

Senseonics Announces the Last Patient Completion of the 365-Day ENHANCE Pivotal Clinical Study



September 26, 2023

Study Data to Support FDA Submission for the first 365-day Continuous Glucose Monitoring System

GERMANTOWN, Md.--(BUSINESS WIRE)-- Senseonics Holdings, Inc. (NYSE American: SENS), a medical technology company focused on the development and manufacturing of long-term, implantable continuous glucose monitoring (CGM) systems for people with diabetes, today announced the completion of the ENHANCE Pivotal Clinical Study adult cohort following the recently completed 365-day visit for the final study patient.

“We are pleased that all patients have completed the testing for the adult arm of the ENHANCE clinical study. Demonstration of safe and accurate performance of Eversense® for 365 days in this study would further validate its ability to facilitate more effective and longer-term management of diabetes. This represents a major milestone for Senseonics as we work towards offering the differentiated benefits of implantable CGM for one full year with just a single sensor,” said Francine Kaufman, M.D., Chief Medical Officer of Senseonics. “We appreciate the efforts of the participating investigators and patients and look forward to analyzing the data, preparing the submission and working with the FDA with the goal to secure approval for the planned 365-day Eversense® system in the coming quarters.”

The ENHANCE study is designed to evaluate the accuracy and safety of the Eversense system for one year. Over 165 adult subjects were inserted with Eversense systems in four centers across the United States. Enrollment for the 365-day sensor configuration was completed in September 2022. Data gathered in this study was also used to support the FDA submission for the integrated continuous glucose monitoring, iCGM, designation earlier in 2023. An investigational device exemption (“IDE”) supplement was submitted and approved for expansion of the study to allow for pediatric patients 14 to 18 years of age and the first pediatric study participants were enrolled in Q2 2023.

About Senseonics

Senseonics Holdings, Inc. (“Senseonics”) is a medical technology company focused on the development and manufacturing of glucose monitoring products designed to transform lives in the global diabetes community with differentiated, long-term implantable glucose management technology. Senseonics' CGM systems, Eversense®, Eversense® XL and Eversense® E3 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 Statements

Any statements in this press release about future expectations, plans and prospects for Senseonics, including any statements regarding the advancement of the Eversense system development program, the use of data from the ENHANCE trial to prepare and support a submission to the FDA of a longer duration CGM system, the planned 365-day sensor duration of a submission, the timing of any potential approval, and other statements containing the words “believe,” “expect,” “intend,” “may,” “projects,” “will,” “planned,” 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 inherent in the development and registration of new technology, uncertainties related to the analysis and results of the ENHANCE study data and whether such data will support the Company's planned submissions, uncertainties in insurer, regulatory and administrative processes and decisions, uncertainties related to the commercialization of new technology, uncertainties relating to the current economic environment, 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, 2022, the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 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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