MannKind Announces FDA Approval of Afrezza®, the First and Only Inhaled Mealtime Insulin for Use in Children and Adolescents Aged 6 and Older Living with Diabetes

05/29/26

- *Enables dosing at the start of a meal, offering flexibility for children and adolescents as they manage school, sports, meals, and snacks throughout the day*
- *Approval advances pediatric diabetes care by introducing a new inhaled mealtime insulin option recognized in the American Diabetes Association (ADA) Standards of Care alongside multiple daily injections (MDI) and insulin pumps*
- *Approval is supported by results from the Phase 3 INHALE-1 study in pediatric patients, along with clinical efficacy and safety evidence generated across thousands of patients over the past 20+ years of Technosphere® inhaled insulin development*
- *Eligible patients can access Afrezza today for $35 or less per month, with dedicated support through MannKind Cares*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., May 29, 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 U.S. Food and Drug Administration (FDA) has approved Afrezza® (insulin human) Inhalation Powder for use in children and adolescents aged 6 and older living with type 1 and type 2 diabetes.

In the United States, more than 350,000 children and adolescents are living with diabetes, the majority of whom have type 1 diabetes and require lifelong insulin therapy. Afrezza delivers insulin into the bloodstream through the lungs using MannKind's proprietary Technosphere® drug-delivery platform, enabling rapid absorption of insulin into systemic circulation. Afrezza is an ultra rapid-acting inhaled insulin taken when you eat that more closely mimics the body's natural insulin response at mealtime.

"Mealtime insulin can be especially challenging for children because eating and snacking patterns, activity levels, and daily settings like school and sports often vary," said Desmond Schatz, Professor of Pediatrics, University of Florida College of Medicine. "With its rapid onset and dosing at the start of a meal, Afrezza may help clinicians better match insulin therapy to how children and families live day to day, while offering a needle-free mealtime option."

This approval expands Afrezza's availability beyond adults, introducing a new mealtime insulin option for pediatric patients and caregivers. The FDA approval is supported by results from the pivotal INHALE-1 clinical trial, along with additional safety, efficacy, and long-term exposure data from studies evaluating inhaled insulin over the past two decades of development.

"For more than a century, insulin therapy for children living with diabetes has largely meant multiple daily injections," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "Children and their families deserve new treatment options that fit the realities of daily life. Afrezza allows dosing at the moment of eating, without the need for pre-meal planning, making it a practical option for unplanned meals and snacks on the go. Our founder, Al Mann, would be proud of the dedication and teamwork that made it possible to bring this novel innovation to children and families."

"For families raising children with diabetes, every day is shaped by treatment decisions – and those decisions are deeply personal," said Jeff Hitchcock, Founder, President and CEO of Children With Diabetes. "Having navigated those choices firsthand for my own child, I understand that what works for one child may not work for another, and parents know this better than anyone. The approval of Afrezza for pediatric use represents a meaningful step forward for children and adolescents living with diabetes, and for the families who support, advocate, and care for them every single day. It adds an important new option to the diabetes toolkit and signals continued progress toward more individualized care for kids and teens."

MannKind is committed to helping people access the medicines they are prescribed and minimizing barriers to care. Afrezza is now available for eligible patients for $35 or less/month, and MannKind Cares provides dedicated support for patients, caregivers and healthcare providers seeking access and coverage information at (844) 323-7399 (toll free).

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 children, adolescent, and 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. Afrezza was first approved by the FDA in June 2014 to improve glycemic control in adult patients (age 18+) with diabetes mellitus, followed by an additional FDA approval for use in pediatric patients (age 6 and older) in May 2026.

Important Safety Information

What is the most important information I should know about AFREZZA?
AFREZZA can cause serious side effects, including:

- Sudden lung problems (bronchospasms). In a study, some AFREZZA-treated patients with asthma, whose asthma medication was temporarily withheld, experienced sudden lung problems. Do not use AFREZZA if you have long-term (chronic) lung problems such as asthma or chronic obstructive pulmonary disease (COPD). Before starting AFREZZA, your healthcare provider will give you a breathing test to check how your lungs are working.

What is AFREZZA?

