MannKind to Showcase New Data at ADA 2026 Advancing Understanding of Inhaled Insulin (Afrezza®) in Pediatric Care, Pregnancy and Use with Automated Insulin Delivery (AID) Systems

05/27/26

- *New analyses examine Afrezza across pediatric A1c and efficacy, patient treatment satisfaction, use with AID algorithms and investigator-led research in pregnancy*
- *Late-breaking comparative data vs. rapid-acting insulin analogs to be presented June 7*
- *Nine posters showcase new clinical and real-world insights across dosing approaches, glycemic control, and patient-reported experience*
- *PDUFA target action date for Afrezza in children and adolescents living with diabetes set for May 29, 2026*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., May 27, 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 along with analyses of FUROSCIX® (furosemide injection) in patients with co-morbidities will be presented at the American Diabetes Association's (ADA) 2026 Scientific Sessions, taking place June 5-8, 2026, in New Orleans, Louisiana.

"As we approach the upcoming FDA target action date of Afrezza for pediatric patients, these new data further strengthen our understanding of inhaled insulin across a range of patient populations and clinical settings," said Dr. Ajay Ahuja, Chief Medical Officer for MannKind Corporation. "We are encouraged by the positive findings in both adult and pediatric populations, which reflect our ongoing commitment to advance meaningful real-world insights that can help individualize diabetes management, consistent with ADA guidelines."

Key highlights include:

- **Pediatric Efficacy & A1c:** Subgroup analysis from the INHALE-1 study examining inhaled insulin versus rapid-acting analogs (RAA) in children and adolescents with diabetes and baseline HbA1c ≤9.5%, including 26-week A1c changes in CGM metrics.
- **Youth Treatment Satisfaction:** Post hoc analysis from the INHALE-1 study evaluating patient-reported treatment satisfaction among children and adolescents with diabetes who achieved HbA1c <8% at 26 weeks, comparing inhaled insulin and RAA using a validated teen and parent survey.
- **AID Algorithm and Inhaled Insulin Use:** Exploratory analysis of inhaled insulin used alongside automated insulin delivery (AID) systems, evaluating how different algorithms may affect glycemic outcomes when inhaled insulin is used for prandial and correction dosing
- **Inhaled Insulin in Gestational Diabetes:** Randomized crossover study evaluating inhaled insulin compared with rapid-acting insulin analogs in individuals with gestational diabetes during controlled meal conditions. The analysis examines postprandial glucose responses and hypoglycemia outcomes in this patient population.

Additionally, MannKind will host booth #909 in the Exhibit Hall, showcasing the latest on inhaled insulin, including a virtual reality (VR) immersion experience that transports you through the lungs to experience mealtime insulin like never before.

Nine poster presentations at ADA 2026 include:

Saturday, June 6, 2026 – 12:30pm CT in Poster Hall (Halls D-E)

Exploratory Evaluation of Technosphere Insulin with Automated Insulin Delivery: Impact of Total Daily Dose Algorithms
Presenter: Joanne K Rinker, MS; MannKind

Efficacy and Safety of Inhaled Technosphere Insulin (TI) vs. Rapid-Acting Analog in Youth with HbA1c ≤9.5%: Subgroup Analysis from INHALE-1
Presenter: Kevin Kaiserman, MD; MannKind

Inhaled Insulin Assessment of Incident Lung Cancer Risk among Adults with Type 2 Diabetes (T2D) Compared with Other Therapies for Diabetes Using Real-World Evidence
Presenter: Kevin Kaiserman, MD; MannKind

Participants Achieving HbA1c <8% in Youth Report Greater Treatment Satisfaction with Inhaled Technosphere Insulin vs. Rapid-Acting Analogs
Presenter: Joanne K Rinker, MS; MannKind

Inhaled Insulin Demonstrates Lower Variability and Faster Onset Compared with Subcutaneous Rapid-Acting Analogs
Presenter: Jennifer Nguyen, PharmD; MannKind

Sunday, June 7, 2026 – 12:30pm CT in Poster Hall (Halls D-E)

Inhaled Insulin Demonstrates Earlier Completion of Total Pharmacodynamic Effect Compared with Lispro
Presenter: Kevin Kaiserman, MD; MannKind

Impact of the Inflation Reduction Act on Afrezza Access: A Retrospective Review of TRx Distribution from Baseline Q4 2022 to Q1 2024
Presenter: Jennifer Nguyen, PharmD; MannKind

Inhaled Technosphere Insulin (TI) Compared with Rapid-Acting Analog Insulin (RAA) in Gestational Diabetes (GDM)
Presenter: Amy Valent, DO; Oregon Health & Science University

Monday, June 8, 2026 – 12:30pm CT in Poster Hall (Halls D-E)

Subcutaneous (SC) Furosemide (FUR) Use for Fluid Overload in Persons Living with Diabetes Mellitus
Presenter: Ajay Ahuja, MD; MannKind

Afrezza Pediatric Indication: FDA Review in Progress, Not Yet Approved
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.

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® (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 (FEV_1) 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 (FEV_1) 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 FEV_1. 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 FEV_1 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 ≥20% in FEV_1 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.

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 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, the risk that continued testing of our products may not yield successful results 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.

MannKind Contacts:

Media Relations:
Christie Iacangelo
(818) 292-3500
media@mnkd.com

Investor Relations:
Kate Miranda
(617) 921-5461
ir@mnkd.com

Source: MannKind