

# Sensors for Medicine and Science Changes Company Name to Senseonics



October 16, 2012

## PIVOTAL STUDY PROTOCOL SUBMITTED TO EUROPEAN REGULATORY BODIES FOR APPROVAL

GERMANTOWN, MD. – October 16, 2012 – Sensors for Medicine and Science, Inc., a privately held medical device company focused on the development and commercialization of the first fully implantable, long-term [continuous glucose monitoring \(CGM\)](#) system, today announced its new company name, Senseonics.

“The new Senseonics name really captures the essence of what we’re about and what makes us unique,” said Tim Goodnow, PhD., President and Chief Executive Officer.

“The name combines **sense** (to detect), **eon** (long time) and **-ics** (suffix to denote body of knowledge) to signal our unequivocal focus on continuous glucose sensors designed for accurate, long-term wear by people with diabetes. Our first generation sensor, currently in clinical studies, is targeted to last for up to six months of continuous wear.”

Along with its new name, the company also announced it has submitted its pivotal clinical study protocol to the Medicines and Healthcare products Regulatory Agency (MHRA) of the U.K. and the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, *BfArM*) in Germany.

The pivotal study is titled PRECISE (Prospective, Multi-Center Evaluation of the Accuracy of a Novel Continuous Implanted Glucose Sensor), and its objective is to evaluate the accuracy of the Senseonics Continuous Glucose Monitoring system over 180 days.

The PRECISE study requires clinical participants with diabetes to use the glucose sensor in the arm and to wear the external receiver to obtain continuous glucose readings during the 180-day study duration. The study will also evaluate safety of the Senseonics CGM system usage during in-clinic and home wear.

“All the study investigators are very much looking forward to proceeding with this first large study of a long-term implantable glucose sensor,” said primary investigator Dr.

Roman Hovorka, University of Cambridge, UK. “This has the potential to be an important technology to help our patients better manage their diabetes.”

The PRECISE study will be conducted in three clinical sites in Germany and two in the U.K. Enrollment in the trial will include up to 50 subjects with diabetes. The trial builds upon previous clinical experience which [demonstrated high accuracy performance](#) for the first time for an implanted biosensor.

“The filing of the PRECISE pivotal study application represents an important milestone in the development of our glucose sensing system, and the study will allow us to gather clinical data for European regulatory approval,” said Goodnow. A successful execution of the PRECISE study is expected to support an application for a CE mark in Europe.

## 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 sensor wear. The Senseonics Continuous Glucose Monitoring System includes a miniaturized sensor and receiver. Based on proprietary breakthrough fluorescence sensing technology, the sensor is inserted into the subcutaneous space under the skin and wirelessly transmits glucose levels to an external receiver. 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 <http://www.senseonics.com>.

## About Diabetes

Diabetes affects nearly 26 million people in the U.S. and an estimated 350 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.