United Therapeutics Issues Statement In Response To Meritless Lawsuit

April 18, 2019

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., April 17, 2019 /PRNewswire/ -- United Therapeutics Corporation (Nasdaq: UTHR) was named as a defendant, along with Smiths Medical ASD, Inc., in a lawsuit filed in federal court by Sandoz Inc. and RareGen, LLC on April 16, 2019. The lawsuit alleges that United Therapeutics engaged in anticompetitive conduct in connection with plaintiffs' efforts to launch their generic version of Remodulin® (treprostinil) Injection. United Therapeutics issued the following statement in response to the lawsuit:

"We are disappointed by these meritless claims against us and expect to ultimately prevail. United Therapeutics was founded with the goal of serving patients with pulmonary arterial hypertension (PAH), and that remains our focus today. In 2015, Smiths Medical publicly announced that it was discontinuing the CADD-MS®3 system, which is used by many patients to deliver Remodulin®, a continuously infused form of treprostinil manufactured by United Therapeutics. In response, we made a significant investment under an agreement with Smiths Medical that ensured the CADD-MS®3 system would continue to be available to deliver Remodulin® for a period of time. Absent United Therapeutics taking this action, thousands of very sick PAH patients may not have been able to access necessary therapy. Meanwhile, we doubled-down on our efforts to innovate and develop new and improved systems to deliver this therapy.

This lawsuit stems from Sandoz's and RareGen's failure to take similar steps to ensure availability of a system to deliver their product, despite having eight years from filing Sandoz's Abbreviated New Drug Application (ANDA) to do so. Sandoz and RareGen now seek to make us responsible for their failure to properly plan to serve their prospective patients. We expect the litigation to vindicate our efforts to protect our PAH patients."

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.

Please Full Prescribing Information for Remodulin. 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]

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 our efforts to defend a lawsuit filed by Sandoz and RareGen, and the likelihood that we will prevail in the litigation, 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. All of these factors could have a material impact on how useful the final results will be to healthcare providers, and how they will be viewed by the FDA and other regulators. In addition, the forward-looking statements in this press release 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 April 17, 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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