JDRF Clinical Panel Recommends Next Steps for Artificial Pancreas Clinical Testing

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WASHINGTON, Nov. 10, 2010 /PRNewswire-USNewswire/ -- 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
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