30 January 2025
EMA/153669/2025
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): onasemnogene abeparvovec

Procedure No. EMEA/H/C/PSUSA/00010848/202405

Period covered by the PSUR: 24 May 2023 To: 23 May 2024

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Scientific conclusions

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

In view of available data on "infusion-related reactions including anaphylactic reactions" and "cardiac adverse events" from clinical studies, the literature, and spontaneous reports the PRAC concluded that the product information of products containing onasemnogene abeparvovec 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 onasemnogene abeparvovec the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing onasemnogene abeparvovec 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.