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MannKind Regains Afrezza® Marketing Rights

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VALENCIA, Calif., April 05, 2016 (GLOBE NEWSWIRE) -- **MannKind Corporation** (NASDAQ:MNKD) (TASE:MNKD) has assumed responsibility for the worldwide development and commercialization of Afrezza® (insulin human) Inhalation Powder from Sanofi, effective today, in a transition that ensures patients will not experience any interruption in their treatment. Under terms of the transfer agreement, Sanofi will continue to distribute Afrezza from its existing inventory until MannKind begins to distribute Afrezza during the third quarter.

"Today's return of control of Afrezza is a landmark day for MannKind," said Matthew Pfeffer, Chief Executive Officer of MannKind. "We are thrilled to begin the process of making Afrezza the successful mealtime treatment for people with diabetes that we always believed it would be. In the coming weeks, we will roll out more information about our commercial team for Afrezza, the resources that we are designing for patients and physicians, and our plans for the future."

Afrezza (uh-FREZZ-uh), approved in 2014 by the U.S. Food and Drug Administration, is a rapid-acting inhaled insulin therapy indicated to improve glycemic control in adult patients with diabetes. Taken at the start of a meal using a specially designed inhaler, 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 use and help to control post-meal blood sugar spikes that affect HbA1C levels. Afrezza should not be used by patients who have problems with their lungs (such as asthma or COPD) and is not recommended in patients who smoke or who have recently stopped smoking.

"The continued availability of Afrezza is welcome news for patients and their physicians who seek effective treatment options for type 1 and type 2 diabetes," said Steven Edelman, M.D., Professor of Medicine, University of California, San Diego and founder and director of Taking Control of Your Diabetes (tcoyd.org). "Afrezza truly addresses an unmet need in diabetes care. Having even a few less injections a week is a benefit for many of my patients."

Afrezza is not a substitute for long-acting insulin but must be used in combination with long-acting insulin in patients with type 1 diabetes.

MannKind will work with the diabetes community to ensure that Afrezza remains available for the many patients who are passionate about its benefits. "I am thrilled to work with MannKind to ensure current and new patients know about the continued availability of Afrezza," said Laura Kronen, author of "Too Sweet: The Not-So-Serious Side to Diabetes", diabetes life coach and an early adopter of Afrezza. "To the diabetes community, Afrezza represents advancement in insulin delivery and a novel way to manage their disease."

MannKind has established an Afrezza Customer Service Center. Customers with questions or comments about Afrezza can call (877) 323-8505. Certain Afrezza patient support programs (including co-pay assistance cards) will continue and new programs will be introduced in the second quarter, replacing legacy programs.

The company also plans to present four abstracts at the American Diabetes Association (ADA) scientific meeting in June, including the results of two completed post-marketing studies. Two additional late-breaking abstracts have also been submitted to the ADA and, if accepted, will be presented.

INDICATION

Prescription Afrezza® (insulin human) Inhalation Powder is a rapid-acting inhaled insulin used to treat adults with diabetes for the control of high blood sugar.

LIMITATIONS OF USE

Do not use Afrezza as a substitute for long-acting insulin; Afrezza must be used in combination with long-acting insulin in patients with type 1 diabetes.

Do not use Afrezza to treat diabetic ketoacidosis.

Afrezza is not recommended in patients who smoke or who have recently stopped smoking.

IMPORTANT SAFETY INFORMATION FOR AFREZZA

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.

Do not use Afrezza if you have problems with your lungs, such as asthma or COPD. Do not use Afrezza during a low blood sugar reaction (hypoglycemia). If you are allergic to any of the ingredients in Afrezza, do not use Afrezza as this may cause a significant and severe allergic reaction.

Before using Afrezza, your doctor will take a medical history, and do a physical exam and a breathing test (called spirometry) to determine if you have lung problems. Patients with lung problems should not use Afrezza. If your doctor finds you have lung problems, use of Afrezza may cause a severe asthma-like breathing problem. Afrezza can reduce lung function, so your doctor will also want to test your breathing 6 months after starting Afrezza, and then each year after that, with more frequent testing done if you have symptoms such as wheezing or coughing. Tell your doctor if you currently have lung cancer or have had it in the past, or if you have an increased risk of developing lung cancer.

You must test your blood sugar levels while using insulin, such as Afrezza. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. Any change of insulin should be made carefully and only under your doctor's care.

The most common side effect of insulin, including Afrezza® (insulin human) Inhalation Powder, is low blood sugar (hypoglycemia), which can be

serious and life-threatening. Some people may experience symptoms such as shaking, sweating, fast heartbeat, and blurred vision. It may cause harm to your heart or brain. It is important for you to understand how to manage the use of Afrezza, and to understand how to lessen the risk of hypoglycemia events.

Tell your doctor about other medicines you take, especially ones commonly called TZDs (thiazolidinediones) and supplements, because they can change the way insulin works. If you have heart failure or other heart problems, it may get worse while you take TZDs with Afrezza. Before starting Afrezza, it is important to tell your doctor about all your medical conditions including if you have a history of lung problems, if you are pregnant or plan to become pregnant, or if you are breast-feeding or planning to breast-feed.

In addition to low blood sugar (hypoglycemia), other possible side effects associated with Afrezza include cough, throat pain or irritation, headache, diarrhea, tiredness, and nausea.

Please see full Prescribing Information for Afrezza, including Boxed WARNING and www.afrezza.com.

About Afrezza®

Afrezza is available in 4-unit, 8-unit and 12-unit single-dose cartridges of insulin powder that can be used, as prescribed by a health care professional, in combination with other diabetes medications to achieve target blood sugar levels. For Afrezza doses exceeding 12 units, patients may use a combination of 4 unit, 8 unit and 12-unit cartridges. The disposable inhaler can be used for up to 15 days, should be kept in a clean, dry place with the mouthpiece cover on and may be wiped with a clean, dry cloth if needed.

About MannKind Corporation

MannKind Corporation (Nasdaq:MNKD) (TASE:MNKD) focuses on the discovery and development 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, including statements regarding MannKind's ability to directly commercialize Afrezza and the commercial potential of Afrezza. 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 MannKind'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 successful transition with Sanofi for the return of Afrezza, the ability to generate significant product sales for MannKind, difficulties or delays in obtaining regulatory feedback or completing and analyzing the results of clinical studies, 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, 2015 and subsequent periodic reports on Form 10-Q and current reports on 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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