MannKind Announces U.S. FDA Accepts for Review its Supplemental Biologics License Application (sBLA) for Inhaled Insulin (Afrezza) in Children and Adolescents Aged 4-17 Years Living with Diabetes

10/13/25

- ***If approved, it would be the first needle-free insulin option for pediatric patients in 100+ years of insulin therapy***
- *sBLA submission based on data from the Phase 3 INHALE-1 study*
- *PDUFA target action date of May 29, 2026*

WESTLAKE VILLAGE, Calif. and DANBURY, Conn., Oct. 13, 2025 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** today announced that the U.S. Food and Drug Administration (FDA) has accepted the supplemental biologics license application (sBLA) seeking approval for Afrezza (insulin human) Inhalation Powder in children and adolescents living with type 1 or type 2 diabetes. The application has been assigned a Prescription Drug User Fee Act (PDUFA) target action date of May 29, 2026.

"Today's milestone brings us one step closer to offering young children and teenagers living with diabetes a potential alternative therapy to multiple daily injections or an insulin pump system," said Dr. Kevin Kaiserman, M.D., Senior Vice President, Therapeutic Area Head, Endocrine Diseases at MannKind Corporation. "Inhaled insulin has been available to adults for over a decade, and we are excited about the potential of adding this treatment choice for the pediatric population."

The sBLA is based on results from the Phase 3 INHALE-1 study in children and adolescents between the ages of 4-17 who are living with either type 1 or type 2 diabetes. The 26-week open-label, randomized clinical trial evaluated Afrezza in combination with basal insulin vs. multiple daily injections (MDI) with basal insulin. Six-month topline results from INHALE-1 were reported in December 2024. The submission also included safety data from the study's 26-week extension phase in which all remaining MDI patients switched to Afrezza. Full results will be shared at the International Society for Pediatric and Adolescent Diabetes (ISPAD) in early November.

Afrezza was first approved by the FDA for adults (age 18+) in June 2014 and is also approved in India and Brazil. It is recognized as part of the American Diabetes Association's Standards of Care.

About Afrezza
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.

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

- Acute bronchospasm has been observed in Afrezza-treated patients with asthma and 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
This press release contains forward-looking statements that involve risks and uncertainties, such as statements about a potential regulatory action date, the planned presentation of scientific data and the potential expanded patient population of Afrezza. 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 issues that develop in the review by the FDA may subject us to unanticipated delays or prevent us from obtaining the expanded indication as well as other risks detailed in MannKind’s filings with the Securities and Exchange Commission, including under the “Risk Factors” heading of 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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