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Update as of 24 June 2022:

The applicant for Tuznue has requested a re-examination of EMA's May 2022 opinion. Upon receipt of the grounds of the request, the Agency will re-examine its opinion and issue a final recommendation.

20 May 2022

Refusal of the marketing authorisation for Tuznue (trastuzumab)

The European Medicines Agency has recommended the refusal of the marketing authorisation for Tuznue, a medicine intended for the treatment of certain forms of breast cancer and gastric (stomach) cancer.

The Agency issued its opinion on 19 May 2022. Prestige Biopharma Belgium, the company that applied for the authorisation, may ask for re-examination of the refusal within 15 days of receiving the opinion.

What is Tuznue and what was it intended to be used for?

Tuznue was intended for use in adults, alone or in combination with other cancer medicines, to treat early breast cancer and breast cancer that has spread to other parts of the body. It was also intended to be used together with other cancer medicines to treat gastric (stomach) cancer that has spread to other parts of the body.

Tuznue was only to be used in patients with HER2-positive cancer, meaning that the cancer produces a protein called human epidermal growth factor receptor 2 (HER2) in large quantities on the surface of the tumour cells, which makes the tumour cells grow more quickly.

Tuznue contains the active substance trastuzumab and was to be available as a powder to be made into a solution for infusion (drip) into a vein.

Tuznue was developed as a 'biosimilar' medicine. This means that Tuznue was intended to be highly similar to another biological medicine already authorised in the European Union (the 'reference medicine'). The reference medicine for Tuznue is Herceptin. For more information on biosimilar medicines, see the question-and-answer document here.

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How does Tuznue work?

Tuznue was expected to work in the same way as the reference medicine, Herceptin. The active substance in Tuznue, trastuzumab, is a monoclonal antibody (a type of protein that attaches to a target on cells in the body). Trastuzumab is designed to recognise and attach to the HER2 protein. By attaching to HER2, trastuzumab activates cells of the immune system, which then kill the tumour cells. Trastuzumab also stops HER2 from producing signals that cause the tumour cells to grow.

What did the company present to support its application?

The company presented laboratory results comparing Tuznue with the reference medicine to investigate whether the active substance in Tuznue is highly similar to that in Herceptin in terms of structure, purity and biological activity. Results were also presented from two studies carried out to investigate whether giving Tuznue produces similar levels of the active substance in the blood compared to giving the reference medicine.

In addition, the company presented the results of one main study which looked at the safety and effectiveness of Tuznue in comparison with the reference medicine in approximately 500 patients with HER2-positive early-stage breast cancer. Effectiveness was measured by looking at the number of patients who had no sign of cancer in breast cells and lymph nodes in the armpit after treatment.

What were the main reasons for refusing the marketing authorisation?

The Agency considered that the manufacturing process of the medicine used during clinical testing differed from the process for commercial production of the medicine. As a result, the studies presented did not provide enough evidence to show that the commercially produced medicine will be biosimilar to the reference medicine. Therefore, the Agency's opinion was that the balance of benefits and risks of Tuznue could not be established in the applied therapeutic context. Hence, the Agency recommended refusing the marketing authorisation.

Does this refusal affect patients in clinical trials?

The company informed the Agency that there are no ongoing trials with Tuznue.