

# Senseonics Announces the First Pediatric Study Participant Insertions in the ENHANCE Clinical Trial



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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 first pediatric study participant has been inserted with Eversense® 365-day system as part of the pivotal ENHANCE clinical trial at the AMCR Institute, a clinical research center focused on pre-diabetes, type 1, type 2 diabetes and obesity, under the direction of Dr. Timothy Bailey.

“It is a priority for Senseonics to extend the benefits of Eversense to the pediatric patient population. Positive results in the trial would support expanding our ability to transform lives in the global diabetes community,” said Francine Kaufman, M.D., Chief Medical Officer of Senseonics. “The differentiated features of our long-term implantable Eversense system are uniquely suited to benefit pediatrics and enable parents and their children to work together to manage diabetes. Young people would have the ability to remove their transmitters to participate in activities, without having to worry about wasting valuable sensors, and enjoy ring-free vibrating alarms to help manage their sugar levels without attracting unwanted attention to themselves.”

“I am excited to be one of the investigators in the ENHANCE Trial and thrilled to be the first to enroll subjects in the pediatric extension,” said Timothy Bailey, M.D., head of AMCR Institute in Escondido, California. “In our experience, CGM is an essential tool for all people with diabetes, especially for those who take insulin. We believe having additional accurate, and especially long-term wear, CGM options for our pediatric patients and their families will increase utilization of the technology and improve the quality of their lives.”

The ENHANCE Trial is designed to evaluate the accuracy and safety of the Eversense system for up to one year. Over 165 adult subjects were inserted with Eversense systems in four centers across the United States. Enrollment for the 365-day sensor configuration was completed in September 2022 and the last patient is expected to complete their 365-day visit during the third quarter of 2023. Data gathered in this trial is also planned to be used to submit for the integrated continuous glucose monitoring,

iCGM, designation in 2023. An investigational device exemption (“IDE”) supplement was submitted and approved for expansion of the trial to allow for pediatric patients 14 to 18 years of age and the first pediatric study participants were enrolled in Q2 2023.

## **About Senseonics**

Senseonics Holdings, Inc. (“Senseonics”) 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.

## **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://www.ascensiadiabetes.com/eversense/safety-info/>.

## **Forward Looking Statements**

Any statements in this press release about future expectations, plans and prospects for Senseonics, including statements about expanding the benefits of Eversense to additional populations, statements regarding patient perceptions of the benefits of Eversense, statements regarding user adoption of Eversense, statements regarding advancing development programs, statements regarding regulatory submissions, 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 of Eversense® E3 CGM system and commercial expansion of the Eversense product, uncertainties inherent in the transition of commercialization responsibilities to Ascensia Diabetes Care and its commercial initiatives, uncertainties inherent in collaborating with a new partner in the Nurse Practitioner Group and that partner’s assumption of certain

clinical and administrative activities, uncertainties in insurer, regulatory and administrative processes and decisions, uncertainties in the duration and severity of the COVID-19 pandemic, uncertainties inherent in the development and registration of new technology, uncertainties relating to the current economic environment, 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 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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