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Animas Makes Progress in Development of a First-Generation Closed-Loop Insulin Delivery System With Study Participants Maintaining Safe Glucose Levels for Over 90 Percent of the Overnight Period

Development Continues With Data Presented at the American Diabetes Association (ADA) Scientific Sessions

WEST CHESTER, Pa., June 21, 2013 – Animas Corporation announced today further promising results from the second phase of human clinical trials of a first-generation closed-loop insulin delivery system in development. Data investigating the predictive Hypoglycemia-Hyperglycemia Minimizer (HMM) System* demonstrated that the system is capable of maintaining safe glucose levels overnight. The data was presented at the 73rd Scientific Sessions of the American Diabetes Association (ADA) in Chicago, Illinois.

The feasibility study of the predictive glucose control system in development was conducted in 20 adults with type 1 diabetes and designed to investigate the System's automatic control algorithm, with emphasis on the overnight period from 9 PM to 7 AM. The System showed encouraging performance with the participants, on average, spending over 90 percent of the overnight period with blood glucose values in the range between 70-180 mg/dl. Additionally, fewer than half of the study participants had blood glucose values less than 70 mg/dL during the overnight period.

These results build on the data Animas presented from the same feasibility study earlier this year at the annual Advanced Technologies and Treatments for Diabetes (ATTD) conference, which demonstrated that the System shows promising ability to minimize the number, duration and severity of hypoglycemic events with no safety concerns. The study was conducted 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.

"Avoiding hypoglycemia during the overnight period is a primary concern for people with diabetes, so maintaining safe glucose levels during this time frame is crucial in helping to not only achieve better control, but also helps ease worry throughout the night," said Ramakrishna Venugopalan, Director, Research & Development at Animas Corporation. "We are encouraged by the results of this overnight study, and we are excited to be one step closer to bringing this technology to patients."

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 Animas’ latest findings that indicate the System is able to control overnight blood glucose levels safely,” said Aaron Kowalski, Ph.D., Vice President of Treatment Therapies Research at JDRF. “For children and their families living with diabetes, the fear of hypoglycemia during the night is very real, so any peace of mind we can provide, particularly in the overnight period, would be a tremendous benefit.

* 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 an automatic control algorithm of a predictive glucose control system in development during the overnight period of 9 PM – 7 AM. Glucose-related metrics calculated specifically for this overnight period were based on both continuous glucose monitor (CGM) readings and readings obtained from the YSI 2300 STAT Plus. The results demonstrated that the System was capable of maintaining safe glucose levels overnight, and indicate feasibility for continuing development.

During the study, the System dosed insulin automatically based on CGM values. The mean overnight glucose value based on CGM was 135 mg/dl (129 mg/dl by YSI) for the entire cohort. The median percentage of overnight time spent at glucose values between 70-180 mg/dl was 93.8% (90.9% by YSI). The median percentage of overnight time spent at glucose values less than 70 mg/dl was 0% by both CGM and YSI.

About Animas Corporation

With a shared vision of “creating a world without limits” for people with diabetes, Animas is a part of Johnson & Johnson Diabetes Solutions Companies, a cross-company collaboration that reflects an ongoing commitment to better serve the diabetes community with integrated solutions that meet the needs of people with diabetes across the continuum of care. Animas provides a wide range of insulin delivery products for people living with diabetes, 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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