



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

26 March 2026  
EMADOC-1700519818-3128519  
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): ciltacabtagene autoleucel

Procedure No. PSUSA/00011000/202508

Period covered by the PSUR: 6 months to 27 August 2025

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### **Scientific conclusions**

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

In view of available data on risk(s) from clinical trial(s) and spontaneous reports including in a close temporal relationship, the PRAC considers a causal relationship between ciltacabtagene autoleucl and **infusion related reactions** is at least a reasonable possibility. The PRAC concluded that the product information of products containing ciltacabtagene 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 ciltacabtagene autoleucl the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ciltacabtagene 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.