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MannKind Announces New Clinical Data From Inhale-3 Study to be Presented by Dr. Irl B. Hirsch at ATTD on March 8

March 5, 2024 11:05 AM EST

Dr. Hirsch to present meal challenge results when switching from multiple daily injections (MDI) or insulin pumps to inhaled insulin (Afrezza® (insulin human) Inhalation Powder)

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., March 05, 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, announced today that new clinical data from the INHALE-3 study first meal challenge will be presented at the upcoming 17th International Conference on Advanced Technologies and Treatments for Diabetes (ATTD) in Florence on March 6-9. INHALE-3 is a Phase 4 U.S. clinical trial evaluating inhaled insulin (plus basal) vs. standard of care.

Dr. Irl B. Hirsch, Professor of Medicine and Diabetes Treatment and Teaching Chair at the University of Washington and the INHALE-3 Study Protocol Chair, will provide an oral presentation focused on findings from a standardized meal challenge, including:

- Post-prandial glucose with inhaled insulin vs. subcutaneous rapid-acting analogue (RAA)
- Glucose outcomes including AUC and time to peak during the first two hours and beyond
- Frequency of post-meal hypoglycemia in both groups

"We are looking forward to the first slice of INHALE-3 data being presented here that builds upon findings from our pilot ABC study shared at last year's ATTD Conference," said Dr. Kevin Kaiserman, Senior Vice President, Clinical Development and Medical Affairs for MannKind Corporation. "With ABC and this trial, we used a higher initial conversion dose for inhaled insulin than in our current label. In the ABC study, this conversion dose produced significantly lowered post-prandial glucose levels that peaked 30 minutes sooner than standard of care. At ATTD, we are presenting INHALE-3's meal challenge with a much larger comparator group across treatment regimens."

Dr. Hirsch will deliver his oral presentation at 11:15 a.m. EST (5:15 p.m. CET) on Friday, March 8, 2024. Further data will be provided post-conference.

INHALE-3 is a 17-week randomized controlled trial with a 13-week extension. The study randomly assigned participants over 18 years of age with T1D who are using MDI, an AID system, or a pump without automation to either continue their standard of care or adopt an insulin regimen of a daily basal injection plus Afrezza at mealtimes. Both arms utilized continuous glucose monitoring to assess mealtime control and A1c levels. More information on the study is available at: ClinicalTrials.gov(NCT05904743).

About MannKind

MannKind Corporation (Nasdaq: MNKD) focuses on the development and commercialization of innovative 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, pulmonary arterial hypertension (PAH) and nontuberculous mycobacterial (NTM) lung disease. 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.

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, Twitter 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, 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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