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NEW ORLEANS, June 6 /PRNewswire-FirstCall/ -- AFRESA® (insulin human [rDNA origin]) Inhalation Powder is a well-tolerated, ultra rapid acting insulin with changes in pulmonary function tests comparable to usual antidiabetic treatment, according to data presented today at the American Diabetes Association's 69th Scientific Sessions. Results from the prospective, multicenter, phase 3 study conducted over a two-year period showed no difference in mean change in forced expiratory volume in one second (FEV(1)) between those treated with AFRESA and those treated with standard insulin therapy.

"Current mealtime insulin therapies, while accepted as an effective means to control glucose levels, have several limitations," said Peter Richardson, Corporate Vice President and Chief Scientific Officer, MannKind Corporation. "Our encouraging findings indicate that AFRESA may be a promising new treatment option with less weight gain and lower risk of hypoglycemia compared with current mealtime insulin therapy."

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 3 clinical program, a New Drug Application (NDA) has been accepted 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) over a 2-year period in subjects with type 1 and 2 diabetes mellitus receiving AFRESA (n=730) or usual antidiabetic treatment (n=824), along with nondiabetic subjects (n=145). The main study end-point was change from baseline in pre-bronchodilator FEV(1) at 2 years (non inferiority margin of 50 ml/year). Secondary endpoints included change from baseline in other PFT parameters (forced vital capacity, total lung capacity, and carbon monoxide diffusion test).

Consistent with the normal course of aging, PFTs declined in all groups, including the nondiabetic group. Based on the predefined endpoint, over 2 years, there was no difference in mean change in FEV(1) (mean change = 0.037 +/- 0.012) from baseline to 24 months between AFRESA and usual care, consisting of insulin or oral therapies.

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, which has completed phase 3 clinical trials, and MKC253, which is currently in phase 1 clinical trials. Both of these investigational products are being evaluated for their safety and efficacy in the treatment of diabetes. 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 SEC or posts certain other information to the website.

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