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Sanofi and MannKind Announce Afrezza®, the Only Inhaled Insulin, Now Available in the U.S.

PARIS and VALENCIA, Calif., Feb. 3, 2015 /PRNewswire/ -- [Sanofi](#) and [MannKind Corporation](#) announced today that Afrezza® (insulin human) Inhalation Powder, the only inhaled insulin, is now available by prescription in U.S. retail pharmacies nationwide. Afrezza is approved by the U.S. Food and Drug Administration to control high blood sugar in adults with type 1 and type 2 diabetes.

Experience the interactive Multimedia News Release here: <http://www.multivu.com/players/English/7412351-sanofi-mannkind-afrezza/>

"Many people living with diabetes are not able to control their blood sugar on their current medications and may benefit from using insulin. Now they have another option to administer insulin that is not an injection," said Dr. Janet McGill, M.D., Professor of Medicine at Washington University School of Medicine in St. Louis and Afrezza clinical trial investigator. "This delivery option may help change the dialogue between health care professionals and people living with diabetes about initiating or intensifying insulin therapy."

Afrezza is a drug-device combination product that consists of a dry formulation of human insulin delivered from a small and portable inhaler to help patients achieve blood sugar control. Afrezza is rapidly absorbed and has a short duration of action. It is administered at the beginning of a meal.



Afrezza can help control high blood sugar as part of a diabetes management plan that may include diet, exercise and other diabetes medications. Afrezza should not be used in patients with chronic lung disease such as asthma or COPD. Afrezza cannot be used to treat diabetic ketoacidosis. Afrezza is not recommended in patients who smoke or who have recently stopped smoking.

"Afrezza is an important addition to Sanofi's growing diabetes portfolio of integrated, personalized offerings, and it is one that highlights our dedication to bringing innovative therapies to people with this disease," said Pierre Chancel, Senior Vice President Diabetes Division, Sanofi. "There is a recognized need for an insulin that doesn't require an injection, and our organization is committed to making this new treatment option available to patients."

"We are extremely proud to see the many years of work that went into developing Afrezza culminate in the day when it is now available to help people manage their diabetes," stated Alfred Mann, Executive Chairman, MannKind Corporation.

About Afrezza

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 and 8-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 8 units, patients may use a combination of 4 unit and 8 unit cartridges. Other sizes of cartridges are being considered. 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.

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.

INDICATION

Prescription Afrezza is a rapid-acting inhaled insulin used to treat adults with type 1 and type 2 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, 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 at www.Afrezza.com.

About Sanofi Diabetes

Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insights that come from listening to and engaging with people living with diabetes, the Company is forming partnerships to offer diagnostics, therapies, services, and devices including blood glucose monitoring systems. Sanofi markets injectable, oral and inhaled medications for people with type 1 or type 2 diabetes.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

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 as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's and MannKind's management teams believe that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi and MannKind, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi and MannKind, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2013, and those risks and uncertainties listed in MannKind's annual report on Form 10-K for the year ended December 31, 2013, and listed or described in subsequent reports filed by MannKind with the Securities and Exchange Commission. Other than as required by applicable law, neither Sanofi nor MannKind undertake any obligation to update or revise any forward-looking information or statements.

Disclosure: After being involved in clinical trials of Afrezza, Dr. Janet McGill served as a consultant for MannKind Corporation and Sanofi in 2014. She is currently a consultant for Sanofi.

Afrezza® is a registered trademark of MannKind Corporation.

Patented: See <http://www.mannkindcorp.com/our-technology-patent-notice.htm>

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