



MannKind Updates Status of New Drug Application for AFREZZA(R)

12/28/10

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VALENCIA, Calif., Dec 28, 2010 (BUSINESS WIRE) -- MannKind Corporation (Nasdaq: MNKD) today announced that it was informed on December 27, 2010 by the U.S. Food & Drug Administration (FDA) that the agency will not be able to complete the review of the New Drug Application (NDA) for AFREZZA[®] (insulin human [rDNA origin]) Inhalation Powder by the action date of December 29, 2010. The FDA stated that it will require approximately four additional weeks to complete its review of the NDA.

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 and type 2 diabetes for the control of hyperglycemia. It is a combination product, consisting of AFREZZA Inhalation Powder pre-metered into single use dose cartridges and delivered via a small, 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 early release of mealtime 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. MannKind has 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. MKC253 is currently in phase 1 clinical trials. Other products in MannKind's pipeline include the cancer immunotherapy platform MKC1106, which is currently in phase 2 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 regulatory approval process with respect to AFREZZA, that involve risks and uncertainties. Words such as "anticipates", "intends", "plans", "proposes", "expects", "will", and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon MannKind'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, risks related to difficulties or delays in seeking or obtaining regulatory approval 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 and expressly disclaims any duty 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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