



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 February 2024
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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. EMEA/H/C/PSUSA/00010903/202307

Period covered by the PSUR: 24/01/2023 To: 23/07/2023



Scientific conclusions

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

In view of available data on immune effector cell-associated neurotoxicity syndrome (ICANS) from clinical trials, the literature, spontaneous reports, the PRAC considers a causal relationship between brexucabtagene autoleucel and ICANS is at least a reasonable possibility. The PRAC concluded that the product information of products containing brexucabtagene autoleucel 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 autoleucel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing brexucabtagene autoleucel 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.