# MannKind Updates Status of New Drug Application

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VALENCIA, Calif., Jan 08, 2010 (BUSINESS WIRE) -- MannKind Corporation (Nasdaq:MNKD) announced that it was informed today by the Food and Drug Administration that the FDA will not be able to complete the review of MannKind's new drug application (NDA) for its ultra rapid-acting insulin therapy by the action date of January 16, 2010.

The FDA explained that it has not yet completed its inspection of the insulin manufacturing facilities of N.V. Organon, a third-party supplier to MannKind. Organon is a subsidiary of Merck Inc. MannKind's new drug application references Organon's drug master file for recombinant human insulin.

"We are pleased with the progress of our discussions with the FDA and the agency's review of our application," said Alfred Mann, Chairman and Chief Executive Officer. "However, the agency must complete this inspection before it can finalize its review of our NDA. To our knowledge, all other FDA inspections of third-party suppliers and clinical trial sites are complete, as is the pre-approval inspection of MannKind's manufacturing facility in Danbury, Connecticut. At this time, there are no pending answers to any FDA questions or other deliverables due on MannKind's part."

As part of the ongoing discussions between MannKind and the FDA, the agency has accepted AFREZZA (insulin human [rDNA origin] Inhalation Powder) as the trade name for the product, which was formerly known as AFRESA®. The agency had requested that the name of the product be changed in order to avoid confusion with another medication.

MannKind and the FDA have also discussed the basis for obtaining a waiver and deferral for pediatric studies. MannKind agreed to conduct a Phase 4 study of AFREZZA in 500 pediatric patients at least four years of age.

MannKind has not yet been informed about the expected timing for the agency's final determination on the NDA, which will be provided in an Action Letter.

**About AFREZZA**

AFREZZA (insulin human [rDNA origin] Inhalation Powder) is an ultra rapid acting insulin product that has completed Phase 3 trials. The pharmacokinetic profile of AFREZZA sets it apart from all other insulin products. The large surface area of the lung provides unique access to the circulatory system. The pH-sensitive AFREZZA particles immediately dissolve upon contact with the lung surface, releasing insulin monomers that rapidly enter the bloodstream. It achieves peak insulin levels within 12-14 minutes of administration, effectively mimicking the release of meal-time insulin observed in healthy individuals, but which is absent from patients with 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 (formerly AFRESA®) and MKC253. MannKind has 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. MKC253 is 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.

SOURCE: MannKind Corporation

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