MannKind Opens Enrollment of Phase 1 Trial of Treprostinil Technosphere for Pulmonary Arterial Hypertension

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WESTLAKE VILLAGE, Calif., March 01, 2018 (GLOBE NEWSWIRE) -- **MannKind Corporation**(Nasdaq:MNKD), focused on the development and commercialization of inhaled therapeutic products for patients with diseases such as diabetes and pulmonary arterial hypertension, today announced that it will initiate enrollment of patients in a Phase 1 clinical study of Treprostinil Technosphere (TreT) under an Investigational New Drug (IND) application filed with the Food and Drug Administration (FDA). TreT is proposed as a drug-device combination product for the treatment of patients with pulmonary arterial hypertension (PAH), utilizing a small, portable, breath-powered inhaler that is intended to simplify drug dosing.

“We are excited to initiate enrollment of our Phase 1 clinical study and to extend the potential application of the Technosphere platform for unmet patient needs in a serious chronic disease such as PAH,” said Dr. David Kendall, Chief Medical Officer of MannKind. “We believe this study will allow for rapid evaluation of treprostonil dosing and therapeutic use in pulmonary arterial hypertension. If successful, this Phase 1 study will lead to registration studies in 2019.”

The primary objective of the Phase 1 clinical study is to investigate the safety, tolerability, and pharmacokinetics of TreT in healthy volunteers after dosing by oral inhalation. Secondary endpoints include the evaluation of systemic exposure and pharmacokinetics of TreT, including dose proportionality. For more information about the study, please visit ClinicalTrials.gov.

About Pulmonary Arterial Hypertension

Pulmonary Arterial Hypertension (PAH) is a rare, chronic, progressive, and ultimately fatal disease. It is caused by the hardening and narrowing of the pulmonary arteries, which results in abnormally high blood pressure in these arteries, and leads, with time, to heart failure. The symptoms of PAH include shortness of breath, dizziness and fatigue, which grow more severe as the disease progresses. Patients with PAH have severe restrictions on their exercise capacity, reduced quality of life, and a shorter life expectancy. There is no cure for PAH; currently available treatments manage the symptoms only.

About MannKind Corporation

MannKind Corporation (NASDAQ:MNKD) focuses on the development and commercialization of inhaled therapeutic products for patients with diseases such as diabetes and pulmonary arterial hypertension. MannKind is currently commercializing Afrezza® (insulin human) inhalation powder, the Company's first FDA-approved product and the only inhaled rapid-acting mealtime insulin in the United States, where it is available by prescription from pharmacies nationwide. MannKind is headquartered in Westlake Village, California, and has a state-of-the art manufacturing facility in Danbury, Connecticut. The Company also employs field sales and medical representatives across the U.S. For further information, visit www.mannkindcorp.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties, including statements regarding MannKind's ability to enroll patients in clinical trials. Words such as "believes", "anticipates", "plans", "expects", "intend", "will", "goal", "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon the MannKind's current expectations. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, difficulties in enrolling subjects in clinical trials, the results of clinical trials, the ability to obtain regulatory approvals, and other risks detailed in MannKind's filings with the Securities and Exchange Commission, including the Annual Report on Form 10-K for the year ended December 31, 2017 and subsequent periodic reports on Form 10-Q and current reports on Form 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and MannKind undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this press release.

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