Triumph-1 Trial of Viveta in Pulmonary Arterial Hypertension Meets Primary Endpoint

Preliminary Analysis Demonstrates a 20-Meter Improvement in Six-Minute Walk Distance (p<0.0006) Conference Call to be Held at 9:00 a.m. Eastern Time on November 1, 2007

SILVER SPRING, Md., Nov 01, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- United Therapeutics Corporation (Nasdaq: UTHR) and its wholly-owned subsidiary, Lung Rx, Inc., announced today the completion of their TRIUMPH-1 Phase 3 trial of Viveta, an inhaled formulation of treprostinil, in pulmonary arterial hypertension (PAH). Preliminary analysis demonstrates that the trial has robustly met its primary endpoint.

The TRIUMPH-1 (TReprostinil Sodium Inhalation Used in the Management of Pulmonary Arterial Hypertension) trial was a randomized, double-blind, placebo-controlled trial of patients with severe PAH, a chronic, life- threatening illness. The study population consisted of 235 patients who were optimized on an approved oral therapy for PAH, either bosentan (Tracleer), an endothelin receptor antagonist, or sildenafil (Revatio), a phosphodiesterase-5 inhibitor. In addition to one of these oral therapies, patients were administered Viveta or placebo in four daily inhalation sessions with a maximum dose of 45 micrograms per session over the course of the 12-week trial. The majority (~98%) of patients were New York Heart Association (NYHA) Class III of varied etiologies, including idiopathic or familial PAH (~55%), collagen vascular disease associated PAH (~35%), and PAH associated with HIV, anorexigens or other associated conditions (~10%). Mean baseline walk distance was approximately 350 meters.

The primary efficacy endpoint of the trial was the change in six-minute walk (6MW) distance at 12 weeks measured at peak exposure, defined by the trial protocol as 10-60 minutes after inhalation of Viveta, relative to baseline. Preliminary analysis of the TRIUMPH-1 results demonstrates an improvement in median 6MW distance by approximately 20 meters ($p<0.0006$, Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical analysis plan), in patients receiving Viveta as compared to patients receiving placebo.

The trough exposure, defined by the trial protocol as a minimum of four hours after inhalation of Viveta, for treatment change in 6MW distance at week 12 relative to baseline was also significantly improved, with an increase in median 6MW distance of approximately 14 meters ($p<0.01$). Additionally, the 6MW distance at week 6 relative to baseline was significantly improved, with an increase in median 6MW distance of approximately 18 meters ($p<0.0005$).

Preliminary analysis of other secondary efficacy measures, including change in Borg Dyspnea Scale rating (shortness of breath test), NYHA functional class, time to clinical worsening (as defined by death, transplant, atrial septostomy, hospitalization due to PAH, or initiation of another approved PAH therapy), and the 6MW distance at treatment day 1, did not differ significantly between the Viveta and placebo groups ($p>0.05$). Analysis of two remaining secondary endpoints, quality of life and signs and symptoms of disease (composite measure) is ongoing.

Viveta was generally well-tolerated in the trial and adverse events appeared to be similar to those previously reported for treprostinil. The most common adverse events seen in the trial were transient cough, headache, nausea, dizziness and flushing. Detailed analysis of the reported adverse events is ongoing. All patients in the trial had the option to continue receiving Viveta in an open-label continuation study after completion of the 12-week study period. Of the 212 patients who completed the 12-week study period, approximately 200 patients entered the open-label continuation study. Approximately 160 patients are currently being treated with Viveta, with the longest duration of treatment exceeding two years.

"I am elated by the success of our TRIUMPH study," said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of both United Therapeutics and Lung Rx. "Special recognition is owed to the two physicians who urged us to develop this medicine, Professor Werner Seeger of the University of Giessen in Germany and Professor Lewis Rubin of the University of California San Diego, as well as to our hard-working investigators and clinical development teams led by David Zaccardelli and Ted Staub."

"These results build upon the treprostinil franchise we have established with our previous approvals of subcutaneous and intravenous Remodulin. We are excited that the primary efficacy analysis so conclusively confirms the benefits of Viveta as combination therapy on 6MW distance, as the delivery of treprostinil by inhalation following regulatory approval will provide another important treatment option for patients with this severe disease," said Roger Jeffs, Ph.D., President and Chief Operating Officer of United Therapeutics. "We will now focus our energies on completing the necessary regulatory filings so that patients worldwide can have access to inhaled Viveta as a prescribed route of delivery."

