Mannkind and United Therapeutics Reach a Milestone in the Development of Tyvaso DPI™ With New Drug Application Submitted to the FDA

April 19, 2021

Following Afrezza®, Tyvaso DPI is the second compound formulated with Technosphere® technology to be reviewed by FDA

WESTLAKE VILLAGE, Calif. and DANBURY, Conn., April 19, 2021 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq: MNKD) and United Therapeutics (Nasdaq: UTHR) reached a milestone today in the development of Tyvaso DPI ™ as United Therapeutics submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA).

"The NDA submitted today by United Therapeutics builds upon a drug master file previously submitted by MannKind," said Michael Castagna, CEO of MannKind Corporation. "We are excited to see the second compound formulated with our technology complete a rigorous clinical development program. If approved by the FDA, Tyvaso DPI is expected to provide a major advancement in the delivery of inhaled treprostinil for PAH and PH-ILD patients."

MannKind and United Therapeutics entered into a worldwide exclusive licensing and collaboration agreement in September 2018 for the development and commercialization of Tyvaso DPI, a dry powder formulation of treprostinil, delivered via a small, portable dry powder inhaler. Tyvaso DPI incorporates the dry powder formulation technology and Dreamboat® inhalation device technology used in MannKind's Afrezza ® (insulin human) Inhalation Powder, which was approved by the FDA in 2014.

Tyvaso DPI, if approved, is expected to provide a convenient choice of inhaled administration for patients with pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). There are approximately 45,000 treated PAH patients in the U.S. and United Therapeutics estimates at least 30,000 treatable PH-ILD patients in the U.S.

United Therapeutics has applied a priority review voucher to the NDA that could provide for an FDA decision by December 2021. The FDA must first accept the application for review and issue a formal decision date in accordance with the Prescription Drug User Fee Act.

MannKind and United Therapeutics are also developing BluHale®, a Bluetooth-connected accessory for the Tyvaso DPI inhaler with a companion mobile application intended to help the patient track information about inhaler use.

Tyvaso DPI is an investigational therapy that is not approved for any use in any country or indication and the Tyvaso DPI tradename is pending final FDA review.

About MannKind Corporation

MannKind Corporation (Nasdaq: MNKD) focuses on the development and commercialization of inhaled therapeutic products for patients with endocrine and orphan lung diseases. MannKind is currently commercializing Afrezza® (insulin human) Inhalation Powder, the Company's first FDA-approved product and the only inhaled ultra-rapid-acting mealtime insulin in the United States, where it is available by prescription in Brazil, where it is commercialized by the Company's partner, Biomm SA. MannKind was established in 1991, and is headquartered in Westlake Village, Calif. with a state-of-the-art manufacturing facility based in Danbury, Conn. The Company also employs field sales and medical representatives across the U.S. Please visit mannkindcorp.com to learn more.

Forward-looking Statements

This press release contains forward-looking statements that involve risks and uncertainties, including statements regarding MannKind's expected use of proceeds from the offering. 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 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, uncertainties regarding the regulatory approval process, and other risks detailed in MannKind's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2020 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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