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INHALE-3 Study Reveals Positive Readout in Head-to-Head Comparison of Inhaled Insulin vs. Usual Care in T1D; New Data Presented at American Diabetes Association's 84th Scientific Sessions

06/22/24

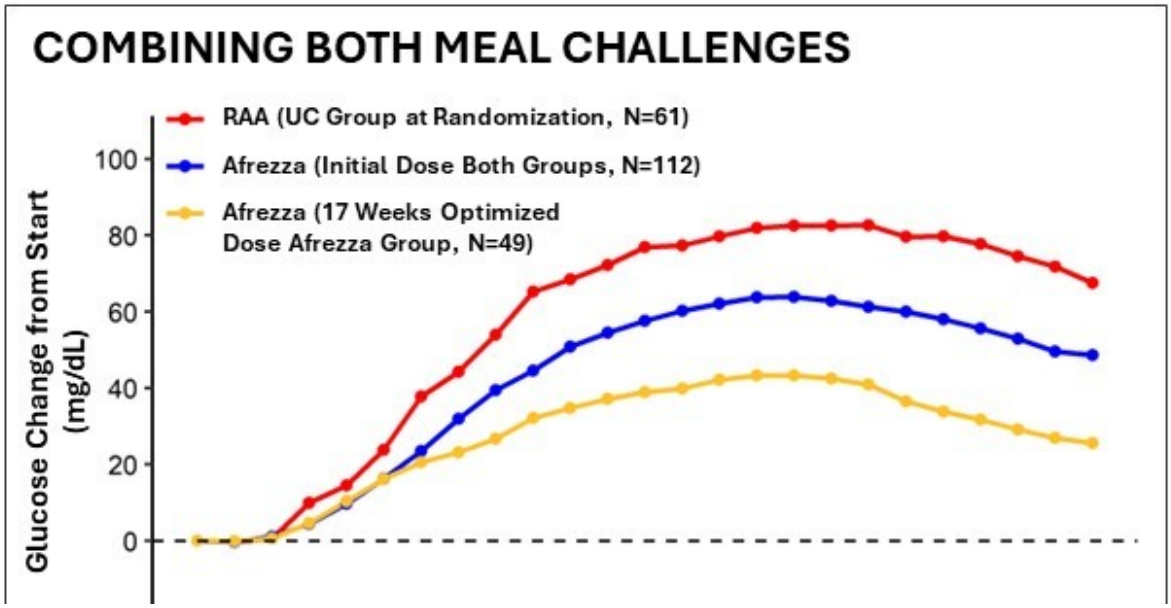
- *Study proves inhaled insulin is as effective as usual care (primarily automated insulin delivery pumps or multiple daily injections) for adults living with T1D meeting the primary endpoint*
- *Patients utilizing inhaled insulin reached target A1c (less than 7%) 30% of the time compared to 17% with usual care and 24% had time-in-range (TIR) above 70% with no increased hypoglycemia compared with 13% with usual care*
- *More than 50% of subjects at the end of the study expressed an interest in continuing to use Afrezza®*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., June 22, 2024 (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 positive 17-week results from the INHALE-3 study, a Phase 4 U.S. clinical trial evaluating Afrezza® (plus basal insulin) vs. usual care (defined as multiple daily injections (MDI), an automated insulin delivery system, (AID) or a pump without automation) utilizing a higher initial conversion dose from mealtime injectable insulin to inhaled insulin. The study, which was presented by the INHALE-3 investigational team at the American Diabetes Association's (ADA) 84th Scientific Sessions in Orlando, met its primary efficacy endpoint of a non-inferior change in HbA1c between baseline and week 17 compared to the usual care group.

Key sub-analysis findings included:

- More subjects utilizing inhaled insulin achieved glycemic targets:
  - 30% of inhaled insulin group reached <7% (HbA1c) at 17 weeks vs. 17% of the usual care group
  - 21% of inhaled insulin group vs. 0% of usual care group met A1c goal of <7% if baseline was >7%
  - 24% of the Afrezza group and 13% of the usual care group achieved TIR above 70% with no increased hypoglycemia in the inhaled insulin group
- No difference in CGM-measured hypoglycemia between the groups
- Study helps to establish a titrated basal-bolus ratio that is approximately 70/30 inhaled insulin to basal vs. 50/50 for usual care
- While more people met the glycemic target of A1c (less than 7%) with Afrezza, some subjects worsened when switching from usual care to inhaled insulin, potentially due to missing doses of inhaled insulin during the day and/or underdosing going into bedtime
- More than 50% of subjects at the end of the study expressed an interest in continuing to use Afrezza

"Inhaled insulin demonstrated improved mealtime control, which is significant given how this continues to be a significant unmet need," said Dr. Irl Hirsch, Professor of Medicine and Diabetes Treatment and Teaching Chair at the University of Washington and the INHALE-3 Study Protocol Chair. "The INHALE-3 study delivered data that supports inhaled insulin being an important treatment option for adults living with diabetes."



RAA, rapid-acting insulin analog; UC, usual care.
Data on File (INHALE-3 Clinical Study Report, 2024). MannKind Corporation.

"INHALE-3 adds to the body of evidence that when combined with basal insulin, inhaled insulin's effect on HbA1c/TIR is similar to that of the usual care (inclusive of AID pumps) with no new safety concerns," said Dr. Kevin Kaiserman, Senior Vice President, Clinical Development and Medical Affairs for MannKind Corporation. "Our data continues to show the importance of Afrezza as a safe and effective tool for managing diabetes."

The INHALE-3 study is 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). Both arms utilized continuous glucose monitoring to assess glucose control. A1c levels were obtained at baseline, 17 and 30-weeks. The full 30-week results of INHALE-3 will be presented at future conferences. More information on the INHALE-3 study is available at: ClinicalTrials.gov(NCT05904743).

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 the planned release of results from an ongoing clinical study 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 we may not achieve our projected development goals in the timeframes we expect, the risk that continued testing of our products may not yield successful results as well as 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, 2023, 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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Photos accompanying this announcement are available at:

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Source: MannKind

Afrezza®

Afrezza® (insulin human) Inhalation Powder.

INHALE-3

INHALE-3 study graph sharing data from combining both meal challenges.