

Senseonics Announces First Study Participant Implanted in the U.S. as Part of the PROMISE 180-Day Sensor Clinical Study and the Submission of Key PMA Supplements to the FDA to Advance Current 90-Day Product



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GERMANTOWN, Md.--(BUSINESS WIRE)-- Senseonics Holdings, Inc. (NYSE-American: SENS), a medical technology company focused on the development and commercialization of a long-term, implantable continuous glucose monitoring (CGM) system for people with diabetes, today announced that the extended life Eversense® XL sensor that lasts up to 180 days has been implanted in the first U.S. study participant as part of the clinical trial for pre-market application submission to the Food and Drug Administration.

The PROMISE Clinical Study is intended to evaluate the safety and efficacy of the Eversense CGM system in people with diabetes over a 180-day period. Approximately 180 study participants at up to 15 locations across the United States are planned to enroll in the study. The Eversense XL sensor previously received the CE Mark and is currently marketed to patients across the European Union.

Senseonics also announced that the company has completed its submission of PMA supplements to the FDA to secure an insulin dosing claim and to remove the contraindication related to the Magnetic Resonance Imaging (MRI) exposure on the 90-day system which is currently available in the United States.

“I am thrilled to be able to offer a long term implantable sensor to my patients through the PROMISE 180-day Clinical Study,” said Dr. Mark Christiansen, Co-Medical Director of Diablo Clinical Research and the first physician to insert the extended life long-term sensor. “We are looking forward to providing patients six months of continuous sensing and the potential benefits of a long-term sensor.”

“We are pleased to have enrolled the first participant in this important study which demonstrates our continued progress in transforming CGM technology. This is the first

study in the US in which participants are implanted with a single sensor designed to produce accurate continuous glucose measurements for half of a year,” said Tim Goodnow, President and Chief Executive Officer. “Our submission of the Supplements to secure the dosing claim and to remove the MRI contraindication for the current 90-Day Eversense system are significant step forward in reducing the burden of diabetes management and providing patients peace of mind.”

About Senseonics

Senseonics Holdings, Inc. is a medical technology company focused on the design, development and commercialization of transformative glucose monitoring products designed to help people with diabetes confidently live their lives with ease. From its inception, Senseonics has been advancing the integration of novel, fluorescence sensor technology with smart wearable devices. The Eversense® CGM System received PMA approval from the FDA for up to 90 days of continuous use and is available in the United States. The Eversense® XL CGM System received CE mark for up to 180 days of continuous use and is available in Europe. For more information on Senseonics, please visit www.senseonics.com.

Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for Senseonics, including statements about clinical development of longer life sensors or system enhancements, label expansion and changes, additional regulatory approvals, and other statements containing the words “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 relating to study conduct and results, uncertainties in the clinical development and regulatory approval processes, uncertainties inherent in the commercial launch and commercial expansion of the product, 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, 2017, Senseonics’ Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, 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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