EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2023
EMA/152946/2023
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): voretigene neparvovec

Procedure No. EMEA/H/C/PSUSA/00010742/202207

Period covered by the PSUR: 24 July 2021 to 23 July 2022

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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:

To reflect the new development of cases with chorioretinal atrophy reporting visual impairment, the MAH proposed to amend the SmPC, section 4.8, to inform that isolated cases reporting visual impairment due to chorioretinal atrophy have been observed. Additionally, from the PRAC's point of view the amendment should also include the information that chorioretinal atrophy was reported also outside of the bleb area.

In view of available data on chorioretinal atrophy from the literature and spontaneous reports, including in some cases a temporal relationship, the PRAC considers a causal relationship between voretigene neparvovec and chorioretinal atrophy is at least a reasonable possibility. The PRAC 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.