

# MannKind Corporation Providing AFREZZA(R) to Juvenile Diabetes Research Foundation for Artificial Pancreas Project

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VALENCIA, Calif., Aug 23, 2010 (BUSINESS WIRE) --

MannKind Corporation (Nasdaq: MNKD) today announced that the company will supply its novel, ultra rapid acting insulin AFREZZA® (insulin human [rDNA origin]) for use in a study being conducted by the Juvenile Diabetes Research Foundation (JDRF) as part of its Artificial Pancreas Project. The planned two-year study in patients with type 1 diabetes will leverage the unique rapid action of AFREZZA for use in a closed-loop blood sugar monitoring and insulin delivery system, termed the "artificial pancreas" by the JDRF. The study will be managed in conjunction with the Sansum Diabetes Research Institute and the University of California, Santa Barbara.

The JDRF is the leader in research leading to a cure for type 1 diabetes in the world. The JDRF's Artificial Pancreas Project is a partnership that brings together diabetes researchers and business focused on making the artificial pancreas a reality. The goal of the Project is to speed the development of automated diabetes management systems.

"MannKind is pleased to provide our investigational therapy AFREZZA to the Juvenile Diabetes Research Foundation for this important initiative," said Dr. Peter Richardson, MRCP, Corporate Vice President and Chief Scientific Officer of MannKind Corporation. "We support and share the goals of the Foundation to advance diabetes research, address poorly met needs in diabetes therapy, and help the people with this challenging disease achieve better outcomes."

AFREZZA is a novel, ultra rapid acting mealtime insulin therapy with an action profile that mimics meal-related early insulin release, and is conveniently administered by oral inhalation.

"We are grateful for MannKind's contribution to this exciting JDRF research, and the opportunity to use AFREZZA in our study at Sansum, because AFREZZA has a pharmacokinetic profile that is similar to the body's natural insulin release," said Howard Zisser, MD, Director of Clinical Research and Diabetes Technology, Sansum Diabetes Research Institute, and Adjunct Professor, Department of Chemical Engineering, University of California, Santa Barbara. "This PK profile has not been achieved by any of the insulins used in artificial pancreas projects or by existing insulin pumps."

Researchers at UC Santa Barbara have developed a uniquely flexible Artificial Pancreas System platform that enables investigators to use a variety of blood glucose sensors and insulin delivery devices in their research.

"This is the only system that allows fully automated closed-loop clinical trials, and its design allows it to be expanded as new devices and drugs become available," said Dr. Eyal Dassau, lead scientist for UC Santa Barbara's Artificial Pancreas System. "The use of AFREZZA in conjunction with the UCSB / Sansum Artificial Pancreas System will help in blunting the meal response and improving glycemic control."

#### **About Diabetes**

Diabetes, which affects 23.6 million people in the U.S., or 8 percent of the population, is characterized by the body's inability to properly regulate levels of blood glucose, or blood sugar. Insulin, a hormone produced by the pancreas, normally regulates the body's glucose levels, but in people with diabetes insufficient levels of insulin are produced (type 1 diabetes) or the body fails to respond adequately to the insulin it produces (type 2 diabetes). Historically, mealtime insulin therapy regimens have had a number of limitations, including the risk of severe hypoglycemia, the likelihood of weight gain, inadequate post-meal glucose control, the need for complex titration of insulin doses in connection with meals and the need for injections. Additionally, therapies have not mimicked the natural time-action profile of insulin normally seen in healthy individuals and presented challenges in maintaining compliance.

## **About AFREZZA®**

AFREZZA<sup>®</sup> (insulin human [rDNA origin]) is a novel, ultra rapid acting mealtime insulin therapy being developed by MannKind Corporation for the treatment of adult patients with type 1 and type 2 diabetes for the control of hyperglycemia. It is a drug-device combination product, consisting of AFREZZA Inhalation Powder pre-metered into single use dose cartridges and the light, discreet and easy-to-use AFREZZA Inhaler. Administered at the start of a meal, AFREZZA dissolves immediately upon inhalation and delivers insulin quickly to the blood stream. Peak insulin levels are achieved within 12 to 14 minutes of administration, mimicking the release of meal-time insulin observed in healthy individuals. To date, the AFREZZA clinical program has involved more than 50 different studies and over 5,000 adult patients with both type 1 and type 2 diabetes.

### **About MannKind Corporation**

MannKind Corporation (Nasdaq: MNKD) focuses on the discovery, development and commercialization of therapeutic products for patients with diseases such as diabetes and cancer. Its diabetes pipeline includes AFREZZA® and MKC253. MKC253 is currently in phase 1 clinical trials. In March 2009, MannKind submitted a NDA to the FDA requesting approval of AFREZZA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. In March 2010, MannKind received a Complete Response letter to this NDA from the FDA, requesting additional information. In July 2010, the FDA accepted MannKind's reply to the Complete Response letter and set a PDUFA action date of December 29, 2010. Other products in MannKind's pipeline include the cancer immunotherapy products MKC1106-PP and MKC1106-MT, which are currently in phase 1 clinical trials. MannKind maintains a website at <a href="http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2Fw2Fwww.mannkindcorp.com&esheet=6403063&lan=en-US&anchor=http%3A%2Fw2Fwww.mannkindcorp.com&index=1&md5=1acc704f6cfaf6b67bf35aa62e7789ff">http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2Fw2Fwww.mannkindcorp.com&esheet=6403063&lan=en-US&anchor=http%3A%2Fw2Fwww.mannkindcorp.com&index=1&md5=1acc704f6cfaf6b67bf35aa62e7789ff</a> 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.

UC Santa Barbara is a world-renowned research institution. Scientists at the university who are involved in type 1 diabetes research are part of the Department of Chemical Engineering, in 2007 ranked ninth in the country by *U.S. News and World Report*, and the Biomolecular Science and Engineering Program, which offers a unique interdisciplinary approach to graduate training and research spanning biochemistry, molecular biology, bioengineering and biomolecular materials.

#### **About Sansum Diabetes Research Institute**

The Sansum Diabetes Research Institute is a non-profit research center devoted to the prevention, treatment and cure of diabetes through research and education. It is best known for its work on diabetes and pregnancy and its expertise in new diabetes technology.

SOURCE: MannKind Corporation

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