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**Update of 21 September 2018:**

The company that applied to change the marketing authorisation of Blincyto has requested a re-examination of the CHMP's July 2018 opinion. Upon receipt of the grounds for the request, the CHMP will re-examine its opinion and issue a final recommendation.

27 July 2018

# Refusal of a change to the marketing authorisation for Blincyto (blinatumomab)

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of a change to the marketing authorisation for Blincyto, which is used to treat B-precursor acute lymphoblastic leukaemia (ALL). The change concerned an extension of use that would allow the medicine to be used in patients with residual cancer cells in the body after previous treatment.

The company that applied for the change to the authorisation is Amgen Europe B.V. It may request a re-examination of the opinion within 15 days of receipt of notification of this negative opinion.

## What is Blincyto?

Blincyto is a cancer medicine currently used to treat a type of blood cancer called B-precursor acute lymphoblastic leukaemia (ALL) when the cancer has come back or has not improved with previous treatment.

Blincyto is used in patients who are 'Philadelphia-chromosome-negative', which means that the patients do not have an abnormal chromosome called the Philadelphia chromosome.

The medicine has been authorised since November 2015 and contains the active substance blinatumomab.

Further information on Blincyto's current uses can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

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Blincyto was designated an 'orphan medicine' (a medicine to be used in rare diseases) on 24 July 2009 for ALL. Further information on the orphan designation can be found here.

## What was Blincyto expected to be used for?

Blincyto was also expected to be used to treat patients with minimal residual disease (MRD), which means they have residual cancer cells in their body after previous treatment with other medicines and could therefore be at higher risk of B-precursor ALL returning.

## How does Blincyto work?

In B-precursor ALL, certain cells that give rise to B cells (a type of white blood cell) multiply too quickly and eventually these abnormal cells replace normal blood cells.

The active substance in Blincyto, blinatumomab, is an antibody that has been designed to recognise and attach to a protein (CD19) found on all B cells, including ALL cells. It also attaches to a protein (CD3) found on T cells (another type of white blood cell).

Blincyto therefore acts as a bridge, bringing the T cells and the B cells together and causing the activation of T cells, which release substances that eventually kill B cells.

## What did the company present to support its application?

The company presented data from a main study in 116 patients with residual cancer cells who were treated with Blincyto. The study did not compare Blincyto with any other treatment. It looked at how many patients no longer had residual disease after one treatment cycle.

## What were the CHMP's main concerns that led to the refusal of the change to the marketing authorisation?

The CHMP noted that although Blincyto helped clear away residual cells in many patients, there is no strong evidence that it leads to improved survival in patients.

Given the uncertainty, the CHMP was of the opinion that the benefits of Blincyto in patients with residual B-precursor ALL cells did not outweigh its risks. The CHMP therefore recommended that the change to the marketing authorisation be refused.

## What consequences does this refusal have for patients in clinical trials?

The company informed the CHMP that there are no consequences for patients in clinical trials.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.

## What is happening with Blincyto for treatment of other patients with B-precursor ALL?

There are no consequences for Blincyto in its authorised use.