EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2013
EMA/CHMP/13369/2014
Committee for Medicinal Products for Human Use (CHMP)

Benlysta

International non-proprietary name: belimumab

Procedure No. EMEA/H/C/002015/PSUV/0019

Period covered by the PSUR: 9 September 2012 – 8 March 2013

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Scientific conclusions

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

The MAH has presented a PSUR according to the the GVP module VII. Three signals have been investigated (Fatigue, suicide and hypersentity reaction). Although hypersensitivity reactions are broadly covered in the current Global Data Sheet (GDS) as is a delay in the onset of acute hypersensitivity reactions, delayed-type (non-acute) hypersensitivity reactions are not specifically labelled. This review provides evidence for an association of belimumab with delayed-type (non-acute) hypersensitivity reactions. This evidence consists of two clinical trial cases which, although they contain confounding factors, most likely indicate non-serious events of delayed-type hypersensitivity, and one serious spontaneous case for which limited information is available but does include report of positive re-challenge. Additionally, delayed-type (non-acute) hypersensitivity reactions are known to occur in association with other monoclonal antibodies, which provides further support for an association with belimumab. Therefore, in view of the available data, the PRAC considered that changes to the product information as discussed above were acceptable. The risk of Delayed-type, non-acute hypersensitivity reactions will be included in the updated SmPC.

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

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Benlysta, the CHMP is of the opinion that the benefit-risk balance of the medicinal product 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 should be varied.