



MannKind Resubmits New Drug Application to U.S. FDA for AFREZZA for the Treatment of Adults with Diabetes

10/14/13

VALENCIA, Calif.--(BUSINESS WIRE)--Oct. 14, 2013-- **MannKind Corporation (Nasdaq: MNKD)** today announced the resubmission on October 13, 2013 of a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for the marketing and sale of AFREZZA[®] (insulin human [rDNA origin]) Inhalation Powder with an indication to improve glycemic control in adults with type 1 or type 2 diabetes. The resubmission is based on the entire data set from the extensive AFREZZA clinical development program and particularly the positive results from two recent Phase 3 trials, one in patients with type 1 diabetes (study 171) and one in patients with type 2 diabetes (study 175).

"We designed the recent studies with input and guidance from the FDA, and both achieved their primary efficacy endpoints and safety objectives," said Alfred Mann, Chairman and Chief Executive Officer of MannKind Corporation. "I am very proud of our team for completing an extensive submission on a very ambitious schedule. We will continue to work with the FDA to bring AFREZZA to market for the millions of diabetes patients in the United States who might benefit from this novel product."

About AFREZZA[®]

AFREZZA[®] (uh-FREZZ-uh) is a novel, ultra rapid-acting mealtime insulin therapy developed by MannKind Corporation to improve glycemic control in adult patients with type 1 or type 2 diabetes. It is a drug-device combination product, consisting of AFREZZA Inhalation Powder delivered using a small, discreet and easy-to-use inhaler. Administered at the start of a meal, AFREZZA Inhalation Powder dissolves immediately upon inhalation to the deep lung and delivers insulin quickly to the bloodstream. Peak insulin levels are achieved within 12 to 15 minutes of administration, compared to 45-90 minutes for injected rapid acting insulin analogs and 90-150 minutes for injected regular human insulin.

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 and the potential use of AFREZZA to improve glycemic control in diabetes patients, 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 our 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: the risk that the FDA may not accept the NDA for review, the risk that the FDA may disagree with our interpretation of our Phase 3 study results, the risk that the FDA may not approve the NDA for AFREZZA, the timing of regulatory review and decisions, our ability to manage our 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 we undertake no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this press release.



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