March 15, 2010

FDA Requests Additional Information Regarding AFREZZA(TM) in Complete Response Letter to MannKind

VALENCIA, Calif., Mar 15, 2010 (BUSINESS WIRE) -- MannKind Corporation (Nasdaq:MNKD) today announced that it has received a Complete Response letter from the U.S. Food & Drug Administration (FDA) regarding the New Drug Application (NDA) for AFREZZA™ (insulin human [rDNA origin]) Inhalation Powder for the treatment of adult patients with type 1 and type 2 diabetes mellitus for the control of hyperglycemia.

A Complete Response letter is issued by the FDA's Center for Drug Evaluation and Research when the review of a file is completed and questions remain that preclude the approval of the NDA in its current form.

The Complete Response letter related to the AFREZZA application requested several items, including information and currently available clinical data that support the clinical utility of AFREZZA and information about the comparability of the commercial version of the MedTone inhaler to the earlier version of this device that was used in pivotal clinical trials. The letter cited no safety concerns, but requested updated safety data related to AFREZZA. The letter also requested changes to the proposed labeling of the cartridges, foil pouches and cartons.

The letter did not require any additional pre-marketing clinical studies in order for the FDA to complete its review of the NDA. As recommended by the FDA, MannKind will request an End-of-Review meeting with the agency to discuss its approach for resolving the remaining issues.

"We are currently reviewing the Complete Response letter and fully expect that we will be able to respond to the FDA's requests in a timely manner," said Alfred Mann, Chairman and Chief Executive Officer. "We had always planned to follow the original NDA for AFREZZA with a regulatory submission for our next-generation inhaler rather than launch with the commercial version of the MedTone device. We will discuss with the FDA whether it is appropriate to use what would otherwise have been a supplemental NDA submission, which we had planned to make during the second quarter of this year, to address the agency's requests. If this approach is acceptable, we believe that this regulatory action will not have a significant impact on the timing of the commercial launch of AFREZZA. We will work closely with the FDA to answer quickly the agency's questions and satisfy the requirements. We are committed to working with the FDA to make AFREZZA available to patients as soon as possible."

MannKind will host a conference call at 9:00 am EDT on March 16, 2010. To participate in the live call by telephone, please dial 888-955-8944 or 800-369-1120 and use the participant passcode: MANNKIND. Those interested in listening to the conference call live via the Internet may do so by visiting the Company's website at www.mannkindcorp.com. A telephone replay of the call will be accessible for approximately 14 days following completion of the call by dialing 800-889-9139. A replay will also be available on MannKind's website for 14 days.

About AFREZZA™

AFREZZA™ (insulin human [rDNA origin]) Inhalation Powder is a novel, ultra rapid acting mealtime insulin therapy being studied for use in adult patients with type 1 and type 2 diabetes mellitus for the treatment of hyperglycemia. AFREZZA is a drug-device combination product, consisting of AFREZZA Inhalation Powder pre-metered into single use dose cartridges and a 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, effectively mimicking the release of meal-time insulin observed in healthy individuals. The AFREZZA clinical program included over 5,000 adult patients.

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 an 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 to this NDA. Currently, AFREZZA remains under regulatory review. Other products in its pipeline include the cancer immunotherapy products MKC1106-PP and MKC1106-MT, which are currently in phase 1 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 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, 2008 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.