Senseonics Announces Results of the PROMISE Study Demonstrating Strong Accuracy of 180 Day CGM Sensor

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-Overall MARD of 8.5%-9.1% during 180 Day Period

GERMANTOWN, Md.--(BUSINESS WIRE)-- Senseonics Holdings, Inc. (NYSE-American: SENS), a medical technology company focused on the development and commercialization of the first and only long-term, implantable continuous glucose monitoring (CGM) system – the Eversense® CGM System – today announced the results of the PROMISE Study evaluating the accuracy and safety of the next generation Eversense CGM System for up to 180 days with reduced calibrations. The data was presented by Satish Garg, MD, Professor of Medicine at the Barbara Davis Center of the University of Colorado, Denver, and the study group Principal Investigator (PI), as an oral presentation at the 14th Annual ATTD Meeting. Results were presented for both the primary sensor and for a secondary sensor with modified chemistry (referred to as the SBA sensor) in a subset of study participants.

“The value of CGM for patients with diabetes, especially those requiring insulin, is unquestioned,” said study PI, Dr. Satish Garg. “To enable more patients to utilize CGM, there needs to be choice in product features. The accuracy profile demonstrated by Eversense in the PROMISE Study validates the role that long-term implantable CGM systems can play in helping people manage their glucose levels.”

Study results:

- Overall mean absolute relative difference (MARD) against reference value was 9.1% for the primary sensor over 49,000 paired points and 8.5% for the SBA sensor over 12,000 paired points.
- The percent sensor readings within 20 mg/dL or 20% of reference values (20/20% agreement rate) were as follows:
  - Across the full 40-400 mg/dL range, the agreement rate was 92.9% for the primary sensor and 93.9% for the SBA sensor.
  - In the hypoglycemic ranges of 40-60 mg/dL and 61-80 mg/dL, the agreement rates were 89.4% and 92.2% for the primary sensor and 96.5% and 96.8% for the SBA sensor, respectively.

- Confirmed hypoglycemic alert detection rate was 93% for primary sensor and 94% for the SBA sensor.
- There were no related serious adverse events, all sensors were removed during the initial removal procedure and 1.1% of patients had a mild infection at the procedure site.

“We are very pleased with the results of the PROMISE Study which demonstrate an excellent safety and accuracy profile for the 180-day sensor. This study was initiated December 2018 and we’re very grateful to the tireless Clinical Investigators and the devoted study subjects for participating in this important clinical trial,” said Tim Goodnow, PhD, President and CEO of Senseonics. “As we await hearing from the US and European regulatory agencies concerning our pre-market submissions of data from both the primary and the SBA sensors, we are pleased to continue to offer the Eversense CGM systems in both the US and Europe with our commercialization partner, Ascensia Diabetes Care.”

The PROMISE Study was a prospective, multicenter trial designed to evaluate the Eversense CGM System in people with diabetes over a 180-day period and was the basis of the pre-market application submissions to the U.S. Food and Drug Administration and to BSI for CE mark in Europe. One hundred and eighty-one (181) study participants at eight sites across the United States had a primary sensor inserted subcutaneously in their left upper arm; 43 of these participants also had an SBA sensor inserted in their right arm. Participants underwent 10 clinic visits between days 1-180 to measure accuracy by comparing the sensor glucose values with the standard reference YSI glucose values obtained simultaneously. Subjects also underwent hypoglycemia and hyperglycemia challenges to assess performance over the glucose range of 40-400 mg/dL, the reporting range of the device. Data from both the primary and the SBA sensors were subsequently included in the pre-market submissions.

The Eversense CGM System consists of a fluorescence-based sensor, a smart transmitter worn over the sensor to facilitate data communication, and a mobile app for displaying glucose values, trends and alerts. In addition to featuring the first long-term and first implantable CGM sensor, the system is also first to feature a smart transmitter that provides wearers with discreet on-body vibratory alerts for high and low glucose and can be removed, recharged and re-attached to the skin without discarding the sensor. Eversense users are able to make treatment decisions based on their Eversense readings in the US. The sensor is inserted subcutaneously in the upper arm by a health care provider via a brief in-office procedure.

About Eversense

The Eversense® Continuous Glucose Monitoring (CGM) System is indicated for continually measuring glucose levels in persons age 18 and older with diabetes for up to 90 days in the US and 180 days in Europe. The system is indicated for use to

replace fingerstick blood glucose (BG) measurements for diabetes treatment decisions in the US. Fingerstick BG measurements are still required for calibration twice per day, and when symptoms do not match CGM information or when taking medications of the tetracycline class. The sensor insertion and removal procedures are performed by a healthcare provider. The Eversense CGM System is a prescription device; patients should talk to their health care provider to learn more. For important safety information, see https://eversensediabetes.com/safety-info/.

About Senseonics

Senseonics Holdings, Inc. is a medical technology company focused on the design, development and commercialization of transformational glucose monitoring products designed to help people with diabetes confidently live their lives with ease. Senseonics' CGM Systems, Eversense® and Eversense® XL, include a small sensor inserted completely under the skin that communicates with a smart transmitter worn over the sensor. The glucose data are automatically sent every 5 minutes to a mobile app on the user's smartphone.

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