

August 1, 2016

## **MannKind Assumes Responsibility for Distribution of Afrezza® and Launches Patient Reimbursement and Adherence Support Programs**

### **Frank Pompilio, PharmD, joins as Vice President, North America Medical Affairs**

VALENCIA, Calif., Aug. 01, 2016 (GLOBE NEWSWIRE) -- **MannKind Corporation** (Nasdaq:MNKD) (TASE:MNKD) announced it is now distributing MannKind-branded Afrezza® (insulin human) Inhalation Powder directly to major wholesalers and that Afrezza is available by prescription from retail pharmacies nationwide. The MannKind-branded product is associated with new National Drug Code (NDC) numbers, as noted in the table below. With distribution channels now stocked, the Company announced several key programs to promote access, adoption and adherence to Afrezza therapy.

MannKind leveraged nearly two years of experience regarding patient selection and payor access, as well as new clinical data and a better understanding of how patients in the real world manage their titration, to guide its relaunch plans for Afrezza. These plans include the following programs to enhance education and uptake of Afrezza:

- | A new 30-day titration pack combining 90 4-unit cartridges and 90 8-unit cartridges, allowing patients greater flexibility to adjust their dose as they learn how to titrate Afrezza.
- | MannKind Cares, a patient reimbursement support program.
- | A new and enhanced copay assistance program.
- | Creation of an opportunity for physician offices to purchase in-office spirometers, allowing them to perform pulmonary function testing during the patient visit.
- | A speakers bureau to educate healthcare providers about Afrezza.

"Relaunching Afrezza as a MannKind brand is one of the most significant milestones in our company's history," said Matthew Pfeffer, Chief Executive Officer of MannKind. "We are encouraged by the overwhelmingly positive response we have received from patients, physicians and advocates, who have provided us with tremendous feedback on our relaunch of Afrezza, and whose inputs directly influenced some of the programs announced today."

While Afrezza is currently covered by commercial payers representing 70% of covered lives, many health plans still require a prior authorization. The MannKind Cares program will streamline the patient and provider experience around the prior authorization process, usually enabling patients to start on Afrezza within days, and enroll patients into a customized adherence program. This program will be available to physicians' offices beginning the week of August 8<sup>th</sup>.

MannKind also launched a new and improved copay assistance program, which will reduce the out-of-pocket cost to patients to as little as \$15 per month for commercially insured patients. With out-of-pocket costs continuing to be shifted to patients, these programs are important to help patients stay on their treatment plans. The new copay card can be accessed on the Afrezza website, [www.Afrezza.com](http://www.Afrezza.com). Prior copay cards activated with Sanofi will continue to be honored and accepted by MannKind.

"Afrezza is a key therapy in the paradigm shift for insulin treatment, but with any major change in healthcare comes a need for education and support services that increase patient and physician awareness," added Michael Castagna, Chief Commercial Officer of MannKind. "In addition to assembling a best-in-class salesforce with deep device and diabetes experience, our new programs will help streamline and enhance the patient and provider experience with Afrezza. The national sales force began calling on targeted segments across the United States and Puerto Rico in early July."

In conjunction with launching the commercialization structure and programs, MannKind also announced the appointment of Frank Pompilio, PharmD, as Vice President, of North America Medical Affairs reporting to Chief Medical Officer, Dr. Raymond Urbanski. Dr. Pompilio has over 20 years of experience in healthcare, pharmaceutical, and biotechnology industries. His most current position was Senior Director, Medical Communications at Allergan PLC, where he was responsible for the North American Medical Information call center. Prior to the acquisition of Kythera Biopharmaceuticals by Allergan in 2015, Dr. Pompilio was responsible for the development of the Medical Communications and Medical Information functions at Kythera. Before Kythera, he served as Scientific Affairs Director and Inflammation Medical Communications Therapeutic Area Lead at Amgen Inc. and led a team focused on the synthesis and communication of clinical and scientific data in a balanced and ethical manner to engage and educate the healthcare community with the goal of optimizing patient care.

"Frank is an integral addition to our Clinical Development and Medical Affairs team as we continue to build medical affairs capabilities and infrastructure," said Dr. Raymond Urbanski. "He has immediate responsibility for MannKind's medical science liaisons, reaching out to key opinion leaders, managing our medical information platform, and developing and executing our Afrezza medical affairs strategy. I am excited to have Frank's extensive industry experience at MannKind."

## **INDICATION**

Prescription Afrezza<sup>®</sup> (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<sup>®</sup> (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 breastfeeding or planning to breastfeed.

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](http://www.afrezza.com).

## **ABOUT AFREZZA<sup>®</sup>**

Afrezza is a rapid-acting, inhaled insulin used to control high blood sugar in adults with type 1 and type 2 diabetes. The product consists of a dry formulation of human insulin delivered from a small and portable inhaler. Administered at the beginning of a meal, Afrezza dissolves rapidly upon inhalation to the lung and delivers insulin quickly to the bloodstream.

Peak insulin levels are achieved within 12—15 minutes of administration. 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. 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.

<b>Product</b>	<b>Afrezza 90x4U</b>	<b>Afrezza 30x4U + 60x8U</b>	<b>Afrezza 60x4U + 30x8U</b>	<b>Afrezza 60x8U + 30x12U</b>	<b>Afrezza 90x4U + 90x8U</b>
Previous NDC Number	0024-5874-90	0024-5882-36	0024-5884-63	0024-5894-63	n/a
<b>New NDC Number</b>	<b>47918-874-90</b>	<b>47918-882-36</b>	<b>47918-884-63</b>	<b>47918-894-63</b>	<b>47918-880-18</b>

#### **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](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, 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 ability to generate significant product sales for MannKind, 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.

#### Company Contact:

Rose Alinaya  
SVP, Finance  
661-775-5300  
[ralinaya@mannkindcorp.com](mailto:ralinaya@mannkindcorp.com)