Animas' Development of a First-Generation Closed Loop Insulin Delivery System Progresses With Data Presented at the Advanced Technologies & Treatments for Diabetes (ATTD) Conference

Predictive Glucose Control System in Development Shows Promising Ability to Minimize Number, Duration and Severity of Hypoglycemic Events with No Safety Concerns

WEST CHESTER, Pa., February 28, 2013– Animas Corporation announced today positive results from the second phase of human clinical trials of a first-generation closed-loop insulin delivery system in development, designed to predict a rise or fall in blood glucose and correspondingly increase, decrease, suspend and resume insulin delivery. The data were presented at the Advanced Technologies & Treatments for Diabetes (ATTD) Conference in Paris, France.

The feasibility study of the predictive Hypoglycemia-Hyperglycemia Minimizer (HHM) System* in development was conducted in 20 adults with type 1 diabetes and designed to investigate the System's ability to adjust insulin dosing to proactively mitigate hypoglycemia and hyperglycemia. The study, which was the first conducted in humans to investigate the configuration of the predictive algorithm, revealed differences in the algorithm's insulin-dosing characteristics and provided insights into the sensititivy of the System. The results also indicated that the System reduced insulin delivery in advance of hypoglycemia and triggered timely warnings. The study was conducted by Animas Corporation in partnership with leading academic research institutions, including the University of California, Santa Barbara; Sansum Diabetes Research Institute; and the Center for Diabetes Technology at the University of Virginia.

 "We are encouraged by these results, which strengthen our understanding of the complex algorithms required of a closed-loop insulin delivery system and further our confidence in this technology platform," said Ramakrishna Venugopalan, Director, Research & Development at Animas Corporation. "The scope of this study also reflects our commitment to create innovative and robust solutions for people living with diabetes."

Animas began collaborating with industry, academia and advocacy organizations, including the JDRF (formerly the Juvenile Diabetes Research Foundation), in 2010. After receiving Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) in 2011, researchers began the first human clinical feasibility studies for the development of a closed-loop insulin delivery system.

Together with these key partners, Animas continues to work toward developing such an automated system to help people living with type 1 diabetes better control their disease.

"We are encouraged by the results and progress Animas has made in the first stage of development of a closed loop insulin delivery system," said Aaron Kowalski, Ph.D., Vice President of Treatment Therapies Research at JDRF. "A predictive system that can not only detect, but can predict blood sugar levels and make automatic adjustments to insulin delivery would be a major advance for people with Type 1 diabetes."

* The HHM System includes a continuous subcutaneous insulin infusion pump, a continuous glucose monitor (CGM) and a control algorithm used to predict changes in blood glucose.

About the Clinical Study
The study investigated the effect of a fundamental algorithm parameter on the quantitative insulin-dosing characteristics of the System. The parameter, known as the "aggressiveness factor," affects how readily the algorithm adjusts insulin delivery in response to glucose fluctuations. This is the first study in humans to investigate tuning such an algorithm parameter. The results demonstrated differences in the algorithm's insulin-dosing characteristics based on three aggressiveness factors and reinforced the importance of investigating the sensitivity of the System to its key parameters.

The study also investigated the predictive, proactive methods by which the System mitigates hypoglycemia, especially as compared to reactive, threshold-based systems. In particular, two predictive hypoglycemia safeguards of the System were investigated: its ability to decrease/suspend insulin delivery before a hypoglycemic threshold is reached, and its ability to trigger timely alerts for imminent hypoglycemia. The results indicated that the System reduced insulin delivery in advance of breaches of a hypoglycemic threshold and triggered timely warnings for imminent hypoglycemica.

Regarding general glucose control, the System demonstrated promising results, keeping glucose levels at an average of 133 mg/dL for the entire cohort. On average, 82.8 percent of the closed-loop time was spent at glucose levels between 70-180 mg/dL, and little time (3.4 percent) was spent at levels below 70 mg/dL. There were no safety concerns, including diabetic ketoacidosis or severe hypoglycemia.

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, Animas® Vibe™ insulin pump and CGM 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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