

Sernova Receives US FDA IND Allowance to Initiate a US Clinical Trial of its Cell Pouch for the Treatment of Type 1 Diabetes

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LONDON, ONTARIO – (Globe Newswire – Monday December 11, 2017) – Sernova Corp. (TSX-V: SVA) (OTCQB: SEOVF) (FSE: PSH), a clinical stage company developing regenerative medicine technologies for the long-term treatment of diseases including diabetes and hemophilia, is pleased to announce it has received US Food and Drug Administration (FDA) notice of allowance for its IND for a new human clinical trial with the Cell Pouch System (TM) (CPS) in the United States. The Company will host a conference call for shareholders with Dr. Philip Toleikis, President and CEO on Monday, December 11th at 10:00am Eastern Standard Time to discuss the trial.

Sernova plans to initiate the new clinical trial under this US IND to investigate the Cell Pouch for treatment of type 1 diabetes (T1D) in individuals with hypoglycemia unawareness. The trial is a Phase I/II prospective single arm study of islets transplanted into the subcutaneously implanted Cell Pouch. The primary objective of the study is to demonstrate safety and tolerability of islet transplantation into the Cell Pouch and the secondary objective is to assess efficacy through a series of defined measures.

JDRF has previously committed to provide Sernova up to \$2.45 million USD to support the clinical trial.

“Hypoglycemia unawareness is a serious consequence of type 1 diabetes,” said Derek Rapp, President & CEO, JDRF International. “We are excited to see progress in this and other potentially life-saving JDRF-funded research, which could help prevent people with hypoglycemia unawareness from experiencing dangerous lows, as we strive to achieve our vision of a world without T1D.”

“We are extremely enthusiastic about the promise of Sernova’s regenerative medicine platform to provide a new therapeutic option for diabetes patients with hypoglycemia unawareness. We believe Sernova’s multiple advancing cell based therapies have the potential to deliver significant improvement in the quality of life of patients suffering from diabetes and other debilitating diseases,” said Dr. Philip Toleikis, Sernova’s president & CEO.

About the Trial

The study is a Phase I/II single site, single arm, Company sponsored trial. Following approval by the Institutional Review Board, patients with hypoglycemia unawareness will be enrolled into the study under informed consent. Patients will then be implanted with the Cell Pouch including sentinel devices. Following vascularized tissue development, a dose of purified islets under strict release criteria will be transplanted into the Cell Pouch and patients followed for safety and efficacy measures for approximately six months. At this point a decision will be made whether to transplant a second islet dose with subsequent safety and efficacy follow up. Patients will then be further followed for one year.

“Sernova’s FDA clearance to commence human clinical trials in the United States is an exciting step forward in diabetes research, initially focused to reduce the risk of hypoglycemia unawareness, a complication in which a patient is unaware of a deep drop in blood sugar that can have life threatening

consequences,” said Dave Prowten, President and CEO of JDRF Canada. “This is also an example of the international collaboration fostered by JDRF-funded projects to accelerate transformative research to benefit the T1D community,” added Mr. Prowten.

About Sernova’s Cell Pouch

The Cell Pouch is a novel, proprietary, scalable, implantable macroencapsulation device for the long-term survival and function of therapeutic cells (donor, stem cell derived cells and xenogeneic cells) which then release proteins and/or hormones as required to treat disease. The device is designed upon implantation to incorporate with tissue, forming highly vascularized tissue chambers for the transplantation and function of therapeutic cells. The device with therapeutic cells has been shown to provide long term safety and efficacy in small and large animal models of diabetes and has been proven to provide a biologically compatible environment for insulin producing cells in humans.

About Diabetes

T1D is a life-threatening disease in which the body's immune system mistakenly attacks and kills the pancreatic cells that produce insulin—a hormone that is essential for life because of its role to help the body use glucose. The existing standard of care for patients with T1D is suboptimal. To date, there is no cure for T1D, and people living with the disease are dependent on exogenous insulin therapy to help keep their blood-sugar levels from spiking too high, which can lead to long-term complications such as kidney and heart diseases or an acute, potentially deadly health crisis. Present-day insulin therapy is, however, an imperfect treatment method that requires people with T1D to carefully monitor their blood sugar throughout the day and take multiple, calculated doses of insulin based on food intake, exercise, stress, illness and other factors. A miscalculation or unexpected variable leading to high or low blood sugar episodes are daily threats, and only a third of people with T1D achieve their long-term blood glucose targets, placing them at risk for T1D-related health complications.

Conference Call Details

To participate in this live conference call, please dial + [1-877-858-5743](tel:1-877-858-5743) prior to the scheduled conference call time. International callers should dial +[1-858-609-8959](tel:1-858-609-8959). The conference participant pass code is [355-040](tel:355-040). Following the conference call a recording will be available at www.sernova.com

About Sernova Corp

Sernova Corp is developing disruptive regenerative medical technologies using a medical device and immune protected therapeutic cells to improve the treatment and quality of life of people with chronic metabolic diseases such as insulin-dependent diabetes, blood disorders including hemophilia, and other diseases treated through replacement of proteins or hormones missing or in short supply within the body. For more information, please visit www.sernova.com

About JDRF

JDRF is the leading global organization funding type 1 diabetes (T1D) research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications. To accomplish this, JDRF has invested nearly \$2 billion in research funding since our inception. We are an organization built on a grassroots model of people connecting in their local communities, collaborating regionally for efficiency and broader fundraising impact, and uniting on a national stage to pool

resources, passion, and energy. We collaborate with academic institutions, policymakers, and corporate and industry partners to develop and deliver a pipeline of innovative therapies to people living with T1D. Our staff and volunteers throughout the United States and our six international affiliates are dedicated to advocacy, community engagement and our vision of a world without T1D. For more information, please visit jdrf.org or follow us on Twitter: @JDRF

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