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CORRECTING and REPLACING MannKind Reports Positive Data from a Phase 3 Clinical Study of AFREZZA in Patients with Type 1 Diabetes

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CORRECTING and REPLACING MannKind Reports Positive Data from a Phase 3 Clinical Study of AFREZZA in Patients with Type 1 DiabetesVALENCIA, Calif.--(BUSINESS WIRE)--Aug. 14, 2013--Second graph under Other Results subhead, second sentence should read: The event rate of severe hypoglycemia was also lower in the AFREZZA-Gen2 group (8.05 events per 100 subject-months) than in the insulin aspart group (14.45 events per 100 subject-months); however, this difference was not statistically significant (p=0.1022) (sted The event rate of severe hypoglycemia was also lower in the AFREZZA-Gen2 group (8.05 events per subject-month) than in the insulin aspart group (14.45 events per subject-month); however, this difference was not statistically significant (p=0.1022)).

The corrected release reads:

MANNKIND REPORTS POSITIVE DATA FROM A PHASE 3 CLINICAL STUDY OF AFREZZA IN PATIENTS WITH TYPE 1 DIABETES

MannKind Corporation (Nasdaq: MNKD) today announced positive preliminary results from Study 171, a Phase 3 clinical study of AFREZZA® (insulin human [rDNA origin]) Inhalation Powder, an investigational, ultra rapid-acting mealtime insulin therapy, administered using MannKind's next-generation (Gen2) inhaler (also known as the Dreamboat&#8482 inhaler), in patients with type 1 diabetes.

Highlights

AFREZZA-Gen2, compared to insulin aspart, showed:

Non-inferior decreases in A1c levels; Significantly less hypoglycemia; Significant decreases in fasting blood glucose levels; and Significant weight advantage. In addition, the changes in pulmonary function observed in the AFREZZA-Gen2 group were no different than those observed in an AFREZZA treatment group that utilized MannKind's first-generation (MedTone) inhaler. This finding will facilitate bridging the Gen2 inhaler to the pulmonary safety data that was collected in earlier clinical studies using the MedTone inhaler.

"We are pleased that Study 171 met its primary endpoint of non-inferiority, by demonstrating that AFREZZA produces A1c reductions comparable to insulin aspart," stated Alfred Mann, Chairman and Chief Executive Officer of MannKind Corporation. "Importantly, this study also established a bridge between the Gen2 inhaler and the large body of pulmonary safety data that was previously collected for AFREZZA using the MedTone inhaler. Consistent with previous studies of AFREZZA, including a two-year safety study involving 2,035 subjects, the use of AFREZZA was associated with a clinically insignificant decrease in lung function that appeared at the onset of therapy, did not progress during therapy and resolved fully upon cessation of therapy. Based on the results of this study, we believe that AFREZZA can be used to achieve glycemic control that is comparable to the current standard of care while at the same time offering potential advantages in terms of lower fasting blood glucose levels, weight neutrality and a lower overall risk of hypoglycemia."

Study 171

Study 171 was an open-label study involving 518 patients with type 1 diabetes on basal/bolus insulin therapy who were studied at sites in the United States, Russia, Ukraine and Brazil. After a four-week run-in period to optimize their basal insulin, patients entered a 24-week treatment period in which they were randomized in one of three ways:

Continuing on subcutaneous insulin aspart in combination with a basal insulin (170 patients); Switching to AFREZZA administered using the Gen2 inhaler in combination with their basal insulin (174 patients); or Switching to AFREZZA administered using the MedTone inhaler in combination with their basal insulin (174 patients). The treatment period consisted of 12 weeks of prandial insulin optimization with continued basal titration followed by a 12-week period during which subjects maintained stable doses of insulin (prandial and basal). There was also a follow-up visit four weeks after completion of the treatment period.

Over the 24-week treatment period of this study, A1c levels decreased comparably in the AFREZZA-Gen2 group (-0.21%) and the insulin aspart group (-0.40%). The 95% confidence interval (0.02% to 0.36%) of the between-group difference did not exceed the predetermined threshold of 0.40%, thereby establishing non-inferiority between AFREZZA-Gen2 and insulin aspart, which was the primary endpoint of the study.

Other Results

There was a significant difference in fasting blood glucose (FBG) levels in the AFREZZA-Gen2 group compared to the insulin aspart group. In the AFREZZA-Gen2 group, mean FBG levels decreased by 25.3 mg/dL by the end of the treatment period whereas the insulin aspart group experienced an increase of 10.2 mg/dL in FBG levels over the same period (p=0.0027). After the four-week follow-up period, during which all patients received insulin aspart and a basal insulin, there was no longer any difference in FBG levels between the treatment groups, demonstrating that this effect on FBG levels was attributable to AFREZZA therapy.

Significantly less total hypoglycemia was observed in the AFREZZA-Gen2 group (9.80 events per subject-month) compared to the insulin aspart group (13.97 events per subject-month; p