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Withdrawal of application for the marketing authorisation of Tuznue (trastuzumab)

Prestige Biopharma Belgium BVBA withdrew its application for a marketing authorisation of Tuznue for the treatment of certain forms of breast cancer and gastric (stomach) cancer.

The company withdrew the application on 14 September 2022.

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 metastatic 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.

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.

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What did the company present to support its application?

The company presented laboratory results comparing Tuznue with the reference medicine Herceptin 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 benefits of Tuznue in comparison with the reference medicine in approximately 500 patients with HER2-positive early-stage breast cancer. The benefits were measured by looking at the number of patients who had no sign of cancer in the breast and lymph nodes in the armpit after treatment.

How far into the evaluation was the application when it was withdrawn?

The evaluation had finished and the European Medicines Agency had recommended refusing marketing authorisation which was under re-examination at the company's request at the time of withdrawal. The company withdrew the application before the re-examination had completed.

What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had recommended refusing marketing authorisation for Tuznue for the treatment of certain forms of breast cancer and gastric cancer.

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 quality of the medicine used during clinical testing differed from the quality of the proposed commercial medicine. Therefore, the studies presented did not provide enough evidence to show that the commercially produced medicine will be highly similar to the reference medicine.

At the time of the withdrawal, while the re-examination was ongoing, the Agency was still of the opinion that the balance of benefits and risks of Tuznue could not be established in the applied therapeutic context.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that it was withdrawing the application based on the Agency's view that, at the time of withdrawal, the data provided would not have been sufficient to support a positive opinion on the marketing authorisation of Tuznue.

Does this withdrawal affect patients in clinical trials?

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