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Press Office

Press release

Novartis Europharm Ltd withdraws its marketing authorisation application for Ruvise (imatinib mesilate)

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 Ruvise (imatinib mesilate), 100 and 400 mg film-coated tablets. It was intended to be used for adults as add-on therapy for the treatment of pulmonary arterial hypertension (PAH).

The application for the marketing authorisation for Ruvise was submitted to the Agency on 29 February 2012. At the time of the withdrawal, the medicine was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that it is withdrawing the application since additional data are required to address CHMP questions relating to the benefit-risk assessment of imatinib in PAH patients. These data will not be available within the timeframe allowed in the centralised procedure.

More information about Ruvise and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document will be published on the Agency's website after the CHMP meeting of 18-21 February 2013.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Contact our press officers

Monika Benstetter or Martin Harvey

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu