European Medicines Agency
Press office

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PRESS RELEASE

Novartis withdraws its application to extend the marketing authorisation for Glivec

The European Medicines Agency has been formally notified by Novartis Europharm Ltd of its decision to withdraw its application for a change to the marketing authorisation for Glivec (imatinib mesilate) 50 mg and 100 mg capsules and 100 mg and 400 mg film-coated tablets.

On 16 February 2006, Novartis submitted an application for the extension of the marketing authorisation to include the treatment of aggressive systemic mastocytosis in adults. Mastocytosis is a rare disease in which mast cells accumulate excessively in the bone marrow and in other organs, such as the liver, spleen and intestine. This disease can lead to organ failure and usually has a poor long-term outcome. Imatinib mesilate was designated as an orphan medicinal product for the treatment of mastocytosis on 26 August 2005.

In its official letter, the company stated that the reason for withdrawing this application was the consideration of the Agency's Committee for Medicinal Products for Human Use (CHMP) that the limited data provided did not allow it to conclude on a positive benefit-risk balance of the use of Glivec in aggressive systemic mastocytosis.

Glivec was first authorised in the European Union on 7 November 2001. It is currently indicated for the treatment of adult and paediatric patients with Philadelphia chromosome (bcr-abl) positive chronic myeloid leukaemia, adult patients with Philadelphia chromosome-positive acute lymphoblastic leukaemia (Ph+ ALL), adult patients with Kit (CD 117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST), and adult patients with dermatofibrosarcoma protuberans (DFSP).

In addition, during its meeting on 16-18 October 2006, the CHMP recommended an extension of the marketing authorisation for Glivec to include treatment of myelodysplastic syndromes and myeloproliferative diseases (MDS/MPD), as well as treatment of adult patients with hypereosinophilic syndrome and chronic eosinophilic leukaemia (HES/CEL).

More information about Glivec and the state of the scientific assessment at the time of withdrawal of the application concerned will be made available in a separate question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website after the next meeting of the CHMP on 13-16 November 2006.

--ENDS--

NOTES

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. More information about Glivec is available in the European Public Assessment Report (EPAR): http://www.emea.europa.eu/humandocs/Humans/EPAR/glivec/glivec.htm.
3. More information about the CHMP's recent recommendations on the extension of the marketing authorisation for Glivec can be found here.
4. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.europa.eu

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