United Therapeutics And DEKA Announce FDA Clearance Of The Unity Subcutaneous Delivery System For Remodulin®

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RESEARCH TRIANGLE PARK, N.C. and MANCHESTER, N.H., May 7, 2019 /PRNewswire/ -- United Therapeutics Corporation (Nasdaq: UTHR) and DEKA Research & Development Corp. today announced receipt of 510(k) clearance by the U.S. Food and Drug Administration (FDA) for the Unity Subcutaneous Delivery System for Remodulin (treprostinil) Injection, also referred to as the RemUnity™ system.

The RemUnity system, which has been jointly developed by United Therapeutics and DEKA, is indicated for subcutaneous delivery of Remodulin to treat pulmonary arterial hypertension, or PAH. The RemUnity system consists of a small, lightweight, durable pump that is intended to have a service life of at least three years. The RemUnity system uses disposable cartridges, which are connected to the pump.

DEKA intends to submit a Special 510(k) filing to the FDA shortly to enable cartridges to be pre-filled with Remodulin by contracted specialty pharmacy distributors in order to improve convenience for patients. United Therapeutics intends to launch the product when this additional FDA clearance has been obtained. United Therapeutics and DEKA are also developing a version of the system that includes disposable cartridges that are pre-filled as part of the manufacturing process.

"We developed the RemUnity system to address safety and patient convenience problems with current subcutaneous infusion pumps," said Martine Rothblatt, Chairman and Chief Executive Officer of United Therapeutics. "We believe the RemUnity system reduces the risk of bolus dosing due to pump failures and provides wider arrays of notifications, alerts and alarms than current pumps. Most importantly, the acoustic volume sensing technology and solid-state actuator of the RemUnity system enables it to control Remodulin flow rates without the use of a motor."

"We are excited to be launching this innovative delivery technology with United Therapeutics. We are confident that it will substantially improve the lives of patients who depend on UT's unique pharmaceutical advances," said Dean Kamen, Founder and President of DEKA. "We look forward to continuing to deliver advanced solutions for patients in need."

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%).
In patients with PAH requiring transition from epoprostenol, Remodulin is indicated to diminish the rate of clinical deterioration. Consider the risks and benefits of each drug prior to transition.

Important Safety Information for Remodulin

Warnings and Precautions

- Chronic intravenous (IV) infusions of Remodulin delivered with an external infusion pump using an indwelling central venous catheter are 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.
- Avoid abrupt withdrawal or sudden large reductions in dosage of Remodulin, which may result in worsening of PAH symptoms.
- Titrate slowly in patients with hepatic or renal insufficiency because such patients will likely be exposed to greater systemic concentrations relative to patients with normal hepatic or renal function.
- Remodulin is a potent pulmonary and systemic vasodilator. In patients with low systemic arterial pressure, treatment with Remodulin may produce symptomatic hypotension
- Remodulin inhibits platelet aggregation and increases the risk of bleeding.

Adverse Reactions

- Adverse Reactions: 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 with an external infusion pump 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 (27% vs. 23%), diarrhea (25% vs. 16%), nausea (22% vs. 18%), jaw pain (13% vs. 5%), vasodilatation (11% vs. 5%), edema (9% vs. 3%), and hypotension (4% vs. 2%).

Drug Interactions

- Remodulin dosage adjustment may be necessary if inhibitors or inducers of CYP2C8 are added or withdrawn.

Specific Populations

- In patients with mild or moderate hepatic insufficiency, decrease the initial dose of Remodulin to 0.625 ng/kg/min ideal body weight. Remodulin has not been studied in patients with severe hepatic insufficiency.
- Safety and effectiveness of Remodulin in pediatric patients have not been established.
- It is unknown if geriatric patients respond differently than younger patients. Caution should be used when selecting a dose for geriatric patients.
- There are no adequate and well-controlled studies with Remodulin in pregnant women. It is not known whether treprostinil is excreted in human milk.

For additional information, visit http://www.remodulin.com or call the Customer Service Line at 1-877-UNITHER (1-877-864-8437).

About United Therapeutics

United Therapeutics Corporation focuses on the strength of a balanced, value-creating biotechnology model. We are confident in our future thanks to our fundamental attributes, namely our obsession with quality and innovation, the power of our brands, our entrepreneurial culture and our bioinformatics leadership. We also believe that our determination to be responsible citizens – having a positive impact on patients, the environment and society – will sustain our success in the long term.

Through our wholly-owned subsidiary, Lung Biotechnology PBC, we are focused on addressing the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply. Lung Biotechnology is the first public benefit corporation subsidiary of a public biotechnology or pharmaceutical company. [uthr-g]

About DEKA

Based in Manchester, NH, DEKA is a research and development company of more than 600 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.

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 commercialization of the RemUnity system and additional regulatory submissions relating thereto, the ability of our business model to create value, our ability to sustain long-term success, and our organ transplantation research and development programs. 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. 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 May 7, 2019, 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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SOURCE United Therapeutics Corporation; DEKA

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