



## Sanofi and MannKind Announce Global Licensing Agreement for Afrezza® (insulin human) Rapid-Acting Inhaled Insulin

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**Paris and Valencia, Calif. - August 11, 2014** - [Sanofi](#) (EURONEXT: SAN and NYSE: SNY) and [MannKind Corporation](#) (Nasdaq: MNKD) announced today that they have entered into a worldwide exclusive licensing agreement for development and commercialization of Afrezza® (insulin human) Inhalation Powder, a new rapid-acting inhaled insulin therapy for adults with type 1 and type 2 diabetes. The companies plan to launch Afrezza in the United States in the first quarter of 2015.

Under the collaboration and license agreement, Sanofi will be responsible for global commercial, regulatory and development activities. Under a separate supply agreement, MannKind will manufacture Afrezza at its manufacturing facility in Danbury, Connecticut. In addition, the companies are planning to collaborate to expand manufacturing capacity to meet global demand as necessary.

Under the terms of the agreement, MannKind Corporation will receive an upfront payment of \$150 million and potential milestone payments of up to \$775 million. The milestone payments are dependent upon specific regulatory and development targets, as well as sales thresholds. Sanofi and MannKind will share profits and losses on a global basis, with Sanofi retaining 65% and MannKind receiving 35%. Sanofi has agreed to advance to MannKind its share of the collaboration's expenses up to a limit of \$175 million.

*"Afrezza is an innovative drug-device combination product consisting of a dry formulation of human insulin delivered through a small, discreet inhaler,"* said Pierre Chancel, Sanofi Senior Vice President Diabetes Division. *"Afrezza is a further addition to our growing portfolio of integrated diabetes solutions. It is uniquely positioned to provide patients with another insulin therapy option to manage their diabetes but does not require multiple daily injections."*

*"We are so very pleased and honored that Sanofi has joined with MannKind to bring Afrezza to patients with diabetes worldwide,"* stated Alfred Mann, MannKind's Chairman and Chief Executive Officer. *"Sanofi is the ideal partner given their complementary product portfolio, their vast insulin market presence and a leading global commercial infrastructure. Our profit-sharing agreement aligns the interests of MannKind and Sanofi to optimize development, commercialization and manufacturing costs."*

Sanofi's diabetes solutions portfolio includes medications as well as drug delivery systems and blood glucose monitoring devices. As a leader in diabetes management, the addition of Afrezza to Sanofi's leading portfolio of pharmaceuticals represents the latest opportunity for the company to bring another insulin option to people with diabetes around the globe.

The closing of the transaction is subject to customary Hart-Scott-Rodino approval and completion of financing documentation.

Greenhill & Co. served as exclusive financial advisor to MannKind with respect to this transaction.

MannKind will host a conference call to discuss the collaboration with Sanofi at 8:30 AM (Eastern Time) on August 11, 2014. To view and listen to the webcast, visit MannKind's website at [www.mannkindcorp.com](http://www.mannkindcorp.com) <<http://www.mannkindcorp.com>> and click on the "MannKind 8/11/14 Conference Call" link in the Webcast section of News & Events. To participate in the live call by telephone, please dial (800) 708-4540 or (847) 619-6397 and use the participant passcode: 37856089.

A telephone replay of the call will be accessible for approximately 14 days following completion of the call by dialing (888) 843-7419 or (630) 652-3042 and use the participant passcode: 3785 6089#. A replay will also be available on MannKind's website for 14 days.

The U.S. Food & Drug Administration (FDA) approved Afrezza Inhalation Powder on June 27, 2014, to improve glycemic control in adult patients with diabetes mellitus.

Afrezza (uh-FREZZ-uh) is a 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 an 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.

**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 U.S. Prescribing Information, including Boxed Warning, Medication Guide and Instructions for Use is available at [Afrezza.com](http://Afrezza.com).

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 U.S. Prescribing Information.

#### **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**

1.) 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. 2.) Change in Insulin Regimen: Carry out under close medical supervision and increase frequency of blood glucose monitoring. 3.) 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. 4.) 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. 5.) 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. 6.) 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. 7.) Hypersensitivity Reactions: May be life-threatening. Discontinue Afrezza, monitor and treat if indicated. 8.) Hypokalemia: May be life-threatening. Monitor Potassium levels in patients at risk of hypokalemia and treat if indicated. 9.) 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](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.

#### **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).

#### **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 labelling 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.*

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