



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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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/00010460/201612

Period covered by the PSUR: 24 May 2016 - 02 December 2016



## **Scientific conclusions**

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

Taking into account cases of cranial nerve disorder reported with blinatumomab from clinical trials, spontaneous reporting and post-marketing surveillance, including a number of serious cases, cases with positive de-challenge, two cases of positive re-challenge, biological plausibility, suggestive temporal chronology and the fact that cranial nerve disorders were reported as isolated symptoms without other signs of neurotoxicity, the term cranial nerve disorders should be added to the list of adverse drug reactions with frequency uncommon ( $\geq 1/1000$  to  $< 1/100$ ).

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that change to the product information of medicinal product containing blinatumomab was warranted.

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.