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**Positive Results from First Human Clinical Trials of a First-Generation Artificial Pancreas System is Significant Step Forward for Millions with Type 1 Diabetes**

*System in Development from Animas-JDRF Partnership Successfully Detects Highs and Lows, and Shown to Safely and Automatically Adjust Insulin Delivery in Clinical Setting*

**WEST CHESTER, Pa., June 11, 2012** – Results from the first feasibility study of an advanced first-generation artificial pancreas system were presented today at the 72<sup>nd</sup> Annual American Diabetes Association Meeting in Philadelphia. Findings from the study indicated that the Hypoglycemia-Hyperglycemia Minimizer (HHM) System was able to automatically predict a rise and fall in blood glucose and correspondingly increase and/or decrease insulin delivery safely. The HHM System included a continuous, subcutaneous insulin pump, a continuous glucose monitor (CGM) and special software used to predict changes in blood glucose. The study was conducted by Animas Corporation in collaboration with JDRF as part of an ongoing partnership to advance the development of a closed-loop artificial pancreas system for patients with Type 1 diabetes.

“The successful completion of this study using the HHM System in a human clinical trial setting is a significant step forward in the development of an advanced first-generation artificial pancreas system,” said Dr. Henry Anhalt, Animas Chief Medical Officer and Medical Director of the Artificial Pancreas Program. “It lays the foundation for subsequent clinical trials, bringing us one step closer to making the dream of an artificial pancreas a reality for millions of people living with Type 1 diabetes.”

In June 2011, Animas received Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) to proceed with human clinical feasibility studies for the development of a closed-loop artificial pancreas system. The company partnered with the JDRF in January 2010 to begin developing such an automated system to help people living with Type 1 diabetes better control their disease.

“We are encouraged by the results of the first human trials in this partnership with Animas,” said Aaron Kowalski, Ph.D., Assistant Vice President of Research at JDRF. “An artificial pancreas

system that can not only detect, but can predict high and low blood sugar levels and make automatic adjustments to insulin delivery would be a major advance for people with Type 1 diabetes. Such a system could alleviate a huge burden of managing this disease.”

#### **About the Studies**

The trial was a non-randomized, uncontrolled feasibility study of 13 participants with Type 1 diabetes at one trial site in the United States. The investigational Hypoglycemia-Hyperglycemia Minimizer (HHM) system was studied for approximately 24 hours for each study participant during periods of open and closed loop control via a model predictive control algorithm with a safety module run from a laptop platform. Insulin and food variables were manipulated throughout the study time period to challenge and assess the system.

The primary endpoint was to evaluate the ability of the algorithm to predict a rise and fall in glucose above or below set thresholds and to command the pump to increase, decrease, suspend and/or resume insulin infusion accordingly. The secondary endpoint was to understand the HHM system’s ability to safely keep glucose levels within a target range and to provide guidance for future system development. The study also examined the relationship between CGM trends and the control model’s algorithm for insulin delivery.

#### **About Animas Corporation**

As part of the Johnson & Johnson Family of Companies, Animas is dedicated to creating a world without limits for people with diabetes through a wide range of products, including the OneTouch® Ping® Glucose Management System and the Animas® 2020 insulin pump. Animas, from the Latin word meaning “true inner self or soul,” has been committed since 1996 to meeting individual patient needs through the development of life-performance technology and customer service 24 hours a day, 7 days a week, 365 days a year. To learn more about Animas, visit <http://www.animas.com/>.

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