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Questions and answers

Withdrawal of the marketing authorisation application for Ozespa (briakinumab)

On 14 January 2011, Abbott Laboratories Ltd officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Ozespa, for the treatment of plaque psoriasis (a disease causing red, scaly patches on the skin).

What is Ozespa?

Ozespa is medicine that contains the active substance briakinumab. It was to be available as a solution for injection.

What was Ozespa expected to be used for?

Ozespa was expected to be used to treat moderate to severe plaque psoriasis in adults who failed to respond to or cannot use other systemic (whole-body) treatments for psoriasis, including ciclosporin, methotrexate and PUVA (psoralen ultraviolet-A).

How is Ozespa expected to work?

The active substance in Ozespa, briakinumab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen) in the body. Briakinumab was designed to attach to a part of two 'cytokines' (messenger molecules) in the immune system called interleukin-12 and interleukin-23. These cytokines are involved in causing the inflammation and other processes that cause psoriasis. By attaching to them, briakinumab was expected to block their activity, thereby reducing the activity of the immune system and the symptoms of the disease.

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What did the company present to support its application?

The effects of Ozespa were first tested in experimental models before being studied in humans.

The company presented the results of four main studies in 2,479 adults with psoriasis. Ozespa was compared with placebo (a dummy treatment), etanercept and methotrexate (other medicines used to treat psoriasis). Two of the studies lasted 12 weeks, and two lasted 52 weeks. The main measure of effectiveness was the change in the symptom scores, as measured using two standard scales for psoriasis.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn before 'day 120'. This means that the CHMP was still evaluating the initial documentation provided by the company.

What was the recommendation of the CHMP at that time?

As the CHMP was evaluating the initial documentation provided by the company, it had not yet made any recommendations.

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

The letter from the company notifying the Agency of the withdrawal of the application is available under the tab 'All documents'.

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

The company informed the CHMP that its current clinical trials will continue.

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