American Diabetes Association.

NEWS RELEASE

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Artificial Pancreas Improves Overnight Glucose Control for Range of Real-Life Situations, Latest Data Show

Researchers Also Identify Psychosocial Barriers to Use of CGM Devices;
Symposium Provides Update on Advances That Could Lead to Rapid Commercial Development of an Artificial Pancreas System

June 27, 2010 (Orlando, FL) – Research into whether an "artificial pancreas" can effectively control blood glucose levels in children and adults with type 1 diabetes continues to make rapid advances, leading those in the field to predict that technology could become commercially available within the next few years, according to speakers at a joint American Diabetes Association - Juvenile Diabetes Research Foundation (JDRF) symposium at the Association's 70th Scientific Sessions®.

Results, presented for the first time at today's symposium, show that adults with type 1 diabetes can use the artificial pancreas technology to significantly improve overnight blood glucose control without increasing the risk for hypoglycemia, across a range of real-life situations -- even after eating a large meal and drinking a glass of white wine. Lead researcher Roman Hovorka, Ph.D, Principal Research Associate at the University of Cambridge Metabolic Research Laboratories, noted that such a system could greatly improve the lives of those who are insulin-dependent.

A second study, also presented for the first time at the Association's 70th Scientific Sessions, helped to identify the psychosocial characteristics of people with type 1 diabetes most likely to successfully utilize continuous glucose monitoring (CGM) devices, an important component of an artificial pancreas system. This data, presented by Marilyn Ritholz, Ph.D, Senior Psychologist at the Joslin Diabetes Center and Assistant Professor at Harvard Medical School, should help physicians and other diabetes care providers to identify patients for whom the new devices are most likely to be beneficial.

Both studies are part of the JDRF'S Artificial Pancreas Project, a partnership that brings together diabetes researchers and businesses focused on making the artificial pancreas a reality. The American Diabetes Association joined forces with JDRF at its Scientific Sessions to promote the research behind this project and to raise awareness of efforts underway to improve the lives of people with diabetes who are insulin-dependent.

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"This joint symposium highlights how major organizations working together can move these technologies forward," said Richard Bergenstal, MD, Executive Director of the International Diabetes Center and American Diabetes Association's President, Medicine & Science. "It's going to require collaboration between many different organizations to come together to tackle this problem."

"It's very exciting to work together to help people with diabetes achieve their outcomes," said Aaron Kowalski, Ph.D, Research Director of the Artificial Pancreas Project. "We're all interested in people with diabetes achieving better glucose control. The community needs to hear what's happening and where we are headed."

The JDRF research involving artificial pancreas technology combines CGM with an insulin pump and a sophisticated computer program (called an algorithm) that can automate when and how much insulin to deliver. All but the computer program are technologies already commercially available to people with diabetes. Research trials performed so far within the JDRF Artificial Pancreas Project have tested various levels of automation, multiple computer programs, and a range of in-clinic situations, including large and small meals, nighttime control, and exercise.

However, "a fully automated system that administers insulin as needed during the night without human intervention is planned to be tested on children in their homes in the United Kingdom. Nobody has done such a study before," Hovorka said.

"I think artificial pancreas systems are going to turn out to be among the most promising short-term clinical benefits of diabetes research," said Richard Insel, Executive Vice President of Research at JDRF. "They are going to obviously allow individuals to more effectively manage their blood glucose levels, especially after eating, when exercising, and during the night while they sleep. Not only will that help prevent long-term complications of the disease, but low blood sugars will be prevented, and living with diabetes will be easier. Just preventing the swings in glucose levels will help. The benefits are countless."

Partially Automated Systems in Development

Hovorka and his team from the University of Cambridge have completed several recent studies of the artificial pancreas that hold promise for both children and adults with type 1 diabetes. Earlier this year, *The Lancet* published their landmark study of children and teenagers with type 1 diabetes who experienced better control of blood glucose levels and lower incidence of hypoglycemia while sleeping, using a closed loop artificial pancreas system.

Today, during the joint American Diabetes Association-JDRF symposium, Hovorka outlined results of his most recent study, which showed these benefits remain consistent even after adults with type 1 eat a large meal and drink a glass of white wine before bedtime. The study found that using the artificial pancreas system, these adults spent 70 percent of their time within their target blood glucose range, up from 47 percent of the time they spend within target overnight without use of the artificial pancreas system. As in the other studies, time spent in hypoglycemia tended to be reduced, even though alcohol is known to increase the risk of nocturnal/next morning hypoglycemia for people with type 1 diabetes. Full results will be presented on Monday.

