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Withdrawal of application for the marketing authorisation of Jivadco (trastuzumab duocarmazine)

Medac Gesellschaft für klinische Spezialpräparate mbH withdrew its application for a marketing authorisation of Jivadco for the treatment of HER2-positive breast cancer.

The company withdrew the application on 12 September 2023.

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

Jivadco was developed as a medicine for treating HER2-positive breast cancer that is locally advanced (has spread to nearby tissue) or has spread to other parts of the body.

'HER2-positive' means that the cancer cells produce a large amount of a protein called HER2 on their surface, which makes the tumour cells grow more quickly.

The medicine was intended for patients whose cancer worsened despite at least 2 treatments targeting HER2 or treatment with trastuzumab emtansine.

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

How does Jivadco work?

The active substance in Jivadco is made up of two components, trastuzumab and duocarmazine, which are linked together.

Trastuzumab is a monoclonal antibody (a type of protein) that has been designed to attach to HER2. By attaching to HER2, it activates cells of the immune system, which then kill the cancer cells. Trastuzumab also stops HER2 from stimulating the growth of cancer cells.

Duocarmazine is a substance that can kill cancer cells directly. Once the trastuzumab component of the medicine attaches to HER2 on the cancer cells, duocarmazine can enter the cells and kill them by interfering with their ability to divide and grow.

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What did the company present to support its application?

The company presented results of a main study involving 437 patients with HER2-positive breast cancer that was either locally advanced and could not be surgically removed or had spread to other parts of the body. The study compared Jivadco with other standard treatments chosen by the doctor.

The main measure of effectiveness was progression-free survival, how long patients lived without their disease getting worse.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after that the European Medicines Agency had evaluated the information from the company and prepared questions about the application. The company had not responded to the last round of questions at the time of the withdrawal.

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 some significant concerns and its provisional opinion was that Jivadco could not have been authorised for the treatment of HER2-positive breast cancer.

EMA's human medicines committee (CHMP) had concerns about the way the company analysed the data on progression-free survival, which made it difficult to determine how well the medicine works. The analysis did not adequately address patients who stopped treatment, and patients were not followed up adequately. In addition, an inspection of the clinical trial sites revealed some findings that could affect the reliability of the results.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Jivadco did not outweigh its risks.

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 withdrew the application because it could not address EMA's concerns within the required time limit.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that all clinical trials have been finalised.