World First: Sernova's Cell Pouch Shown to Provide a Safe Environment for Therapeutic Insulin Producing Islets in Humans with Type 1 Diabetes

The Associated Press

Sernova Corp today announced that Dr. James Shapiro, principal investigator of the clinical study, presented encouraging safety and biocompatibility results for the Cell Pouch and following islet transplant, proof of islet cell survival and the presence of insulin in the first two patients of an up to 20 patient study. The explanted Cell Pouch also showed no evidence of immune system attack of the islet cells. The results were presented in a podium session at the XIV World Congress of the International Pancreas and Islet Transplantation Association in Monterey, California.

"We are really encouraged by the initial results of this ground-breaking study. The preliminary findings that human islets survive under the skin within the Cell Pouch pave the way for our ongoing studies in patients that will now test how effective this new approach will be," said Dr. James Shapiro. "Importantly, the islets were shown to be residing within a natural tissue matrix in the device, and were nicely integrated with microvessels, and stained for insulin, glucagon, somatostatin and polypeptide at the 30 day time point." Dr. Shapiro further stated, "We will now begin to assess both the longer-term safety and efficacy of islets placed in the Cell Pouch in patients with diabetes, and will follow them for up to three years. We look forward to presentation of additional results as the study progresses."

In this study, patient volunteers with insulin-dependent diabetes and hypoglycemia unawareness who are receiving an islet transplant following informed consent are being implanted with the Cell Pouch which is subsequently transplanted with human donor islets. To protect the islets from immune cell attack, the patients are given an antibody and immunosuppressive medications.

In an initial assessment, the Cell Pouches in these first two patients were shown to meet the primary endpoint of being safe after implantation and prior to transplantation. The Cell Pouches were then transplanted with human donor islets followed by removal up to 30 days post-transplantation and islet survival assessed. The Cell Pouches were prepared for comprehensive histological analysis and assessed by experts in an independent blinded analysis for key features including device biocompatibility, tissue and microvessel development into the device, islet survival and the presence of insulin, glucagon, somatostatin, and polypeptide as well as protection of islets from immune system attack.

"The findings in these initial patients parallel the results in Sernova's multiple small and large animal safety and efficacy studies of the Cell Pouch. These showed an exemplary safety profile, and that islets were well-vascularised with microvessels

and produced insulin. In addition, the islet-rich Cell Pouches then went on to show long-term glucose control in the diabetic animals," said Dr. David White, Professor Emeritus and Chair of Sernova's Scientific Advisory Board.

"We see these initial findings, in humans as an important next step in confirming the utility of the Cell Pouch in the clinical setting as providing a safe environment for therapeutic cells. We look forward to further results in this study and are excited to continue working in clinical indications where therapeutic cells can improve the quality of life for patients not only with diabetes but for those with other chronic debilitating diseases," said Philip Toleikis, President and CEO, Sernova Corp.

Sernova is developing the Cell Pouch as an enabling platform to treat a variety of chronic debilitating diseases including diabetes and hemophilia (in collaboration with Medicyte GmbH) with immune-protected therapeutic cells and is currently evaluating the safety and efficacy of the Cell Pouch in human clinical trials for diabetes.

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