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MannKind Presents Positive Afrezza® Clinical Data from Three Studies at ADA 79th Scientific Sessions

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WESTLAKE VILLAGE, Calif., June 09, 2019 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** announced that new data from three different studies of Afrezza® (insulin human) Inhalation Powder were released at the American Diabetes Association's 79th Scientific Sessions, being held June 7-11, in San Francisco, California.

Poster 1350-P: Safety and Pharmacokinetics of Technosphere Insulin in Pediatric Patients

MannKind will present a poster with initial information from its ongoing study of Safety and Pharmacokinetics of Technosphere Insulin (Afrezza) in Pediatric Patients [1] on Monday, June 10. This study is the first step in preparation for a phase 3 safety and efficacy study.

Poster Highlights:

- In pediatric patients, the rapid rise in insulin concentrations corresponded with early postprandial glucose control within the first hour post-dose. The profile is similar to that previously observed in adults.
- Consistent with its safety profile in adults, Afrezza was generally well-tolerated in pediatric patients; most treatment emergent adverse events were of mild severity, and no severe hypoglycemia was observed.
- These data will help guide the finalization of the protocol for a phase 3 safety and efficacy study.

"We are excited to share the progress of the ongoing pediatric study program," said David Kendall, M.D., Chief Medical Officer of MannKind. "As is well known, type 1 diabetes is often diagnosed in children and adolescents, and these individuals will continue to require insulin therapy throughout their lives. Evaluating as quickly as possible the potential use of Afrezza in children and adolescents as an option for mealtime insulin therapy is a top priority for MannKind."

Poster 136-LB: Effective Treatment of T2D Patients Uncontrolled on Multiple Diabetes Medications by Adding Afrezza® Mealtime Ultra-Rapid Insulin

Dr. Philip Levin and colleagues presented data from an independent study supported and funded by MannKind. Dr. Levin presented late-breaking clinical data on interim results of a study[2] showing how a fixed titration schedule can be implemented to achieve better time in range and reduction of overall A1c.

Late Breaking Poster Highlights:

- Enrolled adult patients with uncontrolled type 2 diabetes on two or more therapies (orals/ basal/ GLPs) – with the addition of Afrezza at all meals by means of a rapid and ongoing titration protocol
- Observed a mean decrease in A1c of ~1.6% (all subjects with A1c reduction over 12 weeks of study)
- 93% (13 of 14 subjects) achieved A1c below 8% (mean baseline A1c 9.1%)
- Reduced hyperglycemia (>250mg/dL) by 74%
- Increased time in range more than 75%; daily glucose decreased by ~50 mg/dL as measured by blinded continuous glucose monitoring
- No significant difference in rates of hypoglycemia with the addition of Afrezza

"We are pleased to share the interim analysis from our independent investigator-initiated trial of Afrezza therapy. These preliminary data significantly advance our understanding of the potential clinical benefits and practical use of Afrezza therapy for those living with type 2 diabetes," stated Philip Levin, M.D. of Bay West Endocrinology Associates and MODEL Clinical Research in Baltimore, MD. "Data generated to this point are encouraging and support the use of Afrezza as prandial therapy earlier in the treatment of type 2 diabetes."

Oral Abstract
151-OR: Technosphere Insulin Provides Better Early Postprandial Glucose Control than Subcutaneous Rapid-Acting Analog

MannKind investigators also shared data at an oral presentation[3] using mixed meal tolerance testing to assess glucose control, Afrezza dosing and overall safety in a cohort of individuals with type 1 diabetes.

Oral Presentation Highlights:

- When compared to rapid acting injected insulin, Afrezza provided significantly better glucose control in the first two hours following the meal.
- Even when adjusting the dose of Afrezza using up to two times the dose of injected insulin aspart, Afrezza treatment was

associated with lower rates of overall and level 2 hypoglycemia - an observation that was particularly evident in the late (>2 hour) post-meal period.

Dr. Anne Peters, Clinical Professor of Medicine at the Keck School of Medicine at USC and Director of the USC Westside Center for Diabetes Care noted that “the improved post-meal glucose levels and lower rates of low blood sugars seen in this study of individuals with type 1 diabetes support my growing clinical experience. The presentation of these data provides further evidence that proper dosing of Afrezza has the potential to safely and effectively get more patients into target range at meal times.”

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 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 orally 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 quarterly report on Form 10-Q for the quarter ended March 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 – Poster Information

(1) Poster Presentation: *Safety and Pharmacokinetics of Technosphere Insulin (TI) in Pediatric Patients*
Presenter: David M. Kendall, M.D.
Poster No. 1350-P
Date/Time: Monday, June 10; 12:00 PM - 1:00 PM, Hall F (North, Exhibition Level)

(2) Late-Breaking Poster Presentation: *Effective Treatment of T2D Patients Uncontrolled on Multiple Diabetes Medications by Adding Afrezza Mealtime Ultra-Rapid Insulin*
Presenter: Philip Levin, M.D.
Poster No: 136-LB (late breaking poster)
Date/Time: Sunday, June 9; 12:00 PM - 1:00 PM, Hall F (North, Exhibition Level)

(3) Oral Presentation: *Technosphere Insulin Provides Better Early Postprandial Glucose Control than Subcutaneous Rapid-Acting Analog*
Presenter: David M. Kendall, M.D.
Poster No: 151-OR
Date/Time: Sunday, June 9; 9:45 AM

Source: MannKind