MannKind Presents Positive Afrezza® Clinical Data from STAT and AFFINITY Studies at ADA 78th Scientific Sessions

June 23, 2018

Poster 1017-P: Afrezza provides improved Time-in-Range on Continuous Glucose Monitoring compared to insulin aspart

Poster 102-LB: Hypoglycemia is reduced with use of Afrezza compared to insulin aspart

WESTLAKE VILLAGE, Calif., June 23, 2018 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq:MNKD) announced that new 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) were released today at the American Diabetes Association's 78 th Scientific Sessions, being held June 22-26, 2018, in Orlando, Florida. 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 postprandial glucose (PPG) excursions in the 1-4 hour post-meal period. PPG control results from this study will be presented as an oral presentation on Monday June 25th, 2018 in Session 348-OR.

STAT Study Poster Highlights:

Title:	Improved Time-in-Range (TIR) on Continuous Glucose Monitor (CGM) with Technosphere Inhaled Insulin (TI) compared to insulin Aspart in Patients with T1D—STAT Study
Presenter:	Janet-Snell-Bergeon, Ph.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 improved all-day glucose time-in-range by an average of 1.5 hours, or 12% • Significantly decreased daytime glucose variability by 17% • Significantly reduced the time spent in hypoglycemia (i.e., <70 mg/dl) by 41% or approximately 23 minutes per day
Conclusion:	The faster action with shorter duration profile of Afrezza when compared to rapid-acting insulin analogs may provide a flexible approach for patients to optimize post-prandial glucose control without increasing risk of hypoglycemia

"We are very pleased to present results of the novel STAT trial. This is the first time we have seen a rapid-acting mealtime insulin provide a superior outcome when utilized with CGM in a treat-to-target dosing strategy. The results demonstrated that Afrezza dosed before and (as needed) after meals significantly improved all-day glucose time-in-range, limited daytime glucose variability and significantly reduced the overall rate and time spent in hypoglycemia," stated David Kendall, M.D., Chief Medical Officer of MannKind Corporation.

MannKind also presented a late-breaking poster presenting a post-hoc analysis of a representative subset of the AFFINITY 1 study that demonstrated the use of Afrezza significantly lowers the rate of hypoglycemia in patients with Type 1 diabetes while providing non-inferior glycemic control.

Affinity-1 Late Breaking Poster Highlights:

Title:	Total and Severe Hypoglycemia is Reduced With Use of Inhaled Technosphere® Insulin (AFREZZA®) Relative to Insulin Aspart in Type 1 Diabetes
Presenter:	Lawrence Blonde

Highlights:	Compared to insulin aspart:
	• Use of Afrezza significantly lowers the rate of hypoglycemia in Type 1 diabetes while providing similar or better glycemic control (54.1 events per subject vs. 78.2 events per subject, a reduction of 31%)
	• On average, 26% lower rates of hypoglycemia were observed with Afrezza across the range of HbA1c levels, allowing the same degree of glycemic control with less hypoglycemia than insulin aspart. For example,
	  ○ a patient with an HbA1c of 8.0% on insulin aspart would experience the same rate of hypoglycemia (12.2 events per month) as a patient on Afrezza with an HbA1c of 6.8% (ΔHbA1c = -1.2%)
	  ○ Alternatively, patients with HbA1c of 6.8% on Afrezza would be estimated to experience 4 fewer hypoglycemic events per month than a similar patient on insulin aspart

Conclusion:	Use of Afrezza in a multi-dose insulin regimen may permit treatment intensification to be achieved with less hypoglycemia. Switching to Afrezza may also benefit patients already at goal by reducing the frequency of hypoglycemia events.

"The late breaking poster presentation, from a post-hoc regression analysis of a representative subset of the AFFINITY 1 study patient, evaluated overall and severe hypoglycemia event rates with AFREZZA relative to insulin aspart in Type 1 diabetes patients. This analysis, which controlled for a number of variables that can impact glucose control and rates of hypoglycemia, demonstrated that use of Afrezza resulted in significantly lower rates of hypoglycemia in Type 1 diabetes patients across a wide range of HbA1c as compared to insulin aspart. Hypoglycemia remains one of the major factors that limit to the ability of healthcare providers and patients to intensify insulin therapy and can further limit the ability to achieve optimal glucose control," continued Dr. Kendall.

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.

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