



Update on Tyvaso DPI™ New Drug Application

02/24/22

WESTLAKE VILLAGE, Calif. and DANBURY, Conn., Feb. 24, 2022 (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, was informed that the U.S. Food and Drug Administration (FDA) issued an information request to United Therapeutics Corporation earlier this month regarding the New Drug Application (NDA) for Tyvaso DPI, requesting additional information regarding the pulmonary safety of Tyvaso DPI related to a pending Citizen Petition. United Therapeutics promptly responded to the agency's request. MannKind has now learned that the FDA considers the response to be a major amendment to the NDA, thereby extending to May 2022 the FDA's deadline to complete its review of the pending NDA.

MannKind will host a conference call to discuss its 2021 financial results and corporate updates at 5:00 p.m. (Eastern Time) on Thursday, February 24, 2022. Those interested in listening to the conference call live via the internet may do so by visiting the Investors page of the Company's website at mannkindcorp.com under [Events & Presentations](#). A replay will also be available on MannKind's website for 14 days.

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 located in Danbury, Conn., and Westlake Village, Calif. 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 the timing for FDA action regarding 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 September 30, 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 an investigational combination product that is not approved for any use in any country. The Tyvaso DPI tradename is pending final FDA review.

TYVASO DPI is a trademark of United Therapeutics Corporation.

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