



October 23, 2012

United Therapeutics Announces Receipt Of Complete Response Letter For Oral Treprostinil NDA

Conference Call to be Held at 4:45 p.m. Eastern Time today, October 23, 2012

SILVER SPRING, Md., Oct. 23, 2012 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) announced today that it received a complete response letter from the United States Food and Drug Administration (FDA) declining to approve its new drug application (NDA) for treprostinil diethanolamine extended release tablets (oral treprostinil) for the treatment of pulmonary arterial hypertension (PAH).

The FDA letter questioned the clinical importance of the 6 Minute Walk Distance (6MWD) effect size shown in the FREEDOM-M study, the inability to demonstrate an improvement in time to clinical worsening in all three Phase III studies of oral treprostinil, and the inability to demonstrate a statistically significant effect on 6MWD in the two FREEDOM-C studies as reasons for being unable to approve the NDA in its current form. The FDA noted that it was unsure whether an additional clinical study could alter these impressions, but if United Therapeutics did undertake an additional study it should consider, among other things, a fixed dose design and more frequent dosing.

"We will continue using our best efforts to gain approval of oral treprostinil, and we will focus on doing so within the next four years," said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics. "We will convene with our experts over the next several weeks to decide which of several paths forward to pursue."

Conference Call Today

On Tuesday, October 23, 2012 at 4:45 p.m. Eastern Time, United Therapeutics will host a conference call to answer questions related to the FDA's complete response letter.

The conference call is accessible by dialing 1-877-351-5881, with international callers dialing 1-970-315-0533. A rebroadcast of the conference call will be available for two weeks and can be accessed by dialing 1-855-859-2056, with international callers dialing 1-404-537-3406, and using conference code: 56801607.

This conference call is also being webcast and can be accessed via our website at <http://ir.unither.com/events.cfm>.

About United Therapeutics

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening conditions.

Forward-looking Statements

Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, statements regarding United Therapeutics' efforts to gain approval of oral treprostinil, the related timing of those efforts, and actions United Therapeutics may take in response to the FDA's complete response letter. These forward-looking statements are subject to certain risks and uncertainties and are qualified by the cautionary statements, cautionary language and risk factors set forth in our periodic reports and documents filed with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and current reports on Form 8-K, which could cause actual results to differ materially from anticipated results. We are providing this information as of October 23, 2012, and assume no obligation to update or revise the information contained in this press release whether as a result of new information, future events or any other reason. [uthr-g]

SOURCE United Therapeutics Corporation

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