London, 20 January 2010
EMA/CHMP/21426/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Arzerra

ofatumumab

On 20 January 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Arzerra, 20mg/ml, concentrate for solution for infusion intended for the treatment of chronic lymphocytic leukaemia (CLL). Arzerra was designated as an orphan medicinal product on 7 November 2008. The applicant for this medicinal product is Glaxo Group Ltd. 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 Arzerra is ofatumumab, a monoclonal antibody medicinal product (L01XC10) targeting CD20, a cell surface marker of B lymphocytes, which is followed by cell lysis via Complement Dependent Cytotoxicity (CDC) and Antibody Dependent Cell-mediated Cytotoxicity (ADCC).

The benefit with Arzerra is the control of chronic lymphocytic leukaemia in patients who are refractory to both fludarabine and alemtuzumab, which was indicated by a high response rate of the disease to the drug. The most common side effects are infections and infusion reactions.

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

The approved indication is: treatment of chronic lymphocytic leukaemia (CLL) in patients refractory to fludarabine and alemtuzumab". It is proposed that Arzerra is prescribed by physicians experienced in the use of cancer therapy and administered in an environment where full resuscitation facilities are immediately available.

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.

[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 CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Arzerra and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional[2].

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.