14 September 2017
EMA/CHMP/601079/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Benlysta

belimumab

On 14 September 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Benlysta. The marketing authorisation holder for this medicinal product is Glaxo Group Ltd.

The CHMP recommended approval of a new pharmaceutical form: Benlysta 200 mg solution for injection under the skin in a pre-filled syringe and pre-filled pen. The new form will be available in addition to the existing ones: Benlysta 120 mg and 400 mg powder for concentrate for solution for infusion.

The new pharmaceutical form allows patients or their carers to administer the medicine themselves.

The indication of Benlysta remains unchanged and is as follows:

“Add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g positive anti-dsDNA and low complement) despite standard therapy.”

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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