



## **MannKind Announces Positive Clinical Data for AFREZZA; Both AFFINITY Phase 3 Studies Meet Primary Endpoints**

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VALENCIA, Calif.--(BUSINESS WIRE)--Aug. 14, 2013-- **MannKind Corporation (Nasdaq:MNKD)** today announced that it will hold a conference call at 4:00 pm (EDT) today to discuss preliminary results from Study 171 and Study 175, two Phase 3 clinical studies 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).

#### **Highlights of Study 171**

In patients with type 1 diabetes, AFREZZA, 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.

#### **Highlights of Study 175**

In patients with type 2 diabetes treated with oral therapy, AFREZZA, 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.

These preliminary results are subject to further analysis. More detailed preliminary results are included in separate releases that accompany this announcement.

"We are pleased that both Phase 3 studies met their primary efficacy endpoints and that Study 171 also achieved its other main objective of demonstrating comparability between the Gen2 and MedTone inhalers," stated Alfred Mann, Chairman and Chief Executive Officer of MannKind Corporation. "The positive results of Study 171 and Study 175 will form the basis of an amendment to our new drug application for AFREZZA, which we expect to submit to the Food and Drug Administration early in the fourth quarter of this year."

#### **Conference Call**

MannKind will host a conference call to discuss the second quarter financial results and recent clinical trial results at 4:00 PM (Eastern Time) on August 14, 2013. Presenting from the Company will be its Chairman and Chief Executive Officer, Alfred Mann; President and Chief Operating Officer, Hakan Edstrom; Corporate Vice President and Chief Financial Officer, Matthew Pfeffer; and Senior Vice President, Clinical Sciences, Robert Baughman.

To participate in the live call by telephone, please dial (800) 447-0521 or (847) 413-3238 and use the participant passcode: 34087263. Those interested in listening to the conference call live via the Internet may do so by visiting the Company's website at <http://www.mannkindcorp.com>.

A telephone replay of the call will be accessible for approximately 14 days following completion of the call by dialing (888) 843-7419 or (630) 652-3042 and use the participant passcode: 3408 7263#. A replay will also be available on MannKind's website for 14 days.

#### **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<sup>®</sup>, has completed Phase 3 clinical trials. MannKind maintains a website at [www.mannkindcorp.com](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.

#### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements related to the results of clinical studies and the timing of regulatory submissions, 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 these studies, whether the data from these two studies will satisfy all requirements of the Food and Drug Administration and will be sufficient to support approval of the 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.

Source: MannKind Corporation

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