



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2025
EMA/214980/2025
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): lisocabtagene maraleucel / lisocabtagene maraleucel

Procedure No. EMEA/H/C/PSUSA/00010990/202408

Period covered by the PSUR:
05 February 2024 to: 04 August 2024



Scientific conclusions

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

In view of available data on viral reactivation, specifically progressive multifocal leukoencephalopathy (PML), from clinical trials, the literature, and spontaneous reports, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between lisocabtagene maraleucel and viral reactivation, specifically progressive multifocal leukoencephalopathy (PML), is at least a reasonable possibility. The PRAC concluded that the product information of products containing lisocabtagene maraleucel 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 lisocabtagene maraleucel / lisocabtagene maraleucel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lisocabtagene maraleucel / lisocabtagene maraleucel 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.