Senseonics Reports CGM Europe Pivotal Study Results

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PRIMARY EFFECTIVENESS AND SAFETY ENDPOINTS MET; CE MARK PENDING

GERMANTOWN, MD – October 27, 2015 – Senseonics, Incorporated, a privately held medical device company focused on the development and commercialization of the first fully implantable, long-term continuous glucose monitoring (CGM) system, announced it has met its primary effectiveness and safety endpoints of the interim phase of the PRECISE (A Prospective, Multicenter Evaluation of the Accuracy of a Novel Continuous Implanted Glucose Sensor) Study. The interim phase was pre-specified in the study to determine the effectiveness and safety of the company's long-term implantable CGM system for the first 90 days of continuous glucose sensor wear.

Jort Kropff, MD, co-investigator at Academic Medical Centre, University of Amsterdam, presented the study results at last week's 15th Annual Diabetes Technology Meeting in Bethesda, Maryland. Results from 44 subjects with diabetes demonstrated strong accuracy throughout the entire 90-day continuous wear period with a mean absolute relative difference (MARD) of 11.4% in the 75-400 mg/dL range when compared to YSI blood reference values. The mean absolute difference (MAD) in the <75 mg/dL range was 13.5 mg/dL. Eighty-four percent (84%) of the sensor values were within 20% of the YSI reference. There were no significant adverse events reported related to the Senseonics CGM system.

Subjects underwent bilateral sensor insertions in the clinic on day 1 and used the system's smart transmitter and mobile app at home for the next 90 days. Subjects were able to view their real-time glucose readings and trends during home-use and sensor readings were not used to adjust their treatment. Clinic visits were scheduled throughout the 90 days in order to obtain lab reference glucose values for comparison with the sensor values.

J. Hans DeVries, MD, Academic Medical Centre, University of Amsterdam, and study lead investigator, said "Overall our patients were very satisfied with the device and regretted that they couldn't continue using it after the trial". The Academic Medical Centre is one of seven sites in the Netherlands, the United Kingdom, and Germany that participated in the study.

The company has submitted the Design Dossier to its European Notified Body (TUV SUD) to obtain CE Marking for the CGM system. The company plans to initiate sales in Scandinavia, followed by other European countries, once the CE mark is received.

“The promising interim results from the PRECISE study, as well as the subsequent submission of our CE mark application, are major milestones for the company,” said Tim Goodnow, PhD., CEO and President of Senseonics. “When it receives clearance, our 90-day CGM system will be the longest-lasting glucose sensor that is safe and accurate for people with diabetes to use.”

The PRECISE study is ongoing and will collect information on the longer-term 180-day use of the system. The company expects to have the 180-day results by the beginning of 2016.

About Senseonics

Senseonics, Incorporated is developing the first fully implantable continuous glucose sensor designed for highly accurate, long-term wear. The Senseonics Continuous Glucose Monitoring System includes a miniaturized sensor, smart transmitter and mobile app. Based on proprietary breakthrough fluorescence sensing technology, the sensor is designed to be inserted subcutaneously and communicate with the smart transmitter to wirelessly transmit glucose levels to a mobile device. After insertion, the sensor functions automatically and continuously. The system is intended to enable people with diabetes to confidently live their lives with ease. For more information on Senseonics, please visit us at www.senseonics.com.