MannKind Corporation

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Study Shows AFREZZA(R) Controls Blood Sugar Levels in Type 1 Diabetes, Results in Weight Loss, Less Hypoglycemia Than Usual Care

Two-year data on investigational therapy presented at the American Association of Clinical Endocrinologists 19th Annual Meeting

BOSTON, Apr 23, 2010 (BUSINESS WIRE) --Diabetes treatment regimens containing AFREZZA® (insulin human [rDNA origin]) Inhalation Powder, a well-tolerated, ultra rapid acting insulin, provide glucose control similar to standard insulin therapy along with weight loss and reduced incidence of hypoglycemia in patients with Type 1 diabetes and poorly controlled blood sugar levels, according to a two-year study presented today at the American Association of Clinical Endocrinologists 19th Annual Meeting (Poster #283).

"Standard mealtime insulin therapies are effective in managing blood sugars in patients with Type 1 diabetes, but are known to cause weight gain and severely low blood sugar levels," said Philip Raskin, M.D., Clifton and Betsy Robinson Chair in Biomedical Research, Southwestern Medical School, University of Texas. "Our study shows that treatment regimens incorporating AFREZZA offer glycemic control comparable to conventional regimens, with the added benefits of weight loss and less incidence of hypoglycemia, making AFREZZA a potentially important and useful new treatment option in the diabetes space."

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, 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 light, 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 49 different studies and over 5,000 adult patients.

Study Design and Key Findings

Findings from a prospective, multisite parallel-group study comparing the efficacy and safety of AFREZZA versus usual diabetes care in patients with diabetes mellitus and inadequate glycemic control (HbA_{1c} >6.6% and <12.0%) despite subcutaneous insulin therapy were evaluated based on prespecified secondary safety endpoints. Endpoints included change in HbA_{1c}, change in body weight and frequency of defined mild, moderate and severe hypoglycemia. Patients were followed for a total of up to two years and were randomly assigned to a treatment regimen of either AFREZZA plus subcutaneous basal insulin or usual diabetes treatment regimens of any insulin. Of the 538 Type 1 patients in the study, 267 subjects received AFREZZA along with subcutaneous basal insulin and 271 subjects received usual antidiabetic regimen.

At the end of two years, there was a comparable reduction in HbA_{1c} levels (by 0.29% and 0.31% in the AFREZZA and usual care groups, respectively). Additionally, AFREZZA resulted in weight loss, while standard diabetes care resulted in weight gain (-0.59 versus +1.38kg, respectively; p=0.0007). There was a lower incidence of hypoglycemic events in the AFREZZA group (61.8% versus 66.05% for the usual care group). As well, there were 2.36 severe events per 100 subject-months in the AFREZZA group compared to 3.76 for the usual diabetes care group.

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 an NDA to the 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. Currently, AFREZZA remains under regulatory review. Other products in its 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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