



MannKind to Present New Data From Pediatric and Adult Studies of Afrezza® at ATTD 2026

03/09/26

- *Presentations highlight real-world dosing and titration patterns in youth, and post-prandial glucose management strategies using inhaled insulin in both adults and youth with T1D*
- *Data to be featured across oral and poster sessions at the Advanced Technologies & Treatments for Diabetes Conference (ATTD)*
- *PDUFA target action date for Afrezza in children and adolescents living with type 1 or type 2 diabetes set for May 29, 2026*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., March 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 new clinical and real-world data related to Afrezza® (insulin human) Inhalation Powder will be presented at the 19th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2026), taking place March 11–14, 2026, in Barcelona, Spain.

"We look forward to presenting important new data for Afrezza at this year's ATTD and contributing to the scientific dialogue around meal-time diabetes management across both adult and pediatric populations," said Kevin Kaiserman, MD, Senior Vice President, Therapeutic Area Head, Diabetes for MannKind Corporation. "ATTD is a key forum for advancing how clinicians think about insulin use at meals, and we value the opportunity to engage with the global diabetes community on this important topic."

The data will include two oral presentations, one comparing the efficacy of Afrezza for post-prandial glucose control across several different clinical studies, and the second one highlighting data from the INHALE-1 study of Afrezza in pediatric patients with type 1 or type 2 diabetes. A poster will also be presented at the meeting highlighting dosing and titration patterns of inhaled insulin from the INHALE1 study of Afrezza in children and adolescents, where patients were initiated at an approximately 2:1 conversion from rapid-acting insulin analogs (RAA) in children and adolescents. Together, these presentations reflect MannKind's continued commitment to advancing the understanding of how inhaled insulin can be used to support individualized diabetes management across patient populations.

"The INHALE -1 study was designed to better characterize how inhaled insulin is initiated, used and adjusted over time in pediatric patients with diabetes," said Roy Beck, MD, PhD, Medical Director of the Jaeb Center for Health Research. "By examining the clinical study data, we can gain additional insights that help set practical expectations for clinicians and support thoughtful discussions at ATTD about real-world considerations in pediatric diabetes care."

The following data will be presented at ATTD 2026:

Inhaled Insulin Dosing & Post Prandial Glucose Excursions Across Multiple Studies

Thursday, March 12, 2026 – 5:10pm CET in Hall 212

Presenter: Kevin Kaiserman, MD

Refining Care of Type 1 Diabetes: Inhaled Insulin Use in Pediatrics – INHALE-1 Study

Saturday, March 14, 2026 - 10:30am CET in Hall 114

Presenter: Roy Beck, MD, PhD

Inhaled Technosphere Insulin Dosing in Youth with T1D

ePoster available via gallery on UNLOK, the mobile app, or at any of the ePoster stations

Afrezza Pediatric Indication: FDA Review in Progress

In October 2025, the FDA [accepted](#) for review a supplemental Biologics License Application (sBLA) for Afrezza in children and adolescents between the ages of 4-17 who are 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.

About Afrezza

Afrezza® (pronounced uh-frezz-uh) Inhalation Powder is the only ultra rapid-acting inhaled insulin approved by the U.S. Food and Drug Administration to improve glycemic control in adult patients with diabetes mellitus. Administered at the beginning of meals using a small, portable inhaler, Afrezza delivers insulin via MannKind's proprietary Technosphere® technology, enabling ultra-rapid absorption through the lungs. Afrezza has a fast onset of action and a short duration, more closely mirroring the body's natural insulin response to meals.

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 (FEV₁) to identify potential lung disease in all patients.

Afrezza is contraindicated: during episodes of hypoglycemia, in patients with chronic lung disease (such as asthma or COPD) because of the risk of acute bronchospasm, and in patients with previous severe hypersensitivity reaction to regular human insulin product or any of the inactive ingredients in Afrezza. Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with Afrezza.

In a study of patients with asthma whose bronchodilators were temporarily withheld for assessment, bronchoconstriction and wheezing following Afrezza dosing was reported. Before initiating therapy, evaluate all patients with a medical history, physical examination, and spirometry (FEV₁) to identify potential underlying lung disease. Do not use in patients with chronic lung disease such as asthma or COPD.

