



## MannKind Awarded Breakthrough T1D Grant to Support Advancement of INHALE-1ST Pediatric Trial of Afrezza® in Youth with Newly-Diagnosed T1D

06/23/26

- *Collaboration underscores interest in inhaled insulin and strengthens bringing innovation and new options to pediatric diabetes care*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., June 23, 2026 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)**, a company focused on the development and commercialization of inhaled therapeutic products and devices for patients with endocrine and orphan lung diseases, today announced it has been awarded a grant from Breakthrough T1D (formerly JDRF), the leading global type 1 diabetes (T1D) research and advocacy organization, through its Industry Discovery and Development Partnership (IDDP) program, to support the ongoing INHALE-1<sup>ST</sup> clinical study evaluating the initiation of Afrezza® (insulin human) Inhalation Powder shortly after a type 1 diabetes diagnosis in pediatric patients.

The INHALE-1<sup>ST</sup> study is a multi-center clinical trial 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. Building on the recent FDA approval of inhaled insulin for use in pediatric patients (aged 6 and older), the addition of strategic support from Breakthrough T1D further reinforces the importance of advancing new therapeutic options that can help address unmet needs in pediatric diabetes care.

“This collaboration with Breakthrough T1D represents meaningful external support of both Afrezza’s potential role in transforming insulin therapy and of the INHALE-1<sup>ST</sup> trial,” said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. “We believe this reflects growing confidence and increased interest in advancing the potential of inhaled insulin in newly-diagnosed pediatric patients.”

“Advancing therapies that can reduce the daily burden of living with type 1 diabetes is a Breakthrough T1D priority,” said Jonathan Rosen, Ph.D., Breakthrough T1D Director of Research. “Afrezza has made a difference in the lives of adults with T1D, and now we can assess its impact in the new-onset pediatric population. If Afrezza can help children and adolescents start off their T1D journeys with a well-tolerated treatment and good time-in-range, that’s a win for our community.”

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. Taken at the start of a meal, 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 the only ultra rapid-acting inhaled insulin that more closely mimics the body’s natural insulin response at mealtime.

MannKind recently completed enrollment of the pilot phase of the INHALE-1<sup>ST</sup> trial, Site locations and more information is available at: [ClinicalTrials.gov \(NCT07224321\)](https://clinicaltrials.gov/NCT07224321).

### **About INHALE-1<sup>ST</sup>**

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 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 primary endpoint is the percentage of participants with a continuous glucose monitor (CGM) who measured time-in-range (TIR) of 70-180 mg/dL ≥70% during 14 days prior to the 13-week visit.

### **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](http://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](http://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](http://mannkindcorp.com).

#### **About Breakthrough T1D, Formerly JDRF**

As the leading global type 1 diabetes research and advocacy organization, Breakthrough T1D helps make everyday life with type 1 diabetes better while driving toward cures. We do this by investing in the most promising research, advocating for progress by working with government to address issues that impact the T1D community, and helping educate and empower individuals facing this condition.

#### **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 growing confidence and increased interest in inhaled insulin in newly-diagnosed pediatric patients, and how inhaled insulin may be well tolerated in children and adolescents and help them achieve good glucose control. 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 continued testing of a product 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.

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Contacts: ☐

Christie Iacangelo, MannKind  
Media Relations  
(818) 292-3500  
[media@mnkd.com](mailto:media@mnkd.com) <mailto:media@mannkindcorp.com>

Kate Miranda, MannKind

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

Casey Fielder, Breakthrough T1D  
Media Relations  
cfielder@BreakthroughT1D.org  
(509) 651-0087

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