



October 5, 2012

## **MannKind Completes Patient Recruitment in Two Phase 3 Clinical Studies of AFREZZA**

VALENCIA, Calif.--(BUSINESS WIRE)--Oct. 5, 2012-- **MannKind Corporation (Nasdaq: MNKD)** today announced that it has completed recruiting patients for two Phase 3 clinical studies of AFREZZA® (insulin human [rDNA origin]), an investigational, ultra rapid-acting mealtime insulin therapy, administered using MannKind's to-be-marketed next-generation inhaler.

The first of these studies (study 171) is an open-label study in patients with type 1 diabetes. After a run-in period, during which all patients are optimized on their basal insulin regimen, at least 471 subjects are to be randomized to one of three arms for mealtime insulin: a control arm, in which patients utilize injected rapid-acting insulin, or one of two AFREZZA arms, one for the MedTone inhaler and the other for the next-generation inhaler. After the mealtime insulin is titrated, there is a 12-week observation period on stable doses of the mealtime insulin to assess HbA1c levels, which is the primary outcome parameter. Another objective of this study is to compare the safety profile of the two AFREZZA treatment groups.

The other study (study 175) is assessing AFREZZA using the next-generation inhaler in patients with type 2 diabetes whose disease is inadequately controlled on metformin with or without a second or third oral medication. After a run-in period during which the subjects remain on their oral medication, at least 328 patients will be randomized to additional treatment with AFREZZA or to Technosphere® inhalation powder (placebo). The study will also have a titration period, followed by a 12-week evaluation period to assess HbA1c levels.

"Completing patient recruitment is the initial element, and often the lengthiest, in the conduct of large scale Phase 3 clinical trials," said Alfred Mann, Chairman and Chief Executive Officer. "Both studies are on track to be completed in the second quarter of 2013 and we expect to report top-line results next summer. Our objective is to resubmit the NDA for AFREZZA in the third quarter of next year."

### **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 blood stream. Peak insulin levels are achieved within 12 to 14 minutes of administration, mimicking the release of meal-time insulin observed in healthy individuals. To date, the AFREZZA clinical program has involved 61 different clinical studies and over 5,600 adult patients.

### **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 lead product candidate, AFREZZA®, is in late stage clinical investigation for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia.

### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements related to the completion of clinical studies, the reporting of top-line results and the submission of data to the U.S. Food and Drug Administration, 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, 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, 2011 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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