19 February 2010
EMA/107943/2010
Press Office

Press release

United Therapeutics Europe Ltd withdraws its marketing authorisation application for Tyvaso

The European Medicines Agency has been formally notified by United Therapeutics Europe Ltd of its decision to withdraw its application for a centralised marketing authorisation for the medicine Tyvaso (treprostinil sodium) 0.6 mg/ml nebuliser solution.

This medicine was intended to be used as adjuvant therapy in patients with pulmonary arterial hypertension who were also receiving either an endothelin receptor antagonist or a phosphodiesterase-5 inhibitor.

The application for the marketing authorisation for Tyvaso was submitted to the Agency on 24 December 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 its decision to withdraw the application was based on a major objection of the CHMP that findings of non-compliance with good clinical practice (GCP) at two sites would preclude a recommendation for approval.

More information about Tyvaso 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 on 15-18 March 2010.

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.ema.europa.eu

Contact our press officers

Martin Harvey Allchurch or Monika Benstetter

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8416
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu