28 January 2021
EMA/224770/2021
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): blinatumomab

Procedure No. EMEA/H/C/PSUSA/00010460/202006

Period covered by the PSUR: 1 December 2019 – 1 June 2020

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 blinatumomab, the scientific conclusions of CHMP are as follows:

In view of available data on CD19 negative relapse of Ph negative B-precursor acute lymphatic leukemia (ALL) while maintaining identical phenotypical and immunophenotypic features and lineage switch from B-precursor ALL to acute myeloid leukemia (AML) from clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between blinatumomab and CD19 negativity of Ph negative acute lymphatic leukemia in relapsed patients is established and a causal relationship between blinatumomab and lineage switch from ALL to acute myeloid leukemia in relapsed patients is at least a reasonable possibility. The PRAC concluded that the product information of products containing blinatumomab 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 blinatumomab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing blinatumomab 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.