European Medicines Agency
Press office

London, 4 August 2008
Doc. Ref. EMEA/417535/2008

PRESS RELEASE
Pharmion Ltd withdraws its marketing authorisation application for Orplatna (satraplatin)

The European Medicines Agency (EMEA) has been formally notified by Celgene Europe Ltd of Pharmion Ltd's decision to withdraw the application for a centralised marketing authorisation for the medicine Orplatna (satraplatin) 10 mg and 50 mg capsules. Orplatna was expected to be used, in combination with prednisone and prednisolone, in the treatment of patients with metastatic hormone-refractory prostate cancer who have failed prior chemotherapy.

The application for marketing authorisation for Orplatna was submitted to the EMEA on 22 June 2007. 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 the withdrawal of Orplatna was based on the CHMP's view that the data provided do not allow the Committee to conclude a positive benefit-risk balance for Orplatna for the applied indication.

More information about Orplatna 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 EMEA website in due course.

-- ENDS --

Notes:
1. Pharmion Ltd was acquired by Celgene Europe Ltd in March 2008.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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