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JDRF Celebrates FDA Approval of Artificial Pancreas System

*-- FDA’s Approval of the Medtronic Hybrid Closed Loop System Will Significantly Improve Glucose Control and Reduce the Burden of Type 1 Diabetes --*

**NEW YORK, NY** — September 28, 2016 – JDRF, which for a decade through its research and advocacy work has catalyzed development of artificial pancreas systems, commended the Food and Drug Administration today for being the first regulator in the world to approve a commercial version of this life-saving technology, the Medtronic MiniMed 670G hybrid closed-loop system. JDRF is the leading global organization funding type 1 diabetes (T1D) research.

“This announcement is a historic achievement for JDRF. After years of laying the ground work, this breakthrough is a testament to the reason JDRF exists – to help people with T1D lead better, safer, healthier lives while we continue on the path to cure and prevent the disease altogether,” said JDRF CEO Derek Rapp. “It marks a major accomplishment in one of our highest priority research areas.”

“This is a fantastic step forward, but we are not done. JDRF will continue supporting other artificial pancreas advancements and advocating for broad access to this life-changing technology,” said JDRF Chief Mission Officer, Aaron J. Kowalski, PhD. “Several other technologies are in the pipeline that could also provide better outcomes and less burden for those living with T1D. Our work will not be finished until we cure and prevent T1D.”

"JDRF's vision and leadership has been a critical catalyst to drive the field from a concept to today’s reality," said leading Artificial Pancreas researcher Stuart Weinzimer M.D. of Yale University. "A decade ago, JDRF launched their Artificial Pancreas Project. This initiative dramatically accelerated progress by fostering collaboration among academic investigators in the field, industry, and other funding and advocacy agencies. I look forward to my patients benefitting from this very important advance."

Artificial pancreas systems are composed of insulin pumps, continuous glucose monitors and smart software to automate the delivery of the right amount of insulin at the right time. JDRF has played a pivotal role in their development by supporting research and development of multiple systems across the globe, as well as validating system benefits.

The new system is the first ever approved to automate insulin dosing to reduce high blood sugar levels. In clinical trials, the 670G system kept people with T1D within their desired blood sugar range 72 percent of the time, vs. 67 percent without the system. At night, the most dangerous time for blood sugar highs and lows, the difference was even more pronounced, 75 percent in range vs. 67 percent without the technology. Overall glucose control, as measured by HbA1c levels, improved from 7.4% at baseline to 6.9% at study end.

The system will use the new Medtronic pump body, a 4th generation sensor and a control algorithm to automate basal insulin delivery to maximize the time glucose levels are in a healthy range throughout the day and night. Previous systems stop insulin in response to existing or predicted low sensor glucose values, hybrid closed-loop systems combine user-delivered pre-meal boluses with automatic insulin delivery.

**The Path to the Artificial Pancreas**

JDRF has been pivotal in developing and pursuing its Artificial Pancreas Project since 2006. In less than 10 years, JDRF transformed the AP field, working closely with numerous partners, researchers and companies to overcome the challenges that prevented AP technology from moving forward. Together, JDRF, the Helmsley Charitable Trust, and the National Institutes of Health’s Special Diabetes Program have funded hundreds of millions of dollars in research across the globe to develop and test sophisticated computer algorithms and components needed for the AP systems.

JDRF developed a roadmap to create successively advanced versions of the AP, which has been embraced by manufacturers to guide their own R&D programs. JDRF has also worked with the leadership of the Senate and House Diabetes Caucus and other allies in Congress to provide research funding through the Special Diabetes Program and overcome obstacles that could delay delivery of AP systems to people with T1D.

JDRF funded early artificial pancreas research as part of its hypoglycemia prevention efforts, and in 2006, JDRF launched the Artificial Pancreas Consortium, made up of leading endocrinologists, mathematicians, and engineers at top research institutions in the U.S. and Europe. JDRF and the FDA partnered to proactively address regulatory obstacles, leading to the 2012 FDA guidance for artificial pancreas device systems, which provided a regulatory pathway for system commercialization.

In the past decade, JDRF has invested more than $116 million in diverse artificial pancreas research projects, with the goal of aiding the development of multiple, reliable treatment choices for people living with T1D, as well as helping people have broad access to the resulting products. Today’s announcement is a group success that could not have been accomplished without the dedication of JDRF, its many partners, the research teams and the support of the diabetes community overall.

**About JDRF**JDRF is the leading global organization funding type 1 diabetes (T1D) research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications. To accomplish this, JDRF has invested more than $2 billion in research funding since our inception. We are an organization built on a grassroots model of people connecting in their local communities, collaborating regionally for efficiency and broader fundraising impact, and uniting on a national stage to pool resources, passion, and energy. We collaborate with academic institutions, policymakers, and corporate and industry partners to develop and deliver a pipeline of innovative therapies to people living with T1D. Our staff and volunteers throughout the United States and our six international affiliates are dedicated to advocacy, community engagement and our vision of a world without T1D. For more information, please visit jdrf.org or follow us on Twitter: @JDRF