21 April 2017
EMA/CHMP/245560/2017
Committee for Medicinal Products for Human Use (CHMP)

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

# Besponsa

## inotuzumab ozogamicin

On 21 April 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Besponsa, intended for the treatment of adults with acute lymphoblastic leukaemia. Besponsa was designated as an orphan medicinal product on 7 June 2013. The applicant for this medicinal product is Pfizer Limited.

Besponsa will be available as a 1-mg powder for concentrate for solution for infusion. The active substance of Besponsa is inotuzumab ozogamicin, a humanised immunoglobulin class G subtype 4 (IgG4) antibody (ATC code: L01XC26) that specifically recognises human CD22.

Besponsa has been shown to increase the proportion of patients who have complete remission and molecular remission and to delay the progression of disease. The most common side effects are thrombocytopenia, neutropenia, anaemia, leucopenia, infection, haemorrhage and venoocclusive liver disease/sinusoidal obstruction syndrome.

The full indication is: "Besponsa is indicated as monotherapy for the treatment of adults with relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL). Adult patients with Philadelphia chromosome positive (Ph+) relapsed or refractory B cell precursor ALL should have failed treatment with at least 1 tyrosine kinase inhibitor (TKI)".

It is proposed that Besponsa be prescribed by physicians experienced in treating cancer.

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

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