

Sanofi, MannKind ink exclusive licensing agreement

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Afrezza is a new, rapid-acting inhaled insulin therapy for adults with type-1 and type-2 diabetes.

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 USFDA approved Afrezza Inhalation Powder on June 27, 2014, to improve glycemic control in adult patients with diabetes mellitus.

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 percent and MannKind receiving 35 percent.

Sanofi has agreed to advance to MannKind its share of the collaboration's expenses up to a limit of \$175 million.

The companies plan to launch Afrezza in the United States in the first quarter of 2015.

"Afrezza is an innovative drug-device combination product consisting of a dry formulation of human insulin delivered through a small, discreet inhaler," said Mr Pierre Chancel, Sanofi's 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."

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, USA. In addition, the companies are planning to collaborate to expand manufacturing capacity to meet global demand as necessary.

"We are so very pleased and honored that Sanofi has joined with MannKind to bring Afrezza to patients with diabetes worldwide," stated Mr Alfred Mann, MannKind's chairman and CEO. "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."

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.

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.