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First U.S. Outpatient Artificial Pancreas Trial Gets FDA Approval

JDRF Applauds Major Advancement in Development of Lifesaving Diabetes Technology

NEW YORK, March 19, 2012 --- JDRF applauds the recent approval by the U.S. Food and Drug Administration (FDA) of the first outpatient artificial pancreas trial in the United States, marking a critical development in the effort by JDRF and its allies to bring this innovative and lifesaving diabetes technology to people with type 1 diabetes (T1D).

The JDRF-funded study will test an artificial pancreas (AP) system's ability to function outside of a hospital setting, and is similar to the current outpatient trials being conducted in Europe.

The study is part of the first outpatient trials using an approach developed by the JDRF-supported Artificial Pancreas Consortium, an international research group including teams from Montpellier University Hospital (France), the Universities of Padova and Pavia (Italy), and the Universities of Virginia in Charlottesville and of California in Santa Barbara (USA).

"We commend the FDA for its leadership and this concrete step in meeting its commitment to accelerate the development of artificial pancreas systems. These technologies could truly transform the lives of those living with type 1 diabetes, enabling them to live longer and healthier lives, and preventing some of the personal and financial toll diabetes places on our nation," said Aaron Kowalski, Ph.D., assistant vice president of treatment therapies for JDRF. "While this is a small feasibility study, this is a major step forward in the field of artificial pancreas research and we congratulate the researchers and the FDA on this important milestone."

The approval of this milestone study follows a major 18-month long effort by JDRF and allies to ensure a clear and reasonable regulatory pathway for outpatient artificial pancreas studies, and ultimately for AP systems to be approved and made available by the FDA. JDRF-funded studies have shown improved clinical outcomes from early trials of prototype AP systems. In early 2011, JDRF proposed guidance to the FDA, based on recommendations from an external expert panel. In the following months, over 100,000 people in the diabetes community signed JDRF's petition, and numerous leading clinical organizations, as well as over 60 Senators and 250 Representatives joined JDRF in urging

FDA to act. The FDA met its promised deadline and released draft guidance for AP systems on December 1, 2011.

JDRF recently completed an evaluation of the draft FDA AP guidance, and submitted comments to FDA on March 3rd. JDRF believes that the draft contains many positive elements that will encourage research and development of artificial pancreas technologies and lead to their eventual availability in the U.S.

"While there were some areas of concern in the guidance, we have begun a dialogue with FDA about these issues, and we will continue to urge the agency to revise these in the guidance before it is finalized so that we will continue to see more outpatient trials approved, and people with diabetes will ultimately have access to these lifesaving technologies as soon as possible," added Kowalski. JDRF's comments can be read here.

The development of an artificial pancreas is one of JDRF's top priorities. JDRF and the National Institutes of Health's Special Diabetes Program have funded groundbreaking work in recent years to advance its research and development.

About the Artificial Pancreas

The artificial pancreas (AP) is an external device under development 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.

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 $1.6 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.

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