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AFREZZA® Demonstrates Long-Term Efficacy in Controlling Blood Sugar Levels in Patients with Type 2 Diabetes

June 28, 2010 4:00 AM EDT

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ORLANDO, Fla., Jun 28, 2010 (BUSINESS WIRE) --

AFREZZA® (insulin human [rDNA origin]) Inhalation Powder, a well-tolerated, investigational ultra rapid acting mealtime insulin, as part of a diabetes treatment regimen, provides long-term glucose control comparable to usual insulin therapy but with a significantly reduced incidence of hypoglycemia and less weight gain in patients with Type 2 diabetes, according to a two-year study presented today at the American Diabetes Association's 70th Scientific Sessions.

"While insulin therapy is accepted as an effective means to control glucose levels, currently available mealtime insulin products have several limitations, including the risk of severe hypoglycemia," said Philip Raskin, M.D., Clifton and Betsy Robinson Chair in Biomedical Research, Southwestern Medical School, University of Texas. "Our results add to the growing body of evidence that AFREZZA is effective in controlling blood sugar levels in patients with Type 2 diabetes, and provides the added benefits of a significant reduction in severely low blood sugar levels and less weight gain as compared to standard of care insulin therapy."

Diabetes, which affects 23.6 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 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 more than 50 different studies and over 5,000 adult patients.

Study Design and Key Findings

A prospective, multisite parallel-group study compared the safety and efficacy of AFREZZA versus usual diabetes care in Type 2 diabetic patients with inadequate glycemic control (HbA_{1c} >6.6% and <12.0%). The study was primarily a safety trial with efficacy as a secondary endpoint. Over two years, 678 patients received their usual antihyperglycemic regimen (insulin, oral hypoglycemics and/or diet and exercise) and 656 subjects incorporated AFREZZA into their usual antihyperglycemic regimen. The safety results from this study were reported at the American Diabetes Association's 69th Scientific Sessions® in June 2009.

The efficacy data show that at the end of two years, there was a comparable reduction in HbA_{1c} levels (by 0.70% and 0.59% in the AFREZZA and usual care groups, respectively, p=0.30). According to study findings, total hypoglycemic event rates were significantly lower in patients treated with AFREZZA versus usual care (0.15 per subject-month versus 0.24 per subject-month, p=0.03). Mild or moderate hypoglycemic event rates were also significantly lower in the AFREZZA-treated group versus those maintaining usual care (0.15 per subject-month versus 0.24 per subject-month, p=0.04). A reduction in severe hypoglycemic event rates was also observed (0.53 per 100 subject-months for patients treated with AFREZZA versus 1.17 per 100 subject-months for usual care subjects, p=0.67). Additionally, AFREZZA-treated patients experienced less weight gain, 1.56 kg versus 1.75 kg for patients treated with standard diabetic care (p=0.67).

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.

SOURCE: MannKind Corporation

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