MannKind and United Therapeutics Achieve a Major Milestone in the Development of Tyvaso DPI™ With New Drug Application Acceptance From the FDA

June 16, 2021

- *Tyvaso DPI includes the second compound formulated with MannKind's Technosphere ® technology to be reviewed by the FDA*
- *FDA review expected to be complete in October 2021*
- *Hiring expansion underway at MannKind's manufacturing facility in Connecticut*

DANBURY, Conn., June 16, 2021 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq: MNKD) and United Therapeutics Corporation (Nasdaq: UTHR) reached a major milestone today with the announcement that the U.S. Food and Drug Administration (FDA) accepted for priority review of the New Drug Application (NDA) for Tyvaso DPI™ (inhaled treprostinil) for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). The development marks the second compound formulated with MannKind's Technosphere® technology to be reviewed by the FDA, which is expected to be complete in October 2021. The FDA has also indicated that they have not identified any potential review issues at this time.

A next-generation formulation of treprostinil, 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. 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 patients track information about their inhaler use.

"We are energized by the acceptance of the Tyvaso DPI NDA for priority review," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "MannKind is driven to deliver therapeutics in ways that can help improve patient lives for the better. With this key regulatory step, we are excited to progress the next Technosphere product towards providing thousands of PAH and PH-ILD patients a more convenient method of treprostinil therapy administration."

MannKind and United Therapeutics entered into a worldwide exclusive licensing and collaboration agreement in September 2018 for the development and commercialization of Tyvaso DPI. In its communications with United Therapeutics, the FDA indicated that approval of the NDA will be subject to an inspection of the Tyvaso DPI manufacturing facility operated by MannKind; FDA and MannKind have jointly targeted the third quarter of 2021 to complete the inspection.

The NDA includes data from the *BREEZE* clinical study that demonstrated safety and tolerability of Tyvaso DPI in patients with PAH transitioning from Tyvaso® (treprostinil) Inhalation Solution. A separate study in healthy volunteers demonstrated comparable treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution.

MannKind is entering an expansion phase as it prepares to transition from producing clinical supply to building pre-launch inventory of Tyvaso DPI, pending FDA approval. The company's manufacturing and R&D facility in Danbury is scaling up by hiring more than 100 positions, as well as readying essential equipment and production lines. A variety of MannKind jobs in commercial manufacturing, engineering, quality control, warehouse operations, maintenance, and more are currently open and planned to be filled this year. Positions include both non-exempt and exempt positions.

"It's exciting to bring growth and expansion to Danbury and the surrounding communities as MannKind continues to build upon its Technosphere® technology," said Joe Kocinsky, MS, MBA, Chief Technology Officer of MannKind Corporation. "Our site will practically double in size as we spend the next months preparing for Tyvaso DPI, pending FDA approval."

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 from pharmacies nationwide. Afrezza is also 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 manufacturing and R&D 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, the level of preparedness for an inspection by a regulatory agency, challenges encountered during the scale up of manufacturing operations, 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.

AFREZZA, BLUHALE, TECHNOSPHERE and DREAMBOAT are registered trademarks of MannKind Corporation.

CONTACTS:

For MannKind:
Christie Iacangelo, Corporate Communications
(818) 292-3500
Email: media@mannkindcorp.com

Rose Alinaya, Investor Relations
(818) 661-5000
Email: ir@mannkindcorp.com

For United Therapeutics:
Dewey Steadman, Investor Relations
(202) 919-4097
Email: ir@unither.com

Source: MannKind