19 May 2011
EMA/CHMP/296249/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Benlysta

belimumab

On 19 May 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Benlysta, 120 mg and 400 mg, powder for concentrate for solution for infusion intended as add-on therapy in adult patients with active autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity despite standard therapy. The applicant for this medicinal product is Glaxo Group Limited. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Benlysta is belimumab, a monoclonal antibody (ATC code: L04AA26) specific for soluble human B Lymphocyte Stimulator protein (BLyS, also referred to as BAFF and TNFSF13B). Benlysta blocks the binding of soluble BLyS, a B cell survival factor, to its receptors on B cells. Benlysta does not bind B cells directly, but by binding BLyS, Benlysta inhibits the survival of B cells, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells.

The benefits with Benlysta are its ability to reduce the disease activity as measured by three validated tools: the SELENA SLEDAI score, Physician's Global Assessment (PGA) and the BILAG index. While the effects of belimumab treatment were rather modest in the overall patient population studied, a clinically relevant treatment effect was shown in patients with high disease activity (anti-dsDNA antibodies and low levels of C3 and/or C4). The addition of 10 mg/kg belimumab to standard SLE therapy was generally well tolerated The most common side effects are nausea, diarrhoea, and pyrexia. Some patients developed infusion related reactions, some of which were reminiscent of hypersensitivity reactions. The mechanism of action of Benlysta could increase the potential risk for the development of infections including opportunistic infections. Also, as an immunomodulating drug, a potential risk for malignancies cannot be ruled out.

A pharmacovigilance plan for Benlysta will be implemented as part of the marketing authorisation.

[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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The approved indication is: 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. It is proposed that Benlysta is prescribed by physicians experienced in the diagnosis and treatment of SLE.

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

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Benlysta and therefore recommends the granting of the marketing authorisation.