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United Therapeutics Announces Signing Of Agreement For New Remodulin Delivery System

SILVER SPRING, Md., Dec. 31, 2014 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) announced today the signing of an agreement with DEKA Research & Development Corp. for the development of a potential technology breakthrough in the subcutaneous delivery of Remodulin® (treprostinil) Injection to patients with pulmonary arterial hypertension (PAH) via a pre-filled semi-disposable pump system.

"The new DEKA semi-disposable pump system will advance the convenience and delivery of subcutaneous Remodulin," said Martine Rothblatt, Ph.D., Chairman and Co-CEO of United Therapeutics. "In addition, it may bring the benefits of parenteral prostacyclin therapy to the thousands of PAH patients who are using the current delivery system or for those patients who no longer receive adequate benefit from oral and inhaled treatments."

"We are pleased to advance the state of technology and engineering in subcutaneous drug delivery systems," said Dean Kamen, President of DEKA. "Our mastery of precision fluid dynamics, coupled with drug pre-filled in special modules, has enabled an unparalleled reduction in pump size for the benefit of patients."

United Therapeutics expects to introduce the new subcutaneous Remodulin delivery system in the 2016-2018 timeframe. Financial terms of the agreement were not announced.

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.

About DEKA Research & Development Corp.

Based in Manchester, NH, DEKA is a research and development company of about 500 employees comprised of engineering, manufacturing and quality assurance professionals focused on the development of new technologies that span a diverse set of applications. The company was founded in 1982 by Dean Kamen, an inventor who holds hundreds of U.S. and foreign patents and numerous awards, many of them for innovative medical devices that have expanded the frontiers of healthcare worldwide.

About Remodulin (treprostinil) Injection

Indication

Remodulin is a prostacyclin vasodilator indicated 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%). It 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 for Remodulin

- Chronic intravenous (IV) infusions of Remodulin are delivered using an indwelling central venous catheter. This route is associated with the risk of blood stream infections (BSI) and sepsis, which may be fatal. Therefore, continuous subcutaneous (SC) 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
- Adverse Events: In clinical studies of SC Remodulin infusion, the most common adverse events reported were infusion site pain and infusion site reaction (redness and swelling). These symptoms were often severe and sometimes required treatment with narcotics or discontinuation of Remodulin. The IV infusion of Remodulin has been associated with a risk of blood stream infections, arm swelling, paresthesias, hematoma, and pain. Other common adverse events (≥3% more than placebo) seen with either SC or IV Remodulin were headache, diarrhea, nausea, jaw pain, vasodilatation, and edema

For Full Prescribing Information for Remodulin in the United States, visit http://www.remodulin.com, or call the Customer Service Line at 1-877-UNITHER (1-877-864-8437). [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, statements regarding the convenience and accessibility of DEKA's subcutaneous Remodulin delivery system, timing of the availability of the system, and the system's benefit and impact to current and future patients. 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 December 31, 2014, 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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/united-therapeutics-announces-signing-of-agreement-for-new-remodulin-delivery-system-300014678.html

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