



## MannKind to Manufacture 12 Unit Cartridge Strength of AFREZZA(R) Following FDA Approval

April 27, 2015 4:00 AM EDT

VALENCIA, Calif., April 27, 2015 (GLOBE NEWSWIRE) -- **MannKind Corporation** (Nasdaq:MNKD) today announced that it will begin to manufacture a 12 unit cartridge strength of AFREZZA (insulin human) Inhalation Powder to improve glycemic control in adult patients with diabetes. The 12 unit cartridge was approved by the U.S. Food and Drug Administration on April 17, 2015 and is expected to be launched by Sanofi in the second half of 2015.

The new dosage strength complements the existing 4 unit and 8 unit cartridges and will provide patients with another option to receive their prescribed dose.

### About Afrezza®

Afrezza® (insulin human) Inhalation Powder is used to control high blood sugar in adults with type 1 and type 2 diabetes. The drug-device combination product consists of a dry formulation of human insulin delivered in a specially designed inhaler. Administered at the beginning of a meal, Afrezza® delivers insulin into the body through the lungs with peak insulin levels achieved within 12 to 15 minutes. Afrezza® is available in 4-unit and 8-unit single-use cartridges that can be combined to meet the prescribed dose. In addition, the U.S. Food and Drug Administration (FDA) recently approved a 12-unit cartridge strength of insulin powder for Afrezza®. The disposable inhaler can be used to take the cartridges for up to 15 days and does not require cleaning or maintenance.

Sanofi and MannKind have entered into a worldwide exclusive licensing agreement to develop and commercialize Afrezza®. Under the collaboration agreement, Sanofi is responsible for global commercial, regulatory and development activities.

### INDICATIONS AND USAGE FOR AFREZZA® (insulin human) Inhalation Powder

Prescription Afrezza® is a man-made rapid acting inhaled insulin breathed through your lungs and is used to control high blood sugar in adults with type 1 and type 2 diabetes.

#### Limitations of Use:

- Do not use Afrezza® in place of long-acting insulin; Afrezza® must be used with a long-acting insulin in patients with type 1 diabetes.
- Do not use Afrezza® to treat diabetic ketoacidosis.
- It is not known if Afrezza® is safe and effective for use in people who smoke. Afrezza® is not for use in patients who smoke or who have recently stopped smoking (less than 6 months).
- It is not known if Afrezza® is safe and effective in children under 18 years of age.

#### Important Safety Information for Afrezza®

**WARNING: RISK OF SUDDEN LUNG PROBLEMS (BRONCHOSPASMS) IN PATIENTS WITH LONG-TERM (CHRONIC) LUNG DISEASE**

- **Sudden lung problems (acute bronchospasm) have been seen in patients with asthma and COPD (chronic obstructive pulmonary disease) using Afrezza®.**
- **Afrezza® is not to be used in patients with long-term lung disease such as asthma or COPD.**
- **Before initiating Afrezza®, your doctor will perform a detailed medical history, physical examination, and a breathing test (called spirometry) to identify potential lung problems.**

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

Before using Afrezza®, it is important to tell your doctor about all your medical conditions, including if you have a history of lung problems, if you smoke or have recently quit smoking, if you are pregnant or plan to become pregnant, or if you are breast feeding or planning to breast-feed. Tell your doctor about all other medicines and supplements you take.

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, even if you have no lung symptoms. More frequent testing should be done if you have symptoms such as wheezing or coughing.

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.

**There are certain serious side-effects that are associated with the use of Afrezza®.**

Severe allergic reaction (including whole body reaction) is one of the serious side effects. Get medical help right away if you have any signs or symptoms of a severe allergic reaction, including a rash over your whole body, trouble breathing, a fast heartbeat, or sweating.

Low blood sugar (hypoglycemia) is one of the most common side effects of insulin, including Afrezza®, which can be serious and life-threatening. Common symptoms of hypoglycemia are dizziness or light-headedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability or mood change, or hunger. 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.

Lung cancer occurred in more people who were taking Afrezza® compared to other diabetes medications. There were too few cases to know if lung cancer was related to Afrezza®. Tell your doctor if you currently have lung cancer, have had it in the past, or if you have an increased risk of developing lung cancer.

Heart failure can occur if you are taking insulin together with certain medicines called TZDs (thiazolidinediones), even if you have never had heart failure or other heart problems. If you already have heart failure it may get worse while you take TZDs with Afrezza®. Tell your doctor if you have any new or worsening symptoms of heart failure including shortness of breath, swelling of your ankles or feet or sudden weight gain. Your treatment with Afrezza and TZDs may need to be changed or stopped if you have new or worsening heart failure.

Get emergency help if you have trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue, or throat, sweating, extreme drowsiness, dizziness, or confusion.

While using Afrezza do not drive or operate heavy machinery until you know how Afrezza affects you. You should not drink alcohol or use other medicines that contain alcohol and you should not smoke.

The most common side effects of Afrezza® include low blood sugar (hypoglycemia), cough, sore throat, headache, diarrhea, tiredness, and nausea.

Please see full Prescribing Information, including **Boxed WARNING**, at [www.afrezza.com](http://www.afrezza.com).

Afrezza® is a registered trademark of MannKind Corporation.

**About MannKind Corporation**

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

**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, MannKind's dependency on Sanofi for commercialization of Afrezza, manufacturing effectiveness 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, 2014 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.

CONTACT: Company Contact:

Matthew J. Pfeffer

Chief Financial Officer

661-775-5300 [

mpfeffer@mannkindcorp.com