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MannKind Confirms Design of Pivotal Studies

VALENCIA, Calif., Aug 11, 2011 (BUSINESS WIRE) -- **MannKind Corporation (Nasdaq: MNKD)** today announced that it has confirmed with the U.S. Food and Drug Administration the design of two clinical studies that evaluate the efficacy and safety of AFREZZA® (insulin human [rDNA origin]), an investigational, ultra rapid-acting mealtime insulin therapy, administered using MannKind's next-generation inhaler. The FDA had previously requested that MannKind conduct two clinical trials with the next-generation inhaler (one in patients with type 1 diabetes and one in patients with type 2 diabetes), with at least one trial including a treatment group using the previously studied MedTone inhaler in order to obtain a head-to-head comparison of the pulmonary safety data for the two devices.

Hakan Edstrom, President and Chief Operating Officer, reported that, "We held a successful meeting with the FDA yesterday, confirming the protocols for the type 1 and type 2 studies. We were also encouraged to proceed promptly with the initiation of both clinical trials."

Study 171 is an open-label study in patients with type 1 diabetes. After a run-in period, during which all patients will be optimized on their basal insulin regimen, subjects will be randomized to one of three arms: a control arm, in which patients utilize injected rapid-acting insulin at mealtimes, or one of two AFREZZA arms, one each for the MedTone and next-generation device. After the mealtime insulin is titrated, there will be a 12-week observation period on stable doses of the mealtime insulin to assess HbA1c levels, which is the primary outcome parameter.

Study 174 will assess AFREZZA using the next-generation inhaler in patients with type 2 diabetes who are inadequately controlled on metformin with or without a second or third oral medication. Patients will be randomized to treatment with AFREZZA or placebo in a randomized fashion. The study will have a titration period, followed by a 12-week observation period to assess HbA1c levels.

Alfred Mann, Chairman and Chief Executive Officer, added, "We are very encouraged and pleased with this outcome. Our attention now turns to the execution of these trials. The protocol for Study 171 has already been sent to Institutional Review Boards and the protocol for Study 174 is being finalized and will be distributed to our sites shortly."

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 dose cartridges and the light, discreet and easy- to-use AFREZZA 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 56 different studies and over 5,300 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. MannKind maintains a website at 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 initiation of clinical studies, 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, 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, 2010 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

MannKind Corporation
Matthew Pfeffer
Chief Financial Officer
661-775-5300
mpfeffer@mannkindcorp.com