Gemeinsamer Bundesausschuss

# Resolution

## of the Federal Joint Committee on a Finding in the Procedure of Routine Practice Data Collection and Evaluations according to Section 35a, paragraph 3b SGB V: Autologous anti-CD19-transduced CD3+ cells (relapsed or refractory mantle cell lymphoma) – final review of study protocol and statistical analysis plan

of 16 November 2023

At its session on 16 November 2023, the Federal Joint Committee (G-BA) decided the following in the procedure for routine practice data collection and evaluations according to Section 35a, paragraph 3b SGB V for the active ingredient autologous anti-CD19-transduced CD3+ cells (hereinafter referred to as brexucabtagene autoleucel; relapsed or refractory mantle cell lymphoma):

I. It is established that the adjustments to the study protocol and the statistical analysis plan considered necessary in the declaratory resolution of 20 July 2023 were not fully implemented in the submitted revised version of the study protocol (version 3.0; 16 August 2023) and the statistical analysis plan (SAP; version 3.0; 16 August 2023). Furthermore, the following adjustments to the study protocol and the SAP considered necessary shall be made:

a) Question according to PICO: Outcome, patient-reported endpoints

The 5th step of the baseline collection describes documenting the day on which the questionnaire is received by the data trustee. This step is described as "day x + 90 days" for the data collection time points from month 12 onwards. This information is implausible and must be corrected.

The planned procedure, including the timeline for following up patients for the collection of patient-reported endpoints who have not returned their questionnaire to the data trustee on time, must be adapted in accordance with the information on the baseline collection. The tolerance ranges for the collection of patient-reported endpoints are still too broad and inappropriate. The tolerance ranges must be recorded in accordance with Table 2 of version 1.0 of the study protocol.

b) Data evaluation: Dealing with missing data

A comprehensive justification for the use of a complete case dataset (among others, necessity, design) must be added.

In addition, against the background of the resolution of the G-BA on the amendment of the requirement of routine practice data collection and evaluations of brexucabtagene autoleucel in the indication relapsed or refractory mantle cell lymphoma of 16 November 2023, the following adjustments to the study protocol and the SAP are considered necessary:

c) Question according to PICO: Comparator

For the comparator of routine practice data collection, the active ingredient venetoclax should be added and the therapy option R-CHOP/R-DHAP should be deleted.

In order to avoid inconsistencies, the pharmaceutical company must check whether the need for changes in the study protocol described here leads to corresponding subsequent changes in the SAP and vice versa.

II. The revised study protocol and the revised SAP are to be submitted to the G-BA by 21 February 2025 for the first interim analysis.

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 16 November 2023.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 16 November 2023

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken