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Questions and answers

Withdrawal of the marketing authorisation application for Graspa (eryaspase)

On 14 November 2016, Erytech Pharma SA officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Graspa, for the treatment of acute lymphoblastic leukaemia.

What is Graspa?

Graspa is a cancer medicine that contains the active substance eryaspase (a version of the enzyme asparaginase enclosed in red blood cells compatible with the patient's blood group). Asparaginase is an enzyme that has been used to treat cancer for many years, and is already approved under various trade names in the EU.

What was Graspa expected to be used for?

Graspa was expected to be used in combination with other cancer medicines to treat adults and children over 1 year of age who have acute lymphoblastic leukaemia (ALL), a cancer of white blood cells. The medicine was intended for use in patients whose cancer was classed 'Philadelphia chromosome negative' and had not responded to initial treatment, or had come back after treatment.

Graspa was designated an 'orphan medicine' (a medicine to be used in rare diseases) on 26 October 2006 for ALL. Further information on the orphan designation can be found here.

How does Graspa work?

The asparaginase in Graspa works by breaking up and reducing the blood levels of the amino acid asparagine. Cancer cells need this amino acid to grow and multiply, and so its reduction in the blood causes the cells to die. Normal cells, by contrast, can produce their own asparagine and are less affected by the medicine. The asparaginase in Graspa is enclosed in red blood cells with the intention of helping protect the enzyme from being broken down in the body. Because asparaginase is a protein,

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it can cause allergic reactions, but by enclosing it in red blood cells the risk of allergy is expected to be reduced.

What did the company present to support its application?

The company provided data on Graspa, including the results of a main study involving 80 patients with ALL whose disease had come back after initial treatment or who had not responded to initial treatment, some of whom had an allergy to other products containing asparaginase.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the documentation provided by the company and formulated lists of questions. The company had not responded to the last round of questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the review of the data, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Graspa could not have been approved for the treatment of ALL. The CHMP was concerned about the way the effectiveness of the medicine had been measured in the main study, and whether the results of this study could be extended to patients taking other combinations of cancer medicines. In addition, the company had changed the way the asparaginase in the medicine was made, and the Committee asked for supportive information to show that this would not affect the effectiveness of the product.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the company had not provided enough data to support the application for Graspa.

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 because the additional data the CHMP considered necessary to support the application could not be obtained in the time available.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials?

The company informed the CHMP that there are no consequences for patients currently included in clinical trials using Graspa.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.