Intravenous Remodulin Approved for the Treatment of Pulmonary Arterial Hypertension in Most of the European Union

New Drug Application for Oral Treprostinil Submitted to the FDA

SILVER SPRING, Md. and CHERTSEY, England, Dec. 27, 2011 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) and its wholly-owned subsidiary, United Therapeutics Europe, Ltd., announced today that the French regulatory agency *Agence Francaise de Securite Sanitaire des Produits de Sante* (AFSSAPS) has approved intravenous use of Remodulin® (treprostinil) for the treatment of pulmonary arterial hypertension (PAH). Remodulin is already approved in most of Europe for the continuous subcutaneous infusion treatment of idiopathic or heritable PAH to improve exercise tolerance and symptoms of the disease in patients classified as New York Heart Association (NYHA) functional class III. The AFSSAPS' approval follows a review period during which 22 European member nations, each of which had previously approved subcutaneous Remodulin through the mutual recognition process, reviewed and endorsed the final variation assessment report (FVAR) issued by AFSSAPS, which will allow the use of the intravenous route of delivery to the Remodulin in the labeling in those nations.

"It is with great satisfaction that intravenous use of Remodulin will now be available to PAH patients in Europe," said Roger A. Jeffs, Ph.D., President and Chief Operating Officer. "This approval significantly expands the treatment options for PAH patients using parenteral therapy in Europe."

In Europe, risk management plans (RMPs) are routinely required as part of the regulatory approval process for new medicines and also for significant variations involving a change to the route of administration, formulation or indication. For intravenous Remodulin, United Therapeutics will implement an RMP focused on minimizing the known risks of central venous catheter-related blood stream infections associated with intravenous administration.

Oral Treprostinil New Drug Application Submitted to the FDA

United Therapeutics also announced today that it submitted to the U.S. Food and Drug Administration a New Drug Application (NDA) for treprostinil diethanolamine sustained release tablets (oral treprostinil) for the treatment of PAH on December 27, 2011. The submission starts a 60-day period during which the FDA will examine the application for completeness. If the FDA accepts the NDA for review, then it is expected to be subject to the standard review period of 10 months from the submission date, before an action letter is issued.

About Remodulin (treprostinil) Injection

Indication
Remodulin is a prostacyclin vasodilator indicated in the United States for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%). Remodulin may be administered as a continuous subcutaneous infusion or continuous intravenous infusion; however, because of the risks associated with chronic indwelling central venous catheters, including serious blood stream infections, continuous intravenous infusion should be reserved for patients who are intolerant of the subcutaneous route, or in whom these risks are considered warranted.

In patients with PAH requiring transition from Flolan® (epoprostenol sodium), Remodulin is indicated to diminish the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition.

Important Safety Information
Chronic intravenous infusions of Remodulin are delivered using an indwelling central venous catheter. This route is associated with the risk of blood stream infections, or BSI, and sepsis, which may be fatal. Therefore, continuous subcutaneous infusion is the preferred mode of administration.

Remodulin should be used only by clinicians experienced in the diagnosis and treatment of PAH. Remodulin is a potent pulmonary and systemic vasodilator. It lowers blood pressure, which may be further lowered by other drugs that also reduce blood pressure. Remodulin inhibits platelet aggregation and therefore, may increase the risk of bleeding, particularly in patients on anticoagulants. Remodulin dosage adjustment may be necessary if inhibitors or inducers of CYP2C8 are added or

withdrawn. Initiation of Remodulin must be performed in a setting with adequate personnel and equipment for physiological monitoring and emergency care. Therapy with Remodulin may be used for prolonged periods, and the patient's ability to administer Remodulin and care for an infusion system should be carefully considered.

Remodulin dosage should be increased for lack of improvement in, or worsening of, symptoms and it should be decreased for excessive pharmacologic effects or for unacceptable infusion site symptoms.

Abrupt withdrawal or sudden large reductions in dosage of Remodulin may result in worsening of PAH symptoms and should be avoided. Caution should be used in patients with hepatic or renal insufficiency.

The most common side effects of Remodulin included those related to the method of infusion. For subcutaneous infusion, infusion site pain and infusion site reaction (redness and swelling) occurred in the majority of patients. These symptoms were often severe and could lead to treatment with narcotics or discontinuation of Remodulin. For intravenous infusion, line infections, sepsis, arm swelling, tingling sensations, bruising, and pain were most common. General side effects (> 5% more than placebo) were diarrhea, jaw pain, vasodilatation and edema.

For full prescribing information for Remodulin in the United States, visit http://www.remodulin.com/images/pdf/PI.pdf, or call 1-877-864-8437.

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. [uthr-g]

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, our expectation that Remodulin will be available by intravenous delivery in Europe and that the oral treprostinil NDA will be subject to a standard 10-month review period. These forward-looking statements are subject to certain risks and uncertainties, such as those described in our periodic and other reports filed with the Securities and Exchange Commission, that could cause actual results to differ materially from anticipated results. These risks and uncertainties include, among others, failure to obtain pricing approvals in some or all of the countries that have accepted our label expansion and failure to obtain FDA acceptance of the oral treprostinil NDA, and 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 Litigation Reform Act of 1995 for forward-looking statements. We are providing this information as of December 27, 2011, 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.

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