25 April 2024
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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): idecabtagene vicleucel

Procedure No. EMEA/H/C/PSUSA/00010954/202309

Period covered by the PSUR: 24 March 2023 to 24 September 2023

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Scientific conclusions

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

In view of available data on ICANS from spontaneous reports and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between idecabtagene vicleucel (ide-cel) and ICANs is at least a reasonable possibility. The PRAC concluded that the product information of products containing idecabtagene vicleucel (ide-cel) should be amended accordingly. Furthermore, patients need to be given information about the frequencies also for serious ADRs. The PIL section 4 has been updated accordingly. Finally, Annex II, describing the key elements of the educational material has been updated 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 idecabtagene vicleucel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing idecabtagene vicleucel 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.