18 September 2025
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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/00010903/202501

Period covered by the PSUR: 6 months to 22 January 2025

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Scientific conclusions

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

In view of available data on status epilepticus from clinical trials, spontaneous reports including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between brexucabtagene autoleucel and status epilepticus 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.