

# Senseonics Announces the Completion of US Patient Enrollment in the PROMISE 180-Day Sensor Clinical Study



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GERMANTOWN, Md.--(BUSINESS WIRE)-- Senseonics Holdings, Inc. (NYSE-American: SENS), a medical technology company focused on the development and commercialization of the first and only long-term, implantable continuous glucose monitoring (CGM) system for people with diabetes, today announced the completion of patient enrollment in the Eversense PROMISE 180-day sensor Clinical Study.

The PROMISE Clinical Study is intended to evaluate the safety and efficacy of the Eversense CGM System in people with diabetes over a 180-day period for the pre-market application submission to the U.S. Food and Drug Administration. This system has previously received its CE Mark and is currently commercially available across Europe. The 181 study participants at 8 sites across the United States had the Eversense CGM System inserted subcutaneously as part of the study.

“I am thrilled to be able to offer a long-term implantable sensor to my patients through the Eversense 180-day clinical study,” said Satish Garg, MD, Professor of Medicine and Pediatrics at the Barbara Davis Center, University of Colorado Health. “This long-term CGM could be a game changer for people with diabetes. At the Barbara Davis Center, we actively participate in clinical trials that bring the latest diabetes technology and treatments to patients which change the way they manage their diabetes – now and in the future. The PROMISE study promises to do so.”

“We are pleased to have completed enrollment in this important study which demonstrates our continued progress in transforming CGM technology,” said Katherine Tweden, PhD, Vice President, Clinical Sciences at Senseonics. “This is the first study in the US in which study participants are implanted with a single sensor which will produce accurate continuous glucose measurements for up to half of a year. We expect to have the full data for analysis at the end of the first quarter of 2020 for submission to the FDA later that year.”

## About Eversense

The Eversense<sup>®</sup> 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. Starting this fall, the system will be used to replace fingerstick blood glucose (BG) measurements for diabetes treatment decisions. Fingerstick BG measurements will still be 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://eversensediababetes.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<sup>®</sup> and Eversense<sup>®</sup> 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.

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