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United Therapeutics Announces Submission Of Pre-Market Approval Application For Implantable Drug Infusion System To Deliver Remodulin

SILVER SPRING, Md., Dec. 24, 2014 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) announced today that Medtronic, Inc. (NYSE: MDT) has submitted a pre-market approval application to the U.S. Food and Drug Administration (FDA) for the use of Medtronic's SynchroMed® II implantable drug infusion system (including a newly developed catheter) for use with United Therapeutics' Remodulin® (treprostinil) Injection delivered intravenously to patients with pulmonary arterial hypertension.

United Therapeutics plans to submit to the FDA a supplement to its New Drug Application for Remodulin in January 2015, in order to amend Remodulin's labeling to support the use of the drug with the SynchroMed II implantable drug infusion system.

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 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 FDA applications relating to the SynchroMed II implantable drug infusion system and the use of Remodulin with the system. 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 24, 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-submission-of-pre-market-approval-application-for-implantable-drug-infusion-system-to-deliver-remodulin-300013933.html

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