MedicalXpress

JDRF clinical panel recommends next steps for artificial pancreas clinical testing

November 10 2010

Diabetes experts at a meeting convened by the U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH) took the next step in advancing efforts toward the development of an artificial pancreas: putting forth clinical recommendations to ensure the safe and effective testing of artificial pancreas technology in real-life situations. We are pleased at today's meeting there was a strong consensus among leading clinicians, researchers and industry leaders regarding the path toward outpatient studies for both low-glucose suspend and artificial pancreas systems.

Even with treatments available today, tight blood sugar control remains a challenge and daily struggle for those living with type 1 diabetes. In fact, the majority of people living with the disease are not achieving recommended target levels. "An artificial pancreas, essentially a device that would both measure blood sugar and dispense appropriate amounts of insulin to keep levels in optimal range, would take much of the guesswork out of daily management of the disease," said Dr. Aaron Kowalski, Assistant Vice President of Treatment Therapies at JDRF. "In the long-run, controlled blood sugar levels will help to lessen or avert the devastating complications from type 1 diabetes."

To date, artificial pancreas devices have been successfully tested in controlled inpatient or hospital settings, demonstrating the potential for this technology to improve blood sugar control. Now it must be tested safely in real-world conditions. And clear and reasonable regulatory guidelines must be established to ensure that the upcoming studies

advance the technology to reach patients as soon as possible.

"We believe a safe and effective first generation artificial pancreas system is possible with today's technology, even as we continue to encourage development of improved devices. Experts at today's FDA workshop outlined a clear path forward to safely speed the development and delivery of artificial pancreas systems to patients," said Jeffrey Brewer, President and CEO of JDRF.

To help advance these efforts, JDRF formed a Clinical Panel of internationally renowned leaders in the diabetes field to make recommendations to FDA on key clinical steps and issues critical to the advancement of studies of these systems outside of the hospital. Panel members speaking at today's workshop included David Nathan, Director, Clinical Research Center and Diabetes Center at Massachusetts General Hospital and Professor of Medicine, Harvard Medical School; and William Tamborlane, Professor and Chief of Pediatric Endocrinology and Diabetes, Yale University School of Medicine.

The panel developed a series of clinical recommendations that were shared at today's meeting. They were based on key areas addressed by the FDA, NIH, JDRF, clinicians and industry. First, the recommendations addressed questions on how should studies on artificial pancreas systems move safely from inpatient (hospital) settings to outpatient (real-world) testing. Second, the panel identified which subset of patients should be considered when testing artificial pancreas systems. The third area focused on how to ensure the safety of patients participating in the studies and eventually for everyday use. Lastly, the panel identified what outcomes should be measured in studies to demonstrate the safety and effectiveness of the device.

A summary of the panel's recommendations is available here. A full report by the panel will be forthcoming.

According to panel chair Robert Sherwin, M.D., Yale University, "The panel believes, with certain safeguards, artificial pancreas systems can be safely tested in real world settings."

"The incidence of type 1 diabetes is on the rise. Today's tools to manage the disease are insufficient. We have the technology at our disposal to make an artificial pancreas work. Now it's time to move forward quickly to define the regulatory pathway so final studies can be completed and better technologies can be made available to adults and children struggling with this difficult disease," added Mr. Brewer.

About JDRF's Artificial Pancreas Project

JDRF launched the Artificial Pancreas Project in 2005 to speed the development of automated diabetes management systems. A self-regulating system, the artificial pancreas would be able to sense sugar levels continuously and automatically release the right amount of insulin at the right times – eliminating the need for multiple blood tests, insulin injections and therefore lifting the daily burden associated with managing diabetes.

Since that time, JDRF has supported a number of initiatives that have advanced progress toward the development of an artificial pancreas. This has included the formation of the Artificial Pancreas Consortium, a group of university-based mathematicians, engineers, and diabetes experts to develop the computer algorithms that are needed to connect the devices needed to form a closed-loop system.

In addition to the consortium, JDRF has collaborated with several industry partners to develop a first-generation artificial pancreas system, as well as better and faster-acting insulin products, a key component of developing a safe and effective artificial pancreas system.

More information: www.jdrf.org/artificialpancreasproject

Provided by Juvenile Diabetes Research Foundation International