

# Senseonics Submits PMA Application for 180-Day Eversense System to the FDA



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## *PROMISE Study Demonstrated Strong Accuracy Performance, Consistent with Current Eversense CGM System*

GERMANTOWN, Md.--(BUSINESS WIRE)-- Senseonics Holdings, Inc. (NYSE American: SENS), a medical technology company focused on the development and commercialization of long-term, implantable continuous glucose monitoring (CGM) systems for people with diabetes, today announced the Premarket Approval (PMA) supplement application to extend the wearable life of the Eversense® CGM System to 180 days was submitted to the United States Food and Drug Administration (FDA) on September 30. Summary accuracy results from the PROMISE Clinical Study for the 180-day product were also announced.

The PMA application is supported by clinical data generated from the PROMISE Clinical Study. The 181 study participants had the Eversense sensor inserted subcutaneously at eight sites across the United States where the safety and efficacy of the system was evaluated over a 180-day period. Study results demonstrate performance matching that of the current Eversense 90-day product available in the United States, with a mean absolute relative difference (MARD) of 8.5%-9.6%. This result was achieved with reduced calibration, down to one per day, while also doubling the sensor life to 180 days. Research results from the PROMISE Clinical Study will be presented at future diabetes meetings, as well as through scientific publications.

“The Barbara Davis Research Center, a leading Type 1 Diabetes Clinic, was pleased to participate in this important clinical trial that was designed to evaluate the new 180-day long-term implanted Eversense CGM System. In my practice, CGM use has proven to be one of the most effective tools for diabetes management, but unless patients are consistently compliant with system usage, these benefits cannot be realized. The majority of our patients, greater than 70%, use one of the FDA approved CGM Systems for their day-to-day diabetes management. In the PROMISE Clinical Study, we observed that the implantable sensor provides ease of use and convenience to patients that helps maximize the benefits of CGM,” said Satish Garg, MD, National Principal Investigator of the PROMISE Clinical Study and Professor of Medicine and Pediatrics at the Barbara Davis Center, University of Colorado Health. “We seek to provide patients with cutting-edge, leading technology to help manage their diabetes and are

excited about the offering an implantable CGM that only has to be inserted twice per year to our patients once it is approved by the FDA.”

In addition to the extended life of the implantable sensor, the next generation Eversense System features an improved algorithm and a reduced calibration scheme, down to one calibration per day. If the 180-day Eversense product is approved by the FDA, Senseonics’ partner Ascensia Diabetes Care will initiate sales in the United States. The Eversense® XL 180-day CGM system without the reduced calibration scheme is currently available to patients in Europe.

“We would like to thank our team, the clinical investigators and the research participants for all their hard work completing the largest and longest CGM study. This submission to the FDA represents a milestone for Senseonics and diabetes patients. Senseonics is once again redefining the meaning of long-term for CGM sensors. In addition to enhanced convenience and improved patient experience, the PROMISE Clinical Study showed the 180-day Eversense CGM System continues to offer the strong accuracy performance that patients have come to expect from the Eversense brand,” said Tim Goodnow, PhD, President and CEO of Senseonics. “The next phase of growth for the company began this month with the initiation of our commercial efforts with Ascensia. We look forward to ramping up activities to deliver the life changing benefits of Eversense to more patients. A decision on approval of the 180-day Eversense System is anticipated during the first half of next year.”

## **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 Statements**

Any statements in this press release about future expectations, plans and prospects for Senseonics, including statements about the potential FDA approval for the 180-day Eversense product, the timing of future decisions by the FDA, the potential initiation of sales by Ascensia in the United States, 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 in the regulatory approval process, uncertainties inherent in the

commercial launch and commercial expansion of the product, uncertainties in insurer, regulatory and administrative processes and decisions, uncertainties in the duration and severity of the COVID-19 pandemic, 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, 2019, Senseonics' Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 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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