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BOSTON, Apr 23, 2010 (BUSINESS WIRE) --Pulmonary function test results (PFTs) in patients treated with AFREZZA® (insulin human [rDNA origin]) Inhalation Powder, a well-tolerated, ultra rapid acting insulin, at follow-up measurements were similar to PFT results observed in patients receiving standard antidiabetic therapy, according to data presented today at the American Association of Clinical Endocrinologists 19th Annual Meeting (Poster #267). Results from the follow-up study suggest that the pattern and magnitude of changes in lung function associated with the use of AFREZZA in patients with Type 1 and Type 2 diabetes are not likely due to any structural alterations in the lungs and are not clinically meaningful.

"Our findings add to the growing body of clinical evidence that indicates AFREZZA is comparable to standard of care insulin therapy in terms of lung safety," said Peter Richardson, MRCP, Corporate Vice President and Chief Scientific Officer, MannKind Corporation. "We are encouraged by these PFT data, which support our belief that AFREZZA, clinically shown to provide glycemic control similar to standard therapy with less risk of hypoglycemia and weight gain, is a promising new option that may address a poorly-met need in diabetes treatment."

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 (Type 1 diabetes) or the body fails to respond adequately to the insulin it produces (Type 2 diabetes). 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 were based on changes in pulmonary function after ending treatment with AFREZZA and resuming usual antidiabetic treatment in patients with Type 1 and Type 2 diabetes mellitus. Adults with diabetes who participated in any of four controlled clinical trials of AFREZZA were invited to participate in this follow-up trial. Patients were followed for a total of up to three months with PFTs assessed at the end of the parent trial and one and three months after completion of the parent trial. Of the 649 patients in the study, 315 subjects received AFREZZA and 334 subjects received usual antidiabetic regimen without AFREZZA during the parent trials.

During the parent trials, small, non-progressive differences in mean changes from baseline in forced expiratory volume in 1 second (FEV_1) and carbon monoxide diffusing capacity (DLCO) were observed in the AFREZZA group. During the follow-up trial, these changes disappeared, regardless of the duration of exposure to AFREZZA, when the groups were compared three months after ending treatment with AFREZZA and resuming usual antidiabetic therapy (FEV_1: -0.08 L in the ex-AFREZZA group, -0.11 L in the non-AFREZZA group [p=0.1388]; DLCO: -1.29 mL/min/mm Hg in the ex-AFREZZA group, -1.37 mL/min/mm Hg in the non-AFREZZA group [p=0.9360]). There was also no statistical difference in FEV_1 between the treatment groups when examining subjects with Type 1 and Type 2 diabetes (p=0.6158 and p=0.1795, 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 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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