22 October 2015
EMA/765899/2015
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: ipilimumab

Procedure No. EMEA/H/C/PSUSA/00009200/201503

Period covered by the PSUR: 25 September 2014 – 24 March 2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2015. Reproduction is authorised provided the source is acknowledged.

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for ipilimumab, the scientific conclusions of CHMP are as follows:

The MAH has presented a review of cases of Vogt-Koyanagi-Harada syndrome. Although the number of cases is limited, the prevalence is twice higher than that reported for VKH in the general populations. In addition, there is evidence of a possible immune-related mode of action involving Th17 cells that may justify a causal role of ipilimumab. Based on this evidence a causal relationship between VKH syndrome and ipilimumab treatment cannot be refuted. Therefore, the Summary of Product Characteristics (SmPC) should be updated with Vogt-Koyanagi-Harada syndrome as an adverse drug reaction in sections 4.4 and 4.8. The Package Leaflet already covers adequately immune related adverse reactions, therefore no updates are necessary.
Therefore, in view of available data regarding ipilimumab, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for ipilimumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing ipilimumab is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.