9 November 2017
EMA/44071/2018
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): olaratumab

Procedure No. EMEA/H/C/PSUSA/00010541/201704

Period covered by the PSUR: 19 October 2016 – 19 April 2017

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

Based on cases of anaphylactic reaction and anaphylactic shock reported in the post-marketing setting, these adverse drug reactions should be specifically be mentioned under the category of infusion-related reactions in section 4.8 of the SmPC. The frequency of anaphylactic reactions/anaphylactic shock is already calculated as part of grade 3-4 infusion-related reactions in the table of Adverse Drug Reactions (ADRs) in the same section of the SmPC. The current wording of the Package leaflet is considered sufficient to communicate this risk.

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