Senseonics Publishes Positive Longitudinal Performance Over Multiple Sensor Insertions and Removal Cycles of the Eversense® CGM System

November 21, 2019

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, announced the publication of an assessment of the performance of multiple sequential cycles of Eversense 90 and 180-day CGM System use in the peer reviewed scientific journal *Diabetes Technology and Therapeutics*. This real-world data of 945 adult users in the home-setting demonstrated that the performance of the sensor over four sensor cycles is stable and does not decrease over time. In addition, there was no degradation of patient glucose outcomes over the four sensor cycles.

“Our extensive real-world data shows that almost 1,000 Eversense users stayed in the target glucose range for 63-64%[1] of the time, while other recent clinical studies show that patients using a sensor and pump only stayed in the target glucose range for 59%[2] of the time. The Eversense real-world data demonstrates the difference an accurate, long-term CGM sensor can make when it is worn more than 80% of the time,” explained Francine R. Kaufman, MD, Endocrinologist, Chief Medical Officer and Board Member at Senseonics. “A significant proportion of Eversense users are also choosing to have a new sensor implanted at the end of each sensor cycle. This large real-world data set supports the clinical relevance and accuracy of the Eversense system to the healthcare provider and payer communities as we seek further expansion of coverage for Eversense as a clinically-proven choice for CGM therapy.”

For this study, the Eversense Data Management System (DMS) was evaluated for accuracy by comparing sensor glucose values (SG) with self-monitored blood glucose values (SMBG) during the time period from June 2016 through August 2019 in Eversense users in Europe and South Africa who had gone through at least four sensor cycles.

REAL-WORLD CLINICAL PERFORMANCE SUMMARY[1]

- **Time in Range** – 63-64% of time spent between 70-180 mg/dL demonstrating promising and durable time in range throughout multiple sensor wear cycles
- **Estimated A1c*** – 7.0-7.1 over 4 sensor cycles demonstrating sustained real-world glycemic control
- **Wear Time** – 83.2% to 85.8% median wear time across all 4 sensor cycles confirming patient adherence to the device over a multi-cycle wear periods including almost 1300 patient-years of real-world follow-up.
- **SustainedExcellent performance** – demonstrating sustained accuracy from sensor 1 through sensor 4 with no deterioration over time. These data show the ability of Eversense to consistently perform over multiple cycles of sensor wear for up to 2 years duration.

**Glucose Management Index (GMI) - mathematical estimate of HbA1c*

	Sensor 1	Sensor 2	Sensor 3	Sensor 4
MEAN CGM METRICS				
SG Mean, mg/dL	156.5	158.2	157.4	156.5
SG CV	0.35	0.35	0.35	0.36
GMI, %	7.04	7.08	7.06	7.04
MEAN % TIME IN RANGE (Minutes)				
<54 mg/dL	1.1 (16 min)	1.2 (17 min)	1.2 (17 min)	1.3 (19 min)
<70 mg/dL	4.6 (66 min)	4.7 (68 min)	4.8 (69 min)	5.0 (72 min)
70-180 mg/dL	64.5 (929 min)	63.2 (910 min)	63.7 (917 min)	64.0 (922 min)
>180 mg/dL	30.9 (445 min)	32.0 (461 min)	31.5 (455 min)	31.0 (446 min)

>250 mg/dL	8.1 (117 min)	8.8 (127 min)	8.6 (124 min)	8.6 (124 min)
SENSOR PERFORMANCE				
Matched Pairs vs. SMBG	152,206	174,645	206,024	172,587
MARD	11.9	11.5	11.8	11.5
20/20%	83.0	83.9	82.9	83.8
Median Wear Time (%)	83.2	83.6	84.8	85.8

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 when high or low glucose thresholds are crossed and can be removed, recharged and re-adhered without discarding the sensor. The sensor is inserted subcutaneously in the upper arm by a health care provider via a brief in-office procedure.

Reference

1 Dr. Katherine S Tweden, Dr. Dorothee Deiss, Dr. Ravi Rastogi, Mr. Suresh Addaguduru, and Dr. Francine Kaufman. Longitudinal Analysis of Real-World Performance of an Implantable Continuous Glucose Sensor Over Multiple Sensor Insertion and Removal Cycles. Diabetes Technology & Therapeutics. *http://doi.org/10.1089/dia.2019.0342*
2 Brown SA, Kovatchev D, Raghinaru JW, et al. Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes. N Engl J Med. 2019;381(18):1707-17. DOI: 10.1056/NEJMoa1907863

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 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://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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20191121006006/en/

Senseonics Investor Contact:

Lynn Lewis or Philip Taylor

Investor Relations

415-937-5406

investors@senseonics.com

Senseonics Media Contact:

Karen Hynes

Public Relations

619-206-9811

Karen.hynes@senseonics.com

Source: Senseonics Holdings, Inc.