# mannkind

## FDA Accepts MannKind's Submission and Files NDA for AFRESA

## May 18, 2009 4:00 AM EDT FDA Accepts MannKind's Submission and Files NDA for AFRESA

VALENCIA, Calif.--(BUSINESS WIRE)--May. 18, 2009-- **MannKind Corporation (Nasdaq:MNKD)** today announced that the U.S. Food and Drug Administration (FDA) has accepted and filed MannKind's New Drug Application (NDA) for AFRESA <sup>®</sup>, an ultra rapid-acting insulin. MannKind is seeking FDA approval of AFRESA for the treatment of adults with type 1 or type 2 diabetes mellitus for the control of hyperglycemia.

### About AFRESA

AFRESA 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. It is a drug-device combination product, consisting of AFRESA Inhalation Powder pre-metered into single use dose cartridges and the light, discreet and easy to use AFRESA Inhaler. Administered at the start of a meal, AFRESA 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.

#### 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 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 <a href="http://www.mannkindcorp.com">http://www.mannkindcorp.com</a> 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 Securities and Exchange Commission or posts certain other information to the website.

Source: MannKind Corporation

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