MannKind Announces Enrollment Goal Completion of INHALE-1 Pediatric Diabetes Trial Utilizing Afrezza®

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- *Reached enrollment goal of 305 patients living with Type 1 or Type 2 diabetes*
- *Primary endpoint analysis expected in 4Q 2024*
- *Data dissemination and FDA submission expected in 2025*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Feb. 15, 2024 (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 that it has fully enrolled 305 patients living with type 1 or type 2 diabetes in its INHALE-1 study assessing efficacy and safety of inhaled insulin in the pediatric population.

As reported by pediatric study investigator Lori Laffel, MD, MPH, “There remains a need for innovative insulin preparations to help manage glucose levels at mealtimes in children and adolescents living with diabetes.” Dr. Laffel is Chief of the Pediatric, Adolescent and Young Adult Section at Joslin Diabetes Center and Professor of Pediatrics at Harvard Medical School. Dr. Laffel goes on to note that “It is especially important that young people have as many treatment options as their adult counterparts with diabetes, and this trial has the potential to expand the treatment choices for children and adolescents living with diabetes.”

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. The multi-center study evaluated Afrezza in combination with basal insulin vs. multiple daily injections (MDI) of insulin in children and adolescents aged 4-17 who are living with type 1 or type 2 diabetes.

“We are excited to reach this milestone in exploring the potential of Afrezza for a younger generation living with diabetes,” said Dr. Kevin Kaiserman, Senior Vice President, Clinical Development and Medical Affairs for MannKind Corporation. “We expect to complete a primary endpoint analysis in the fourth quarter.”

More information on the study details is available at: https://www.clinicaltrials.gov/study/NCT04974528

About MannKind
MannKind Corporation (Nasdaq: MNKD) focuses on the development and commercialization of innovative therapeutic products and devices to address serious unmet medical needs for those living with endocrine and orphan lung diseases.

We are committed to using our formulation capabilities and device engineering prowess to lessen the burden of diseases such as diabetes, pulmonary arterial hypertension (PAH) and nontuberculous mycobacterial (NTM) lung disease. Our signature technologies – dry-powder formulations and inhalation devices – offer rapid and convenient delivery of medicines to the deep lung where they can exert an effect locally or enter the systemic circulation.

With a passionate team of Mannitarians collaborating nationwide, we are on a mission to give people control of their health and the freedom to live life.

Please visit mannkindcorp.com to learn more, and follow us on LinkedIn, Facebook, Twitter or Instagram.

Forward-Looking Statements
Statements in this press release that are not statements of historical fact are forward-looking statements that involve risks and uncertainties. These statements include, without limitation, statements regarding the completion of randomization and the read-out of an ongoing clinical study as well as a potential regulatory submission. Words such as “believes”, “anticipates”, “plans”, “expects”, “intends”, “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 various risks and uncertainties, which include, without limitation, the risk that we may not achieve our projected development goals in the timeframes we expect, as well as 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, 2022, 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.

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