15 November 2018
EMA/CHMP/799482/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Blincyto

blinatumomab

On 15 November 2018, the Committee for Medicinal Products for Human Use (CHMP), following a re-examination procedure, adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Blincyto. The marketing authorisation holder for this medicinal product is Amgen Europe B.V.

The CHMP adopted a new indication as follows:

> "Blincyto is indicated as monotherapy for the treatment of adults with Philadelphia chromosome negative CD19 positive B-precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%."

For information, the full indications for Blincyto will be as follows:[2]

> Blincyto is indicated as monotherapy for the treatment of adults with Philadelphia chromosome negative CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL).
>
> **Blincyto is indicated as monotherapy for the treatment of adults with Philadelphia chromosome negative CD19 positive B-precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.**
>
> Blincyto is indicated as monotherapy for the treatment of paediatric patients aged 1 year or older with Philadelphia chromosome negative CD19 positive B-precursor ALL which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic hematopoietic stem cell transplantation."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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
[2] New text in bold

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