

24 Hour Summary

Clinical Chemistry and Clinical Toxicology

Devices Panel Meeting

Senseonics Eversense Continuous Glucose Monitoring System

March 29, 2018

Introduction:

The Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee to the Food and Drug Administration met on March 29, 2018 to discuss and make recommendations on the sponsor's proposal to market a CGM device which requires minor surgery to implant and remove, and which would, if approved, would be the first fully implanted CGM sensor, the first CGM sensor to last for up to 90 days, and the first to use fluorescence to detect glucose.

Device Description:

The Eversense Continuous Glucose Monitoring System consists of a subcutaneously implanted glucose sensor, an externally worn transmitter (Eversense Smart Transmitter), Sensor Insertion Tools, and the Eversense Mobile Medical Application (MMA). The sensor is a radiofrequency (RF)-powered device that collects readings and sends them to the transmitter. The transmitter calculates, stores, and transmits the glucose data via Bluetooth Low Energy (BLE) to the MMA.

The sponsor has proposed the following Indications for Use:

The Eversense Continuous Glucose Monitoring System is indicated for continually measuring glucose levels in adults (age 18 and older) with diabetes for the operating life of the sensor.

The system is intended to:

- Provide real-time glucose readings.
- Provide glucose trend information.
- Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns seen over time. The system is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices.

Panel Deliberations/FDA Questions:

Question 1: Clinical Study Design

The consensus of the panel was that the studies and data presented were sufficient regarding the short- and long-term performance of the sensor. However, they encouraged the Sponsor to provide clinical guidance for how the system should be used during the first seven days of sensor wear, when system performance is lower.

The consensus of the panel was that the current data have not identified unreasonable risks of recurrent sensor insertions. However, they encouraged the Sponsor to assess potential

issues with subcutaneous insulin administration pharmacokinetics at the site(s) of previous sensor insertions moving forward.

Question 2: Safety and Effectiveness Regarding Modifications

The consensus of the panel was that the validation conducted for the four system design modifications from the Sponsor were sufficient and driven largely by participant safety concerns.

The consensus of the panel was for the Sponsor to collect adverse events moving forward given that the current modifications have yet to be rigorously tested in real life patients.

Question 3: Drug Interference

The consensus of the panel was to include the tetracycline drug class (rather than just tetracycline specifically) as potential interferent agents.

The consensus of the panel was that the Sponsor consider evaluating the latency effect of an interfering agent and provide additional recommendations to patients for the time interval between the discontinuation of the interfering agent and the reliability of the sensor readings.

Question 4: Safety and Effectiveness

The consensus of the panel was that a post-approval study should be conducted that included collection of adverse events, safety, short- and long-term complications related to insertion and removal, a clinician satisfaction assessment, and patient reported outcomes (PROs).

The consensus of the panel was that the proposed size of the post-approval study may be adequate to address questions about the physical use the device. However, the panel suggested that the post-approval study potentially be increased in size and duration to more rigorously study various sub-populations of participants (e.g., pregnancy, hemodialysis, peritoneal dialysis, those with microvascular complications, etc.). The panel also recommended that the proposed study size may be inadequate to assess more rarely occurring adverse events.

Panel Voting Results:

- Question 1, the panel voted unanimously that the data shows reasonable assurance that the Senseonics Eversense Continuous Glucose Monitoring System device is safe for determining Insulin dose use in patients who meet the criteria specified in the proposed indications.
- Question 2, the panel voted unanimously that there is reasonable assurance that the Senseonics Eversense Continuous Glucose Monitoring System is effective for determining insulin dose in patients who meet the criteria specified in the proposed indications.
- Question 3, the panel voted unanimously that the benefits of the Senseonics Eversense Continuous Glucose Monitoring System device to determine insulin dose outweigh the risks for use in patients who meet the criteria specified in the proposed indications.

Note: There were eight voting members on the panel and all three voting questions received the following votes:

- Eight, yes-votes
- Zero, Abstain-votes
- Zero, No-votes

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