24 September 2015
EMA/CHMP/571712/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Blincyto

blinatumomab

On 24 September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Blincyto, intended for the treatment of adults with Philadelphia chromosome-negative acute lymphoblastic leukaemia (ALL). Blincyto was designated as an orphan medicinal product on 24 July 2009. The applicant for this medicinal product is Amgen Europe B.V.

Blincyto will be available as a powder (1 vial of 38.5 micrograms for preparing a concentrate for solution for infusion) and a stabilising solution. The active substance of Blincyto is blinatumomab, a bispecific T-cell engager antibody (ATC code: L01XC19).

The benefits with Blincyto are its ability to increase the proportion of patients who have complete remission and molecular remission within the first two treatment cycles. Complete remission and molecular remission are in fact associated with better relapse-free survival and overall survival rates; moreover, patients who receive haematopoietic stem cell transplant in complete response / molecular response have the higher chance to reach cure.

The most common side effects are infusion-related reactions, pyrexia, headache, febrile neutropenia, peripheral oedema, nausea, hypokalaemia, constipation, anaemia, diarrhoea, tremor, fatigue and chills.

The full indication is: “Blincyto is indicated for the treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL)”. It is proposed that Blincyto treatment should be started and supervised by physicians experienced in the treatment of haematological malignancies.

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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