



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 February 2026
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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): brexucabtagene autoleucel

Procedure No. PSUSA/00010903/202507

Period covered by the PSUR: 6 months to 23 July 2025



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for brexucabtagene autoleucl, the scientific conclusions of PRAC are as follows:

In view of available data on secondary malignancy of myeloid origin from clinical trial(s), the literature, and spontaneous reports including cases with a fatal outcome, the PRAC considers that a warning on secondary malignancy of myeloid origin is warranted. The PRAC concluded that the product information of products containing brexucabtagene autoleucl should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for brexucabtagene autoleucl the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing brexucabtagene autoleucl is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.