January 19, 2011

MannKind Corporation Receives Complete Response Letter from the FDA for AFREZZA(R)

VALENCIA, Calif., Jan 19, 2011 (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 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 principal issue raised by the FDA concerned the usage of *in vitro* performance data and clinical pharmacology data to bridge MannKind's next-generation inhaler to the phase 3 trials conducted using its MedTone® inhaler. The FDA has requested that MannKind conduct two clinical trials with the next-generation inhaler (one in patients with type 1 diabetes and one in patients with type 2 diabetes), with at least one trial including a treatment group using the MedTone inhaler in order to obtain a head-to-head comparison of the data for the two devices. In the complete response letter, the FDA stated that after an adequate titration of study medication there should be at least twelve weeks of relatively stable insulin dosing at the end of the treatment period.

The FDA has also requested additional information concerning the performance characteristics, usage, handling, shipment and storage of the next-generation device, an update of safety information related to AFREZZA as well as information on proposed user training and changes to the proposed labeling of the device, blister pack, foil wrap and cartons.

"As we reported last fall, we have already begun a series of studies of the next-generation device in patients with type 1 (Affinity 1) and type 2 (Affinity 2) diabetes," said Alfred Mann, Chairman and Chief Executive Officer of MannKind Corporation. "Consistent with the direction we received in the complete response letter, these trials are designed to focus on careful titration of insulin dose and include at least twelve weeks of stable dosing. We plan to meet with the agency as quickly as possible in order to be confident that these trials, with appropriate modifications to incorporate a comparison to the MedTone device, will suffice in addressing the agency's questions about patient use and robustness of the next-generation device."

Mr. Mann continued, "While we are disappointed with the complete response letter, we are encouraged that the FDA is asking for clinical studies only to confirm the bridging and handling of the next-generation device in order to compare it to the device used in our extensive clinical program. We remain committed to working with the FDA to make AFREZZA available to people with diabetes."

MannKind will host a conference call at 4:00 pm (Eastern Time) on January 19, 2011. To participate in the live call by telephone, please dial 888-942-9866 or 415-228-3901 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 888-562-4434. A replay will also be available on MannKind's website for 14 days.

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 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 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 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 MannKind's clinical trials, future interactions with the FDA, MannKind's plans for the development and commercialization of AFREZZA and the regulatory status 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, MannKind's ability to manage its 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, 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

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