- AFREZZA is a man-made insulin that is breathed-in through your lungs (inhaled) and is used to control high blood sugar in adults and children 6 years of age and older, with diabetes mellitus.
- AFREZZA is not for use to treat diabetic ketoacidosis. AFREZZA must be used with basal insulin in people who have type 1 diabetes mellitus.
- It is not known if AFREZZA is safe and effective for use in people who smoke. AFREZZA is not for use in people who smoke or have recently stopped smoking (less than 6 months).
- It is not known if AFREZZA is safe and effective in children under 6 years of age.

Who should not use AFREZZA?
Do not use AFREZZA if you:

- Are having an episode of low blood sugar (hypoglycemia).
- Have chronic lung problems such as asthma or COPD.
- Are allergic to regular human insulin or any of the ingredients in AFREZZA.

What should I tell my healthcare provider before using AFREZZA?
Before using AFREZZA, tell your healthcare provider about all your medical conditions, including if you:

- Have lung problems such as asthma or COPD
- Have or have had lung cancer
- Are using any inhaled medications
- Smoke or have recently stopped smoking
- Have kidney or liver problems
- Are pregnant, planning to become pregnant, or are breastfeeding. AFREZZA may harm your unborn or breastfeeding baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins or herbal supplements.

Before you start using AFREZZA, talk to your healthcare provider about low blood sugar and how to manage it.

What should I avoid while using AFREZZA?
While using AFREZZA do not:

- Drive or operate heavy machinery, until you know how AFREZZA affects you
- Drink alcohol or use over-the-counter medicines that contain alcohol
- Smoke

What are the possible side effects of AFREZZA?
AFREZZA may cause serious side effects that can lead to death, including:
See “What is the most important information I should know about AFREZZA?”

Low blood sugar (hypoglycemia). Signs and symptoms that may indicate low blood sugar include:

- Dizziness or light-headedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability or mood change, hunger.

Decreased lung function. Your healthcare provider should check how your lungs are working before you start using AFREZZA, 6 months after you start using it, and yearly after that.

Lung cancer. In studies of AFREZZA in people with diabetes, lung cancer occurred in a few more people who were taking AFREZZA than in people who were taking other diabetes medications. There were too few cases to know if lung cancer was related to AFREZZA. If you have lung cancer, you and your healthcare provider should decide if you should use AFREZZA.

Diabetic ketoacidosis. Talk to your healthcare provider if you have an illness. Your AFREZZA dose or how often you check your blood sugar may need to be changed.

Severe allergic reaction (whole body reaction). Get medical help right away if you have any of these signs or symptoms of a severe allergic reaction:

- A rash over your whole body, trouble breathing, a fast heartbeat, or sweating.

Low potassium in your blood (hypokalemia).

Heart failure. Taking certain diabetes pills called thiazolidinediones or “TZDs” with AFREZZA may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure it may get worse while you take TZDs with AFREZZA. Your healthcare provider should monitor you closely while you are taking TZDs with AFREZZA. Tell your healthcare provider if you have any new or worse symptoms of heart failure including:

- Shortness of breath, swelling of your ankles or feet, sudden weight gain.

Treatment with TZDs and AFREZZA may need to be changed or stopped by your healthcare provider if you have new or worse heart failure.

Get emergency medical help if you have:

- Trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue, or throat, sweating, extreme drowsiness, dizziness, confusion.

The most common side effects of AFREZZA include:

- Low blood sugar (hypoglycemia), cough, sore throat.

These are not all the possible side effects of AFREZZA. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088 (1-800-332-1088).

Please See Full Prescribing Information, including BOXED WARNING, Medication Guide and Instructions for Use at 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 about how Afrezza may help clinicians better match insulin therapy to daily life, and how Afrezza represents a meaningful step forward for children and teens with diabetes. Words such as “believes”, “anticipates”, “plans”, “expects”, “intends”, “may”, “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 products we commercialize may only achieve a limited degree of commercial success 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.

A photo accompanying this announcement is available at:
https://www.globenewswire.com/NewsRoom/AttachmentNg/f03226ab-008e-469b-b0ef-dea826bb2eab
https://www.globenewswire.com/NewsRoom/AttachmentNg/162f5fc2-d065-41d9-954f-b45b856ed9f2
https://www.globenewswire.com/NewsRoom/AttachmentNg/316f5791-ab91-4a94-a781-17197c9b0261

MannKind Contacts:

Media Relations:

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

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

Afrezza Inhaler

Afrezza inhaler.

Afrezza

Inhaled insulin

Afrezza Inhaler in Hand

Afrezza inhaler in hand.