 90.2)
Month 15	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 18	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 21	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)

Prior SCT therapy: Yes		
	Local assessment N=19	**IRC assessment N=19**
Month 24	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 27	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 30	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 33	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 36	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 39	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 42	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 45	67.4 (37.6, 85.3)	67.4 (37.6, 85.3)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244l
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Prior SCT therapy
Enrolled set

Prior SCT therapy: No	**Local assessment N=26**	**IRC assessment N=26**
Events/Responders (%)	8/26 (30.8)	8/26 (30.8)
Maximum follow-up (months)	29.4	29.4
Median follow-up (months)	8.38	8.38
Percentiles (95% CI) [1]		
25th	5.9 (3.4, NE)	5.9 (3.4, NE)
50th	NE (5.9, NE)	NE (5.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	96.2 (75.7, 99.4)	96.2 (75.7, 99.4)
Month 6	72.4 (48.0, 86.7)	72.4 (48.0, 86.7)
Month 9	72.4 (48.0, 86.7)	72.4 (48.0, 86.7)
Month 12	66.8 (42.1, 82.9)	66.8 (42.1, 82.9)
Month 15	59.4 (33.6, 78.0)	59.4 (33.6, 78.0)
Month 18	59.4 (33.6, 78.0)	59.4 (33.6, 78.0)
Month 21	59.4 (33.6, 78.0)	59.4 (33.6, 78.0)

Prior SCT therapy: No

	Local assessment N=26	IRC assessment N=26
Month 24	59.4 (33.6, 78.0)	NE
Month 27	59.4 (33.6, 78.0)	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244m
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes	**Local assessment N=12**	**IRC assessment N=12**
Events/Responders (%)	4/12 (33.3)	4/12 (33.3)
Maximum follow-up (months)	23.4	23.4
Median follow-up (months)	13.95	13.95
Percentiles (95% CI) [1]		
25th	5.9 (3.5, NE)	5.9 (3.5, NE)
50th	NE (5.3, NE)	NE (5.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	73.3 (37.9, 90.6)	73.3 (37.9, 90.6)
Month 9	73.3 (37.9, 90.6)	73.3 (37.9, 90.6)
Month 12	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 15	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 18	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 21	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)

Eligibility for SCT: Yes

	Local assessment N=12	IRC assessment N=12
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244m
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Eligibility for SCT
Enrolled set

Eligibility for SCT: No	**Local assessment N=33**	**IRC assessment N=33**
Events/Responders (%)	9/33 (27.3)	9/33 (27.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.68	10.68
Percentiles (95% CI) [1]		
25th	7.6 (3.4, NE)	7.6 (3.4, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.9 (77.9, 98.4)	93.9 (77.9, 98.4)
Month 6	82.4 (62.4, 92.4)	82.5 (62.6, 92.4)
Month 9	73.7 (52.2, 86.7)	73.8 (52.3, 86.8)
Month 12	73.7 (52.2, 86.7)	73.8 (52.3, 86.8)
Month 15	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 18	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 21	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)

Eligibility for SCT: No

	Local assessment N=33	IRC assessment N=33
Month 24	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 27	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 30	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 33	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 36	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 39	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 42	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 45	62.4 (38.9, 79.0)	62.5 (39.0, 79.1)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244n
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low	**Local assessment N=16**	**IRC assessment N=16**
Events/Responders (%)	3/16 (18.8)	3/16 (18.8)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	15.95	15.95
Percentiles (95% CI) [1]		
25th	NE (5.4, NE)	NE (5.4, NE)
50th	NE (5.9, NE)	NE (5.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	83.9 (49.4, 95.7)	83.9 (49.4, 95.7)
Month 9	83.9 (49.4, 95.7)	83.9 (49.4, 95.7)
Month 12	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 15	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 18	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 21	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)

Baseline bone marrow tumor burden: Low		
	Local assessment N=16	**IRC assessment N=16**
Month 24	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 27	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 30	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 33	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 36	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 39	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 42	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 45	75.5 (41.6, 91.4)	75.5 (41.6, 91.4)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244n
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High	**Local assessment N=29**	**IRC assessment N=29**
Events/Responders (%)	10/29 (34.5)	10/29 (34.5)
Maximum follow-up (months)	24.2	24.2
Median follow-up (months)	10.68	10.68
Percentiles (95% CI) [1]		
25th	6.9 (3.4, 14.8)	6.9 (3.4, 14.8)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.1 (75.1, 98.2)	93.1 (75.1, 98.2)
Month 6	76.9 (55.2, 89.0)	76.9 (55.2, 89.0)
Month 9	67.8 (45.4, 82.6)	67.8 (45.4, 82.6)
Month 12	67.8 (45.4, 82.6)	67.8 (45.4, 82.6)
Month 15	54.4 (29.9, 73.5)	54.4 (29.9, 73.5)
Month 18	54.4 (29.9, 73.5)	54.4 (29.9, 73.5)
Month 21	54.4 (29.9, 73.5)	54.4 (29.9, 73.5)

