



MannKind Presents Positive Afrezza® STAT Study Clinical Data at 54th Annual Meeting of the European Association for the Study of Diabetes

10/04/18

Poster 813; PS 068 **Improved post-prandial blood glucose excursions with Technosphere inhaled insulin compared to aspart in adult patients with type 1 diabetes: STAT study intention to treat analysis**

Poster 677; PS 051 **Improved time-in-range on continuous glucose monitor with Technosphere insulin compared to insulin aspart in adults with type 1 diabetes: STAT study per protocol analysis**

WESTLAKE VILLAGE, Calif., Oct. 04, 2018 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq:MNKD), a company focused on the development and commercialization of inhaled therapeutic products for patients with diseases such as diabetes and pulmonary arterial hypertension, presented data 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) at the 54th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Berlin, Germany. The STAT study is the first randomized, controlled study to assess diabetes control using continuous glucose monitoring (CGM) and Afrezza® in individuals with type 1 diabetes. The dual primary endpoints were an assessment of glucose time-in-range (TIR) as well as post-prandial glucose excursions (PPGE) in the 1-4 hour post-meal period. The two poster presentations took place on Tuesday, October 2, 2018 (poster 813; PS 068) and Wednesday, October 3, 2018 (poster 677; PS 051).

"We continue to advance the understanding of the potential clinical benefits of Afrezza by sharing the positive data from the STAT study at the 2018 EASD conference," said David Kendall, M.D., Chief Medical Officer of MannKind Corporation. "These data highlight the potential clinical benefits that Afrezza offers individuals living with type 1 diabetes in managing their glucose levels, and support our belief that Afrezza is more effective than insulin aspart in improving post-prandial glucose (PPG) control for type 1 diabetes patients. Further, the STAT study results offer important insights into ways that individuals with diabetes can potentially improve their experience and outcomes by using mealtime inhaled insulin, and 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."

Afrezza STAT Study Poster Presentations at EASD

Title: **Improved Post-prandial Blood Glucose Excursions with Technosphere Inhaled Insulin Compared to Aspart in Adult Patients with Type 1 Diabetes: STAT Study Intention to Treat Analysis** (poster 813; PS 068)

Presenter: Halis K. Akturk, M.D.

Highlights:

- Technosphere Insulin (Afrezza) significantly improved post-prandial blood glucose (PPBG) at 60 and 90 minutes
- Afrezza significantly decreased PPGE at breakfast and lunch
- Afrezza improved daytime TIR and significantly decreased glucose variability
- Time spent in hypoglycemia defined as <60 mg/dL and < 50 mg/dL was significantly less with Afrezza vs insulin aspart, respectively

Conclusion: Afrezza, when administered at the beginning of a meal, and supplemented at appropriate post meal intervals as needed, significantly improved PPGE and improved TIR when compared with insulin aspart in adult patients with type 1 diabetes.

Title: **Improved Time-in-Range on Continuous Glucose Monitor with Technosphere Insulin Compared to Insulin Aspart in Adults with Type 1 Diabetes: STAT study Per Protocol Analysis** (poster 677; PS 051)

Presenter: Janet Snell-Bergeon, Ph.D.

Highlights:

- Afrezza improved PPG as well as all-day glucose TIR when additional post-prandial TI doses were taken as needed
- Afrezza decreased PPGE, 2-hour glucose area under the curve and daytime glucose variability when taken per protocol (additional doses 1hour – 2hour post-meal as needed)

- There was no increase in hypoglycemia with the use of TI when compared with aspart

Conclusion: The use of Afrezza, with proper supplemental dosing per protocol, significantly improved 24 hour TIR and lowered PPGE (1-4 hours) when compared to insulin aspart. In addition, these data suggest that Afrezza can reduce time in hypoglycemia in adult patients with type 1 diabetes when compared to aspart.

"We are very pleased to have the opportunity to present results of the STAT study at EASD," said Michael Castagna, Chief Executive Officer of MannKind Corporation. "The International Diabetes Federation estimates that approximately 425 million people are living with diabetes worldwide, including 58 million in Europe. It's a chance for those living with diabetes in this part of the world to learn more about rapid-acting mealtime insulin and, hopefully one day, extend the potential opportunity for this population with diabetes to manage their disease with our novel mealtime insulin."

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.

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