



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers

Refusal of the marketing authorisation for Lympreva (dasiprotimut-T)

On 23 April 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Lympreva, intended for the treatment of patients with follicular non-Hodgkin's lymphoma.

The company that applied for authorisation is Biovest Europe Ltd. It may request a re-examination of the opinion within 15 days of receipt of notification of this negative opinion.

What is Lympreva?

Lympreva is a medicine that contains the active substance dasiprotimut-T. It was to be available as a suspension for injection under the skin.

What was Lympreva expected to be used for?

Lympreva was expected to be used to treat adults with follicular non-Hodgkin's lymphoma, a cancer of a type of white blood cells called 'B cells'. It was expected to be used in combination with another medicine called granulocyte macrophage colony-stimulating factor (GM-CSF). Lympreva was expected to be given to patients whose signs of disease had disappeared following an 'induction' treatment, to maintain the complete disappearance of symptoms of cancer.

Lympreva was designated an 'orphan medicine' (a medicine to be used in rare diseases) on 28 August 2006, for the treatment of follicular lymphoma. Further information can be found here:

ema.europa.eu/Find_medicine/Human_medicines/Rare_disease_designation.



How is Lympreva expected to work?

Lympreva is a type of 'cancer immunotherapy' medicine, a medicine designed to stimulate the patient's immune system (the body's natural defences) so that it attacks and kills the cancer cells.

Lympreva is prepared individually for each patient from a sample of their own lymphoma cells. The medicine is made up of a protein found in the patient's lymphoma cells, attached to a molecule called haemocyanin, which helps to activate the immune system against the lymphoma cells.

When injected into the patient's body, these lymphoma-specific proteins are expected to stimulate certain components of the immune system to attack and kill the lymphoma cells.

What did the company present to support its application?

The company provided data in experimental models from the scientific literature.

The company also presented the results of one main study involving a total of 177 adults with follicular lymphoma who had responded to induction treatment with an established therapy known as PACE (prednisone, doxyrubicin, cyclophosphamide, and etoposide) and who had no sign of their disease. Patients were given either Lympreva together with GM-CSF, or haemocyanin with GM-CSF. The main measure of effectiveness was based on how long the patients lived without their cancer symptoms reappearing or until death.

What were the CHMP's main concerns that led to the refusal?

The CHMP considered that the way the main study was designed and carried out was inadequate to allow the Committee to establish the medicine's benefit. In addition, the effectiveness of Lympreva following induction treatment with the current standard of care (the so-called 'anti-CD20' therapies) has not been demonstrated. The CHMP also had some concerns regarding some aspects of the manufacture and quality control of the medicine.

Therefore, at that point in time, the CHMP was of the opinion that the benefits of Lympreva did not outweigh its risks and recommended that it be refused marketing authorisation.

What consequences does this refusal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that there are no ongoing clinical trials or compassionate use programmes with Lympreva.