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EMA/CHMP/13367/2014
Committee for Medicinal Products for Human Use (CHMP)

Benlysta

International non-proprietary name: belimumab

Procedure No. EMEA/H/C/002015/PSU/0016

Period covered by the PSUR: 9 March 2012 – 8 September 2012

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

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

Based on the clinical trials and the post marketing reports, a higher incidence of Herpes Zoster has been recorded for belimumab patients. Confounding factors mainly related to concomitant immunosuppressive treatments and higher susceptibility to infections of the patients have been considered during data analysis. Nevertheless, based on the current data, the information on infection in section 4.8 of the SmPC has been revised to state more clearly that opportunistic infections have been reported in patients treated with Benlysta. Additional data will be collected during the 1 year controlled safety study (BASE) and the 5 Year Safety registry study (SABLE). Moreover the MAH will continue close surveillance through routine pharmacovigilance. This approach is endorsed, while noting that events of infection are an area of special interest for belimumab.

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

Grounds recommending the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for Benlysta the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing the active substance belimumab is favourable subject to the proposed changes to the product information.

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