mannkind

MannKind Reports Positive Data from a Phase 3 Clinical Study of Technosphere Insulin in Type 1 Diabetes

September 16, 2008 4:00 AM EDT
MannKind Reports Positive Data from a Phase 3 Clinical Study of Technosphere Insulin in Type 1 DiabetesStudy 009 meets its primary endpoint of non-inferiority to a rapid-acting insulin analog

VALENCIA, Calif., Sept. 16 /PRNewswire-FirstCall/ -- MannKind Corporation (Nasdaq: MNKD) today released preliminary top-line results from a Phase 3 clinical study of the Technosphere® Insulin System in patients with type 1 diabetes (Study 009). This study compared the safety and efficacy of prandial inhalations of Technosphere Insulin (the TI group) versus prandial subcutaneous injections of insulin aspart (the comparator group). Both groups also received daily subcutaneous injections of a basal insulin (insulin glargine).

Study Highlights Technosphere Insulin, compared to a rapid-acting insulin analog, showed:

Comparable reductions in A1C levels Comparable numbers of patients reaching pre-defined A1C goals Superior fasting blood glucose levels Better early post-prandial glucose control Fewer patients experiencing hypoglycemic events Weight loss versus weight gain No adverse effects on pulmonary function

Dr. Peter Richardson, MannKind's Chief Scientific Officer, commented, "We are very pleased with the results of this study, the first of our three completed pivotal Phase 3 studies. These observations confirm the results of earlier studies and build on the important differentiating features of this product, including its positive effects on fasting glucose levels. Technosphere Insulin promises to be an important additional option for the treatment of patients with type 1 diabetes. Our next step is to lock the databases for the remaining two pivotal studies, which further examine long-term efficacy and safety in patients with diabetes. We are also continuing our preparations to submit a new drug application by year-end or shortly thereafter."

About Study 009

The primary objective of this trial was to compare the efficacy (as expressed by the change in A1C levels) of the treatment received by the TI group versus the treatment received by the comparator group. A total of 565 patients were studied in sites in the United States, Europe and Latin America. A total of 293 patients received Technosphere Insulin, and 272 patients received insulin aspart.

Over the 52-week period of this study, A1C levels decreased comparably in the two treatment groups, with a between-group difference of -0.24%. The 95% confidence interval (-0.09% to -0.40%) did not exceed the predetermined threshold of 0.40%, thereby establishing non-inferiority between Technosphere Insulin and insulin aspart. There were no interactions associated with the data from different sites or different countries; the statistical analysis was conducted on the entire intention-to-treat (ITT) population.

A comparable percentage of patients reached A1C target levels between the two treatment groups. There were no statistically significant differences in the percentage of patients whose A1C level decreased below 8.0% (50.7% for the TI group; 56.3% for the comparator group); 7.0% (16.3%, TI

group; 16.2%, comparator group); and 6.5% (7.4%, TI group; 7.2%, comparator group).

Over the 52-week period of the study, fasting blood glucose (FBG) levels decreased significantly (p