

Sernova Corp.

DEVELOPING A TIERED APPROACH TO THE TREATMENT OF DIABETES

by ROCHELLE EMNACE

By the year 2020, Canadians living with diabetes will cost the healthcare system \$16.9 billion annually. According to the Canadian Diabetes Association, there are more than nine million Canadians living with diabetes or prediabetes, and 10% of these cases are diagnosed with Type-1 diabetes. The unpreventable form of Type-1 diabetes is due to the body's inability to produce insulin, which is caused by the autoimmune destruction of the beta cells in the pancreas. The quality of life for people living with diabetes is grossly reduced and they are more likely to suffer from diabetic

independent for an average of 11.9 months post procedure but there are challenges to islet cell transplantation. According to Dr. James Shapiro, the Director of the Clinical Islet Transplant Program at the University of Alberta, "Most islets don't engraft. Approximately 60% do not survive. There are a limited number of donors available, but millions of patients. Thus, it is important to ensure patients are receiving successful transplants."

Sernova Corp. [SVA-TSXV] has a powerhouse team of directors and scientists, all of whom are primed to conquer diabetes.

forming natural tissue and micro vessel rich chambers for transplanting therapeutic cells. Starting approximately two weeks after implantation, the patient can receive the islet transplant directly into the device. Because of the micro vessel blood supply which naturally surrounds the islets, there is minimal loss of cells and an enhanced opportunity for the cells to engraft and control the diabetes.

On May 2, 2012, Sernova received approval from Health Canada to proceed with human clinical trials for the use of Cell Pouch System™ for therapeutic islet

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complications including heart disease, stroke, blindness, amputation, and kidney disease. Patients with diabetes are twice as likely to die a premature death; 80% of people living with diabetes will die as a result of heart disease or stroke.

The standard treatment for Type-1 diabetes is to take daily regimented doses of insulin. The most recent advances toward a long-term treatment include Islet Cell Transplantation, a procedure whereby qualifying patients are infused with donated islets into a blood vessel of the liver followed by the use of an anti-rejection regimen to protect the islets from destruction by the immune system. This method, also known as the Edmonton Protocol, has shown that islets can take residence and produce insulin. The patients who participated in the original study were able to remain insulin

In their quest to eliminate Type-1 diabetes, Sernova aims to apply a "tiered approach to their product development strategy," whereby their triple platform product will someday provide solutions for treating the unmet needs of Type-1 diabetic patients and potentially the 27% of Type-2 patients who are taking insulin. At present, Sernova is the only company with a viable solution to this problem. Their main product, the Cell Pouch System™, is devised to generate an "organ-like environment" that will deliver cellular-type therapy. Patients who currently require cell therapy are faced with high costs and limited success, attributed to the reduced cell survival. Sernova has developed a medical device that overcomes these limitations. This unique device is implanted under the skin, which allows for blood vessels and tissue to grow into the device

transplantation. According to President and CEO, Dr. Philip Toleikis, "The trial will assess the safety of the Cell Pouch™ and how well the islets will function in the Cell Pouch™ placed under the skin to control blood sugar levels. This has the potential to be a major advance in islet transplantation and for patients with diabetes." While donor islets are a first step in proving the functionality of the Cell Pouch™, the company eventually plans to test insulin producing stem cells. These controversial cells would be ideal for the Cell Pouch™ as the current transplant methods are unable to control the delivery and/or retrieval. An advantage of the Cell Pouch System™ is the accessibility of the device, wherein the Cell Pouch™ can be removed and potentially replaced if required. Toleikis adds that the clinical trial will "provide interim as well as

long-term data regarding safety and efficacy” of the device, but it will also “open whole new set of doors.” According to Dr. Shapiro, “The trial will study up to 20 people with insulin-dependent diabetes undergoing allograft pancreatic islet transplantation. We hope to expand to international sites in the US and across Europe.”

The second product platform is Sertolin™, a cell-based technology that aims to provide local immune protection. Sertolin™ is based on Sertoli cells, which have the capability to modulate the host immune system, and ultimately prevent transplanted cells from becoming rejected. For patients who receive cellular therapy, the standard of care is expensive and toxic while anti-rejection drugs can run a bill ranging from \$10,000-15,000 per year. Any person who receives any form of transplant is required to take

anti-rejection drugs for the rest of their life, so as to prevent the immune system from rejecting the transplanted cells. Toleikis predicts Sertolin™ will be a product that will “significantly improve the quality of life for islet transplantation patients.” Sertolin™ is used in conjunction with therapeutic cell therapy, providing a natural protection against the host immune response. Combined with the Cell Pouch System™, Sertolin™ can be used to reduce or eliminate the need for anti-rejection drug protocols reducing the long-term cost and improving the safety of islet transplantation compared to today’s procedure.

The third platform of the tiered approach is the use of therapeutic cells. Patients who suffer from lack of critical hormones and/or proteins often require daily monitoring and injecting of the necessary proteins. The

alternative to the daily regimented injections is to provide therapeutic cells, used together with the Cell Pouch System™ to establish appropriate delivery and cell survival. As mentioned above, the use of stem cells which produce insulin in the Cell Pouch™ could enable the treatment of millions of patients due to the virtually unlimited source of cells.

Sernova is the only company that has capitalized on producing a product such as the Cell Pouch™. With a natural environment for therapeutic cells and the potential for local immune protection they hope to meet the unmet needs of people with diabetes. It is anticipated that over time, the tiered product approach taken by Sernova will result in safe and long-term treatment of people who suffer from diabetes, haemophilia, liver failure, and hopefully, Parkinson’s disease. ■