Additional Positive Afrezza® Clinical Data from STAT Study To Be Presented at ADA 78th Scientific Sessions

June 25, 2018

Oral presentation (348-OR) at 5:00 pm today

Afrezza provides greater improvement in post-prandial glucose control than insulin aspart

WESTLAKE VILLAGE, Calif., June 25, 2018 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq:MNKD) announced that additional data for Afrezza from the STAT study (**ST**udy comparing prandial insulin **A**spart vs. **T**echnosphere insulin in patients with Type 1 diabetes on multiple daily injections) will be presented in an oral presentation later today at the American Diabetes Association's (ADA) 78th Scientific Sessions. The STAT study involved 60 patients with Type 1 diabetes and is the first randomized, controlled study to use continuous glucose monitoring (CGM) with Afrezza. The dual primary endpoints were assessment of glucose time-in-range and post-prandial glucose (PPG) excursions in the 1-4 hour post-meal period. Time-in-range results were presented in a poster presentation on Saturday, June 23, 2018.

STAT Study Oral Presentation Highlights

Title: Study Comparing Prandial Insulin Aspart vs. Technosphere Insulin (TI) in Patients with Type 1 Diabetes on Multiple Daily Injections: STAT Study

Presenter: Satish Garg, M.D.

Highlights: Compared to insulin aspart, the per-protocol use of Afrezza (i.e., with supplemental doses 1 and/or 2 hours post-meal):

- Significantly lowered PPG values at 1 and 2 hours after meals (-38.2 and -17.9 mg/dl, respectively) as measured by CGM
- Significantly reduced overall PPG excursions (i.e., the peak increase in CGM glucose during the 1-4 hour post-meal period) by 15%. In addition,
  - a 15% reduction in overall PPG excursions was also seen in Afrezza subjects who dosed at mealtimes only and did not follow the supplemental dosing protocol
  - PPG excursions were significantly reduced following breakfast (approximately 20%) and lunch (approximately 25%) (based on an analysis of all subjects in the Afrezza group without regard to their adherence to the supplemental dosing protocol)
- Significantly improved all-day glucose time-in-range by an average of 1.5 hours, or 12%

Conclusion: Afrezza may provide greater improvement in PPG control than insulin aspart

"I am very pleased to have led the novel STAT trial, performed as a collaborative trial with several other investigators at the Barbara Davis Diabetes Center as well as four other sites around the country. This study shows that the use of Afrezza at mealtimes, and as needed following meals, provides significant improvement in postprandial glucose (PPG) when compared to mealtime insulin aspart in Type 1 diabetes patients who are using continuous glucose monitoring," stated Halis Kaan Akturk, M.D., Assistant Professor of Medicine and Pediatrics, Barbara Davis Center for Diabetes, University of Colorado Denver and the principal investigator of the STAT study.

"These new data presented at the ADA's 78th Scientific Sessions significantly advance our understanding of the potential clinical benefits of Afrezza for those living with Type 1 diabetes," stated Michael Castagna, Chief Executive Officer of MannKind. "We believe the last frontier for driving better outcomes for people living with diabetes is the ability to control mealtime glucose levels. Based on the data generated to date, we believe that Afrezza – with its ability to lower HbA1c levels without the same degree of concomitant risk of hypoglycemia as other mealtime insulins – has the potential to be the treatment of choice for those individuals with diabetes requiring mealtime glucose control."

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 about 12 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 on Afrezza, please visit www.afrezza.com.

About MannKind

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 inhaled 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, including its annual report on Form 10-K for the year ended December 31, 2017. 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.

MannKind Contact:
Rose Alinaya
SVP, Investor Relations
818-661-5000
ir@mannkindcorp.com

Primary Logo

Source: MannKind