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Questions and answers

Withdrawal of the marketing authorisation application for Omontys (peginesatide)

On 28 June 2013, Takeda Global Research and Development Centre (Europe) officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Omontys, for the treatment of symptomatic anaemia associated with chronic kidney disease in adult patients undergoing dialysis.

What is Omontys?

Omontys is a medicine containing the active substance peginesatide. It was to be made available as a solution for injection.

What was Omontys expected to be used for?

Omontys was expected to be used to treat adults with symptomatic anaemia (low red blood cell counts) associated with chronic kidney disease (long-term, progressive decrease in the ability of the kidneys to work properly) who are undergoing dialysis (a blood clearance technique used in patients with kidney disease).

How is Omontys expected to work?

The active substance in Omontys, peginesatide, is expected to replace the action of erythropoietin, a natural hormone that stimulates the production of red blood cells from the bone marrow. Erythropoietin is normally produced by the kidneys. Patients with chronic kidney disease can suffer from anaemia because their kidneys do not produce enough of this hormone. Peginesatide is expected to attach to receptors for erythropoietin, thereby stimulating the production of red blood cells in the bone marrow.

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What did the company present to support its application?

The company presented the results of two main studies involving 1,626 patients with chronic kidney disease undergoing dialysis, to assess the effectiveness of Omontys at maintaining red blood cell counts. In both studies, Omontys was compared with another medicine called epoetin. The main measure of effectiveness was the change in levels of haemoglobin (a protein found in red blood cells) between the start of the study and the evaluation period.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the documentation provided by the company and formulated lists of questions.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 yet 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 and the company's responses to the CHMP lists of questions, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Omontys could not have been approved. In particular, the CHMP was concerned by some supportive study results indicating that Omontys may increase the risk of death or heart and circulatory problems in patients treated for the first time compared with similar medicines for stimulating red blood cell production. The Committee was also concerned by the results of inspections indicating that the study data submitted might not be fully reliable. In addition, the CHMP was concerned by reports of serious hypersensitivity (allergic) reactions, including fatal reactions, in some patients given Omontys in the United States, which had led to the removal of Omontys from the US market in February 2013. Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Omontys 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 application, the company stated that it would not be able to address the CHMP's concerns regarding the hypersensitivity reactions seen in the US within the timetable for the application procedure as the investigation into the root cause was still ongoing.

The withdrawal letter is available here.

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

The company informed the CHMP that one clinical study was currently ongoing in patients with pure red cell aplasia (where no red blood cells are produced) associated with chronic kidney disease. It informed the CHMP that recruitment of new patients had been halted (due to the risk of hypersensitivity after the first injection), but patients currently enrolled in this study had the option to continue receiving Omontys.

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