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VALENCIA, Calif., Dec. 18 /PRNewswire-FirstCall/ -- MannKind Corporation (Nasdaq: MNKD) today released preliminary top-line results from two pivotal Phase 3 clinical studies of AFRESA, the company's ultra rapid acting insulin product (Studies 102 and 030). The protocols for these studies were reviewed and prospectively approved by the FDA under its special protocol assessment (SPA) procedure. As previously announced, both studies achieved their primary endpoints.

Study 102 - comparable decreases in A1C levels

Study 102 compared the efficacy of meal-time AFRESA in combination with a long-acting basal insulin versus twice daily injections of pre-mixed insulin (a mixture of rapid-acting insulin and intermediate-acting insulin) in patients with type 2 diabetes. A total of 323 patients were randomized to the AFRESA group and 331 patients were randomized to the pre-mix group.

Over the 52-week period of this study, A1C levels decreased comparably in the two treatment groups, 0.59 in the AFRESA group and 0.71 in the pre-mix group. The 95% confidence interval (0.29%) of the between-group difference did not exceed the predetermined threshold of 0.40%, thereby establishing non- inferiority between AFRESA and pre-mixed insulin.

Other study highlights:

-- A comparable percentage of patients reached A1C target levels in each treatment group.

-- There was a significantly greater decrease in fasting blood glucose levels in the AFRESA group compared to pre-mixed insulin.

-- Patients in the AFRESA group gained significantly less weight than did patients in the pre-mix group.

-- Severe hypoglycemic events were significantly less common in the AFRESA group than in the pre-mix group

-- There were no between-group differences in pulmonary function measures, including FEV1 (forced expiratory volume in one second), FVC (forced vital capacity), DLCo (carbon monoxide diffusing capacity) and TLC (total lung capacity).

-- These preliminary results are subject to further statistical analysis.

Study 030 - no adverse effect on lung function

Study 030 compared the pulmonary safety of meal-time inhalation of AFRESA versus usual care (the comparator group). A total of 938 patients with type 1 and type 2 diabetes were randomized to the AFRESA group; 951 patients were randomized to the comparator group. An additional 164 subjects without diabetes were enrolled into a third arm in order to assess the effect of diabetes on pulmonary function.

The primary endpoint of Study 030 was pre-specified with the FDA as a between-group difference (AFRESA-treated vs. comparator group) of less than 50 mL per year in the decline from baseline measures of FEV1 over the entire study period. After two years of treatment, the difference between mean FEV1 values for the two treatment groups was 37 mL (95% CI: 14-60 mL) -- well within the 100 mL pre-defined limit. Non-inferior results were also observed in secondary measures of lung function, including FVC, TLC and DLCo.

Other study highlights:

-- On average, patients in the AFRESA group gained less weight than did patients in the comparator group or subjects without diabetes.

-- Comparable decreases were observed in A1C levels between the AFRESA- treated group and the comparator group

-- Severe hypoglycemic events were significantly less common in the AFRESA group compared to the comparator group.

These preliminary results are subject to further statistical analysis.

Dr. Peter Richardson, MannKind's Chief Scientific Officer, commented, "We are continuing to analyze the results of our pivotal Phase 3 clinical studies, and plan to share more data at upcoming investor presentations and the American Diabetes Association scientific meeting in June. In addition, we anticipate shortly the completion of the bioequivalency study that compares the clinical version of our inhaler to the more rugged and less costly commercial version. With this gating item behind us, we are now focusing on readying our new drug application for AFRESA for submission to the FDA early in the new year."

About AFRESA

AFRESA is an ultra rapid acting insulin product that has completed Phase 3 trials. The pharmacokinetic profile of AFRESA sets it apart from all other insulin products. The large surface area of the lung provides unique access to the circulatory system. The pH-sensitive AFRESA particles immediately dissolve upon contact with the lung surface, releasing insulin monomers that rapidly enter the bloodstream. It achieves peak insulin levels within 12-14 minutes of administration, effectively mimicking the release of meal-time insulin observed in healthy individuals, but which is absent from patients with diabetes.

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 pipeline includes AFRESA, which has completed Phase 3 clinical trials, and MKC253, which is currently in

phase 1 clinical trials. Both of these investigational products are being evaluated for their safety and efficacy in the treatment of diabetes. MannKind maintains a website at http://www.mannkindcorp.com to which MannKind regularly posts copies of its press release as well as additional information about MannKind. Interested persons can subscribe on the MannKind website to email alerts that are sent automatically when MannKind issues press releases, files its reports with the SEC or posts certain other information to the website.

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to the promise for AFRESA, next steps in the Company's clinical trial program, plans and timing for the submission of a new drug application and expectations regarding potential position and use of AFRESA in the market. Words such as "believes", "anticipates", "plans", "expects", "intend", "will", "goal", "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon MannKind's current expectations and involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to the progress, timing and results of clinical trials, difficulties or delays in seeking or obtaining regulatory approval, MannKind's ability to enter into any collaborations or strategic partnerships, MannKind's ability to raise additional financing and other risks detailed in MannKind's filings with the Securities and Exchange Commission, including the Annual Report on Form 10-K for the year ended December 31, 2007 and periodic reports on Form 10-Q and Form 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and MannKind undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this news release.

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