FDA Accepts AFREZZA Complete Response Resubmission and Sets Target Action Date

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VALENCIA, Calif., Jul 20, 2010 (BUSINESS WIRE) --

MannKind Corporation (NASDAQ:MNKD) today announced that it has submitted, and the U.S. Food and Drug Administration (FDA) has accepted, MannKind's resubmission of its New Drug Application (NDA) for AFREZZA (insulin human [rDNA origin]) and classified it as a Class 2 resubmission. With the Class 2 designation, the FDA set a corresponding Prescription Drug User Fee Act (PDUFA) action date of December 29, 2010.

In March 2010, MannKind received a Complete Response letter to its NDA for AFREZZA from the FDA requesting additional information. In response, MannKind has submitted clinical data from a recently completed efficacy study in patients with type 1 diabetes as well as updated pooled safety data related to AFREZZA and information on the comparability of MannKind's next-generation delivery system to the device that was used in pivotal clinical studies.

"We have worked diligently since March to prepare our resubmission and we are confident that we have addressed the requests that were outlined by the FDA," said Alfred Mann, Chairman and Chief Executive Officer. "We will continue to work closely with the FDA during this final stage of the review process. We firmly believe AFREZZA has the potential to address a poorly-met need in diabetes therapy. Our primary goal is to make this novel therapeutic option available to patients as soon as possible."

About AFREZZA

AFREZZA (insulin human [rDNA origin]) 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 more than 50 different studies and over 5,000 adult patients with both Type 1 and Type 2 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 and cancer. Its diabetes pipeline includes AFREZZA and MKC253. MKC253 is currently in phase 1 clinical trials. In March 2009, MannKind submitted a NDA to the 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 letter to this NDA from the FDA, requesting additional information. In July 2010, the FDA accepted MannKind's reply to the Complete Response letter and set a PDUFA action date of December 29, 2010. 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 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 regulatory status and timeline for commercialization of MannKind's product candidates, 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 seeking or obtaining regulatory approval, competition from other pharmaceutical or biotechnology companies, MannKind's ability to enter into any collaborations or strategic partnerships, the risk that commercialization partners may not be successful in their sales and marketing efforts, intellectual property matters, 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, 2009 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