Senseonics Eversense® Sensor Receives MRI Conditional Approval in Europe

April 28, 2020

- Eversense users who need to have an MRI do not need to remove the Eversense XL Sensor-

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 regulatory approval that the Eversense® XL Sensor is no longer contraindicated for MRI which means that the sensor does NOT need to be removed from under the skin during MRI scanning. During scanning the external Eversense Smart Transmitter must still be removed, and once scanning is completed, the transmitter is easily repositioned on the skin.

“Similar to our approved US indication, the European notified body has now approved that Eversense is safe for patients to leave the Eversense XL Sensor in place when they need to have an MRI*,” said Tim Goodnow, PhD, President and CEO of Senseonics. “Now people using Eversense CGM can be confident that they don’t need to worry about an emergency MRI or delay undergoing a scheduled MRI based on their choice of glucose sensors. This is a first for the CGM category as all other sensors are required to be removed during an MRI scan.”

A patient with this device can be safely scanned in an MRI system meeting the following conditions:

- Static magnetic field of 1.5T or 3.0T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode) for 15 minutes of continuous scanning, or SAR of 2 W/kg for 30 minutes of continuous scanning.
- The on-body Eversense Smart Transmitter, however, must be removed before undergoing an MRI procedure.

The Eversense XL 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 and lasts up to 180 days. Now patients can safely undergo an MRI while still wearing the Eversense XL Sensor – the only CGM sensor with a CE mark that is indicated for this use.

About Eversense XL

The Eversense® XL Continuous Glucose Monitoring (CGM) System is indicated for continually measuring glucose levels in persons age 18 and older with diabetes for up to 180 days. It is intended to complement, not replace, fingerstick blood glucose monitoring. The sensor insertion and removal is performed by a health care provider. The Eversense XL CGM System is a prescription device; patients should talk to their health care provider to learn more. For important safety information, see global.eversensediabetes.com/safety-info.

***MRI Safety Information**

Non-clinical testing has demonstrated the Eversense Sensor is MR Conditional. A patient with this device can be safely scanned in a horizontal, closed bore MR scanner meeting the following conditions:

- Static magnetic field of 1.5T or 3.0T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode) for 15 minutes of continuous scanning, or SAR of 2 W/kg for 30 minutes of continuous scanning.
- The Eversense Smart Transmitter is MR Unsafe and MUST BE REMOVED before undergoing an MRI procedure. Before you undergo an MRI procedure, tell the MRI staff that you have an Eversense Sensor and Smart Transmitter.

Under the scan conditions defined above, non-clinical testing results indicate the Eversense Sensor is expected to produce a maximum temperature rise of less than 5.4 °C. In non-clinical testing, the image artifact caused by the device extends approximately 2.83 inches (72 mm) from the Eversense Sensor when imaged with a gradient echo pulse sequence and a 3T MR system. The Eversense Sensor has not been tested in MR systems that do not meet the conditions above. Exposing the Eversense Sensor to MRI conditions which are outside of the conditions outlined above can cause potential complications such as device migration, heating and tissue damage or erosion through the skin.

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.

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Source: Senseonics Holdings, Inc.