"The use of therapeutic combinations has become the generally accepted treatment paradigm for patients with PAH. This is the first well-controlled pivotal study demonstrating a significant benefit of combination therapy in patients who are optimized on another class of therapy, and provides clear demonstration that patients can be further improved by the addition of inhaled Viveta," said TRIUMPH-1 Steering Committee Co-Chair Lewis J. Rubin, MD, FCCP, Professor of Medicine at University of California San Diego Medical Center. "The promise of a convenient and long-acting prostacyclin therapy delivered four times daily by inhalation has the opportunity to provide incremental benefit to the many patients who are currently receiving oral medications for PAH."

Further review and analysis of the TRIUMPH-1 preliminary results are ongoing. Full data from TRIUMPH-1 will be presented at an upcoming medical meeting and will also be available through the publication of peer-reviewed journal articles.

About Viveta

Viveta is an investigational therapy that has not yet been determined safe or efficacious in humans. Viveta is an inhaled formulation of treprostinil. Treprostinil is a stable synthetic form of prostacyclin. Following regulatory approvals, Viveta will be co-promoted by United Therapeutics' commercialization group, based in Research Triangle Park, North Carolina, and Lung Rx's pulmonary division, based in Silver Spring, Maryland. It is estimated that there are approximately 6,000 physicians in the United States who currently treat their patients with Tracleer and/or Revatio, and such physicians may be able to supplement those treatments with Viveta following regulatory approval.

Conference Call

Lewis J. Rubin, MD, FCCP, the Co-Chair of the TRIUMPH-1 Steering Committee and Professor of Medicine at University of California San Diego Medical Center, will join United Therapeutics' management on a one-hour conference call to answer questions related to TRIUMPH-1.

The teleconference will be held on Thursday, November 1, 2007, at 9:00 a.m. Eastern Time. The teleconference is accessible by dialing 1-800-603-1777, with international callers dialing 1-706-679-8129. A rebroadcast of the teleconference will be available for one week following the teleconference by dialing 1-800-642-1687, with international callers dialing 1-706-645-9291, and using access code 20811764.

This teleconference is also being web cast and can be accessed via United Therapeutics' website at http://ir.unither.com/eventdetail.cfm?eventid=45704.

About United Therapeutics

United Therapeutics is a biotechnology company focused on the development and commercialization of unique products for patients with chronic and life- threatening cardiovascular, cancer and infectious diseases.

About Lung Rx

Lung Rx is a biotechnology company focused on unmet medical needs in pulmonary medicine and pulmonary delivery of innovative therapeutic products.

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 Reform Act of 1995. Forward-looking statements include our expectation regarding the pursuit of regulatory approvals for Viveta, our expectation that Viveta will be co-promoted in the United States by United Therapeutics' commercialization group and Lung Rx's pulmonary division, and our expectation that full data from the trial will be presented at an upcoming medical meeting and will also be available in peer-reviewed journal articles. These forward-looking statements are subject to certain risks and uncertainties, such as those described in our periodic reports filed with the Securities and Exchange Commission, which could cause actual results to differ materially from anticipated results. These risks and uncertainties include, among others, the failure of Viveta and the nebulizers used to administer Viveta to receive regulatory approvals on the schedule expected; the uncertainties of launching a new product on a global scale following receipt of regulatory approvals, if received, due to misestimates of the time and resources required to do so, or for other reasons; the failure of Viveta to receive favorable pricing or reimbursement approvals; the possible inaccuracies of our analysis with respect to the TRIUMPH-1 preliminary trial results and market opportunity; and our or our suppliers' inability to manufacture Viveta and the nebulizers used with Viveta in accordance with all applicable regulatory requirements and in sufficient quantity to support patient demand. Consequently, such forward-looking statements 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. We claim the protection of the safe harbor contained in the Private Securities Reform Act of 1995 for forward-looking

statements. We are providing this information as of November 1, 2007, 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]

Viveta is a trademark of Lung Rx, Inc., and Remodulin is a registered trademark of United Therapeutics Corporation.

Tracleer is a registered trademark of Actelion Ltd.

Revatio is a registered trademark of Pfizer Inc.

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