Senseonics Company Backgrounder

Company Mission

Senseonics Holdings, Inc. (NYSE American: SENS) is a medical technology company focused on the design, development and commercialization of transformative glucose monitoring products designed to help people with diabetes confidently live their lives with ease.

From its inception in 1996, Senseonics has been advancing the integration of novel, fluorescence sensor technology with smart wearable devices. Senseonics' continuous glucose monitoring (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.

U.S. Product Overview

Senseonics' first generation CGM system, Eversense, which received its Premarket Approval (PMA) from the U.S. Food and Drug Administration (FDA) on June 21, 2018, is the first and only CGM system to feature an implantable glucose sensor and provide long-term continuous monitoring for up to three months.[i] The Eversense CGM system includes 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.

The sensor, which is inserted subcutaneously in the upper arm by a physician in a brief in-office procedure, lasts up to three months, thereby eliminating the need for patients to self-administer the weekly and biweekly sensor insertions required by traditional CGM systems. The system's smart transmitter is light, discreet, and comfortable to wear. Interpreting glucose data from the sensor and sending it to the system's mobile application via Bluetooth, the smart transmitter provides on-body vibratory alerts for discretion and added safety, and is the only CGM transmitter that can be removed and recharged without wasting a sensor.

Research & Development

The Eversense CGM System's PMA application was based on the previously-reported results of pivotal trials conducted in the U.S., which studied adults (18 years and older) with type 1 or type 2 diabetes at eight U.S. clinical centers. The studies clearly demonstrated the system's safety and effectiveness over 90 days of continuous glucose sensor wear. In March 2018, the FDA's Clinical Chemistry and Clinical Toxicology Devices panel of independent medical experts voted unanimously, 8 to 0, that the system not only was safe and effective but also that its benefits outweighed the risks.

Senseonics is currently working to innovate and introduce enhanced product offerings and pursue expanded indications to meet the needs of people with diabetes, with the goal of increasing the convenience and functionality of the Eversense system. Senseonics' R&D and clinical groups are seeing

promising results in the development of longer-life sensors, use in pediatric populations, and incorporation in automatic insulin delivery systems.

Global Development and Commercialization

The Eversense CGM System received its CE mark in 2016 and is currently available in 13 European countries plus South Africa. In September 2017, the Eversense XL CGM System, which includes a sensor with an extended life of up to 180 days, received its CE mark. Commercialization of Eversense XL in Europe is underway.

For more information, please visit: http://www.senseonics.com.

[i] 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. It is intended to complement, not replace, fingerstick blood glucose monitoring. The sensor insertion and removal is performed by a physician. The Eversense CGM System is a prescription device; patients should talk to their doctor to learn more. For important safety information, please visit https://eversensediabetes.com/safety-info/

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