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MannKind Corporation Announces FDA Approval of AFREZZA(R); A Novel, Rapid-Acting Inhaled Insulin for the Treatment of Diabetes

VALENCIA, Calif., June 27, 2014 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq:MNKD) today announced that the U.S. Food & Drug Administration (FDA) has approved AFREZZA® (insulin human) Inhalation Powder to improve glycemic control in adult patients with diabetes mellitus.

"Approval of AFREZZA is an important milestone for MannKind, as today's FDA action validates the years of clinical research and commitment that powered the development of this unique therapy," said Alfred Mann, Chief Executive Officer, MannKind Corporation. "We are excited for patients, as we believe that AFREZZA's distinct profile and non-injectable administration will address many of their unmet needs for mealtime insulin therapy, and has the potential to change the way that diabetes is treated. We thank the more than 6,500 adult patients and healthy volunteers who participated in the AFREZZA clinical program."

Currently, diabetes mellitus affects 29.1 million people in the United States, according to the Centers for Disease Control and Prevention. Diabetes mellitus is characterized by the body's inability to regulate levels of blood glucose properly. Insulin, a hormone produced by the pancreas, normally regulates the body's glucose levels, but in people with diabetes mellitus insufficient levels of insulin are produced or the body fails to respond adequately to the insulin it produces. In patients with diabetes, current injected insulins are absorbed into the bloodstream slower than the body's own insulin would be released if the pancreas was healthy.

AFREZZA® (uh-FREZZ-uh) is a novel, rapid-acting inhaled insulin therapy indicated to improve glycemic control in adult patients with diabetes mellitus. The product consists of AFREZZA Inhalation Powder delivered using a small, discreet and easy-to-use inhaler. Administered at the start of a meal, AFREZZA dissolves rapidly upon inhalation to the deep lung and delivers insulin quickly to the bloodstream. Peak insulin levels are achieved within 12 to 15 minutes of administration, and decline to baseline by approximately 180 minutes.

"The FDA approval of AFREZZA provides healthcare professionals with an important new safe and effective treatment option for patients with diabetes," said Janet McGill, M.D., Professor of Medicine at Washington University School of Medicine**.** "We have seen in clinical studies that the combination of rapid action, injection-free delivery and ease of use makes AFREZZA a welcome alternative for many patients who require insulin."

LIMITATIONS OF USE: AFREZZA must be used in combination with a long-acting insulin in patients with type 1 diabetes mellitus. AFREZZA is not recommended for the treatment of diabetic ketoacidosis and is not recommended for patients who smoke.

Full US Prescribing Information, including BOXED WARNING, Medication Guide and Instructions for Use will soon be available at www.afrezza.com. Prior to the label being posted online, a copy of the label may be requested from the MannKind Media contacts listed at the end of this document.

AFREZZA has been approved with a Risk Evaluation and Mitigation Strategy (REMS) required by the FDA to ensure that the benefits of AFREZZA outweigh the potential risk of acute bronchospasm in patients with chronic lung disease.

Important Safety Information about AFREZZA (insulin human Inhalation Powder)

The following information is taken from the highlights section of the US Prescribing Information. Please see full Prescribing Information including boxed warning.

BOXED WARNING: RISK OF ACUTE BRONCHOSPASM IN PATIENTS WITH CHRONIC LUNG DISEASE

Acute bronchospasm has been observed in patients with asthma and COPD using AFREZZA. AFREZZA is contraindicated in patients with chronic lung disease such as asthma or COPD. Before initiating AFREZZA, perform a detailed medical history, physical examination and spirometry (FEV1) to identify potential lung disease in all patients.

CONTRAINDICATIONS

AFREZZA is contraindicated during episodes of hypoglycemia, in patients with chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD), or in patients with a hypersensitivity to regular human insulin or any of the AFREZZA excipients.

WARNINGS AND PRECAUTIONS

Acute Bronchospasm: Acute bronchospasm has been observed in patients with asthma and COPD. Before initiating, perform spirometry (FEV1) in all patients. Do not use in patients with chronic lung disease.

Change in Insulin Regimen: Carry out under close medical supervision and increase frequency of blood glucose monitoring.

Hypoglycemia: May be life-threatening. Increase frequency of glucose monitoring with changes to; insulin dosage, co-administered glucose lowering medications, meal pattern, physical activity; and in patients with renal or hepatic impairment and hypoglycemia unawareness.

Decline in Pulmonary Function: Assess pulmonary function (e.g., spirometry) before initiating, after 6 months of therapy, and annually, even in the absence of pulmonary symptoms.

Lung Cancer: AFREZZA should not be used in patients with active lung cancer. In patients with a history of lung cancer or at risk for lung cancer, the benefit of AFREZZA use should outweigh this potential risk.

Diabetic Ketoacidosis: More patients using AFREZZA experienced diabetic ketoacidosis in clinical trials. In patients at risk for DKA, monitor and change to alternate route of insulin delivery, if indicated.

Hypersensitivity Reactions: May be life-threatening. Discontinue AFREZZA, monitor and treat if indicated.

Hypokalemia: May be life-threatening. Monitor Potassium levels in patients at risk of hypokalemia and treat if indicated.

Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs): Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs.

ADVERSE REACTIONS

The most common adverse reactions associated with AFREZZA (2% or greater incidence) are hypoglycemia, cough, and throat pain or irritation.

About MannKind Corporation

MannKind Corporation (Nasdaq:MNKD) focuses on the discovery, development and commercialization of therapeutic products for patients with diseases such as diabetes. 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 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, the 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, 2013 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.

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