FREEDOM-M Trial of Oral Treprostinil in Pulmonary Arterial Hypertension Meets Primary Endpoint

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SILVER SPRING, Md., June 6, 2011 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR [1]) announced today the completion of its FREEDOM-M Phase 3 trial of treprostinil diethanolamine (oral treprostinil), an investigational sustained release oral formulation of treprostinil, a stable synthetic form of prostacyclin, in patients with pulmonary arterial hypertension (PAH). Preliminary analysis demonstrates that the trial has met its primary endpoint.

FREEDOM-M was a randomized, double-blind, placebo-controlled trial of patients with PAH, a chronic, life-threatening illness. The study enrolled 349 patients who were not receiving any approved PAH medication, with the population for the primary analysis consisting of the 228 patients who had access to the 0.25 mg tablet at randomization. These patients were administered oral treprostinil or placebo twice daily, with the doses titrated to effect over the course of the 12-week trial. The majority of patients were in World Health Organization (WHO) Functional Class II (~33%) and Class III (~66%) of varied etiologies, including idiopathic or familial PAH (~75%), collagen vascular disease associated PAH (~19%), and PAH associated with HIV or other associated conditions (~6%). The patients' mean baseline six-minute walk distance (6MWD) was approximately 330 meters.

The primary efficacy endpoint of the trial was the change in 6MWD at 12 weeks for the 228 patients. Preliminary analysis of the FREEDOM-M results demonstrates that those patients receiving oral treprostinil improved their median 6MWD by approximately 23 meters (p=0.0125, Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical analysis plan) as compared to patients receiving placebo. The median change from baseline was 25 meters for oral treprost
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SOURCE [2]

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