25 July 2019
EMA/429908/2019
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): inotersen

Procedure No. EMEA/H/C/PSUSA/00010697/201901

Period covered by the PSUR: 06 July 2018 To 05 January 2019

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

Three cases of liver transplant rejection have been received from an expanded access programme.

It is plausible that an immune mediated mechanism induced by inotersen could have led to the acute rejection observed in these patients. As patients with a prior liver transplant were excluded from the clinical development programme and given the consequences of acute rejection, it is considered that the evidence is sufficient to justify an update to the product information to include appropriate warning.

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 inotersen the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing inotersen 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.