MannKind Showcases Efficacy, Safety, and Mealtime Control Data from Recent Pediatric and Adult Studies of Afrezza® at the ATTD Conference, March 19-22

03/10/25

- *Five presentations affirm positive outcomes utilizing inhaled insulin*
- *An sNDA filing for Afrezza in pediatric population anticipated in 2025*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., March 10, 2025 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)**, a company focused on the development and commercialization of inhaled therapeutic products and delivery devices for patients with endocrine and orphan lung diseases, will showcase data from recent studies of inhaled insulin across five presentations at the 18th International Conference on Advanced Technologies and Treatments for Diabetes to be held March 19-22 in Amsterdam.

“Data from both the INHALE-1 pediatric and INHALE-3 adult studies continue to drive groundbreaking conversations around inhaled insulin,” said Dr. Kevin Kaiserman, Senior Vice President, Therapeutic Area Head, Endocrine Diseases for MannKind Corporation. "Afrezza continues to be an important treatment option for adults living with diabetes, including those utilizing MDI and AID, and we look forward to the study investigators’ presentations at the ATTD meeting.”

The following oral presentations are on the scientific program at ATTD 2025 to be held virtually and at the RAI Amsterdam Convention Center:

What’s New in Pulmonary Inhaled Insulin?
Thursday, March 20, 2025 – 4:40 PM (CET) in Hall I
Presenter: Dr. Irl B. Hirsch

Inhaled Insulin in Pediatrics (INHALE-1 Peds Study)
Thursday, March 20, 2025 – 4:40 PM (CET) in Hall I
Presenter: Dr. Michael J. Haller

Sustained Benefit from Use of Inhaled Insulin in the INHALE-3 Extension Study
Saturday, March 22, 2025 – 11:05 AM (CET) at Station 4
Presenter: Dr. Grazia Aleppo

Post-Prandial Glucose Excursion with Inhaled Insulin in Youth Compared with Adults with Type 1 Diabetes (INHALE-1 Peds Study)
Saturday, March 22, 2025 – 11:30 AM (CET) in Hall D2
Presenter: Dr. Michael J. Haller

Comparison of a Regimen of Inhaled Technosphere Insulin Plus Insulin Degludec Versus Usual Care in Adults with Type 1 Diabetes
Saturday, March 22, 2025 – 11:30 AM (CET) in Hall D2
Presenter: Dr. Anastasios Manessis

In addition to the planned presentations, MannKind will host booth #40 in the exhibit hall (Hall I) throughout ATTD. Members of MannKind’s Clinical Education Team will be available for scientific exchange in the medical section of the booth.

For more information about ATTD programming, and/or to register to attend the conference (virtual or in person), please visit: https://attd.kenes.com/register/.

About the INHALE-1 Pediatric Study
INHALE-1 is a Phase 3, randomized controlled trial in children and teenagers aged 4-17 with type 1 or type 2 diabetes to evaluate the efficacy and safety of inhaled insulin in combination with basal insulin versus multiple daily injections of rapid acting insulin in combination with basal insulin. The 26-week, open-label clinical trial randomized 230 pediatric subjects to one of two groups: Afrezza or multiple daily injections (MDI) of rapid acting insulin analog (RAA) in combination with basal insulin. The primary endpoint was a non-inferior change in HbA1c levels after 26 weeks. A 26-week extension phase in which all remaining MDI patients switched to Afrezza is still ongoing. Six-month results were announced by MannKind in December 2024, and 12-month findings are expected mid-year 2025.

About the INHALE-3 Study (Adults)
The INHALE-3 study was a 17-week, randomized controlled trial with a 13-week extension conducted across 19 U.S. sites. The study, which enrolled 141 patients (123 randomized), assigned participants over 18 years of age with T1D who are using MDI, an automated insulin delivery system, or a pump without automation to either continue their standard of care or initiate an insulin regimen of a daily basal injection plus Afrezza for boluses (mealtime and corrections). Subjects utilizing Afrezza (inhaled insulin)

received a higher initial conversion dose than in the current U.S. product label. Both arms utilized continuous glucose monitoring to assess glucose control.

The randomized control trial (RCT) included an inhaled insulin group that began with 62 subjects at randomization and 57 at 17 weeks; the usual care group consisted of 61subjects at randomization and 58 at 17 weeks. The 17-week results shared that the study met its primary efficacy endpoint of a non-inferior change in HbA1c between baseline and week 17 compared to the usual care group. At 17 weeks, those who utilized Afrezza (plus basal insulin) continued with it through the extension phase, and those who were on usual care switched over to Afrezza to week 30. The extension phase started with 45 subjects from the inhaled insulin group and 43 completed the extension; the usual care-to-Afrezza group started with 49 in the extension, with 42 completing. There was no control group in the extension phase. A1c levels were obtained at baseline, 17 and 30-weeks. The 30-week results from the study expanded upon the positive 17-week data and showed that more people living with T1D were able to reach target A1c levels when they remain on Afrezza (plus basal insulin) or switch to Afrezza from usual 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) focuses on the development and commercialization of innovative inhaled therapeutic products and devices to address serious unmet medical needs for those living with endocrine and orphan lung diseases.

We are committed to using our formulation capabilities and device engineering prowess to lessen the burden of diseases such as diabetes, nontuberculous mycobacterial (NTM) lung disease, pulmonary fibrosis, and pulmonary hypertension. Our signature technologies – dry-powder formulations and inhalation devices – offer rapid and convenient delivery of medicines to the deep lung where they can exert an effect locally or enter the systemic circulation, depending on the target indication.

With a passionate team of Mannitarians collaborating nationwide, we are on a mission to give people control of their health and the freedom to live life.

Please visit mannkindcorp.com to learn more, and follow us on LinkedIn, Facebook, X or Instagram.

Forward-Looking Statements
This press release contains forward-looking statements about planned presentations at a scientific conference and a potential sNDA submission for Afrezza that involves risks and uncertainties. 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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