Baseline bone marrow tumor burden: High		
	Local assessment N=29	**IRC assessment N=29**
Month 24	54.4 (29.9, 73.5)	54.4 (29.9, 73.5)
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244o
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes		
	Local assessment N=5	**IRC assessment N=5**
Events/Responders (%)	2/5 (40.0)	2/5 (40.0)
Maximum follow-up (months)	30.8	30.8
Median follow-up (months)	14.75	14.75
Percentiles (95% CI) [1]		
25th	9.1 (3.4, NE)	9.1 (3.4, NE)
50th	NE (3.4, NE)	NE (3.4, NE)
75th	NE (3.4, NE)	NE (3.4, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Month 9	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Month 12	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Month 15	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 18	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 21	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)

Baseline extramedullary disease presence: Yes		
	Local assessment N=5	**IRC assessment N=5**
Month 24	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 27	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 30	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244o
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No		
	Local assessment N=40	**IRC assessment N=40**
Events/Responders (%)	11/40 (27.5)	11/40 (27.5)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	10.92	10.92
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.0 (81.5, 98.7)	95.0 (81.5, 98.7)
Month 6	79.6 (61.7, 89.8)	79.7 (61.8, 89.8)
Month 9	73.0 (54.2, 85.0)	73.0 (54.3, 85.1)
Month 12	69.5 (50.4, 82.4)	69.6 (50.5, 82.5)
Month 15	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 18	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 21	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)

Baseline extramedullary disease presence: No		
	Local assessment N=40	**IRC assessment N=40**
Month 24	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 27	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 30	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 33	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 36	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 39	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 42	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 45	65.4 (45.8, 79.4)	65.5 (45.8, 79.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244p
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Down syndrome
Enrolled set

Down syndrome: Yes	**Local assessment N=3**	**IRC assessment N=3**
Events/Responders (%)	0/3 (0.0)	0/3 (0.0)
Maximum follow-up (months)	20.4	20.4
Median follow-up (months)	4.90	4.90
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	NE	NE

Down syndrome: Yes		
	Local assessment N=3	**IRC assessment N=3**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244p
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Down syndrome
Enrolled set

Down syndrome: No	**Local assessment N=42**	**IRC assessment N=42**
Events/Responders (%)	13/42 (31.0)	13/42 (31.0)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	11.20	11.20
Percentiles (95% CI) [1]		
25th	7.6 (4.7, NE)	7.6 (4.7, NE)
50th	NE (13.6, NE)	NE (13.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.2 (82.3, 98.8)	95.2 (82.3, 98.8)
Month 6	78.2 (61.0, 88.5)	78.4 (61.2, 88.6)
Month 9	72.2 (54.3, 84.1)	72.3 (54.5, 84.1)
Month 12	69.1 (50.9, 81.6)	69.2 (51.0, 81.7)
Month 15	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 18	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 21	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)

Down syndrome: No		
	Local assessment N=42	**IRC assessment N=42**
Month 24	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 27	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 30	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 33	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 36	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 39	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 42	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 45	61.1 (41.8, 75.7)	61.2 (41.9, 75.8)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244q
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median	**Local assessment N=23**	**IRC assessment N=23**
Events/Responders (%)	7/23 (30.4)	7/23 (30.4)
Maximum follow-up (months)	29.4	29.4
Median follow-up (months)	13.63	13.63
Percentiles (95% CI) [1]		
25th	10.9 (5.3, NE)	10.9 (5.3, NE)
50th	NE (10.9, NE)	NE (10.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	83.9 (57.9, 94.5)	83.9 (57.9, 94.5)
Month 9	78.3 (51.9, 91.3)	78.3 (51.9, 91.3)
Month 12	72.7 (46.3, 87.6)	72.7 (46.3, 87.6)
Month 15	59.2 (32.4, 78.4)	59.2 (32.4, 78.4)
Month 18	59.2 (32.4, 78.4)	59.2 (32.4, 78.4)
Month 21	59.2 (32.4, 78.4)	59.2 (32.4, 78.4)

