Special Edition

Emerging Technologies in Diabetes Research

JDRF Juvenile Diabetes Research Foundation International
dedicated to finding a cure

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JDRF in Groundbreaking Partnership with Animas to Develop First-Generation Artificial Pancreas System

The development of an artificial pancreas—a fully automated system to dispense insulin to people with diabetes based on real-time changes in blood sugar levels—would be among the most revolutionary advancements in treating type 1 diabetes. Today, JDRF took the first steps on that path, with the groundbreaking announcement of an innovative partnership with Animas Corporation, a Johnson & Johnson company that is a leading pump manufacturer, to develop a first-generation artificial pancreas: an automated system to help people with type 1 diabetes better control their disease.

The objectives of the partnership, a major industry initiative within the JDRF Artificial Pancreas Project, are to develop an automated system to manage diabetes, conduct extensive clinical trials for safety and efficacy, and submit the product to the U.S. Food and Drug Administration (FDA) for approval.

First Steps Towards an Artificial Pancreas

"If successful, the development of this first-generation system would begin the process of automating how people with diabetes manage their blood sugar," said JDRF President and CEO Alan Lewis. "Ultimately, an artificial pancreas will deliver insulin as needed, minute-by-minute, throughout the day to maintain blood sugar within a target range. But even this early system could bring dramatic changes in the quality of life for the three million people in the U.S. with type 1 diabetes, beginning to free kids and adults from testing, calculating, and treating themselves throughout the day and night."

New Automated System

The first-generation system would be partially automated, utilizing an insulin pump connected wirelessly with a continuous glucose monitor (CGM).

The CGM continuously reads glucose levels through a sensor with a hair-thin sensor wire inserted just below the skin, typically on the abdomen. The sensor would transmit those readings to the insulin pump, which delivers insulin through a small tube or patch on the body.

The pump would house a sophisticated computer program that will address safety concerns during the day and night, by helping prevent hypoglycemia and extreme hyperglycemia. It would slow or stop insulin delivery if it detected blood sugar was going too low and would increase insulin delivery if blood sugar was too high.

Here's an example of how this first-generation device would work: The wearer will still need to manually tell the pump to deliver insulin at times, such as around meals, and adjust insulin delivery rates based on activity, illness, and other variables. But the system would "treat to range," that is, try to keep blood sugar within a set range between, for example, 80 mg/dL and 180mg/dL by automatically increasing insulin delivery when it senses blood glucose going above the high end of the range, and slowing down or turning off insulin delivery when it sensed blood glucose levels moving below the low end of the range.

This "hypoglycemia-hyperglycemia minimizer" system would represent a significant step forward in diabetes management, and could provide immediate benefits in terms of blood sugar control by minimizing dangerous highs and lows.

Dr. Lewis noted that JDRF will provide $8 million in funding over the next three years for this project, with a target of having a first-generation system ready for regulatory review within the next four or so years.

DexCom, Inc., a leading manufacturer of CGM devices, will supply the CGM technology for the system to be developed by JDRF and Animas.

Reducing High and Low Blood Sugar

"Although this partnership is focused on a first-generation system, not a fully automated artificial pancreas, such a system could provide better clinical outcomes for those with

type 1 diabetes—reducing if not eliminating the high or low blood sugar problems that send people with diabetes to the hospital, cause accidents or injuries, and make living with diabetes so difficult," explained Aaron Kowalski, JDRF's Research Director of the Artificial Pancreas Project. "And better control would significantly lower the key risk for developing the devastating long-term complications of the disease, including eye disease, kidney disease, nerve disease, or cardiovascular disease."

More information about the JDRF-Animas partnership and the development of a first-generation automated system to manage diabetes is available at **www.jdrf.org/artificialpancreasproject**. The site also includes information for people with type 1 diabetes about research leading to the development of an artificial pancreas, as well as interactive tools, chats with researchers, and access to information about clinical trials.

The JDRF-Animas partnership will build upon the progress made since 2006 in the JDRF-funded Artificial Pancreas Consortium, a group of university-based mathematicians, engineers, and diabetes experts that has developed the computer programs needed for an artificial pancreas, and established their scientific feasibility. The goal of an artificial pancreas has also been embraced by the FDA, which along with JDRF and the National Institutes of Health brought together scientists, regulators, industry, and patients for scientific workshops on the subject in 2005 and 2008; the FDA has designated an artificial pancreas as one of its "critical path" initiatives.

Dr. Kowalski noted that the development of an artificial pancreas system is an essential step towards an ultimate cure for type 1 diabetes—a "bridge to a cure." JDRF's goal is to have multiple versions of an artificial pancreas available for people with diabetes; the organization will continue to explore partnerships with other industry leaders.