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**UNITED THERAPEUTICS AND DEKA ANNOUNCE  
ADDITIONAL FDA CLEARANCE RELATED TO THE  
UNITY SUBCUTANEOUS DELIVERY SYSTEM FOR REMODULIN®**

*~ Remunity™ expected to be available for patients by July 2020 ~*

Research Triangle Park, NC and Manchester, NH, February 24, 2020: United Therapeutics Corporation (Nasdaq: UTHR) and DEKA Research & Development Corp. today announced receipt of an additional 510(k) clearance by the U.S. Food and Drug Administration (FDA) related to the Unity Subcutaneous Delivery System for Remodulin® (treprostinil) Injection, also referred to as the Remunity™ pump, enabling United Therapeutics to launch the system using drug reservoirs that have been prefilled by specialty pharmacies.

The Remunity system, which was jointly developed by United Therapeutics and DEKA, is indicated for continuous subcutaneous delivery of Remodulin to treat pulmonary arterial hypertension, or PAH, in adults greater than 22 years of age. The Remunity system includes a small, lightweight, ambulatory pump with an intended service life of three years, which the patient connects to a disposable prefilled cassette.

The system was initially cleared by the FDA in May 2019 with instructions for patient filling. This additional 510(k) clearance enables cassettes to be prefilled with Remodulin by contracted specialty pharmacies in order to improve convenience for patients. United Therapeutics plans to launch the Remunity system by July 2020. United Therapeutics and DEKA are also developing a future version of the system that will include disposable components that are prefilled as part of the manufacturing process.

“We’re super ‘pumped’ about launching Remunity by Independence Day,” said Dr. Martine Rothblatt, Chairman and Chief Executive Officer of United Therapeutics. “Remunity will provide a new level of freedom to our patients through improved convenience, and we believe it will provide more free time to live their beautiful lives. The system provides a wider array of notifications, alerts, and alarms than current pumps. Most amazingly, 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. To me, because of so few moving parts, it is like the Tesla of parenteral pumps!”

“We are excited to be launching this innovative delivery technology with United Therapeutics. We are confident that the Remunity system, particularly with the additional convenience of cassettes prefilled with Remodulin, has the potential to improve the lives of patients who depend on UT’s unique pharmaceutical advances,” said Dean Kamen, Founder and President of DEKA. “We are extremely proud of UT’s dedication to their patients and grateful to UT for their unwavering support of DEKA as we continue to develop and deliver advanced solutions to address the needs of those patients.”

## **About Remunity™ Pump for Remodulin® (treprostinil) Injection**

### **Indication**

The Remunity™ Pump for Remodulin® (treprostinil) Injection is intended for continuous subcutaneous delivery of Remodulin (treprostinil) Injection for use in adults (greater than 22 years of age).

### **Important Safety Information for Remunity**

#### ***Warnings and Precautions***

**Do not use the system outside the conditions listed in the User Guide.** Retain the User Guide for future reference. Refer to the User Guide for all warnings and cautions. Failure to comply with the following warnings and cautions may result in harm.

**Limited to use with Remodulin.** Only Remunity cassettes may be used with the Remunity pump. Remunity pump is for use only with FDA-cleared infusion sets: Medtronic Quick-set Infusion Set (MMT-392, MMT-393), Medtronic Silhouette Infusion Set (MMT-373), and Smiths Medical Cleo 90 Infusion Set (21-7230-24, 21-7220-24).

#### **Prescription Information**

Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner. Use of this device without the training and supervision of a healthcare practitioner may lead to errors that result in harm.

**See the Remunity Pump for Remodulin (treprostinil) Injection Pharmacy-Filled User Guide for further detailed important safety information including warnings, cautions, and instructions on how to properly use the system.**

**For further information, please call United Therapeutics Corp. at 1-877-864-8437.**

The Remunity Pump for Remodulin (treprostinil) Injection is manufactured for United Therapeutics Corp.

**You may report side effects to the FDA at [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch) or call 1-800-FDA-1088.**

## **About Remodulin® (treprostinil) Injection**

### **Indication or What is Remodulin?**

Remodulin is a prescription medication used to treat adults with pulmonary arterial hypertension (PAH; WHO Group 1), which is high blood pressure in the arteries of your lungs. Remodulin can

reduce symptoms associated with exercise. Remodulin was studied mainly in patients with NYHA Functional Class II-IV symptoms. It is not known if Remodulin is safe and effective in children.

In people with PAH who need to switch from epoprostenol, Remodulin is approved to slow the worsening of symptoms.

### **Important Safety Information for Remodulin**

#### **Before you take Remodulin, tell your healthcare provider if you:**

- Have other medical conditions or take other medicines that may affect your use of Remodulin by increasing the risk of side effects or decreasing the drug's effectiveness.
- Have liver or kidney problems. Your Remodulin dose may need to be adjusted if you have liver problems.
- Have low blood pressure or bleeding problems.
- Are taking gemfibrozil (for high cholesterol), rifampin (for infection) or other drugs that affect liver enzymes. Your doctor may need to adjust your Remodulin dosage.
- Are pregnant, breastfeeding, or planning to become pregnant. It is not known if Remodulin will harm your unborn baby or if Remodulin passes into your breast milk.

#### **What are the serious side effects of Remodulin?**

- Continuous intravenous (IV) infusions of Remodulin delivered using an external infusion pump, with a tube placed in a central vein within the chest, are associated with the risk of blood stream infections and sepsis, which may be fatal. Therefore, continuous subcutaneous (SC) infusion delivered just beneath the skin is the preferred type of delivery.
- Worsening of PAH symptoms. Do not stop taking or greatly reduce your Remodulin dose without consulting your doctor.
- Low blood pressure (symptomatic hypotension). If you have low blood pressure or are taking drugs that lower your blood pressure, the risk of low blood pressure is increased.
- Bleeding problems. Remodulin may increase the risk of bleeding in people who take blood thinners (anticoagulants).

#### **What are the possible side effects of Remodulin?**

- In clinical studies of SC infusion of Remodulin, most people experienced infusion site pain and infusion site reaction (redness, swelling, and rash). These symptoms were sometimes severe and sometimes required treatment with narcotics or discontinuation of Remodulin.
- IV infusion of Remodulin delivered through an external pump has been associated with the risk of blood stream infections, arm swelling, tingling sensations, bruising, and pain.

- The most common side effects seen with either SC or IV Remodulin were headache, diarrhea, nausea, rash, jaw pain, widening of the blood vessels (vasodilatation), and swelling from fluid retention (edema). These are not all the possible side effects of Remodulin. Call your doctor for medical advice about side effects.

**You may report side effects to the FDA at [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch) or call 1-800-FDA-1088.**

The risk information provided here is not comprehensive. To learn more about Remodulin, talk with your healthcare provider. Please see Full Prescribing Information at [www.remodulin.com](http://www.remodulin.com) or call Customer Service 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.

### **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 anticipated launch of the Remunity pump by July 4, 2020, the expected benefits to patients, our plan to develop a machine-filled version of the Remunity system, 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 February 24, 2020, 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.

REMODULIN is a registered trademark of United Therapeutics Corporation.

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