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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): voretigene neparvovec

Procedure No. EMEA/H/C/PSUSA/00010742/202101

Period covered by the PSUR: 24 July 2020 To: 23 January 2021

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Scientific conclusions

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

In view of available data on (chorio)retinal atrophy from the literature and reports from the ongoing US and EU PASSs including in 21 cases a close temporal relationship, and in view of a possible mechanism of action, the PRAC Rapporteur considers a causal relationship between Voretigene neparvovec and (chorio)retinal atrophy is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing Voretigene neparvovec should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for voretigene neparvovec the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing voretigene neparvovec 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.