Afrezza® Safety and Pharmacokinetics Study in Pediatric Patients Opens Enrollment for Cohort 3

July 31, 2019

MannKind announces the opening of enrollment for this final cohort before moving to phase 3 in this pediatric clinical trial

WESTLAKE VILLAGE, Calif., July 31, 2019 (GLOBE NEWSWIRE) -- MannKind Corporation (NASDAQ:MNKD) announced today that the Afrezza® safety and pharmacokinetics study in pediatric patients is now enrolling children 4-7 years of age (Cohort 3) and nearing completion for Cohort 2 (8-12 years of age).

An interim review of data from individuals participating in the second cohort shows that the single-dose pharmacokinetic profile of insulin levels for this age group is consistent with the pattern seen in adults. In addition, dosing over one month demonstrated a safety profile that was also consistent with that observed in adults. As a result of these findings, MannKind and the study investigators are proceeding with enrollment of the third cohort of subjects.

This third and final cohort will study Afrezza in children aged 4-7 years and will assess insulin levels, glucose changes, and the short-term safety and tolerability of multiple doses of Afrezza.

“We are very pleased that we can extend the study to younger children who could benefit from the flexible dosing Afrezza provides and thankful for the families and investigators who have participated to date,” said David Kendall, M.D., Chief Medical Officer of MannKind.

For additional information about the study, please contact John Krueger, Vice President, Clinical Development, MannKind Corporation at jkrueger@mannkindcorp.com.

About Afrezza®

Available by prescription, Afrezza® (insulin human) Inhalation Powder is a rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus. Afrezza consists of a dry powder formulation of human insulin delivered from a small and portable inhaler. Administered at the beginning of a meal, Afrezza dissolves rapidly upon inhalation to the lung and passes quickly into the bloodstream (in less than one minute). This rapid absorption allows Afrezza to begin reducing blood sugar levels within minutes of administration. Afrezza is available in 4-unit, 8-unit and 12-unit single-dose cartridges of insulin powder that can be used, as prescribed by a health care professional, in combination with other diabetes medications to achieve target blood sugar levels. For Afrezza doses exceeding 12 units, patients may use a combination of existing cartridge strengths. For more information about Afrezza, please visit www.afrezza.com.

About MannKind Corporation

MannKind Corporation (NASDAQ:MNKD) focuses on the development and commercialization of inhaled therapeutic products for patients with diseases such as diabetes and pulmonary arterial hypertension. MannKind is currently commercializing Afrezza® (insulin human) Inhalation Powder, the Company's first FDA-approved product and the only orally inhaled ultra rapid-acting mealtime insulin in the United States, where it is available by prescription from pharmacies nationwide. MannKind is headquartered in Westlake Village, California, and has a state-of-the art manufacturing facility in Danbury, Connecticut. The Company also employs field sales and medical representatives across the U.S. For further information, visit www.mannkindcorp.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve 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 detailed in MannKind's filings with the SEC. For a discussion of these and other factors, please refer to MannKind’s quarterly report on Form 10-Q for the quarter ended March 31, 2019 as well as MannKind’s other filings with the SEC. 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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