European Medicines Agency
Press office

London, 23 September 2009
Doc. Ref. EMEA/601200/2009

PRESS RELEASE
CTI Life Sciences Ltd. withdraws its marketing authorisation application for Opaxio (paclitaxel poliglumex)

The European Medicines Agency has been formally notified by CTI Life Sciences Ltd. of its decision to withdraw its application for a centralised marketing authorisation for the medicine Opaxio (paclitaxel poliglumex), 269 mg powder for concentrate for solution for infusion.

Opaxio was expected to be used as a first-line monotherapy treatment of Eastern Co-operative Oncology Group performance-status 2 (PS2) patients with advanced non-small cell lung cancer.

The application for the marketing authorisation for Opaxio was submitted to the Agency on 6 March 2008. 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 the application was based on the CHMP's concerns over how the clinical trials in support of the application were designed, in particular over the choice of comparator and methods of analysis.

More information about Opaxio 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 of 19-22 October 2009.

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Notes:

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

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