19 September 2019
EMA/CHMP/349325/2019
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Benlysta

belimumab

On 19 September 2019, 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 GlaxoSmithKline (Ireland) Limited.

The CHMP adopted an extension to the existing indication as follows:[2]

> "Benlysta is indicated as add-on therapy in ~~adult~~ patients **aged 5 years and older** 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 (see section 5.1)".

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
[2] New text in bold, removed text as strikethrough

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