FDA Approves ADCIRCA(Tadalafil) Tablets for the Treatment of Pulmonary Arterial Hypertension

--Conference Call to be Held at 9:00 a.m. Eastern Time Today, May 26, 2009

SILVER SPRING, Md., May 26, 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 ADCIRCA(TM) (tadalafil) tablets for oral administration, with a recommended dose of 40 mg, as the first once-daily phosphodiesterase type 5 (PDE5) inhibitor for the treatment of pulmonary arterial hypertension (PAH). ADCIRCA is indicated to improve exercise ability in WHO Group I PAH patients, which encompasses patients with multiple forms of PAH including etiologies such as idiopathic and familial PAH as well as PAH associated with scleroderma and congenital heart disease.

"Today, thanks to the clinical development efforts led by Eli Lilly & Company, we are thrilled to make available an effective, convenient and economical therapy for PAH patients," said Martine Rothblatt, Ph.D., United Therapeutics' Chairman and Chief Executive Officer. "The FDA's action in approving once-a-day ADCIRCA is a big plus for all three P's: patients, physicians and payors."

In the PHIRST-1 randomized, double-blind, 16-week placebo-controlled Phase 3 clinical trial of ADCIRCA for PAH, patients taking ADCIRCA 40 mg (administered as two 20 mg tablets) once daily achieved a 33 meter improvement in six-minute walk distance compared to the placebo group. In addition, PHIRST-1 patients taking ADCIRCA 40 mg experienced less clinical worsening (defined as death, lung transplantation, atrial septostomy, hospitalization because of worsening PAH, initiation of new PAH therapy, or worsening WHO functional class) compared to the placebo group. The most common adverse events in the trial were generally transient, mild to moderate in intensity and included headache, muscle pain, flushing, nasopharyngitis, respiratory tract infection, nausea, pain in the arms, legs or back, upset stomach and nasal congestion.

"Our dedicated team at United Therapeutics looks forward to working closely with the PAH community as we prepare to launch ADCIRCA in the United States at the beginning of August this year," said Roger Jeffs, Ph.D., United Therapeutics' President and Chief Operating Officer.

Conference Call

United Therapeutics will host a half-hour teleconference today, May 26, 2009, at 9:00 a.m. Eastern Time. The teleconference is accessible by dialing 877-857-6147, with international callers dialing 719-325-4797. A rebroadcast of the teleconference will be available for one week and can be accessed by dialing 888-203-1112, with international callers dialing 719-457-0820, and using passcode: 2104929.

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

About ADCIRCA

ADCIRCA is a prescription medicine used to treat PAH, a life-threatening disease that constricts the flow of blood through the pulmonary vasculature.

United Therapeutics licensed the rights to develop, market, promote and commercialize ADCIRCA for pulmonary hypertension in the United States and Puerto Rico from Eli Lilly & Company in November 2008. ADCIRCA contains the same active ingredient as CIALIS (tadalafil), which is marketed by Eli Lilly & Company to treat erectile dysfunction (impotence) in more than 100 countries.

Important Safety Information for ADCIRCA

ADCIRCA should not be used in patients taking medicines that contain nitrates (often used for chest pain) as the combination could cause a sudden, unsafe drop in blood pressure. If a patient experiences anginal chest pain after taking ADCIRCA they should seek immediate medical attention. Patients with a known serious hypersensitivity to tadalafil (ADCIRCA or CIALIS) should not take ADCIRCA.

PDE5 inhibitors, including tadalafil, have mild systemic vasodilatory properties that may result in transient decreases in blood pressure. Before prescribing ADCIRCA, physicians should carefully consider whether their patients with underlying cardiovascular disease could be adversely affected by such effects. Pulmonary vasodilators may significantly worsen the cardiovascular status of patients with pulmonary veno-occlusive disease (PVOD) and administration of ADCIRCA to these patients is not recommended. Patients should discuss their medical condition and all medications with their physician before starting ADCIRCA.

The use of ADCIRCA with alpha blockers, blood pressure medications, and alcohol may cause a lowering of blood pressure. Use of ADCIRCA with potent CYP3A inhibitors, such as ketoconazole and itraconazole, should be avoided. For patients on ADCIRCA therapy that require treatment with ritonavir, dosage adjustments are required. Certain populations of PAH patients such as those with mild-to-moderate renal or hepatic impairment or those taking the drug ritonavir should use a dose of 20 mg daily when beginning therapy with ADCIRCA. Use of ADCIRCA with potent inducers of CYP3A, such as rifampin, should be avoided. The safety and efficacy of combinations of ADCIRCA with CIALIS or other PDE5 inhibitors have not been studied. Therefore, the use of such combinations is not recommended.

The most common side effects with ADCIRCA seen in the PHIRST-1 clinical trial were headache, myalgia, nasopharyngitis, flushing, respiratory tract infection, extremity pain, nausea, back pain, dyspepsia and nasal congestion.

In rare instances, patients taking PDE5 inhibitors (including tadalafil) reported a sudden decrease or loss of vision or hearing, or in men, an erection lasting more than four hours. A patient who experiences a decrease or loss in vision or hearing or prolonged erection should seek immediate medical attention.

For full patient information and/or full prescribing information, visit http://www.ADCIRCA.com or call 1-800-545-5979 (1-800-LILLY-RX).

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 the benefits of ADCIRCA for patients, physicians and payors, and United Therapeutics' plans for the product launch for ADCIRCA 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 May 26, 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]

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