



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Novartis Europharm Ltd withdraws its marketing authorisation application for Joulferon (albinterferon alfa-2b)

The European Medicines Agency has been formally notified by Novartis Europharm Ltd of its decision to withdraw its application for a centralised marketing authorisation for the medicine Joulferon (albinterferon alfa-2b), 900 mg powder and solvent for solution for injection in pre-filled pen and vials.

This medicine was intended to be used in combination with ribavirin for the treatment of adults with chronic hepatitis C virus infection who have compensated liver disease and have not been previously treated with interferon alfa.

The application for the marketing authorisation for Joulferon was submitted to the Agency on 3 December 2009. At the time of the withdrawal it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that its decision to withdraw the application was based on preliminary comments of the rapporteurs in the day 80 draft assessment reports that additional new data would be requested for a favourable opinion but that those could not be generated within the timeframe allowed in the centralised procedure.

More information about Joulferon and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website after the next CHMP meeting on 19-22 April 2010.

Notes

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.

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2. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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