



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 February 2018  
EMA/CHMP/85476/2018  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Mylotarg

#### gemtuzumab ozogamicin

On 22 February 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Mylotarg, intended for the treatment of acute myeloid leukaemia. Mylotarg was designated as an orphan medicinal product on 18 October 2000. The applicant for this medicinal product is Pfizer Limited.

Mylotarg will be available as a 5-mg powder for concentrate for solution for infusion. The active substance of Mylotarg is gemtuzumab ozogamicin, a humanised immunoglobulin G subtype 4 (IgG4) antibody (ATC code: L01XC05) directed at CD33 which is conjugated to calicheamicin, a toxin which induces breaks in double-stranded DNA, subsequently inducing cell cycle arrest and apoptotic cell death.

The benefit with Mylotarg is improvement in event-free survival. The most common (> 30%) side effects of Mylotarg when used together with daunorubicin and cytarabine are haemorrhage and infection.

The full indication is: "Mylotarg is indicated for combination therapy with daunorubicin (DNR) and cytarabine (AraC) for the treatment of patients age 15 years and above with previously untreated, de novo CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL)."

It is proposed that Mylotarg should be prescribed by physicians experienced in the use of anticancer medicinal products.

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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