Changes in an insulin regimen (e.g., insulin strength, manufacturer, injection site or type, or method of administration) may affect glycemic control and predispose to hypoglycemia or hyperglycemia. If clinically indicated, make any necessary changes to a patient's insulin regimen under close medical supervision with increased frequency of blood glucose monitoring. For patients with type 2 diabetes, dosage modifications of concomitant oral antidiabetic treatment may be needed.

Hypoglycemia is the most common adverse reaction associated with insulins, including Afrezza. Severe hypoglycemia can cause seizures, may be life-threatening, or cause death. Hypoglycemia can impair concentration ability and reaction time; this may place an individual and others at risk in situations where these abilities are important (e.g., driving or operating other machinery). Hypoglycemia can happen suddenly, and symptoms may differ across patients and change over time in the same patient. Advise patients to recognize and manage hypoglycemia and self-monitor glucose. In patients at higher risk for hypoglycemia and patients who have reduced symptomatic awareness of hypoglycemia, increased frequency of glucose monitoring is recommended.

Afrezza causes a decline in lung pulmonary function over time as measured by FEV₁. In clinical trials excluding patients with chronic lung disease and lasting up to 2 years, Afrezza-treated patients experienced a small (40 mL) but greater FEV₁ decline than comparator-treated patients. Assess pulmonary function with spirometry at baseline, after the first 6 months of therapy and annually thereafter even in the absence of pulmonary symptoms. In patients who have a decline of $\geq 20\%$ in FEV₁ from baseline, consider discontinuing Afrezza. Consider more frequent lung function assessment in patients with pulmonary symptoms, e.g., wheezing, bronchospasm, breathing difficulties, or persistent or recurring cough. If symptoms persist, discontinue Afrezza.

In clinical trials, 2 cases of lung cancer were observed in patients exposed to Afrezza while no cases were reported for the comparators. In both cases, a prior history of heavy tobacco use was identified as a risk factor for lung cancer. Two additional cases of lung cancer (squamous cell and lung blastoma) were reported in non-smokers exposed to Afrezza after the trial completion. These data are insufficient to determine whether Afrezza has an effect on lung or respiratory tract tumors. In patients with active lung cancer, a prior history of lung cancer, or in patients at risk of lung cancer, consider whether the benefits of Afrezza use outweigh this potential risk.

In clinical trials enrolling patients with type 1 diabetes, diabetic ketoacidosis (DKA) was more common in Afrezza-treated patients (0.43%; n=13) than in comparator-treated patients (0.14%; n=3). Patients with type 1 diabetes should always use Afrezza concomitantly with basal insulin. In patients at risk for DKA, such as those with an acute illness or infection, increase the frequency of glucose monitoring and consider discontinuing Afrezza and giving insulin using an alternate route of administration.

Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products. If hypersensitivity reactions occur, discontinue Afrezza, treat per standard of care and monitor until symptoms and signs resolve.

All insulin products, including Afrezza, cause a shift in potassium from the extracellular to intracellular space, possibly leading to hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Closely monitor potassium levels in patients at risk of hypokalemia and treat if indicated.

Thiazolidinediones (TZDs), which are peroxisome proliferator-activated receptor (PPAR)-gamma agonists, can cause dose-related fluid retention, particularly when used in combination with insulin. Fluid retention may lead to or exacerbate heart failure. Observe these patients for signs and symptoms of heart failure. If heart failure develops, it should be managed according to current standards of care, and discontinuation or dose reduction of the TZD should be considered.

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](https://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 anticipated presentation of new clinical data regarding inhaled insulin and the potential timing of regulatory action. 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 and approval by a regulatory agency may subject us to unanticipated delays, 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, 2025 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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The logo for MannKind, featuring the word "mannkind" in a bold, lowercase, sans-serif font. The "m" and "n" are a darker shade of purple, while the "a", "k", "i", "n", "d" are a lighter shade of purple.

Source: MannKind