27 March 2025
EMA/214537/2025
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): tisagenlecleucel

Procedure No. EMEA/H/C/PSUSA/00010702/202408

Period covered by the PSUR:
13 August 2023 to: 12 August 2024

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Scientific conclusions

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

In view of available data on a higher frequency of immune effector cell-associated neurotoxicity syndrome (ICANS) from literature and spontaneous reports, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between tisagenlecleucel and ICANS. The PRAC concluded that the product information of products containing tisagenlecleucel 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 tisagenlecleucel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tisagenlecleucel 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.