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Questions and answers

Withdrawal of the marketing authorisation application for Faldaprevir Boehringer Ingelheim (faldaprevir)

On 10 June 2014, Boehringer Ingelheim International GmbH officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Faldaprevir Boehringer Ingelheim, for the treatment of hepatitis C.

What is Faldaprevir Boehringer Ingelheim?

Faldaprevir Boehringer Ingelheim is an antiviral medicine that contains the active substance faldaprevir. It was to be available as capsules (120 mg).

What was Faldaprevir Boehringer Ingelheim expected to be used for?

Faldaprevir Boehringer Ingelheim was expected to be used to treat adults with chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus). It was to be used in combination with other medicines. Several varieties (genotypes) of hepatitis C virus exist: Faldaprevir Boehringer Ingelheim was intended to be used against genotype 1.

How is Faldaprevir Boehringer Ingelheim expected to work?

The active substance in Faldaprevir Boehringer Ingelheim, faldaprevir, blocks the action of an enzyme called 'NS3/4A serine protease' in the hepatitis C virus, which is essential for the virus to multiply. This stops the hepatitis C virus from multiplying and infecting new cells.

What did the company present to support its application?

The company presented data including the results of three main studies involving 1,705 patients with chronic hepatitis C, in which faldaprevir was compared with placebo (a dummy treatment) when added to two other medicines for hepatitis C, peginterferon and ribavirin. The main measure of effectiveness was the number of patients whose blood tests did not show any sign of hepatitis C virus 12 weeks after

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the end of treatment. A fourth study involving 308 patients examined the effects of treatment with Faldeprevir Boehringer Ingelheim in patients who also had HIV infection.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the initial documentation provided by the company and formulated a list of questions. The company had not yet responded to the 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 had some concerns and was of the provisional opinion that Faldaprevir Boehringer Ingelheim could not have been approved for the treatment of hepatitis C. The Committee had concerns regarding the starting materials used for the manufacture of the active substance. In addition, results of tests on capsules stored in non-refrigerated conditions showed that they did not dissolve as expected, which could affect the release of the active substance from the capsule.

Therefore, up to the time of the withdrawal, the CHMP was of the opinion that due to the concerns about quality the benefits of Faldaprevir Boehringer Ingelheim 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 since several new treatments for hepatitis C had become available after the application was first made, there was no longer an unmet medical need for such a medicine.

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 Faldaprevir Boehringer Ingelheim. Remaining clinical trials were expected to finish on schedule by July 2014.

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