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MannKind Announces Completion of Enrollment in U.S. Phase 4 Inhale-3 Clinical Trial in Patients Living With Type 1 Diabetes

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- Rapidly enrolled 141 patients in less than four months
- Large study will compare A1c from baseline to 17 weeks for adults when switching from injectable insulin or pumps to inhaled insulin (Afrezza[®] (insulin human) Inhalation Powder)
- Initial standardized meal data from INHALE-3 on target for presenting in 1Q 2024 followed by primary endpoint analysis in 2Q 2024

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Nov. 06, 2023 (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 it has fully enrolled patients in INHALE-3, a Phase 4 clinical trial evaluating inhaled insulin (combined with basal insulin) versus usual care in adults living with type 1 diabetes.

"We are excited to see the high level of engagement by INHALE-3 investigators, study staff, and subjects across 19 sites nationwide," said Dr. Kevin Kaiserman, Senior Vice President, Clinical Development and Medical Affairs for MannKind Corporation. "This was a rapid enrollment process, and we are looking forward to sharing results in 2024."

INHALE-3 is a 17-week randomized controlled trial with a 13-week extension. The study will randomly assign participants over 18 years of age with T1D who are using Multiple Daily Injections (MDI), an automated insulin delivery (AID) system, or a pump without automation to either continue their usual care or adopt an insulin regimen of a daily basal injection plus Afrezza at mealtimes. Both arms will utilize 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, Eacebook, 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, 2022, 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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