Time since enrollment to CTL019 infusion: > Median		
	Local assessment N=23	**IRC assessment N=23**
Month 24	59.2 (32.4, 78.4)	59.2 (32.4, 78.4)
Month 27	59.2 (32.4, 78.4)	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244q
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median	**Local assessment N=22**	**IRC assessment N=22**
Events/Responders (%)	6/22 (27.3)	6/22 (27.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	9.12	9.12
Percentiles (95% CI) [1]		
25th	7.6 (1.7, NE)	7.6 (1.7, NE)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	90.9 (68.3, 97.6)	90.9 (68.3, 97.6)
Month 6	75.9 (51.3, 89.3)	76.4 (52.0, 89.5)
Month 9	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 12	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 15	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 18	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 21	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)

Time since enrollment to CTL019 infusion: <=Median		
	Local assessment N=22	**IRC assessment N=22**
Month 24	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 27	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 30	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 33	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 36	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 39	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 42	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 45	69.6 (43.9, 85.3)	70.0 (44.4, 85.5)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 0	**Local assessment N=4**	**IRC assessment N=4**
Events/Responders (%)	0/4 (0.0)	0/4 (0.0)
Maximum follow-up (months)	23.0	23.0
Median follow-up (months)	5.31	5.31
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Number of previous relapses: 0		
	Local assessment N=4	**IRC assessment N=4**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 1	**Local assessment N=15**	**IRC assessment N=15**
Events/Responders (%)	3/15 (20.0)	3/15 (20.0)
Maximum follow-up (months)	30.8	30.8
Median follow-up (months)	10.87	10.87
Percentiles (95% CI) [1]		
25th	10.9 (3.4, NE)	10.9 (3.4, NE)
50th	NE (6.9, NE)	NE (6.9, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	92.9 (59.1, 99.0)	92.9 (59.1, 99.0)
Month 9	82.5 (45.1, 95.5)	82.5 (45.1, 95.5)
Month 12	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 15	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 18	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 21	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)

Number of previous relapses: 1		
	Local assessment N=15	**IRC assessment N=15**
Month 24	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 27	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 30	72.2 (35.3, 90.3)	72.2 (35.3, 90.3)
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 2	**Local assessment N=14**	**IRC assessment N=14**
Events/Responders (%)	6/14 (42.9)	6/14 (42.9)
Maximum follow-up (months)	46.8	46.8
Median follow-up (months)	12.85	12.85
Percentiles (95% CI) [1]		
25th	5.3 (1.9, NE)	5.3 (1.9, NE)
50th	NE (4.7, NE)	NE (4.7, NE)
75th	NE (14.8, NE)	NE (14.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	92.9 (59.1, 99.0)	92.9 (59.1, 99.0)
Month 6	64.3 (34.3, 83.3)	64.3 (34.3, 83.3)
Month 9	64.3 (34.3, 83.3)	64.3 (34.3, 83.3)
Month 12	64.3 (34.3, 83.3)	64.3 (34.3, 83.3)
Month 15	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 18	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)

Number of previous relapses: 2

	Local assessment N=14	IRC assessment N=14
Month 21	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 24	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 27	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 30	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 33	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 36	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 39	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 42	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 45	51.4 (20.0, 76.0)	51.4 (20.0, 76.0)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 244r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: >=3	**Local assessment N=12**	**IRC assessment N=12**
Events/Responders (%)	4/12 (33.3)	4/12 (33.3)
Maximum follow-up (months)	47.1	47.1
Median follow-up (months)	12.30	12.30
Percentiles (95% CI) [1]		
25th	7.6 (1.7, NE)	7.6 (1.7, NE)
50th	NE (5.4, NE)	NE (5.4, NE)
75th	NE (13.6, NE)	NE (13.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	91.7 (53.9, 98.8)	91.7 (53.9, 98.8)
Month 6	81.5 (43.5, 95.1)	81.5 (43.5, 95.1)
Month 9	71.3 (34.4, 89.8)	71.3 (34.4, 89.8)
Month 12	71.3 (34.4, 89.8)	71.3 (34.4, 89.8)
Month 15	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 18	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)

Number of previous relapses: >=3		
	Local assessment N=12	**IRC assessment N=12**
Month 21	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 24	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 27	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 30	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 33	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 36	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 39	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 42	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 45	59.4 (23.8, 82.8)	59.4 (23.8, 82.8)
Month 48	NE	NE

[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.