Senseonics Announces CE Mark Approval of the Eversense E3 Continuous Glucose Monitoring System

June 16, 2022

The long-term implantable E3 CGM system now approved for commercialization in select European markets

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 that it has received CE Mark approval for the next-generation Eversense® E3 CGM System, the longest-lasting system available, with exceptional accuracy. The CE Mark approval confirms that the Eversense E3 meets the requirements of the European Medical Device Regulation (MDR), and enables the commercialization of Eversense E3 in European Union (EU) member countries. Senseonics' commercial partner, Ascensia Diabetes Care, will make the improved system, which can be used for up to 6 months, available from the third quarter of 2022.

"The CE Mark approval for E3 is another demonstration of our commitment to advancing implantable CGM to improve the lives of more diabetes patients worldwide. Not only does E3 strengthen our position in the market, but it enables increased operational efficiency as Senseonics will now commercialize the same product iteration globally for the first time," said Tim Goodnow, PhD, President and Chief Executive Officer of Senseonics. "We are excited for Ascensia to continue to build on the momentum of the E3 launch in the U.S. as they commercialize the improved system in European markets in the coming months."

The Eversense E3 CGM System has been designed to deliver key improvements from the currently available Eversense XL CGM System, which will be retired. The next-generation system offers exceptional accuracy with the longest lasting sensor available, alongside reduced frequency of calibration and enhanced sensor longevity. Unlike the XL System, the new E3 System has also been approved for non-adjunctive use, which provides for readings from the system to inform insulin treatment decisions without confirmation of glucose levels from fingerstick testing. Both Eversense XL and E3 are approved for use for up to 6 months, providing people with diabetes freedom

from the burdens associated with other available CGM systems, such as weekly or bi-weekly self-insertions. Eversense E3 is already available in the U.S. following FDA approval and launch earlier this year.

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[i].

- Industry leading 6-month sensor wear duration, making Eversense the longest lasting CGM sensor available, with essentially two sensor insertion and removal procedures per year.
- Removable smart transmitter [ii], held in place with a gentle, silicone-based adhesive, providing discreet on-body vibratory alerts and data transmission to a mobile app where glucose values, trends, and alerts are displayed.

Following the CE Mark approval in Europe, the E3 System will be distributed in Germany, Italy, Spain (including Andorra), the Netherlands, Poland, Switzerland, Norway and Sweden. People in these markets who are interested in getting started with Eversense XL now can visit www.ascensia.com/eversense for more information, and will be among the first to know when Eversense E3 is commercially available.

About Eversense

The Eversense® E3 Continuous Glucose Monitoring (CGM) System is indicated for continually measuring glucose levels in persons age 18 years and older with diabetes for up to 6 months. 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://global.eversensediabetes.com/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 statements on the timing and geographies of Ascensia making the product available, statements about patient benefits, perceptions, and uptake of the Eversense E3 product, statements regarding launch progress, statements regarding being able to increase operational efficiency, 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 development and regulatory approval processes and timing for the Eversense E3 product, uncertainties inherent in the commercial launch and commercial expansion of the Eversense product, uncertainties inherent in the transition of commercialization responsibilities to Ascensia, 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, 2022, Senseonics’ Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 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.

[i] Garg S. 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 2021; 24(2): 1-9.DOI: 10.1089/dia.2021.0182

[ii] There is no glucose data generated when the transmitter is removed.

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