## mannkind

# FDA Advisory Committee Recommends Approval of AFREZZA(R), MannKind Corporation's Investigational Drug to Treat Diabetes

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VALENCIA, Calif., April 1, 2014 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq:MNKD) today announced that the Endocrinologic and Metabolic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) voted 13 to 1 to recommend that AFREZZA® (insulin human [rDNA origin]) Inhalation Powder be granted marketing approval by the FDA to improve glycemic control in adults with type 1 diabetes and voted 14 to 0 to recommend that AFREZZA be granted marketing approval by the FDA to improve glycemic control in adults with type 2 diabetes. If approved, AFREZZA would be the first ultra rapid-acting mealtime insulin therapy available in the United States.

"We are pleased with the Advisory Committee's approval recommendation in support of AFREZZA, and we appreciate the thoroughness of their review," said Alfred Mann, Chairman and Chief Executive Officer of MannKind Corporation. "We look forward to working with the FDA as they complete their evaluation of AFREZZA. Diabetes is a major health problem in the United States, and we are committed to bring AFREZZA to the many patients who might benefit from this novel product."

The FDA is not bound by the Advisory Committee's recommendation but will consider its guidance in reviewing the New Drug Application (NDA) that was submitted for AFREZZA. The Prescription Drug User Fee Act (PDUFA) date for the FDA to complete its review of AFREZZA is April 15, 2014.

#### 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<sup>®</sup>, is under review by the FDA. MannKind regularly posts copies of its press releases as well as additional information about MannKind on its website <a href="https://www.mannkindcorp.com">www.mannkindcorp.com</a>. Interested persons can subscribe on the 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 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 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, 2013 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.

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