MannKind Announces First Patient Enrolled in INHALE-1ST Pediatric Study Evaluating Afrezza® for Youth with Newly-Diagnosed Type 1 Diabetes (T1D)

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Study to assess safety, efficacy and treatment experience of starting inhaled insulin in youth aged 10 to <18 years recently diagnosed with T1D

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Feb. 09, 2026 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)**, a biopharmaceutical company dedicated to transforming chronic disease care through innovative, patient-centric solutions for cardiometabolic and orphan lung diseases, today announced that the first patient has been enrolled in INHALE-1ST, a clinical study evaluating the initiation of Afrezza® (insulin human) Inhalation Powder shortly after a type 1 diabetes diagnosis in pediatric patients.

“We are excited to kick off the INHALE-1 ST study and begin enrolling patients,” said Roy W. Beck, M.D., Ph.D., Medical Director of the Jaeb Center for Health Research, which is leading the study. “Having lived through one of my children developing type 1 diabetes, I know first-hand how overwhelming it is to find out that your child has been diagnosed with diabetes and has to start giving injections of insulin multiple times a day. The study will help evaluate whether replacing most of the injections with inhalations of insulin may lessen that burden for children and their families as they adjust to managing a lifelong disease.”

INHALE-1ST is designed to assess the safety and efficacy of Afrezza used in combination with subcutaneously injected basal insulin once-daily in youth aged 10 to <18 years newly diagnosed with type 1 diabetes. The study will examine clinical outcomes as well as participant and caregiver satisfaction with use of Afrezza for management of mealtime glucose early in the course of treatment.

The first patient was enrolled at the Barbara Davis Center for Diabetes in Aurora, Colorado, one of about 10 clinical sites participating in the study of approximately 100 patients across the United States.

“Many of the innovations that transformed diabetes care—such as continuous glucose monitors (CGMs) and insulin pumps—proved their full value and impact once they became available to pediatric patients,” said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. “With nearly a decade of safety and real-world adult experience behind Afrezza, INHALE-1ST gives us an important opportunity to assess use earlier in the treatment journey for youth at the time of diagnosis so patients can potentially improve management of their mealtime glucose.”

The single-arm, multi-center, clinical study will follow participants for 13 weeks during the main phase followed by an optional Extension Phase for participants continuing to use Afrezza in combination with basal insulin for up to 26 weeks. The primary endpoint is the percentage of participants with a Continuous Glucose Meter (CGM)-who measured time in range (TIR) 70-180 mg/dL ≥70% during 14 days prior to the 13-week visit. More information on the INHALE-1ST study is available at: ClinicalTrials.gov (NCT07224321).

Afrezza Pediatric Indication: FDA Review in Progress

In October 2025, the FDA accepted for review a supplemental Biologics License Application (sBLA) for Afrezza® Inhalation Powder in children and adolescents living with type 1 or type 2 diabetes, with a PDUFA target action date of May 29, 2026. If approved, it would be the first needle-free insulin option for pediatric patients in 100+ years of insulin therapy.

INDICATION AND IMPORTANT SAFETY INFORMATION WITH WARNINGS

Afrezza (insulin human) Inhalation Powder is a rapid-acting inhaled human insulin indicated to improve glycemic control in adults with diabetes mellitus.

Limitations of Use: Not recommended for the treatment of diabetic ketoacidosis or in patients that smoke or have recently stopped smoking.

WARNING: RISK OF ACUTE BRONCHOSPASM IN PATIENTS WITH CHRONIC LUNG DISEASE

- Acute bronchospasm has been observed in Afrezza-treated patients with asthma and chronic obstructive pulmonary disease (COPD)
- Afrezza is contraindicated in patients with chronic lung disease such as asthma or COPD
- Before initiating Afrezza, perform a detailed medical history, physical examination, and spirometry (FEV_1) to identify potential lung disease in all patients.

Most common adverse reactions are hypoglycemia, cough, and throat pain or irritation.

Please see additional Important Safety Information, Full Prescribing Information, including BOXED WARNING, available on Afrezza.com/safety.

About MannKind
MannKind Corporation (Nasdaq: MNKD) is a biopharmaceutical company dedicated to transforming chronic disease care through innovative, patient-centric solutions. Focused on cardiometabolic and orphan lung diseases, we develop and commercialize treatments that address serious unmet medical needs, including diabetes, pulmonary hypertension, and fluid overload in heart failure and chronic kidney disease.

With deep expertise in drug-device combinations, MannKind aims to deliver therapies designed to fit seamlessly into daily life.

Learn more at mannkindcorp.com.

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 potential for inhaled insulin to lessen the burden of adjusting to a chronic disease. 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 continued testing of a drug may not yield successful results or results that are consistent with earlier testing, 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, 2024 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.

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