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AFRESA(R) Phase 3 Data Show Sustained Glycemic Control, Normal Lung Function in Patients over Four Years of Treatment

October 2, 2009 4:00 AM EDT

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VIENNA--(BUSINESS WIRE)--Oct. 2, 2009-- AFRESA® (insulin human [rDNA origin]) Inhalation Powder, a well-tolerated, ultra rapid acting insulin, showed no significant changes in pulmonary function and sustained glycemic control in adult patients with type 2 diabetes over four years of continuous treatment, according to data presented today at the 45th Annual Meeting of the European Association for the Study of Diabetes. Results from the open-label, controlled study conducted with patients who had previously completed two three-month, randomized phase 2 clinical trials showed minimal mean change in forced expiratory volume in one second (FEV_1) over a four-year period for those treated with AFRESA. Additionally, patients using AFRESA therapy experienced glycemic control for at least four years.

“We are encouraged by this long-term study which demonstrates that over four years, AFRESA maintained glycemic control with changes in lung function comparable to that seen in diabetic patients treated with injectable and oral therapies,” said Peter Richardson, Corporate Vice President and Chief Scientific Officer, MannKind Corporation. “These findings add to the growing body of clinical evidence that AFRESA is a promising therapeutic option for this patient population.”

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.

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.

Study Design and Key Findings

Findings were based on pulmonary function tests (PFTs) and A1C levels over a 4-year period in subjects with type 2 diabetes mellitus receiving AFRESA who had completed any of the two three-month, controlled, randomized, phase 2 clinical trials and continued open-label AFRESA as their exclusive prandial insulin regimen (n=229). The main study end-points were changes in lung functions and glycemic control in adult subjects with type 2 diabetes over 4 years of continued treatment with AFRESA.

Based on the predefined endpoint, over 4 years, changes in lung functions were small and similar to the changes expected in adults with type 2 diabetes. Annualized change in forced expiratory volume in 1 second was -0.048±0.006 l/year, and in diffusing capacity of the lung for carbon monoxide was -0.332±0.085 ml/min/mm Hg after 4 years of continued treatment with AFRESA. Mean A1C levels were 7.97 percent at baseline and remained steady with a slight decline through month 48 (6.45 percent). Overall, hypoglycemia rates remained stable at 0.31 events/subject-month during the first 6 months and 0.42 events/subject-month after 3 years, as measured over the final 12 months of AFRESA therapy.

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.

Presentation #215
Session: 36
Session Title: OP 36 Insulin therapy in type 2 diabetes mellitus
Session Date/Time: Friday, 02 October 2009, 16:00 - 16:15 CEST

Source: MannKind Corporation

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