FDA Approves TYVASO (Treprostinil) Inhalation Solution for the Treatment of Pulmonary Arterial Hypertension

--Conference Call to be Held at 9:00 a.m. Eastern Time, July 31, 2009

SILVER SPRING, Md., July 30, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- United Therapeutics Corporation (Nasdaq: UTHR) announced today that the United States Food and Drug Administration (FDA) has approved TYVASO (treprostinil) Inhalation Solution for the treatment of pulmonary arterial hypertension (PAH) using the TYVASO Inhalation System (which includes the Optineb-ir device and accessories). TYVASO is indicated to increase walk distance in patients with NYHA Class III symptoms associated with WHO Group I PAH, which includes multiple etiologies such as idiopathic and familial PAH as well as PAH associated with scleroderma and congenital heart disease.

"We are thrilled to have a fourth approval from the FDA for treatment of this serious cardio-pulmonary condition," said Martine Rothblatt, Ph.D., United Therapeutics' Chairman and Chief Executive Officer. "I want to specially recognize Drs. Werner Seeger of Germany and Lew Rubin of the United States for their critical pioneering efforts in making this new therapy possible. TYVASO epitomizes the hopes and dreams we had in forming this company."

In connection with the TYVASO approval, United Therapeutics has agreed to Post-Marketing Commitments (PMC) to modify certain aspects of the TYVASO Inhalation System, perform a usability analysis and collect pharmacokinetic data to verify expected dosing with the modified device. "We are well underway with the modifications to the TYVASO Inhalation System," said Roger Jeffs, Ph.D., United Therapeutics' President and Chief Operating Officer, "And we think these modifications will make the device more patient-friendly. In the meantime, patients will use the current version of the device." We have committed to complete the PMC no later than October 31, 2010.

Additionally, United Therapeutics has agreed to a Post-Marketing Requirement (PMR) to conduct a long-term observational study to evaluate the risk of oropharyngeal and pulmonary toxicities among patients using TYVASO. "We welcome the opportunity to gather further information on TYVASO's safety," continued Dr. Jeffs. We have committed to complete the PMR no later than December 15, 2013.

In the TRIUMPH-1 randomized, double-blind, 12-week placebo-controlled clinical trial, patients taking TYVASO in four daily inhalation sessions achieved a 20-meter improvement in six-minute walk distance over those taking placebo ($p<0.0005$). The safety and effectiveness in patients with underlying lung disease has not been established. The most common side effects (>= 10%) seen with TYVASO in the placebo controlled clinical study were cough, headache, nausea, dizziness, flushing, throat irritation, pharyngolaryngeal pain and diarrhea.

United Therapeutics plans to launch TYVASO in conjunction with its wholly-owned subsidiary, Lung Rx, Inc., in the United States at the beginning of September 2009.

Conference Call

United Therapeutics will host a half hour teleconference on July 31, 2009, at 9:00 a.m. Eastern Time. The teleconference is accessible by dialing 1-877-852-6576, with international callers dialing 1-719-325-4788. A rebroadcast of the teleconference will be available for one week and can be accessed by dialing 1-888-203-1112, with international callers dialing 1-719-457-0820, and using conference code: 4416949.

This teleconference is also being webcast and can be accessed via United Therapeutics' website at http://ir.unither.com/events.cfm.

About TYVASO

TYVASO is an inhaled medicine used to treat PAH, a life-threatening disease that constricts the flow of blood through the pulmonary vasculature. TYVASO contains the same active ingredient (treprostinil) as REMODULIN (treprostinil sodium) Injection, which is also approved for the treatment of PAH. TYVASO is marketed by United Therapeutics and its wholly-owned subsidiary, Lung Rx, Inc.

Nearly all clinical experience has been on a background of an endothelin receptor antagonist or a phosphodiesterase type 5

inhibitor.

Important Safety Information for TYVASO

TYVASO is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (WHO Group I) in patients with NYHA Class III symptoms, to increase walk distance. TYVASO is intended for oral inhalation only. TYVASO is approved for use only with the TYVASO Inhalation System. The safety and efficacy of TYVASO have not been established in patients with significant underlying lung disease (such as asthma or chronic obstructive pulmonary disease). Patients with acute pulmonary infections should be carefully monitored to detect any worsening of lung disease and any loss of drug effect. In patients with low systemic arterial pressure, TYVASO may cause symptomatic hypotension. TYVASO may also increase the risk of bleeding, particularly in patients receiving anticoagulants. The concomitant use of TYVASO with diuretics, antihypertensives or other vasodilators may increase the risk of systemic hypotension. Hepatic or renal insufficiency may increase exposure and decrease the tolerability of TYVASO. The most common side effects (>= 10%) seen with TYVASO in the placebo controlled clinical study were cough, headache, nausea, dizziness, flushing, throat irritation, pharyngolaryngeal pain and diarrhea. Please see the TYVASO full prescribing information or patient information for further details.

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 cardiovascular and infectious diseases and cancer.

Forward-looking Statements

Statements included in this press release concerning, among others, the benefits of TYVASO for patients, our future activities to improve the TYVASO Inhalation System and its usability, our conducting a post-marketing usability analysis of the modified TYVASO Inhalation System device, the timing of completing the usability analysis, our conducting a post-marketing observational study of TYVASO, the timing of completing the observational study, and our plans to commercialize TYVASO in the United States are "forward-looking statements" within the meaning of the safe harbor contained in the Private Securities Litigation Reform Act of 1995. These 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, which could cause actual results to differ materially from anticipated results. We are providing this information as of July 31, 2009, 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

http://www.unither.com