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SAN DIEGO, Jun 24, 2011 (BUSINESS WIRE) -- The findings of two separate studies further substantiate that treatment with the investigational ultra rapid acting mealtime insulin AFREZZA® (insulin human [rDNA origin]) Inhalation Powder does not result in excess cardiovascular events in type 1 or type 2 diabetes patients. Furthermore, results demonstrate that inhaled AFREZZA did not produce clinically significant effects on heart rate, PR and QRS interval duration, or cardiac morphology. The data are being presented at the American Diabetes Association's 71st Scientific Sessions®.

AFREZZA® is a novel, ultra rapid-acting mealtime insulin therapy in late stage clinical investigation for the treatment of adult patients with type 1 and type 2 diabetes mellitus for the control of hyperglycemia. Two phase 3, multicenter clinical trials are currently underway to evaluate the efficacy and safety of AFREZZA using MannKind Corporation's next generation inhalation device.

"In response to the recent concern over the cardiovascular risk of diabetes therapies, it is important to carefully analyze all trials and maintain an ongoing program of safety surveillance," said Anders H. Boss, M.D., M.F.P.M., Senior Vice President and Chief Medical Officer at MannKind Corporation. "These most recent safety findings add to the growing body of evidence that AFREZZA may be a promising new therapy for patients with type 1 and type 2 diabetes, without the concern of increased risk for cardiovascular events."

"Overall Cardio" Study Design and Key Findings

To evaluate whether excess cardiovascular events occurred in patients treated with AFREZZA versus current antidiabetic therapies, cardiovascular adverse events, pooled from nine phase 2/3 clinical trials consisting of 4,467 patients treated for periods from three months to two years, were reviewed. The prevalence of prior cardiovascular disease, such as myocardial infarction, coronary artery disease or stroke, was less than 10 percent in patients with type 1 diabetes but approached 40 percent in patients with type 2 diabetes.

In controlled trials, the incidence of cardiovascular events did not show increased risk with AFREZZA use in type 1 (31 vs. 35, 0.85 relative risk), type 2 (167 vs. 136, 1.02 relative risk) or the combined type 1 plus type 2 (198 vs. 171, 1.01 relative risk) diabetes populations. The number of patients with ischemic events was low and similar between treatment groups. Cerebrovascular events and other cardiovascular events, such as coronary artery disease, and arrhythmic events were also similar between treatment groups.

"QTc" Study Design and Key Findings

In a randomized, 4-period crossover, double-blind, double-dummy, placebo- and active-controlled cardiac safety study, healthy men (n=26) and women (n=22) were dosed with inhaled 40 mg Technosphere® particles, 20 mg Technosphere particles, or placebo, and oral 400 mg moxifloxacin was used as the positive control. ECGs were obtained digitally at regular time intervals before and after each dose and independently evaluated. Safety was monitored through evaluation of adverse events, clinical laboratory values, physical exams, vital signs, and pulmonary function tests.

Time-averaged analysis of the placebo-corrected mean QTcI change from baseline for Technosphere particles showed no significant effect on QTc at all times (0.5 ms and 0.3 ms for the 20- and 40-mg Technosphere particles doses, respectively), with the upper 1- sided 95% confidence bound well below the 10 ms threshold. The placebo-corrected mean QTcI change from baseline for moxifloxacin was +5.5 ms, demonstrating the study sensitivity, and the mean change from baseline for placebo was -2.2 ms. The most commonly observed adverse event was cough (54%), which was highest in the Technosphere particles groups.

About Diabetes

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.

About AFREZZA®

AFREZZA® is a novel, ultra rapid acting mealtime insulin therapy being developed by MannKind Corporation for the treatment of adult patients with type 1 or 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 56 different studies and over 5,300 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 lead product candidate, AFREZZA®, is in late stage clinical investigation for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. 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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