



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/CHMP/280012/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Gazyvaro obinutuzumab

On 22 May 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Gazyvaro 1,000 mg concentrate for solution for infusion intended for the treatment in combination with chlorambucil of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) and with comorbidities making them unsuitable for full-dose fludarabine based therapy. Gazyvaro was designated as an orphan medicinal product on 10 October 2012. The applicant for this medicinal product is Roche Registration 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 Gazyvaro is obinutuzumab, a recombinant monoclonal antibody (L01XC15) targeting the CD20 transmembrane antigen on the surface of non-malignant and malignant pre-B and mature B-lymphocytes. In nonclinical studies, obinutuzumab induces direct cell death and mediates antibody dependent cellular cytotoxicity (ADCC) and antibody dependent cellular phagocytosis (ADCP).

The benefits with Gazyvaro used in combination with chlorambucil (Clb) are its ability to delay the progression of disease compared to Clb alone or rituximab in combination with Clb. The most common side effects are infusion-related reactions (IRRs) which occurred in the majority of patients during the first cycle, neutropenia and infections.

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

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 made 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.



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