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The Cambridge team has also begun preliminary research into how such a system might work for pregnant women with type 1 diabetes. Early results have examined overnight glucose control in this population to establish a baseline against which they can measure effectiveness using the closed loop artificial pancreas system. These preliminary results were discussed in a poster presentation here on Saturday.

Barriers to Continuous Glucose Monitoring (CGM)

A major component of the technology needed to produce an artificial pancreas is a continuous glucose monitoring (CGM) system, which relates blood glucose levels and the direction they are trending throughout the day and night, compared to the "snapshots" that are currently taken by pricking the skin and using test strips on a periodic basis. CGM involves inserting a glucose-sensing device called a "sensor" under the skin of the abdomen, where it takes a glucose reading from the tissue every few seconds and relays it to a handheld device or insulin pump.

"CGM has the potential to be one of the most important breakthroughs in diabetes management in many years, especially for type 1, probably since pump therapies were developed in the 1980s," said William Tamborlane, MD, of Yale University, and co-chair of JDRF's Continuous Glucose Monitoring Group. Holding back more wide scale adoption of the technology at present, he said, are technical imperfections that make the devices cumbersome to use and require frequent calibrations and manual confirmations to ensure accuracy. "What we have now are imperfect simulations of the perfect system," he said. But the technology holds great promise because even while not yet perfected, research has shown that using it regularly can significantly reduce A1C levels without increasing severe hypoglycemia in those who used it as directed.

JDRF-funded studies have shown that adults over the age of 25 were able to reduce their A1C levels from 7.6 to 7.1, using CGM in conjunction with an insulin pump, he said. In children ages 8-14, A1C levels dropped from 8.0 to 7.6 using CGM. Teenagers did not see a benefit, but that is likely because they were less likely to comply with using the technology than the other two groups, Tamborlane said. Participants in the trials who used the technology regularly – more than six days per week – saw similar improvement regardless of age.

"To get a benefit from a device, you actually have to use it," he said.

Most importantly, when using CGM, A1C levels were reduced half a percentage point without increasing the risk of severe hypoglycemia, Tamborlane said. Hypoglycemia is perhaps the biggest concern for people with diabetes looking to significantly lower blood glucose levels and can have serious negative consequences, such as loss of consciousness.

The Joslin Center's Ritholz said her team studied the psycho-social barriers that can prevent people from successful use of a CGM system and found that those who used problem-solving skills for coping with frustration and anger; who saw CGM as a mechanism for better understanding glucose patterns; and who had good support from a spouse or significant other were most likely to achieve good results with using this technology. Conversely, those who had anger and impulse control issues, who failed to synthesize the data from CGM and who didn't have good emotional support were less likely to benefit from CGM use.

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Success was defined, in this study, as lowering A1C levels by at least half a percentage point (if levels were above 7 percent at baseline) or decreasing the amount of hypoglycemia (if levels were below 7 percent at baseline), Ritholz said.

"There needs to be attention paid to the people using CGM," she said. "We can't *just* focus on the technology. In determining individualized patient care, it's important to pay attention to who is most likely to succeed with this technology. It's not for everybody."

The American Diabetes Association is leading the fight to stop diabetes and its deadly consequences and fighting for those affected by diabetes. The Association funds research to prevent, cure and manage diabetes; delivers services to hundreds of communities; provides objective and credible information; and gives voice to those denied their rights because of diabetes. Founded in 1940, our mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. For more information please call the American Diabetes Association at 1-800-DIABETES (1-800-342-2383) or visit www.diabetes.org. Information from both these sources is available in English and Spanish.

About JDRF
JDRF is the leader in research leading to a cure for type 1 diabetes in the world. It sets the global agenda for diabetes research, and is the largest charitable funder and advocate of diabetes science worldwide.

The mission of JDRF is to find a cure for diabetes and its complications through the support of research. Type 1 diabetes is an autoimmune disease that strikes children and adults suddenly, and can be fatal. Until a cure is found, people with type 1 diabetes have to test their blood sugar and give themselves insulin injections multiple times or use a pump -- each day, every day of their lives. And even with that intensive care, insulin is not a cure for diabetes, nor does it prevent its eventual and devastating complications, which may include kidney failure, blindness, heart disease, stroke, and amputation. The goal of the JDRF Artificial Pancreas Project is to speed the development of automated diabetes management systems. Since its founding in 1970 by parents of children with type 1 diabetes, JDRF has awarded more than $1.4 billion to diabetes research, including more than $100 million in 20 countries last year alone.

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Symposium, Sunday June 27, 2 P.M.