Senseonics Announces FDA Approval for a Non-Adjunctive Indication (Dosing Claim) for the Eversense® 90-day CGM System

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With a non-adjunctive claim, Eversense users will soon be able to manage their diabetes dosing decisions without confirming with fingersticks

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, announced that they received FDA approval for the non-adjunctive indication (dosing claim) for the Eversense Continuous Glucose Monitoring System. Patients will soon be able to use Eversense as a replacement for fingersticks to make diabetes treatment decisions throughout the day. To use the non-adjunctive dosing indication, users will have to download a new app which will be available in coming months.

“Receiving the non-adjunctive indication from the FDA marks a major milestone for Senseonics. The Eversense CGM will soon be used as a replacement to fingersticks to make treatment decisions,” said Tim Goodnow, President and Chief Executive Officer at Senseonics. “We expect this will allow our users to more conveniently and confidently live their lives with fewer interruptions. This approval is also another step toward providing access to Eversense CGM for people 65 and older, as non-adjunctive labeling is the first requirement for Medicare coverage. We look forward to working with the Centers for Medicare & Medicaid Services leadership team to explore opportunities for Senseonics to provide Eversense and its benefits to the Medicare population.”

The Eversense CGM System consists of a fluorescence-based sensor, a smart transmitter worn over the sensor to facilitate data communication, and a mobile app for displaying glucose values, trends and alerts. In addition to featuring the first long-term and first implantable CGM sensor, the system is also first to feature a smart transmitter that provides wearers with discreet on-body vibratory alerts for high and low glucose and can be removed, recharged and re-attached to the skin without discarding the sensor. The sensor is inserted subcutaneously in the upper arm by a health care

provider via a brief in-office procedure. With the non-adjunctive claim, the Eversense CGM System will still require 2 fingersticks a day.

“This FDA dosing indication helps reduce the burden that patients face when managing their diabetes,” said Francine R. Kaufman, MD, Endocrinologist and Chief Medical Officer at Senseonics. “Patients have expressed that many of the unique features of Eversense - its long-term use, removeable transmitter and predictive, on-body vibe alerts - allow them to be more discreet as they manage their diabetes. In a recent analysis, we have seen that early Eversense users in the US have experienced 62% time in the target range for sensor glucose values of 70-180 mg/dL during their first sensor wear. This non-adjunctive dosing claim is yet another benefit for those patients who want to manage their diabetes with greater ease and freedom.”

Senseonics plans to launch this new, non-adjunctive product early in the fourth quarter of 2019. Patients who are interested in getting started on Eversense can sign up at www.eversensediabetes.com/get-started-today. Physicians, nurse practitioners or physician assistants interested in offering the Eversense CGM System for their patients can contact 844-SENSE4U (844-736-7348).

About Eversense

The Eversense® Continuous Glucose Monitoring (CGM) System is indicated for continually measuring glucose levels in persons age 18 and older with diabetes for up to 90 days. 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 twice per day, 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 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://eversensediabetes.com/safety-info/.

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 ongoing commercialization of Eversense in the U.S., the acceleration of the adoption of Eversense, growing patient and clinician demand for Eversense, and the potential life-enhancing benefits Eversense offers people with diabetes, and other statements containing the words “believe,” “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 in the 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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