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Withdrawal of the marketing authorisation application for canakinumab Novartis (canakinumab)

On 4 December 2018, Novartis Europharm Ltd. officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for canakinumab Novartis, for the prevention of serious events such as stroke, heart attack or death in patients who have had a heart attack.

What is canakinumab Novartis?

Canakinumab Novartis is a medicine that contains the active substance canakinumab. It was to be available as a solution for injection under the skin in pre-filled pens and pre-filled syringes.

What was canakinumab Novartis expected to be used for?

Canakinumab Novartis was expected to be used to prevent serious events such as stroke, heart attack or death in patients who have already had a heart attack.

How does canakinumab Novartis work?

The active substance in canakinumab Novartis, canakinumab, is a monoclonal antibody (a type of protein) which has been designed to recognise and attach to interleukin 1 (IL-1) beta. IL-1 beta is part of the immune system (the body's natural defences) and is involved in the inflammatory processes associated with heart and blood vessels problems.

By attaching to IL-1 beta, canakinumab blocks its activity and reduces inflammation. This is expected to help prevent further heart problems.

What did the company present to support its application?

The company provided the results of one study involving over 10,000 patients who had had a heart attack. Patients were given canakinumab Novartis at different doses (50, 150 or 300 mg) or placebo (a dummy treatment) once every three months for up to six years. Patients also took other medicines

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commonly used to prevent heart problems, such as statins. The main measure of effectiveness was the decrease in the number of serious events such as heart attack, stroke or death.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the documentation provided by the company and formulated lists of questions. After the CHMP had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What was the recommendation of the CHMP at that time?

Based on the review of the data and the company's response to the CHMP lists of questions, at the time of the withdrawal, the CHMP had remaining concerns and was of the provisional opinion that canakinumab Novartis could not have been approved for the prevention of serious heart problems in patients who have already had a heart attack.

In particular, the CHMP was of the opinion that the data provided by the company was not robust enough to clearly demonstrate that canakinumab Novartis is effective in all patients who have had a heart attack. The beneficial effects seen were considered modest, particularly in patients who also took statins, and were not considered to outweigh the increased risks of serious infections in patients treated with the medicine. The CHMP also questioned the appropriateness of the measure chosen by the company to select patients and to monitor the effectiveness of canakinumab Novartis.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of canakinumab Novartis 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 would not be possible for them to reply to the Agency's concerns within the agreed timeframe.

The withdrawal letter is available here.

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

The company informed the CHMP that, while an extension to the above-mentioned study will stop, other studies investigating canakinumab for the treatment of other conditions will continue as planned.

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