Senseonics Receives ISO13485 Certification

The Associated Press

Senseonics, a privately held medical device company focused on the development and commercialization of the first fully implantable, long-term continuous glucose monitoring system, today announced that it has been granted ISO 13485:2003 certification of its quality management system. The scope of certification includes the design, development, manufacturing, servicing and distribution of active implantable glucose sensors and accessories for continuous glucose monitoring.

ISO 13485 represents the requirements for comprehensive quality management system for design and manufacture of medical devices. European Union, Canada and Australia recognize ISO 13485 certification as a means of meeting regulatory requirements for conformity assessment, and U.S. FDA's Quality System Regulations (21CFR820) is harmonized with ISO 13485.

"The successful completion of the ISO registration process is a significant achievement for Senseonics and an important milestone towards achieving our goal of providing an accurate, long life continuous glucose sensor for people with diabetes," said Tim Goodnow, PhD., Senseonics President and Chief Executive Officer. "The ISO registration reflects our commitment to the highest standards of manufacturing, quality assurance, and safety, and comes at a crucial time as we approach the European pivotal clinical trial of our first generation continuous glucose monitoring system."

About Senseonics
Senseonics, Incorporated (formerly Sensors for Medicine and Science, Inc.) is developing the first fully implantable continuous glucose sensor designed for highly accurate, long-term wear. The Senseonics Continuous Glucose Monitoring System includes a miniaturized sensor, transmitter and mobile medical application. Based on proprietary breakthrough fluorescence sensing technology, the sensor is designed to be inserted into the subcutaneous space of the upper arm and communicate with the transmitter to wirelessly transmit glucose levels to a smartphone. After insertion, the sensor functions noninvasively, automatically, and continuously. The system is intended to enable people with diabetes to confidently live their lives with ease. For more information on Senseonics, please visit us on the web at http://www.senseonics.com [1].

About Diabetes
Diabetes affects an estimated 371 million worldwide. Monitoring of glucose levels is essential to managing the disease and avoiding its debilitating complications. Continuous glucose monitoring has the potential to further help diabetes patients examine how their glucose level reacts to insulin, exercise, food, and other factors. Studies have shown that CGM is effective at improving glucose control while minimizing severe hypoglycemia. Accurate continuous glucose monitors are also a key component of the promising artificial pancreas ongoing studies that could

potentially offer additional freedom in the management of diabetes.

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