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MannKind Presents Positive Original Analyses of Afrezza® Clinical Data at American Diabetes Association (ADA) 80th Scientific Sessions

06/15/20

WESTLAKE VILLAGE, Calif., June 15, 2020 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** announced that new data from clinical studies of Afrezza® (insulin human) Inhalation Powder was presented at the **American Diabetes Association's 80th Scientific Sessions** , June 12-16, 2020.

The data presented includes:

- A comprehensive post hoc analysis of four unique studies assessing the **safe and effective dosing** of Afrezza in patients with type 1 diabetes[1] (Poster 1023)
- An analysis demonstrating **treatment with Afrezza is associated with weight loss** in patients with type 2 diabetes, compared to weight gain with injected mealtime insulin[2] (Poster 1024)
- An evaluation of a comprehensive two year safety study showing that significant **changes in FEV_1** (as a measure of pulmonary function) during treatment with Afrezza **are both uncommon and generally transient** in nature[3] (Oral Abstract 235)

"We are pleased to present these clinical studies detailing the safe and effective use of Afrezza at this year's virtual ADA Scientific Sessions," stated David Kendall, MD, Chief Medical Officer MannKind. "These studies provide further support of the effectiveness and clinical safety of Afrezza therapy and offer important insights on effective dosing of Afrezza, the favorable effect of Afrezza on body weight, and the improvement in clinical outcomes possible when converting patients to Afrezza therapy."

Highlights of the presentations are described below. See the appendix for presentation details.

Poster 1023: Dose Titration and Clinical Effects of Inhaled Technosphere® Insulin Compared with Mealtime Subcutaneous (SC) Analog Insulin Therapy in Type 1 Diabetes (T1D)

- Ultra rapid-acting Afrezza can be safely and effectively dosed at **1.5 to 2.0 times** that of injected mealtime insulin
- This dosing ratio appears to be consistent across a range of A1C responses
- Afrezza's ultra rapid-acting profile may supersede the perceived precision of injected mealtime insulin dosing and provides patients the ability to flexibly dose based on glycemic response

Poster 1024: Technosphere® Insulin Added to Basal Insulin Is Associated with Less Weight Gain than Basal Insulin plus Insulin Aspart or Insulin Analog (aspart) 70/30 Mixture in Type 2 DM

- Patients with type 2 diabetes treated with **Afrezza showed modest weight loss** while those treated with insulin aspart or insulin aspart mix resulted in weight gain
- The weight difference estimate between Afrezza and insulin aspart was 1.83 pounds
- The weight difference estimate between Afrezza and biaspart insulin was 3.17 pounds
- The effect on body weight was independent of the magnitude of improvement in glucose control

Oral Abstract 235: Incidence of Significant Changes in Pulmonary Function during A 2-year Study with Inhaled Technosphere® Insulin

- Prior clinical studies have shown a modest (~40 ml) difference in mean change in FEV1 over two years when comparing treatment with Afrezza to other diabetes therapies
- The majority (88%) of individuals treated with Afrezza had no significant change in FEV1 measured at any time
- Overall, **98% of patients on Afrezza (vs. 99% of usual care)** had either **no significant change** (≥15%) or were observed to have **only a transient change in FEV1** over the two years of study

About Afrezza®

Available by prescription, Afrezza® (insulin human) Inhalation Powder is an ultra 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 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 annual report on Form 10-K for the year ended December 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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Appendix – Presentation Details

(1) Poster Presentation: *Dose Titration and Clinical Effects of Inhaled Technosphere® Insulin Compared with Mealtime Subcutaneous (SC) Analog Insulin Therapy in Type 1 Diabetes (T1D)*
Presenter: David M. Kendall, M.D.
Poster No. 1023-P
Date/Time: Saturday, June 13; 10 AM CT

(2) Poster Presentation: *Technosphere® Insulin Added to Basal Insulin Is Associated with Less Weight Gain than Basal Insulin plus Insulin Aspart or Insulin Analog (aspart) 70/30 Mixture in Type 2 DM*
Presenter: David M. Kendall, M.D.
Poster No: 1024-P
Date/Time: Saturday, June 13; 10 AM CT

(3) Oral Presentation: *Incidence of Significant Changes in Pulmonary Function during A 2-year Study with Inhaled Technosphere® Insulin*
Presenter: David M. Kendall, M.D.
Poster No: 235-OR
Date/Time: Sunday, June 14; 5:30 PM CT

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Source: MannKind