

Senseonics Announces FDA Approval of the Eversense® E3 Continuous Glucose Monitoring System for Use for Up to 6 months; Provides 2022 Business Outlook



February 11, 2022

The world's first and only long-term implantable CGM system now offers patients exceptional accuracy for 6 months

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 approval of the next-generation Eversense® E3 CGM System by the Food and Drug Administration (FDA). The Eversense E3, including proprietary sacrificial boronic acid (SBA) technology to extend longevity to 6 months, is planned to be available to patients in the U.S. through Ascensia Diabetes Care, Senseonics' global commercial partner, beginning in the second quarter of 2022.

"We repeatedly hear from our patients with diabetes that what they desire is a long-lasting sensor that is also highly accurate," said Satish Garg, M.D., Professor of Medicine and Director of the Adult Diabetes Program at the Barbara Davis Center of the University of Colorado, and the Principal Investigator of the PROMISE Study¹, which formed the basis for the FDA approval. "The next generation Eversense E3 System delivers on both. Patients will appreciate the excellent accuracy of the system and the ability of the sensor to last 6 months. This is another step forward for patients who desire to manage their diabetes with all the advantages of the Eversense CGM with the fully implantable sensor."

The Eversense E3 CGM System offers patients:

- Fully implantable third generation sensor, with proprietary SBA technology to enhance sensor longevity, demonstrating a mean absolute relative difference (MARD) of 8.5% in the PROMISE Study.
- Industry leading 6 month sensor wear duration, making Eversense the longest lasting CGM system available, with essentially two sensor insertion and removal

procedures per year.

- Removable smart transmitter, held in place with a mild silicone-based adhesive, providing discreet on-body vibratory alerts and data transmission to a mobile app where glucose values, trends, and alerts are displayed.

“Further extending the duration of the longest lasting CGM system to 6 months represents a massive leap forward for patients and towards our mission of transforming lives in the global diabetes community,” said Tim Goodnow, PhD, President and Chief Executive Officer of Senseonics. “The review was delayed by one year due to COVID-19 priorities and now together with our partner Ascensia, we can execute our launch plan to deliver the Eversense E3 CGM System to U.S. patients beginning in the second quarter. We look forward to initiating Eversense E3 sales and believe that, with Ascensia’s newly dedicated CGM commercial organization, the launch of the new 6-month product will establish the foundation for growth in our installed base later in 2022 and beyond.”

After the extended review during COVID-19, and with its next generation product now having been approved in the U.S., the Company concurrently is providing its 2022 financial outlook. The Company expects full year 2022 global net revenue to be in the range of \$14.0 million to \$18.0 million. The Company expects the majority of its expenses for 2022 to be for research and development for ongoing feasibility and pivotal clinical trials for additional products in its product pipeline, including the start of its 365-day pivotal trial, subject to IDE approval. Additionally, the Company currently expects to report unaudited revenues of approximately \$4.0 million for the fourth quarter of 2021 and approximately \$13.7 million for the full year ended December 31, 2021. The unaudited balance of cash, cash equivalents and marketable securities at December 31, 2021 was approximately \$182 million. The Company expects to report its full fourth quarter and fiscal year 2021 financial results after the market close on Tuesday, March 1, 2022. The preliminary financial results described herein have not been audited and are subject to adjustment based on the Company’s completion of year-end financial close processes.

“The Eversense E3 CGM System is an exciting advancement in diabetes management,” said Francine Kaufman, M.D., Chief Medical Officer of Senseonics. “We believe patients and providers are waiting for this step forward. I want to take this opportunity to thank the PROMISE Study investigators, study participants, and the Senseonics team for helping us reach this important milestone, and the diligence of the FDA reviewers in this difficult environment. We are excited to begin making this next generation product available in the U.S. to people with diabetes.”

Patients who are interested in getting started on Eversense today can sign up at www.eversensedidiabetes.com/get-started-today, and will be among the first to know when Eversense E3 is commercially available. Physicians, nurse practitioners and

physician assistants interested in offering the Eversense CGM System for their patients can sign up at <https://www.ascensiadiabetes.com/eversense/become-a-provider/register/>. Or contact 844-SENSE4U (844-736-7348) to learn more about the first and only long-term implantable CGM system.

About Eversense

The Eversense® E3 Continuous Glucose Monitoring (CGM) System is indicated for continually measuring glucose levels for up to 6 months in persons with diabetes age 18 and older. 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 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 trained and certified health care 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://www.ascensiadiabetes.com/eversense/safety-info/>.

About Senseonics

Senseonics Holdings, Inc. 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 2022 revenue projections, statements concerning the Company's unaudited preliminary financial information for the fourth quarter of 2021 and the full year ended December 31, 2021, statements regarding the timing of the commercial launch of the Eversense E3 product, statements regarding patient and provider acceptance of the Eversense product and its attributes, statements regarding future results for patients, statements regarding growth of the installed base of Eversense users, statements regarding future research and study plans, 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 commercial launch and commercial expansion of a new generation of the Eversense product, uncertainties

inherent in the transition of commercialization responsibilities to Ascensia and its commercial initiatives, uncertainties in the development and regulatory approval processes and timing for the E3 product in Europe, 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, 2020 and Senseonics' other filings with the SEC under the heading "Risk Factors," as well as those factors referenced in Senseonics' Current Report on Form 8-K filed with the SEC on February 11, 2022.

The preliminary financial information set forth in this press release is subject to the completion of the Company's audit process and is subject to change. The estimated preliminary results included in this press release should not be viewed as a substitute for the Company's annual financial statements prepared in accordance with U.S. generally accepted accounting principles. There can be no assurance that the estimated preliminary results will be realized, and you are cautioned not to place undue reliance on the preliminary financial information, which reflects management's current expectations and anticipated results of operations, which are subject to known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements, market trends, or industry results to differ materially from those expressed or implied by such forward-looking statements. 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.

¹ Garg SK, MD, Liljenquist D, Bode B, et al. Evaluation of Accuracy and Safety of the Next-Generation Up to 180-Day Long-Term Implantable Eversense Continuous Glucose Monitoring System: The PROMISE Study. DIABETES TECHNOLOGY & THERAPEUTICS 24;2: 2022 DOI: 10.1089/dia.2021.0182

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