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VIENNA--(BUSINESS WIRE)--Sep. 29, 2009-- AFRESA® (insulin human [rDNA origin]) Inhalation Powder is a well-tolerated, ultra rapid acting insulin able to more closely replicate normal glucose suppression than currently available insulins, according to data presented at the 45th Annual Meeting of the European Association for the Study of Diabetes. Results from the open-label, single-dose, three-way crossover study showed that endogenous glucose production (EGP) was suppressed earlier following AFRESA administration compared with subcutaneous insulin lispro and inhaled Exubera in adult patients with type 2 diabetes. The inability to effectively suppress endogenous glucose production significantly increases the risk of fasting hyperglycemia in individuals with type 2 diabetes.

“Many people do not appreciate that most of the excess postprandial glucose increase in individuals with diabetes is due to inadequate suppression of endogenous glucose production by the liver,” said Jay S. Skyler, M.D., MACP, Professor, Division of Endocrinology, Diabetes, & Metabolism, Associate Director, Diabetes Research Institute, University of Miami Miller School of Medicine. “This study demonstrates that more rapid insulin availability better suppresses EGP.”

AFRESA is a novel, ultra rapid acting mealtime insulin therapy with an action profile that mimics meal-related early insulin release. Based on an extensive phase 2/3 clinical program, a New Drug Application (NDA) is currently under review by the U.S. Food and Drug Administration (FDA) requesting approval to market AFRESA Inhalation Powder and the AFRESA Inhaler for use in adult patients with type 1 and type 2 diabetes mellitus for the treatment of hyperglycemia. AFRESA is conveniently administered by oral inhalation.

Study Design and Key Findings

Findings were based on endogenous glucose production (EGP) suppression in 18 insulin-treated subjects with type 2 diabetes mellitus and normal pulmonary function administered 45 U AFRESA administered by inhalation, 12 IU subcutaneous insulin lispro or 4 mg inhaled Exubera. The main study end-point was time to EGP suppression.

EGP suppression occurred earliest with AFRESA, followed by insulin lispro and Exubera (40, 75 and 130 minutes post-dose of the median EGP-time profiles, respectively). Significant differences between insulin lispro and Exubera were observed up to 40 minutes compared with AFRESA ($p<0.002$) and up to 2 hours for the Exubera-AFRESA comparison ($p<0.05$). Median total areas over the EGP curve were comparable across groups (1,938, 1,842 and 2,294 µmol/min). Median postprandial blood glucose areas under the curves were 53,343, 50,608 and 54,598 mg/dl·min for AFRESA, insulin lispro and Exubera, respectively.

About Diabetes

Diabetes, which affects 23.6 million people in the U.S., or 8 percent of the population, is characterized by the body’s inability to properly regulate levels of blood glucose, or blood sugar. Insulin, a hormone produced by the pancreas, normally regulates the body’s glucose levels, but in people with diabetes insufficient levels of insulin are produced (type 1 diabetes) or the body fails to respond adequately to the insulin it produces (type 2 diabetes). Current mealtime insulin therapy regimens have a number of limitations, including the risk of severe hypoglycemia, the likelihood of weight gain, inadequate post-meal glucose control, the need for complex titration of insulin doses in connection with meals and the need for injections. Additionally, current therapies do not mimic the natural time-action profile of insulin normally seen in healthy individuals and present challenges in maintaining compliance.

About Endogenous Glucose Production (EGP)

Glucose found in the bloodstream originates from both exogenous and endogenous sources. The primary source of “exogenous” glucose is ingested food, while “endogenous” glucose from the liver is a result of the breakdown of stored starches, and is supplied to the body during the fasted state. The high blood sugar that is associated with diabetes results from an imbalance between the absorption of glucose, systemic glucose production and glucose utilization. Suppression of Endogenous Glucose Production (EGP) is one of insulin's primary metabolic effects, and failure of this action is a major contributor to the high post-meal glucose concentrations associated with type 2 diabetes mellitus. It is thought that the loss of insulin spikes after a meal, characteristic of those patients with type 2 diabetes, resulting in insulin concentrations that are too low to suppress hepatic glucose production.

About AFRESA®

AFRESA® is a novel, ultra rapid acting mealtime insulin therapy being studied for use in adult patients with type 1 and type 2 diabetes mellitus for the treatment of hyperglycemia. It is a drug-device combination product, consisting of AFRESA Inhalation

Powder pre-metered into single use dose cartridges and the light, discreet and easy to use AFRESA Inhaler. Administered at the start of a meal, AFRESA dissolves immediately upon inhalation and delivers insulin quickly to the blood stream. Peak insulin levels are achieved within 12 to 14 minutes of administration, effectively mimicking the release of meal-time insulin observed in healthy individuals. The AFRESA phase 2/3 clinical program included over 4,500 adult patients.

About MannKind Corporation

MannKind Corporation (Nasdaq: MNKD) focuses on the discovery, development and commercialization of therapeutic products for patients with diseases such as diabetes and cancer. Its pipeline includes AFRESA®, MKC253, MKC1106-PP, and MKC1106-MT. MannKind has submitted an NDA to the FDA requesting approval of AFRESA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. Its other programs are currently in Phase 1 clinical trials. MannKind maintains a website at http://www.mannkindcorp.com to which MannKind regularly posts copies of its press releases as well as additional information about MannKind. Interested persons can subscribe on the MannKind website to e-mail alerts that are sent automatically when MannKind issues press releases, files its reports with the Securities and Exchange Commission or posts certain other information to the website.

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to the promise for AFRESA and expectations regarding potential position and use of AFRESA in the market. Words such as "believes," "anticipates," "plans," "expects," "intend," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon the Company'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 these risks and uncertainties, which include, without limitation, risks inherent in the generation and interpretation of market research, the progress, timing and results of clinical trials, difficulties or delays in seeking or obtaining regulatory approval, the manufacture of AFRESA, competition from other pharmaceutical or biotechnology companies, MannKind's ability to enter into any collaborations or strategic partnerships, intellectual property matters, stock price volatility and other risks detailed in MannKind's filings with the Securities and Exchange Commission, including the Annual Report on Form 10-K for the year ended December 31, 2008 and periodic reports on Form 10-Q and Form 8-K. 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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