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VALENCIA, Calif.--(BUSINESS WIRE)--Aug. 14, 2013-- **MannKind Corporation (Nasdaq: MNKD)** today announced positive preliminary results from Study 175, 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™ inhaler), in patients with type 2 diabetes.

Highlights

AFREZZA combined with oral therapy, compared to oral therapy alone, showed:

- Superior reductions in A1c levels;
- Significantly more patients reached A1c target levels;
- Reduced postprandial glucose excursions; and
- No significant difference in the incidence of severe hypoglycemia.

"We are pleased that Study 175 met its primary endpoint of demonstrating that AFREZZA, when added to a regimen of metformin with or without a second or third oral medication, produced superior A1c reductions compared to oral therapy alone," stated Alfred Mann, Chairman and Chief Executive Officer of MannKind Corporation. "In this study, significantly greater numbers of patients in the AFREZZA group reached the American Diabetes Association goal of A1c levels less than or equal to 7.0% and the American Association of Clinical Endocrinologists goal of less than or equal to 6.5%. As well, the AFREZZA group exhibited noticeably reduced postprandial glucose excursions. As would be expected in a study that added insulin to an oral treatment regimen, hypoglycemic events were more frequent in the AFREZZA group, but no AFREZZA patient discontinued because of hypoglycemic adverse events. Based on the results of this study, we believe that AFREZZA can be used to improve glycemic control in insulin-naive type 2 diabetes patients that are not adequately controlled on conventional oral medications – a potentially large and underserved patient population."

Study 175

Study 175 was a double-blind, placebo-controlled study involving 353 patients with type 2 diabetes whose disease was inadequately controlled on metformin with or without a second or third oral medication. Patients were studied at sites in the United States, Russia, Ukraine and Brazil. After a six-week run-in period during which all patients received dietary counseling and initiated blood glucose monitoring while continuing their oral medications, patients entered a 24-week treatment period in which they were randomized to one of two groups where, in addition to their oral medication, they received either:

- AFREZZA Inhalation Powder, administered using the Gen2 inhaler (177 patients); or
- Technosphere Inhalation Powder (placebo), administered using the Gen2 inhaler (176 patients).

The treatment period consisted of 12 weeks of prandial insulin titration followed by 12 weeks of relatively stable dosing. Subjects could not adjust or alter the doses of their oral medications during the study without discussion between the principal investigator and the medical monitor. There was also a safety follow-up visit four weeks after completion of the treatment period, during which all subjects returned to oral therapy only.

The primary endpoint of the study was the mean change in A1c levels from baseline to week 24 between the two groups. Over the 24-week treatment period, mean A1c levels decreased by 0.82% in the AFREZZA group compared to a decrease of 0.42% in the comparator oral-therapy group. The between-group difference in change in mean A1c levels was statistically significant ($p<0.0001$), thereby establishing the superiority of AFREZZA over the comparator oral-therapy treatment.

Other Results

A significantly greater percentage of patients in the AFREZZA group reached specified A1c target levels than in the comparator oral-therapy group. After 24 weeks of treatment, 37.7% of patients in the AFREZZA group achieved A1c levels below 7.0% compared to only 19.0% of patients in the comparator oral-therapy group ($p=0.0005$), and 15.9% of patients in the AFREZZA group achieved A1c levels below 6.5% compared to only 4.2% of the patients receiving only oral therapy ($p=0.0021$).

During the treatment period, postprandial glucose excursions were reduced in the AFREZZA group compared to those in the comparator oral-therapy group. By week 24, mean blood glucose levels did not exceed 170.2 mg/dL postprandially in the

AFREZZA group whereas mean blood glucose levels reached as high as 194.7 mg/dL postprandially in the comparator oral-therapy group.

Over the treatment period, mean fasting blood glucose levels decreased moderately in the AFREZZA group by 11.2 mg/dL compared to a decrease of 3.8 mg/dL in the comparator oral-therapy group. This difference was not statistically significant (p=0.1698).

Patients in the AFREZZA group gained an average of 0.49 kg over the treatment period compared to an average loss of 1.13 kg by patients in the comparator oral-therapy group (p<0.0001).

As expected, the incidence of mild and moderate hypoglycemia was higher in the AFREZZA group (67.2% of patients) compared to the comparator oral-therapy group (30.1% of patients; p<0.0001). However, there was not a significant difference in the incidence of severe hypoglycemia, which was reported in nine (5.1%) AFREZZA patients compared to three (1.7%) oral-therapy patients (p=0.0943).

In general, treatment with AFREZZA was well-tolerated over 24 weeks by subjects with type 2 diabetes. The incidence of serious adverse events was lower in the AFREZZA group (2.8%) compared to the comparator oral-therapy group (5.1%). The incidence of serious cardiovascular events was low overall and balanced between the groups (AFREZZA: 2 events; oral therapy: 3 events). Similarly, the incidence of adverse events resulting in discontinuation was low overall and balanced between the treatment groups (AFREZZA: 4.0%; oral therapy: 5.1%). The most common adverse event was cough, occurring with comparable incidence in both the AFREZZA (23.7%) group and the oral therapy (19.9%) group (who were also taking a placebo powder). Cough was predominantly dry, intermittent, and usually occurred within 10 minutes of inhalation. The incidence of cough in both treatment groups was highest during the first week of the treatment period and diminished thereafter.

These preliminary results are subject to further analysis.

About AFREZZA®

AFREZZA® is a novel, ultra rapid-acting mealtime insulin therapy being developed by MannKind Corporation for the treatment of adult patients with type 1 or 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 cartridges, and a light, discreet and easy-to-use inhaler. Administered at the start of a meal, AFREZZA dissolves immediately upon inhalation and delivers insulin quickly to the bloodstream. Peak insulin levels are achieved within 12 to 14 minutes of administration, effectively mimicking the release of meal-time insulin observed in healthy individuals, but which is absent in 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. Its lead product candidate, AFREZZA®, has completed Phase 3 clinical trials. MannKind maintains a website at 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.

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to the results of clinical studies, the potential use of AFREZZA to improve glycemic control in insulin-naive type 2 diabetes patients who can no longer be adequately controlled on conventional oral medications, and the potential market opportunity for such use, that involve risks and uncertainties. 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 the Company's current expectations. 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, difficulties or delays in obtaining regulatory feedback or completing and analyzing the results of clinical studies, completion of further statistical analysis of the results of Study 175, whether the data from Study 175, as well as Study 171, the Phase 3 clinical study of AFREZZA in type 1 diabetes patients, will satisfy all requirements of the Food and Drug Administration and will be sufficient to support approval of an amended new drug application for AFREZZA, the timing of regulatory review and decisions, MannKind's ability to manage its existing cash resources or raise additional cash resources, stock price volatility 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, 2012 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 press release.

MannKind Corporation
Matthew Pfeffer
Chief Financial Officer
661-775-5300

mpfeffer@mannkindcorp.com