United Therapeutics
EUROPE LIMITED

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Dr Eric Abadie, CHMP Chair
European Medicines Agency
7 Westferry Circus
Canary Wharf
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17th February 2010

RE: Withdrawal of Marketing Authorisation Application for Tyvaso® (treprostinil sodium) 0.6 mg/ml Nebuliser Solution. (EMEA /H/C/ 001115)

Dear Dr Abadie,

I would like to inform you that, at this point of time, United Therapeutics Europe, Ltd., has taken the decision to withdraw the marketing authorisation application for Tyvaso® (treprostinil sodium), 0.6 mg/ml, nebuliser solution, which was intended for use as adjuvant therapy in patients with pulmonary arterial hypertension who were also receiving either an endothelin receptor antagonist or a phosphodiesterase-5 inhibitor.

The withdrawal is based on the following:

A major objection noted that findings of non-compliance with good clinical practice (GCP) at two clinical sites would preclude a recommendation for approval. There were no major objections at the time of withdrawal on the safety or efficacy of Tyvaso.

At this time there is one on-going clinical study in Europe, the open-label extension safety study, and Tyvaso is also being supplied on a compassionate use basis at one specialist treatment centre in Germany. Treatment of these patients will continue until alternative treatment options are obtained.

United Therapeutics Europe, Ltd. reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website.

Yours sincerely,