Medtronic News

Medtronic Receives FDA Approval for Implantable System for Remodulin® to Treat Patients with Pulmonary Arterial Hypertension

GLOBE NEWSWIRE via COMTEX) --Medtronic SynchroMed(TM) II Pump, Proprietary Catheter Deliver United Therapeutics' Remodulin® (treprostinil) Injection

DUBLIN - July 31, 2018 - Medtronic plc (NYSE:MDT) has received U.S. Food and Drug Administration (FDA) approval for the Implantable System for Remodulin® (ISR) to treat patients with pulmonary arterial hypertension (PAH). Through a first-of-its-kind collaboration, the Medtronic SynchroMed(TM) II drug delivery system and cardiac catheter technologies were leveraged to deliver the PAH medication Remodulin® (treprostinil) Injection developed by United Therapeutics Corporation (NASDAQ:UTHR). United Therapeutics will lead the commercial promotion of the ISR, with Medtronic support.

PAH is a severely debilitating and progressive disease that causes high blood pressure in the pulmonary arteries, ultimately resulting in right-heart failure and premature death. It predominantly affects women, who are typically diagnosed in their late 30s to early 50s.1,2,3

"External infusion pumps have been used to deliver prostacyclins for PAH, but managing the therapy places a significant burden on patients, interferes with their daily activities, and runs a high risk of infections," said David Steinhaus, M.D., general manager of the Heart Failure business, part of the Cardiac and Vascular Group at Medtronic. "This fully implantable drug delivery system was designed to address these serious patient care concerns."

The system is composed of the Company's SynchroMed II implantable drug infusion pump and a newly developed intravascular catheter to deliver Remodulin intravenously to patients who have previously been receiving Remodulin intravenously via an external infusion pump. Medtronic and United Therapeutics pursued parallel regulatory filings for the device and drug, respectively.

FDA approval was based on the DelIVery for PAH trial, a prospective, single-arm, non-randomized, open-label study conducted at 10 sites in the United States. It enrolled 64 patients (60 successfully implanted) and showed the implantable intravascular delivery system effectively delivered treprostinil, with a low rate of catheter-related complications, and a high rate of patient satisfaction.4

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

About Implantable System for Remodulin

The Implantable System for Remodulin is indicated for adult patients with Class I, II and III pulmonary arterial hypertension (PAH) receiving intravenous delivery of Remodulin. Warnings and Precautions include: failure to comply with all instructions can lead to technical errors or improper use of implanted infusion pumps and result in additional surgical procedures, a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose or overdose. During the pivotal clinical trial for the Implantable System for Remodulin, 10 percent of patients experienced pump failures after four years of use. At least 33 percent of these failures occurring after four years of use resulted in the device failing to deliver Remodulin without corresponding error alarm. The remaining percentage of reported malfunctions occurred with a motor stall alarm that was reported by the patient. Patients who cannot tolerate a sudden cessation of Remodulin therapy may not be appropriate candidates for the Implantable System for Remodulin. Patients with hearing loss may not be able to hear pump error alarms

coming from the implanted pump, which may cause delay in therapy if the patient does not hear the alarm and contact the physician in a timely manner. Sources of strong electromagnetic interference (EMI) can affect the operation of a pump. The Implantable System for Remodulin Technical Manual contains contraindications and the complete list of warnings and precautions.

Potential adverse events for the Implantable System for Remodulin include: air embolism; allergic or immune system response; anesthesia-related nausea and vomiting; back pain related to lying on the table; catheter dislocation from the vasculature; catheter occlusion; component failure resulting in loss of therapy or inability to program the pump; damage to components; death; disconnection or breakage; erosion; fibrillation and other arrhythmias; hematoma; hemorrhage and exsanguination; improper injection through the catheter access port; infection or sepsis; injection into pocket or subcutaneous tissue; local or systemic Remodulin toxicity and related side effects; low-grade fever; mild or moderate bruising or ecchymosis; nerve damage; overfilling the reservoir; pulmonary arterial hypertension symptoms-mild exacerbation; pain; pneumothorax and hemothorax; pocket site and incisional pain; poor healing over the pump and catheter incisions; premature end of device service life; programming error; pulmonary embolism or paradoxical embolism; pump inversion or migration; puncture of diaphragm, abdominal organs, or thoracic organs; Remodulin overdose; Remodulin subcutaneous delivery; Remodulin underdose and abrupt cessation; seroma; shoulder pain, discomfort, or stiffness; sleep problems (insomnia); stroke; underdose; venous or arterial dissection or perforation; and venous thrombosis, occlusion, stenosis, insufficiency, or phlebitis.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.>

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

REMODULIN is a registered trademark of United Therapeutics Corporation.

SynchroMed is a registered trademark of Medtronic, Inc.

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1Thenappan T, Shah SJ, Rich S, Gomberg-Maitland M. A USA-based registry for pulmonary arterial hypertension: 1982-2006. Eur Respir J. 2007;30:1103-10

2 Humbert M. Update in pulmonary arterial hypertension. 2007. Am J Respir Crit Care Med. 2008;177:574-9

3 Runo JR, Loyd JE. Primary pulmonary hypertension. Lancet. 2003;361(9368):1533-44.

4 Bourge RC, Waxman AB, Gomberg-Maitland M, et al. Treprostinil administered to treat pulmonary arterial hypertension using a fully implantable programmable intravascular delivery system: Results of the Delivery for PAH trial. Chest. 2016;150(1):27-34.

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Source: Medtronic plc via Globenewswire

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