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VALENCIA, Calif., March 16, 2009 /PRNewswire-FirstCall via COMTEX/ -- MannKind Corporation (Nasdaq: MNKD) today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) requesting approval of AFRESA® (insulin monomer human [rDNA origin]) Inhalation Powder and the AFRESA® Inhaler for the treatment of adults with type 1 or type 2 diabetes mellitus for the control of hyperglycemia.

There are 23.6 million people in the United States, or 8% of the population, who have diabetes. Diabetes currently affects 246 million people worldwide and is expected to affect 380 million by 2025. Each year, a further 7 million people develop diabetes and 3.8 million people succumb to the disease.

AFRESA is an ultra rapid-acting insulin. It is a drug-device combination product, consisting of AFRESA Inhalation Powder pre-metered into single unit dose cartridges and the AFRESA Inhaler as the delivery device for oral inhalation. However, the feature that distinguishes AFRESA from all other insulin products is not the route of administration - it is the pharmacokinetic profile. The large surface area of the lung provides unique access to the circulatory system. The pH-sensitive AFRESA particles immediately dissolve upon contact with the lung surface, releasing insulin monomers that rapidly enter the bloodstream. AFRESA 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 or impaired in patients with diabetes.

The NDA submission is based on an extensive clinical program, involving 44 completed studies and five ongoing studies at the time of submission. The clinical program included over 5,300 patients. More than 2,450 subjects with type 1 or type 2 diabetes were randomly assigned to treatment with AFRESA in the pooled controlled Phase 2/3 clinical studies. In addition, the clinical pharmacology program included more than 450 subjects exposed to AFRESA in single-dose studies. The extent of exposure meets the current guidance from the FDA regarding the development of therapies for the treatment of diabetes.

"We are delighted to have reached this important milestone," said Alfred Mann, Chairman and Chief Executive Officer of MannKind Corporation. "This NDA submission is the culmination of years of clinical research that has supported our long-held belief that AFRESA will be a first-in-class ultra rapid-acting insulin with the potential to change the way diabetes is treated."

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 AFRESA®, an ultra rapid-acting prandial insulin and MKC253, an inhaled formulation of human GLP-1. MannKind also has two cancer immunotherapeutic products in clinical development. MannKind maintains a website at http://www.mannkindcorp.com to which the company regularly posts copies of its press releases as well as additional information. 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 SEC or posts certain other information to the website.

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to the positioning and potential indication for the company's lead product. 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 MannKind's current expectations and involve risks and uncertainties. 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 and uncertainties related to the parties' abilities to obtain the necessary third-party consents and to otherwise complete the transactions contemplated in their agreements 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 news release.

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