European Medicines Agency
*Press office*

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# Press release
# EuroGen Pharmaceuticals withdraws its application for Orathecin

The European Medicines Agency has been formally notified by EuroGen Pharmaceuticals Ltd of its decision to withdraw its application for marketing authorisation for the medicinal product Orathecin (rubitecan).

EuroGen Pharmaceuticals Ltd submitted an application for marketing authorisation to the EMEA on 1 July 2004. At the time the withdrawal has been made, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP). The indication applied for was the treatment of patients with advanced or metastatic pancreatic cancer.

Following review of the data submitted, the CHMP considered that the data presented were not sufficient to demonstrate a clinical benefit for patients treated with Orathecin. The company informed the Agency on 19 January 2006 that it could not address at this stage the issues raised by the CHMP and has decided to withdraw its application.

A 'question and answer' document will be published on the EMEA website, together with the company's letter of withdrawal, after the next CHMP meeting on 23-26 January 2006.

--ENDS--

NOTES

1. This is the first publication of a withdrawal of a marketing authorisation application under the revised EU pharmaceutical legislation. The legal basis for the publication of this withdrawal is Article 11 of Regulation (EC) No 726/2004.
2. Withdrawal of an application does not prejudice the possibility of a company to make a new application at a later stage.
3. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.eu.int

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