



United Therapeutics Announces FDA Acceptance Of Trevyent New Drug Application For Review

September 11, 2019

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., Sept. 11, 2019 /PRNewswire/ -- United Therapeutics Corporation (Nasdaq: UTHR) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for Trevyent® (treprostinil) for the treatment of pulmonary arterial hypertension (PAH). The FDA assigned the NDA a Prescription Drug User Fee Act (PDUFA) target action date of April 27, 2020. Trevyent is a post-phase III development-stage drug-device combination product that combines two-day, single use, disposable PatchPump® technology with treprostinil, for the subcutaneous treatment of PAH.

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 the timing and outcome of the FDA review of the Trevyent NDA. 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 September 11, 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.

TREVYENT and PATCHPUMP are registered trademarks of SteadyMed Ltd., a subsidiary of United Therapeutics Corporation.

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