mannkind

Studies Show AFRESA(R) Controls Post-Meal Sugar Levels With Less Weight Gain and Hypoglycemia Risk for Diabetes Patients

June 6, 2009 4:00 AM EDT

Studies Show AFRESA(R) Controls Post-Meal Sugar Levels With Less Weight Gain and Hypoglycemia Risk for Diabetes Patients

NEW ORLEANS, June 6 /PRNewswire-FirstCall/ -- The findings of two 52-week studies show that the investigational ultra rapid acting insulin AFRESA® (insulin human [rDNA origin]) Inhalation Powder combined with basal insulin is comparable to standard of care therapies in controlling post-meal blood sugar levels, and also results in significantly less weight gain and risk of hypoglycemia for adult patients with diabetes. The data were presented today at the American Diabetes Association's 69th Scientific Sessions.

"The unique pharmacokinetic profile of AFRESA allows this product to rapidly achieve peak insulin levels," said John Gerich, M.D., Program Director, Clinical Research Center, Department of Medicine, University of Rochester School of Medicine and Dentistry. "These results indicate that AFRESA may be a promising new therapy for patients with type 1 and type 2 diabetes, as it controls post meal-time glucose levels with the added benefits of less weight gain and lower risk of hypoglycemia."

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.

Type 2 Study Design and Key Findings

Patients with type 2 diabetes who were inadequately controlled (A1C 7.0% and < /=11.0%) despite insulin with/ without oral anti-hyperglycemic therapy were randomized to a 52-week course of either AFRESA (TI) and bedtime glargine insulin (G) (n=334) or premixed biaspart 70/30 insulin BID (BPA 70/30) twice-a-day (n=343). The primary endpoint was mean change from baseline to week 52 in A1C. Secondary objectives were proportion of subjects reaching specific A1C levels and treatment differences in postprandial plasma glucose (PPG), fasting plasma glucose (FPG), and weight.

A1C was reduced by -0.66% and -0.72% in the TI+G and BPA 70/30 groups, respectively, and the proportion of subjects achieving A1C <7.0% were comparable between treatments (22% vs 27%). One-hour PPG change from baseline after a meal challenge was significantly lower in the TI+G group (37 vs. 54 mg/dL; p<0.0001). TI+G produced significantly less weight gain (0.9 vs. 2.5 kg; p=0.0002) and significantly less mild/moderate (48 percent vs. 69 percent, p<0.001) and severe (4 percent vs. 10 percent, p=0.0066) hypoglycemia compared to the BPA 70/30 group. Mean changes from baseline to week 52 in pulmonary function tests were similar in the two groups.

Type 1 Study Design and Key Findings

In the second study, patients with type 1 diabetes (A1C 7.0% and < /=11.0%) were randomized to a 52-week trial comparing AFRESA (n=301) with insulin aspart, a rapid acting analog (RAA) (n=288), both given at meals with insulin glargine, a long-acting analog (LAA). Pre-specified efficacy endpoints included change in A1C, 1-hour PPG, 2-hour PPG and FPG following a standard meal challenge, and body weight. Adverse events were monitored to compare safety profiles.

Reductions in A1C were comparable in both treatment groups with no significant differences in LAA doses in either group. FPG levels (-35.5 +/- 3.3 vs. -20.6 +/- 3.2, p=0.0012) and 1-hour PPG (20.9 +/- 4.79 vs. 40.5 +/- 4.56, CI=0.0022) values were significantly lower with AFRESA than with RAA. Patients in the AFRESA group lost weight (-0.5 +/- 0.3), while patients in the RAA group gained weight (+1.4 +/- 0.3), with the difference being statistically significant (p<0.0001). Finally, the AFRESA group had a statistically significant reduction in the incidence of mild/moderate (odds ratio [OR] 0.474, confidence interval [CI] 0.271, 0.831; p=0.0091) and total hypoglycemia (OR 0.488; CI 0.278, 0.856; p=0.0124).

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 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.

Poster #466-P; Session PO01, June 6, 11:30 A.M. - 1:30 P.M.

Poster #479-P; Session PO02, June 7, 12:00 P.M. - 2:00 P.M.

CONTACT: Alanna Jamieson, MCS Healthcare Public Relations, alannaj@mcspr.com, (908) 234-9900

SOURCE MannKind Corporation

CONTACT:
Alanna Jamieson,
MCS Healthcare Public Relations,
+1-908-234-9900,
alannaj@mcspr.com,
for MannKind Corporation

Web Site: http://www.mannkindcorp.com