22 April 2021
EMA/363703/2021
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): alemtuzumab

Procedure No. EMEA/H/C/PSUSA/00010055/202009

Period covered by the PSUR: 13 September 2019 To: 12 September 2020

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Scientific conclusions

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

In view of available data on risks from clinical trials, the literature, spontaneous reports, including cases with a plausible temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between alemtuzumab and thrombotic thrombocytopenic purpura (TTP) is established. TTP is a serious and rare risk that has significant impact on the patient with high mortality if not urgently treated. The PRAC concluded that the product information of products containing alemtuzumab should be amended accordingly.

In addition, in view of available data, the PRAC considers that an amendment of the adverse reaction pneumonitis is justified. "Pneumonitis" should be presented under SOC "respiratory, thoracic and mediastinal disorders" instead of SOC "infections and infestations". The PRAC concluded that the product information of products containing alemtuzumab should be amended accordingly.

Update of section 4.4 of the SmPC to add a warning on thrombotic thrombocytopenic purpura and 4.8 to add the adverse reaction thrombotic thrombocytopenic purpura with a frequency rare. Also, an update of section 4.4 and 4.8 of the SmPC to amend the adverse reaction pneumonitis. The Package leaflet is updated 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 alemtuzumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing alemtuzumab 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.