MannKind Corporation

June 24, 2011

Type 1 Diabetes Patients Using AFREZZA Have More Positive View of Therapy Compared to Standard Insulin Therapy

Significantly improved perceptions of convenience, comfort, and ease of regimen adherence of insulin therapy reported by patients using ultra rapid acting mealtime inhaled insulin
Data to be presented at the American Diabetes Association's 71st Scientific Sessions

SAN DIEGO, Jun 24, 2011 (BUSINESS WIRE) -- Results of a new patient-reported outcomes (PRO) study show that patients with type 1 diabetes who received the investigational ultra rapid acting mealtime insulin, AFREZZA® (insulin human [rDNA origin]) Inhalation Powder, combined with basal insulin, came to view insulin therapy more positively during the course of a 16-week study compared with patients using standard therapy insulin lispro, a rapid acting insulin, combined with basal insulin. The data are being presented at the American Diabetes Association's 71st Scientific Sessions®.

In the study, measures of diabetes worries, perceptions of insulin therapy (overall, convenience, comfort, ease of regimen adherence and perceived efficacy), treatment satisfaction and treatment preference were included in an Inhaled Insulin Treatment Questionnaire (IITQ). Perceptions of insulin therapy (overall, convenience, comfort and ease of regimen adherence) showed significant improvement ($P<0.01$) in patients using AFREZZA, with greater improvement than in patients receiving standard therapy ($P<0.05$). In the AFREZZA treatment group treatment satisfaction improved significantly ($P<0.05$), with no significant between-group difference in change.

"The challenge of diabetes and its treatment can have a profound psychosocial impact on the patient, which must be addressed as part of managing the condition," said lead investigator Richard R. Rubin, PhD, CDE, Professor of Medicine and Pediatrics at Johns Hopkins University School of Medicine. "Current mealtime insulin therapy regimens require patients to titrate their insulin and use injections, both of which can negatively affect their perceptions of therapy and their long-term compliance. The patient-reported results of our study show that in a real-world setting, AFREZZA may offer a convenient and easy-to-use insulin delivery option for patients with diabetes."

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 56 different studies and over 5,300 adult patients with both type 1 and type 2 diabetes.

Study Design and Key Findings

In the 16-week, randomized, multicenter study, adults with type 1 diabetes used AFREZZA plus insulin glargine (n=61), or insulin lispro plus insulin glargine (n=65). Secondary study endpoints included IITQ measures of diabetes worries, perceptions of insulin therapy (overall and four subscales: comfort, convenience, ease of adherence and perceived efficacy), treatment satisfaction and treatment preference, and an intent-to-treat analysis using mixed models to estimate differences in mean group changes in IITQ scores PRO from baseline to week 16 (adjusted for baseline scores) were utilized; *t*-tests assessed within-group changes at week 16.

Diabetes worries, perceived efficacy of insulin therapy, and treatment preference did not change significantly from baseline to Week 16 in either treatment group, with no significant between-group differences in change.

Treatment satisfaction improved from baseline to Week 16 in both treatment groups ($p<0.05$), with no significant between-group differences in change. Perceptions of insulin therapy, (overall and three subscales: convenience, comfort, and ease of regimen adherence) improved from baseline to Week 16 in the TI Inhalation Powder group (all $p<0.01$), and comfort improved in the insulin lispro group ($p<0.05$). Overall perceptions of insulin therapy, convenience, comfort, and ease of regimen adherence improved more in the TI Inhalation Powder group than in the insulin aspart group (all $p<0.05$).

Results of the primary endpoints, which show that AFREZZA is clearly non-inferior to standard therapy insulin lispro combined with basal insulin in reducing HbA1c levels in patients with inadequately controlled type 1 diabetes (7% < HbA1c less-than or equal to 9%), are also being presented at the ADA meeting and were announced last year. Other study results reported earlier showed that patients treated with AFREZZA had statistically significant lower rates of hypoglycemia, post-prandial glucose (PPG) levels, and fasting blood glucose (FBG) levels when compared to subcutaneously injected insulin lispro.

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.

SOURCE: MannKind Corporation

Investors:
MannKind Corporation
Matthew Pfeffer
Chief Financial Officer
(661) 775-5300
mpfeffer@mannkindcorp.com
or
Media:
MCS Healthcare Public Relations
Laura de Zutter
(908) 234-9900
laurad@mcspr.com