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Questions and answers

Withdrawal of the marketing authorisation application for Joulferon (albinterferon alfa-2b)

On 16 April 2010, Novartis Europharm Limited officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Joulferon, for the treatment of hepatitis C infection.

What is Joulferon?

Joulferon is a powder and solvent to be made up into a solution for injection. It contains the active substance albinterferon alfa-2b. It was to be available as an injection pen and as vials.

What was Joulferon expected to be used for?

Joulferon was expected to be used to treat adults with long-term hepatitis C (a disease of the liver due to infection with the hepatitis C virus). It was to be used in adults whose liver was damaged and who had not previously been treated with interferon alfa (another medicine for hepatitis C).

How is Joulferon expected to work?

The active substance in Joulferon, albinterferon alfa-2b, belongs to the group 'interferons'. Interferons are natural substances produced by the body to help it fight against attacks such as infections caused by viruses. The exact way that they work in treating viral diseases is not fully understood, but it is thought that they act as immunomodulators (substances that modify how the immune system works). They may also block the multiplication of viruses.

Albinterferon alfa-2b is a 'fusion protein' made up of interferon alfa-2b, which is already available in antiviral medicines in the European Union (EU), attached to a protein called albumin. Attaching the interferon to albumin helps to prolong its action against the hepatitis C virus after each injection. The albinterferon alfa-2b in Joulferon is produced by a method known as 'recombinant DNA technology': it is made by a yeast that has received a gene (DNA), which makes it able to produce albinterferon alfa-2b.

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What did the company present to support its application?

The effects of Joulferon were first tested in experimental models before being studied in humans. The company presented the results of two main studies involving a total of 2,255 adults with hepatitis C infection who had not previously been treated. The studies compared Joulferon with peginterferon alfa-2a (another medicine used to treat hepatitis C). Both groups of patients also took ribavirin (another medicine used in hepatitis C). Treatment lasted between six months and a year. The main measure of effectiveness was based on the level of hepatitis C virus circulating in the blood six months after the end of treatment.

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 here.

What consequences does this withdrawal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that the withdrawal has no impact on ongoing clinical trials, and that it will continue to make Joulferon available to patients enrolled in these trials.