

Senseonics Announces the FDA Approval to Continue the PROMISE Sensor Clinical Study in an Extended Cohort to 365 Days to Gather Feasibility Data



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–The cohort of Eversense[®] CGM users will also test modified sensor chemistry.–

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 FDA approved a subgroup (with a modified chemistry to enhance longevity) of PROMISE study participants to continue for a total of 365 days to gather feasibility data on the safety and accuracy of a 365-day sensor.

“We are very pleased that we received a prompt approval to extend the study to gather valuable data,” said Tim Goodnow, PhD, President and CEO of Senseonics. “The scientific, clinical and technical data we will obtain will be critical to further extend sensor longevity. We’re very grateful to the FDA for the green light, for the tireless clinical investigators, and particularly, to the devoted study participants for giving us this opportunity.”

The goal of the PROMISE Clinical Study is to evaluate the safety and efficacy of the Eversense CGM System in people with diabetes over a 180-day period for the pre-market application submission to the U.S. Food and Drug Administration. One hundred and eighty-one (181) study participants at 8 sites across the United States had the Eversense CGM System inserted subcutaneously as part of the study, which is completing the 180-day duration in March. Now, a sub-set of more than 35 participants who all had a sensor with the modified chemistry will be left undisturbed for 365 days with the goal of measuring accuracy and longevity over the full 365 days.

“Extending this study is really a critical step in developing a 365-day product. Information gathered from this cohort will allow us to characterize the improved sensor design and optimize our glucose algorithm for the extended, 365-day use period,”

explained Mukul Jain, PhD, Chief Operating Officer at Senseonics. “This addition is an exciting extension phase of the PROMISE study and we look forward to evaluating the first multi-clinic investigation of a one-year implantable glucose sensor.”

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 now have the freedom to make treatment decisions based on their Eversense readings. 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. The system is indicated for use to replace fingerstick blood glucose (BG) measurements for diabetes treatment decisions. 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://eversensediababetes.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.

Forward Looking Statement

Any statements in this press release about future expectations, plans and prospects for Senseonics, including statements about future developments to the product, regulatory approvals, and the potential benefits Eversense offers people with diabetes, and other statements containing the words “believe,” “expect,” “intend,” “may,” “projects,” “will,” and similar expressions, constitute forward-looking statements within the meaning of

The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties in the development and regulatory approval processes and such other factors as are set forth in the risk factors detailed in Senseonics' Annual Report on Form 10-K for the year ended December 31, 2018, Senseonics' Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, and Senseonics' other filings with the SEC under the heading "Risk Factors." In addition, the forward-looking statements included in this press release represent Senseonics' views as of the date hereof. Senseonics anticipates that subsequent events and developments will cause Senseonics' views to change. However, while Senseonics may elect to update these forward-looking statements at some point in the future, Senseonics specifically disclaims any obligation to do so except as required by law. These forward-looking statements should not be relied upon as representing Senseonics' views as of any date subsequent to the date hereof.

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