12 October 2023
EMA/442501/2023
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. EMEA/H/C/PSUSA/00011000/202302

Period covered by the PSUR: 27 August 2022 to 27 February 2023

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Scientific conclusions

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

In view of available data on leak from bags of CARVYKTI after thawing from clinical trial(s) and spontaneous reports including in a close temporal relationship, the PRAC considers that a causal relationship between ciltacabtagene autoleucel and product handling issues is at least a reasonable possibility. As well, even though further investigation is warranted in regards to the case of T-Cell Malignancy, the mention of such case has been considered acceptable as intermediary action in the section 4.4 of the SmPC. The PRAC concluded that the product information of products containing ciltacabtagene 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 ciltacabtagene autoleucel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ciltacabtagene 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.