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Positive opinion on the change to the marketing authorisation for Blincyto (blinatumomab)

Outcome of re-examination

On 15 November 2018, the Committee for Medicinal Products for Human Use (CHMP) recommended that a change to the marketing authorisation for the medicinal product Blincyto be granted. Blincyto is currently authorised to treat B-precursor acute lymphoblastic leukaemia (ALL), and the change concerned an extension of use 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.

On 26 July 2018, the CHMP had originally adopted a negative opinion on the extension of the use of Blincyto in patients with residual cancer cells in the body after previous treatment. At the request of the company, the CHMP re-examined its opinion. Following the re-examination, the CHMP adopted a final positive opinion on 15 November 2018 recommending that the change to the marketing authorisation be granted for Blincyto, but requested the company to provide the results from ongoing studies once available.

What is Blincyto?

Blincyto is a cancer medicine currently used to treat a 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/en/medicines/human/summaries-opinion/blincyto.

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 on the Agency's website: ema.europa.eu/medicines/human/orphan-designations/eu309650.

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What is Blincyto to be used for?

Blincyto is also 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 measurable residual disease after one treatment cycle.

What were the CHMP's main concerns that led to the initial negative opinion?

The CHMP noted that although Blincyto helped to reduce the amount of residual cancer cells in many patients, there is no strong evidence that it leads to improved survival.

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 happened during the re-examination?

During the re-examination, the CHMP looked again at all the data and consulted a group of experts in cancer treatments. The CHMP also considered the possibility of the company providing further data on the benefits of the medicine in extending the life of patients with residual cancer cells after the authorisation of this new use.

What were the conclusions of the CHMP following the re-examination?

The CHMP agreed with the expert group's conclusion that, although there is no strong evidence of patients living longer, the available data from the main study indicate a good response to Blincyto, with around 78% of patients not having measurable residual cancer cells after treatment. The Committee also considered that patients with minimal residual disease are at high risk of the disease coming back and have few treatment options.

Therefore, the CHMP concluded that the benefits of Blincyto outweigh its risks and recommended granting the change to the marketing authorisation. However, the CHMP requested the company to provide further data from ongoing studies once available.