Positive Afrezza® Clinical Data from STAT Study Published in Diabetes Technology & Therapeutics

September 13, 2018

Study data show Afrezza provides greater improvement in postprandial glucose control than insulin aspart

WESTLAKE VILLAGE, Calif., Sept. 13, 2018 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq:MNKD) announced today that "Improved Postprandial Glucose with Inhaled Technosphere® Insulin Compared to Insulin Aspart in Patients with Type 1 Diabetes on Multiple Daily Injections: The STAT Study" has been published online in *Diabetes Technology & Therapeutics*.

The STAT study is the first randomized, controlled study to assess diabetes control using continuous glucose monitoring and Afrezza® in individuals with type 1 diabetes. The dual primary endpoints were:

- 24-hour glucose time-in-range (TIR)
- Postprandial glucose excursions (PPGE), defined as the peak increase in glucose in the 1 to 4 hour post-meal period

This trial, supported by funding from MannKind Corporation, was a pilot study led by investigators at the Barbara Davis Center for Diabetes.

Compared to standard of care for mealtime therapy, the per-protocol use of Afrezza (i.e. supplemental doses 1 and/or 2 hours post-meal), on average demonstrated:

- Significantly increased glucose TIR by approximately 2 hours per day
- Significantly reduced time in hyperglycemia > 180 mg/dL
- Significantly lower PPGE 1 to 4 hours post-meal
- Significant reductions in glucose as early as 60 minutes following Afrezza dose
- Less hypoglycemia (as measured by time spent less than 60 mg/dL); notably, the average Afrezza-treated individual spent approximately 3 minutes per day with blood glucose values less than 50 mg/dL compared to approximately 12 minutes per day for aspart-treated individuals

This is the first of a number of planned randomized trials, intended to evaluate the potential benefits of Afrezza (Technosphere Insulin) compared to the standard of care for mealtime plus basal insulin.

“I am very pleased to have helped develop the design of this novel trial (STAT) at the Barbara Davis Center for Diabetes, performed as a collaborative multi-center clinical trial with several other investigators around the country,” 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. “With the peer review publication of these data in *Diabetes Technology & Therapeutics*, we feel that our data supporting the unique time-action profile of Technosphere Insulin (Afrezza®) is helping us to better understand the potential advantages of a truly rapid-acting insulin delivery system for improving control of mealtime glucose. Specifically, individuals with type 1 diabetes, treated with Technosphere Insulin, demonstrated lower blood glucose as early as one hour after meals and, based on our analysis, supplemental dosing with Technosphere Insulin further improved the glucose control measured after meals. These data are the first to demonstrate that individuals living with type 1 diabetes may achieve significant improvement in postprandial glucose with Technosphere Insulin as a mealtime insulin, compared to standard of care, rapid-acting insulin analogs.”

“These new data significantly advance our understanding of the potential clinical benefits of Afrezza therapy for those living with type 1 diabetes,” stated David Kendall, M.D., Chief Medical Officer of MannKind Corporation. “We believe one of the key limitations to optimal glucose control and achieving better outcomes for people living with diabetes is their ability to control mealtime glucose levels. These data generated to date further support the view that Afrezza has the potential to be the treatment of choice for those individuals with diabetes who require alternatives that further improve mealtime glucose control. The completion of this proof-of-concept trial and peer-reviewed publication allows for broad sharing of these data with diabetes healthcare professionals.”

The published research can be found online at https://www.liebertpub.com/doi/10.1089/dia.2018.0200

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 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 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.

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

MannKind Corporation

Source: MannKind