

First implantable continuous glucose sensor to achieve high accuracy performance in people with diabetes



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SMSI STUDY RESULTS SHOW 96.8% ACCURACY

Germantown, Maryland, USA – September 12, 2011 - Sensors for Medicine and Science, Inc. (SMSI) announced today that data from a human pilot study of its fully-implantable continuous glucose sensor demonstrated high accuracy performance for the first time for an implanted biosensor. The data showed high level of glucose accuracy, with 77.6% and 19.2% of the data in the A and B zones of the Clark Error Grid, respectively. The mean absolute relative difference was 12.2%. The results also support the sensor goal of achieving implant time greater than six months.

“We are pleased to report these findings as a first step to realizing a viable long-life implanted sensor to help millions of people with diabetes manage their glucose better,” said Tim Goodnow, Ph.D., CEO and President. “While still early, the pilot study showed comparable performance as current continuous glucose devices.”

The SMSI system includes a miniaturized sensor and reader. The sensor is implanted into the subcutaneous space in the wrist and is inductively powered and remotely interrogated, requiring no battery and no wires connecting the sensor to an external wristwatch-based reader. After implantation, the sensor functions noninvasively, automatically, and continuously.

In the study, 9 subjects with Type 1 diabetes were implanted with a sensor in each wrist for approximately 29 days. Performance was evaluated by comparing 3,000 sensor values with paired YSI blood glucose values. In a Clarke Error Grid (CEG) analysis, 96.8% of the values fell in zones A or B. The CEG compares readings between a lab reference and a glucose monitoring device and assigned into one 5 clinical zones: A, B, C, D, or E. Zone A values are clinically accurate and most consistent with the lab reference value. B values are clinically acceptable. C, D, and E values are progressively less accurate.

“Based on the promising results obtained, we plan to initiate more clinical trials in the very near future, including pursuing collaboration on artificial pancreas research,” said

Dr. Goodnow.

The result of the study will be presented at the European Association for the Study of Diabetes meeting in Lisbon, Portugal on September 16, 2011.

About Sensors for Medicine and Science, Inc.

SMSI is pioneering breakthrough technology that could dramatically improve glucose monitoring for people with diabetes. SMSI has also developed oxygen sensor technology, with potential applications in areas such as metabolic monitoring respiratory and cardiac disease.