JDRF Funded Research

PI Name: Anthony W. Czarnik
Institution Name: Senseonics
Project Duration: 01-July-2000 to 20-June-2003
Mechanism: Priority Research Grant
Project Grant Award: $879,575.00
Grant Key: 1-2000-625
Grant Status: Complete Grant

Project Title: Minimally Invasive Long-Term Implantable Flourescence Based Sensor for Continuous Monitoring of Glucose

Objective: To develop an implantable sensor for the continuous and real-time monitoring of glucose in the interstitial fluid of subcutaneous tissue. The sensor would be used for the monitoring of glucose levels with a frequency of 2 min and without requiring action from the patient. The miniature (size of a grain of rice) implantable sensor contains an inductively powered (i.e. wireless) optical and electronic platform integrated with a glucose sensing fluorescent indicator immobilized into a glucose permeable polymer. The fluorescence based non-consumptive glucose indicator and the inductive powering of the implanted sensor may allow long-term (12 months after implantation) function of the sensor. The information on glucose levels would be communicated to a small wearable external unit. The external unit would display current and historical glucose values, would have hyper- and hypo-glycemic alarm settings and lifestyle event markers.

Sensors for Medicine and Science, Inc. (SMSI) focuses on the development of integrated technologies to commercialize a long-term implantable glucose sensor. The company is conducting research and development in the following areas:

- Design and synthesis of glucose-sensitive fluorophores
- Development and miniaturization of an optoelectronic sensor
- Selection and testing of biomaterials for an implantable sensor
- Approaches for achieving a stable long-term tissue interface
- Testing of sensor prototypes in vitro and in vivo

The company intends to initiate studies of an implantable glucose sensor in animals during the year 2000 and commercialize its first glucose sensor product before end of year 2003.

Background/Rationale: The continuous and real-time monitoring of glucose levels would greatly facilitate the understanding and therapeutic management of diabetes. Current glucose detection methodologies (based on glucose oxidase detection system) consume glucose during measurement and require a certain sample volume for a reasonably accurate measurement. The clinical consensus in the field is that these methodologies are not sufficiently accurate. To achieve long-term, continuous and real-time monitoring, the glucose sensor should be non-consumptive and sensitive enough to measure glucose in a very small volume. Such a sensor can be developed using a glucose sensitive fluorescent indicator coupled with an optoelectronic microfluorometer. Scientists at Sensors for Medicine and Science, Inc. have synthesized and selected several glucose sensitive fluorophores. The achievements in electronic microfabrication make development and commercialization of such sensors feasible.

Description of the Project: During initial one year JDF grant (4/1/99-3/31/00) scientists at Sensors for Medicine and Science, Inc. (SMSI) conducted research and the development of glucose sensitive fluorescent indicators. Several glucose-sensitive indicators were synthesized and tested in physiological medium. Initial

studies show suitability of these indicators for further product development. During the first year of this proposal (4/1/00-3/31/01) scientists and engineers at SMSI will be working on the integration and optimization of the integrated sensor. The integrated sensors will be evaluated for analytical performance (precision, sensitivity, specificity, stability) in vitro in physiological buffer. The effects of the matrix components of interstitial fluid will be studied using serum samples. Pending acceptable performance of sensors in vitro initial animal studies will be performed on animals. During the second and third years of funding we expect to miniaturize the sensor platform and design and assemble commercial product sensors. After functional testing and validation of the product in vitro we will conduct formal preclinical studies and start clinical studies.

Anticipated Outcome: We plan to generate sufficient data in the in vitro and in vivo studies to show the practical feasibility of fluorescence based implantable sensors for continuous glucose monitoring and commercialize this product in the year 2003.

Relevance to Type I Diabetes: The need to frequently and (preferably) continuously monitor glucose is particularly great in juvenile diabetes. A sensor that reports and records glucose levels every few minutes would help in preventing and managing hypo- and hyperglycemic events and would help avoid both the long-term and short-term complications of diabetes.