



MannKind Successfully Completes Phase 1 Trial of Treprostinil Technosphere for Pulmonary Arterial Hypertension Advancing Development to Next Phase

June 7, 2018

- **Study achieved primary endpoint of safety and tolerability**
- **Progressive dosing of Treprostinil Technosphere (TreT) significantly exceeded the corresponding peak plasma and exposure levels of the maximum recommended dose of Tyvaso® Inhalation Solution**
- **Achieved a maximum tolerated dose with no serious adverse events reported**

WESTLAKE VILLAGE, Calif., June 07, 2018 (GLOBE NEWSWIRE) -- **MannKind Corporation**(Nasdaq:MNKD) today announced that it has completed a Phase 1 clinical study of Treprostinil Technosphere (TreT) under an Investigational New Drug application filed with the Food and Drug Administration.

The key highlights of this study are:

- Ability to deliver TreT within 1-2 inhalations in <10 seconds
- Maximum tolerated dose is expected to be able to deliver higher plasma concentrations above the reported data for the current commercially available inhaled treprostinil
- Based on these data, MannKind is preparing the next phase of development to evaluate the safety and tolerability of TreT in patients with PAH
- Data will be submitted to be presented at an upcoming conference

"We are pleased to have completed the TreT Phase 1 trial, which met the study's safety, tolerability and pharmacokinetics objectives," stated David Kendall, Chief Medical Officer of MannKind. "We are excited to utilize our existing technology platform and device capabilities to create an easy-to-use and tolerable formulation of treprostinil to help unmet patient needs in a serious chronic disease such as PAH."

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. The regulatory and development pathway is expected to be capital efficient, using existing safety data of the component API to reduce Phase 3 requirements to a pivotal safety and efficacy trial and a pivotal bioequivalency trial. The regulatory submission in the United States is expected to utilize the 505(b)(2) pathway.

"People living with PAH need more convenient and tolerable treprostinil treatment options to help them live a less intrusive lifestyle. I am excited to see that MannKind was safely able to achieve higher plasma levels than reported for the current standard of care using Technosphere-based treprostinil," stated Lewis Rubin, MD, Emeritus Professor of Medicine at the University of California, San Diego School of Medicine.

This was a single site study with 48 healthy, normal subjects enrolled in 8 cohorts of 6 subjects each. The treatments were intended to establish the maximum tolerated dose, starting at 30 mcg. Each subject received one dose of TreT by oral inhalation during the treatment period. A total of 12 pharmacokinetic blood samples were collected from each subject. Plasma pharmacokinetic samples were analyzed for treprostinil.

The primary objective of the Phase 1 clinical study was 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 www.ClinicalTrials.gov.

About Pulmonary Arterial Hypertension

Pulmonary Arterial Hypertension (PAH) is a chronic, progressive disease characterized by abnormally high blood pressure in the pulmonary arteries between the heart and lungs of an affected individual. Over time, this can cause increased strain on the heart, leading to right-heart failure. Symptoms of PAH include shortness of breath, dizziness and fatigue, which grow more severe as the disease progresses. PAH represents Group I within the Pulmonary Hypertension WHO clinical classification system and is one of five such groups.

About MannKind

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

Statements contained in this press release that are not strictly historical in nature are forward-looking statements that involve risks and uncertainties. These statements include, without limitation, statements regarding MannKind's anticipated use of the proceeds from the offering. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon 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 various risks and uncertainties, including, without limitation, the risks detailed in MannKind's filings with the SEC, including its annual report on Form 10-K for the year ended December 31, 2017. 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.

MannKind Contact:

Rose Alinaya

SVP, Investor Relations
818-661-5000
ir@mannkindcorp.com

Primary Logo

Source: MannKind