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## American Diabetes Association/The Lancet Symposium Will Highlight Study Showing AFREZZA(R) Provides Comparable Glycemic Control with Less Weight Gain and Hypoglycemia than Standard of Care

## Findings on ultra rapid acting insulin also published in The Lancet

ORLANDO, Fla., Jun 24, 2010 (BUSINESS WIRE) --AFREZZA® (insulin human [rDNA origin]) Inhalation Powder, a well-tolerated, investigational ultra rapid acting mealtime insulin, combined with basal insulin is comparable to standard insulin therapy in controlling post-meal blood sugar levels in adult patients with Type 2 diabetes, and offers the added benefits of significantly less weight gain and lower risk of hypoglycemia. These study findings will be presented on Saturday, June 26, at a special symposium co-hosted by The Lancet and the American Diabetes Association (ADA), at the American Diabetes Association's 70th Scientific Sessions®. The study will also be published in the June 26 issue of The Lancet, one of the world's leading medical journals.

"Insulin therapy is often a delayed strategy in patients with Type 2 diabetes, because it is associated with weight gain, hypoglycemia and the need for subcutaneous injections," said Daniel L. Lorber, M.D., F.A.C.P., C.D.E., Medical Director of the Diabetes Control Foundation, Diabetes Care & Information Center in Flushing, NY, and co-author of the published study. "Our findings show that mealtime AFREZZA, in combination with once-daily injected glargine, provides equivalent glucose control with fewer injections, less hypoglycemia and less weight gain than does twice-a-day, premixed insulin."

Dr. Lorber will present the featured study at the ADA/The Lancet symposium on June 26.

"We are honored that the ADA and *TheLancet* chose to spotlight AFREZZA data at this special symposium," said Dr. Peter Richardson, MRCP, Corporate Vice President and Chief Scientific Officer, MannKind Corporation. "Their recognition validates our enthusiasm for AFREZZA's potential to be an important new therapeutic option in the management of diabetes."

Diabetes, which affects 23.6 million people in the U.S., is characterized by the body's inability to properly regulate levels of blood glucose, or blood sugar. Insulin, a hormone produced by the pancreas, normally regulates the body's glucose levels, but in people with diabetes insufficient levels of insulin are produced or the body fails to respond adequately to the insulin it produces. Historically, mealtime insulin therapy regimens have had a number of limitations, including the risk of severe hypoglycemia, the likelihood of weight gain, inadequate post-meal glucose control, the need for complex titration of insulin doses in connection with meals and the need for injections. Additionally, these therapies have not mimicked the natural time-action profile of insulin normally seen in healthy individuals and presented challenges in maintaining compliance.

AFREZZA is a novel, ultra rapid acting mealtime insulin therapy being developed by MannKind Corporation for the treatment of adult patients with Type 1 and 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 50 different studies and over 5,000 adult patients.

## Study Design and Key Findings

Adult patients with Type 2 diabetes mellitus and inadequate glycemic control (A1C >7.0% and less-than or equal to 11.0%) despite insulin with/ without oral anti-hyperglycemic therapy were randomized to a 52-week course of either AFREZZA/Technosphere Insulin (TI) and bedtime glargine insulin (G) (n=334) or premixed biaspart 70/30 insulin BID (BPA 70/30) twice-a-day (n=343). The primary endpoint was mean change in HbA1C between treatment groups from baseline to week 52. Secondary objectives were proportion of subjects reaching specific HbA1C levels and treatment differences in postprandial plasma glucose (PPG), fasting plasma glucose (FPG) and weight.

HbA1C levels were reduced by -0.68% (mean change) and -0.76% in the TI+G and BPA 70/30 groups, respectively; the between-group difference was statistically non-inferior (95% CI -0.13 to 0.27). The proportion of subjects achieving HbA1C <7.0% was comparable between treatments (22% vs 27%; p=0.2793). Notably, TI+G produced significantly less weight gain (0.9 vs. 2.5 kg; p=0.0002) and significantly less mild/moderate (48% vs. 69%, p<0.001) and severe (4% vs. 10%, p=0.0066)

hypoglycemia compared to the BPA 70/30 group. Mean changes from baseline to week 52 in pulmonary function tests were similar in the two groups.

## **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 diabetes pipeline includes AFREZZA™ and MKC253. MKC253 is currently in phase 1 clinical trials. In March 2009, MannKind submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) requesting approval of AFREZZA for the treatment of adults with Type 1 or Type 2 diabetes for the control of hyperglycemia. In March 2010, MannKind received a Complete Response to this NDA from the FDA requesting additional information. An End-of-Review meeting was held in June 2010 and MannKind is currently preparing its resubmission of the AFREZZA NDA. Other products in MannKind's pipeline include the cancer immunotherapy products MKC1106-PP and MKC1106-MT, which are currently in phase 1 clinical trials. MannKind maintains a website at <a href="http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.mannkindcorp.com&esheet=6338721&lan=en-US&anchor=http%3A%2F%2Fwww.mannkindcorp.com&esheet=6338721&lan=en-US&anchor=http%3A%2F%2Fwww.mannkindcorp.com&esheet=63387217a71d 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.

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