

JDRF Encouraged By Draft FDA Artificial Pancreas Guidance

Washington, D.C. – The JDRF today said it is encouraged that the Food and Drug Administration (FDA) has issued a draft guidance which appears to lay a foundation for accelerating the development and availability of artificial pancreas technology (AP) that will improve the lives of millions of Americans living with type 1 diabetes (T1D).

"Our initial review of the draft AP guidance indicates that the FDA has been responsive and listened to the recommendations of leading clinicians and researchers in the type 1 diabetes field," said Jeffrey Brewer, President and CEO of JDRF. "It also appears that the draft guidance lays out a rapid timetable to move from inpatient trials to outpatient trials to prove the AP's safety and efficacy, and if that turns out to be the case it is good news."

Artificial pancreas technologies have the potential to be the most revolutionary advance in treating T1D since the discovery of insulin. They will allow the millions of Americans with T1D to maintain tighter control of blood glucose levels, thus significantly reducing the risk of both high blood sugar (hyperglycemia), which can cause long-term complications including heart disease, blindness and stroke, and low blood sugar (hypoglycemia), which can be life-threatening. It would also free them from much of the daily burden of managing the disease.

In 2006, the FDA added artificial pancreas technology to its Critical Path list, making a commitment to advance these systems. The draft guidance is the first step to getting the technology to those in dire need.

"To be sure, we have a ways to go before AP technologies are available to patients but this draft guidance suggests that Commissioner Hamburg and the FDA are committed to fostering innovation and being a global leader in bringing life-saving technologies for T1D patients to the U.S market," said Brewer. "In the next few weeks, we will review the draft guidance in detail and provide detailed comments to the FDA so that the final guidance unmistakably lays out the pathway to put AP technologies in patient's hands as soon as possible. In the end, that is what this is all about."

About the Artificial Pancreas

The artificial pancreas (AP) is an external device which people with T1D could use to do what their bodies cannot-control both high and low blood sugar around the clock. It works by combining a continuous glucose monitor (CGM) and an insulin pump with sophisticated computer software to provide automatically the right amount of insulin at the right time.

One of JDRF's top priorities is the development of the AP. JDRF-funded studies have shown greatly improved clinical outcomes from early trials of prototype AP systems.

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FDA's guidance on artificial pancreas systems will allow for these systems to be further developed, tested in outpatient pivotal trials, and eventually approved for people with T1D.

An overwhelming amount of support from researchers, clinicians, policymakers, and patients called on the FDA to advance the development of an AP. Over 100,000 people in the diabetes community signed JDRF's petition which urged the FDA to adopt clear guidance, and leading clinical organizations specializing in diabetes care urged the FDA to ensure that the development of an artificial pancreas is not delayed by unnecessary regulatory roadblocks. Furthermore, Congress demonstrated vast support for a reasonable and timely guidance from FDA, with 252 Representatives and 62 Senators having urged the FDA to act in the best interest of type 1 diabetes patients.

About JDRF

JDRF is the leading global organization focused on type 1 diabetes (T1D) research. Driven by passionate, grassroots volunteers connected to children, adolescents, and adults with this disease, JDRF is the largest charitable supporter of T1D research. The goal of JDRF is to improve the lives of every person affected by T1D by accelerating progress on the most promising opportunities for curing, better treating, and preventing T1D. JDRF collaborates with a wide spectrum of partners who share this goal. Since its founding in 1970, JDRF has awarded more than \$1.5 billion to T1D research. More than 80 percent of JDRF's expenditures directly support research and research-related education. Past JDRF research efforts have helped to significantly improve the care of people with this disease, and have expanded the critical scientific understanding of T1D. JDRF will not rest until T1D is fully conquered. For more information, please visit www.jdrf.org [1].

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