MannKind Announces First Patient Enrolled in INHALE-1 Study of Afrezza® in Pediatric Population

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Multi-center study to assess the efficacy and safety of Afrezza in patients aged 4-17 living with type 1 or type 2 diabetes

WESTLAKE VILLAGE, Calif., Oct. 04, 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, announced today the enrollment of the first pediatric patient in the INHALE-1 study. The multi-center study will evaluate the efficacy and safety of Afrezza® (Technosphere Insulin) in combination with basal insulin vs. multiple daily injections of insulin in children and adolescents aged 4-17 who are living with type 1 or type 2 diabetes.

"We are pleased to announce enrollment has begun for the INHALE-1 Phase 3 study, which is designed to assess the safety and efficacy of Afrezza in young people living with type 1 or type 2 diabetes," said Dr. Kevin Kaiserman, Vice President, Medical Affairs and Safety of MannKind Corporation. "MannKind is pleased to sponsor this study with the goal of bringing Afrezza to a younger generation."

INHALE-1 is a 26-week open-label, randomized clinical trial with a 26-week extension. The primary endpoint is change in HbA1c level after 26 weeks. Secondary endpoints include change in fasting plasma glucose after 26 weeks and rate of hypoglycemic events.

Enrollment is underway at several sites, including AM Diabetes & Endocrinology Center in Bartlett, Tenn., where the first patient was enrolled. In all, approximately 260 patients are planned to be enrolled at more than 30 sites across the United States. Details of the study and sites can be found at: https://clinicaltrials.gov/ct2/show/NCT04974528.

"We are glad to see the INHALE-1 study start enrolling pediatric patients and look forward to its expansion to more youth across the country," said Dr. Michael J. Haller, Professor and Chief of Pediatric Endocrinology at the University of Florida and Chair for the INHALE-1 study. "Being involved with studies that can impact a large population of people living with T1D/T2D is so valuable, and I'm looking forward to seeing the data as MannKind continues to explore the potential of Afrezza for youth."

For more information about INHALE-1, please visit go.afrezza.com/INHALE1 or email inhale1@mannkindcorp.com.

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.

AFREZZA is a registered trademark of MannKind Corporation.

Forward looking statements

This press release contains forward-looking statements that involve risks and uncertainties. Words such as "plans," "expects," "intend," "goal," "will," "targeted," "potential" and similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements regarding the enrollment plans for the INHALE-1 study and the potential for Afrezza to be proven safe and effective in a pediatric population. 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 the risk that continued testing of Afrezza may not yield successful results. This and other risks are detailed in MannKind's filings with the Securities and Exchange Commission ("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 report. 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 report.

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