MannKind Corporation

June 10, 2010

AFREZZA Demonstrates Non-Inferiority Compared to Standard Therapy in Controlling Blood Sugar Levels in Type 1 Diabetes Patients

Findings Show Reductions in HbA1c Levels, Plus Significantly Lower Rates of Hypoglycemia and Fasting Blood Glucose Levels

VALENCIA, Calif., Jun 10, 2010 (BUSINESS WIRE) --MannKind Corporation (NASDAQ: MNKD) today announced that results of a new 16-week trial show that the investigational ultra rapid acting mealtime insulin, AFREZZA™ (insulin human [rDNA origin]) Inhalation Powder, combined with basal insulin, is clearly non-inferior to standard therapy insulin lispro, a rapid acting insulin, also combined with basal insulin, in reducing HbA1c levels in subjects with inadequately controlled Type 1 diabetes. In addition, patients treated with AFREZZA had statistically significant lower rates of hypoglycemia, post-prandial glucose (PPG) levels when measured at 30, 60, 90 and 120 minutes, and fasting blood glucose (FBG) levels when compared to subcutaneously injected insulin lispro.

"Effectively controlling blood sugar levels and managing hypoglycemic events go hand in hand as key to successfully treating patients with Type 1 diabetes," said Satish K. Garg, M.D., Professor, Departments of Pediatrics and Medicine, University of Colorado School of Medicine; Head, Young Adult Diabetes Clinic, Barbara Davis Center for Childhood Diabetes, and lead study investigator. "Our findings demonstrate that AFREZZA may offer a significant advance from current mealtime insulin delivery methods, as it is comparable to the standard of care in glycemic control and provides the additional benefit of lower hypoglycemia rates."

Diabetes, which affects 26.8 million people in the U.S., 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 or the body fails to respond adequately to the insulin it produces. Historically, mealtime insulin therapy regimens have had 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, these therapies have not mimicked the natural time-action profile of insulin normally seen in healthy individuals and presented challenges in maintaining compliance.

AFREZZA™ is a novel, ultra rapid acting mealtime insulin therapy being developed by MannKind Corporation for the treatment of adult patients with Type 1 and Type 2 diabetes for the control of hyperglycemia. It is a drug-device combination product, consisting of AFREZZA Inhalation Powder pre-metered into single use dose cartridges and the small, discreet and easy- to-use AFREZZA Inhaler. Administered at the start of a meal, AFREZZA dissolves immediately upon inhalation and delivers insulin quickly to the blood stream. Peak insulin levels are achieved within 12 to 14 minutes of administration, mimicking the release of meal-time insulin observed in healthy individuals. To date, the AFREZZA clinical program has involved more than 50 different studies and over 5,000 adult patients with both Type 1 and Type 2 diabetes.

Study Design and Key Findings

Patients with inadequately controlled Type 1 diabetes (7% < HbA1c less-than or equal to 9%) were randomized to treatment with either AFREZZA plus insulin glargine (n=65) or insulin lispro plus insulin glargine (n=65) over 16 weeks. The primary objective was to demonstrate that the efficacy of AFREZZA in combination with insulin glargine was non-inferior to the efficacy of lispro in combination with insulin glargine . Secondary endpoints included the percentage of patients achieving HbA1c target goals of less-than or equal to 7.0% and less-than or equal to 6.5%, PPG excursions following the ingestion of a standardized meal (meal challenge), and the rates of hypoglycemia.

In the intent-to-treat population, AFREZZA lowered HbA1c by -0.10% (mean change from baseline HbA1c) as compared to -0.03% in the lispro group. The difference of 0.07% between the two groups fell well within the non-inferiority margin of 0.4% (95% CI [-0.31, 0.17]). Similar results were also observed in the intent-to-treat with last observation carried forward population (-0.04%; 95% CI [-0.25, 0.18]). In addition, a significantly higher percentage of patients in the AFREZZA group (9.6%) reached an HbA1c goal of less than 6.5% compared to the lispro group (3.5%, p = 0.0277).

Even with matching levels of glargine, patients treated with AFREZZA experienced significantly greater decreases in FBG levels (mean change from baseline 41.53 mg/dl in the AFREZZA group versus 9.16 mg/dl in the lispro group, p = 0.0107). Patients treated with AFREZZA also experienced significantly lower PPG levels at 30, 60, 90 and 120 minutes (mean PPG levels at 30 minutes AFREZZA 130 mg/dl versus lispro 195.09 mg/dl; 60 minutes: AFREZZA 136 mg/dl versus lispro 214.49 mg/dl; 90

minutes: AFREZZA 163.94 mg/dl versus lispro 228.45 mg/dl; 120 minutes: AFREZZA 199.53 mg/dl versus lispro 241.39 mg/dl). In addition, patients treated with AFREZZA had significantly lower rates of total and mild/moderate hypoglycemia (6.2 versus 8.2 events per subject month [p=0.0345] and 6.0 versus 8.0 events per subject month [p=0.0269], respectively).

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 diabetes pipeline includes AFREZZA™ and MKC253. MKC253 is currently in phase 1 clinical trials. In March 2009, MannKind submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) requesting approval of AFREZZA for the treatment of adults with Type 1 or Type 2 diabetes for the control of hyperglycemia. In March 2010, MannKind received a Complete Response to this NDA from the FDA requesting additional information. An End-of-Review meeting was held in June 2010 and MannKind is currently preparing its resubmission of the AFREZZA NDA. Other products in MannKind's pipeline include the cancer immunotherapy products MKC1106-PP and MKC1106-MT, which 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.

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