Progress Update on Tyvaso DPI™ New Drug Application

10/18/21

- *Complete response received by United Therapeutics cites an open inspection issue at a third-party analytical testing center; no other deficiencies cited*
- *No issues identified regarding operations performed at MannKind's manufacturing facility in Connecticut*

WESTLAKE VILLAGE, Calif. and DANBURY, Conn., Oct. 18, 2021 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)**, a company focused on the development and commercialization of inhaled therapeutic products for patients with endocrine and orphan lung diseases, has learned that the U.S. Food and Drug Administration (FDA) issued a complete response to United Therapeutics Corporation regarding the New Drug Application (NDA) for Tyvaso DPI™ for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). The FDA declined to approve the NDA at this time, noting only one deficiency related to an open inspection issue at a third-party analytical testing center for treprostinil drug substance, the active ingredient of Tyvaso DPI. The complete response did not pertain to MannKind, and no issues were cited by the FDA as it relates to MannKind's facility in Connecticut for manufacturing, testing and packaging of finished Tyvaso DPI, including its associated device.

"We continue to build pre-launch inventory of Tyvaso DPI and look forward to supporting United Therapeutics' efforts in securing approval of Tyvaso DPI in the coming months," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation.

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 United Therapeutics' plan to resubmit the Tyvaso DPI NDA and the ultimate approval of Tyvaso DPI. Words such as "plans," "expects," "intend," "will," "targeted," "potential," "believe" 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, which include, without limitation, risks and uncertainties regarding the regulatory approval process. These and other risks are detailed in MannKind's filings with the SEC, including under the heading "Risk Factors" in MannKind's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, filed with the SEC on August 11, 2021. 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.

TYVASO DPI is a registered trademark of United Therapeutics Corporation.

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