*DRIFCan funded research:*

# VIACYTE, INC. - VIACYTE ANNOUNCES SECOND CLINICAL TRIAL SITE AT UNIVERSITY OF ALBERTA

## DR. JAMES SHAPIRO, WHO LED THE TEAM THAT DEVELOPED THE "EDMONTON PROTOCOL," WILL BE LEAD INVESTIGATOR AT THE CANADIAN SITE

SAN DIEGO, July 29, 2015 – ViaCyte, Inc., a privately-held regenerative medicine company with the first stem cell-derived islet replacement therapy for the treatment of diabetes in clinical trials, today announced the opening of a second site in its Phase 1/2 trial called STEP ONE, or Safety, Tolerability, and Efficacy of VC-01™ Combination Product in Type One Diabetes. The new site, which is the first in Canada, will be at the University of Alberta Hospitals in Edmonton, Alberta.

The lead Edmonton investigator is Dr. James Shapiro, who holds a Canada Research Chair in Transplant Surgery and Regenerative Medicine at the University of Alberta's Faculty of Medicine & Dentistry and whose laboratory developed a procedure for the transplant of pancreatic islets as a treatment for type 1 diabetes. The procedure, known as the Edmonton Protocol, has been used to successfully treat patients around the globe. Dr. Shapiro's research and the STEP ONE clinical trial in Edmonton are being supported in part by a generous Collaborative Research and Innovation Opportunities (CRIO) grant from Alberta Innovates – Health Solutions (AIHS), as well as the JDRF Canadian Clinical Trials Network (CCTN).

"Dr. Shapiro is one of the world's leading experts in the field of islet transplant technologies," said Dr. Paul Laikind, President and CEO of ViaCyte. "We welcome his participation in ViaCyte's STEP ONE clinical trial and we are confident that his extensive experience in the field will prove to be a valuable resource as we continue the development of the VC-01 product candidate as a transformative therapy for patients with type 1 diabetes."

As a transplant surgeon, Shapiro is renowned for determining how to administer human islets, resulting in insulin independence for many diabetes patients, in some cases lasting years. However, these islets, derived from scarce organ donors, are in short supply. Moreover, the Edmonton Protocol requires recipients to take chronic immunosuppressive drugs in order to prevent destruction of the transplant by their immune system. Consequently, while generally effective, the implementation of islet transplant has been limited to type 1 diabetes patients who have the greatest challenge in establishing glycemic control with pharmaceutical approaches, including patients with hypoglycemia unawareness.

"Clinical islet transplantation has transformed many lives, being critical for those patients hardest hit by the disease and for whom insulin injections are insufficient," said Dr. Shapiro. "But the fact remains that new treatments are sorely needed, not only for the high risk patients but for all patients suffering from this life-altering disease. The remarkable promise of the VC-01 product candidate is that a virtually limitless source of appropriate human cells can be transplanted without the need for lifetime immunosuppression. Should this treatment be approved, we will be far closer to a robust cure for diabetes than we have ever been in the past. I am excited to join with ViaCyte as we seek to translate the exciting results demonstrated in pre-clinical studies of the VC-01 product candidate into a novel new therapy that has the potential to help millions of patients."

The VC-01 combination product candidate, comprised of human pancreatic progenitor cells in a macroencapsulation device, is intended to address both of the main limitations of islet transplantation. PEC-01™ cells address the supply issue, as they are manufactured from pluripotent stem cells, which can be expanded virtually indefinitely. And the VC-01 product candidate utilizes ViaCyte's proprietary Encaptra® drug delivery system which is designed to protect the PEC-01 cells from a patient's immune system, obviating the need for immunosuppressive drugs.

The STEP ONE trial launched in late 2014 and has been steadily enrolling subjects with type 1 diabetes at until now, a single site, the University of California San Diego Health System, with the support of the UC San Diego Sanford Stem Cell Clinical Center.

This first clinical trial of the VC-01 product candidate is designed to allow evaluation of the product candidate in two cohorts of patients. The first cohort is intended to evaluate the safety of the product candidate, as well as allow development and optimization of the surgical and post-surgical procedures required for the successful engraftment of the cells. Patients in this first cohort are receiving what is calculated to be a sub-therapeutic dose of cells. The number of patients to be studied in this first phase of the trial will be determined based upon preliminary results related to safety and cell engraftment as well as performance parameters.

Assuming demonstration of safety and procedural optimization, the STEP ONE trial will progress to a second cohort of patients. This second group of patients will receive a higher dose of cells, calculated to provide therapeutic production of insulin and other regulatory proteins, allowing further evaluation of safety, and an initial evaluation of dosing and efficacy.

## *About ViaCyte:*

ViaCyte is a privately-held regenerative medicine company focused on developing a novel cell therapy for the treatment of diabetes. ViaCyte is conducting a Phase 1/2 clinical trial of the Company's lead VC-01 product candidate in patients with type 1 diabetes who have minimal to no insulin-producing beta cell function. ViaCyte's VC-01 combination product is based on the production of pancreatic progenitor cells derived from human pluripotent stem cells. These progenitor cells are implanted in a durable and retrievable encapsulation device. Once implanted and matured, these cells are designed to secrete insulin and other regulatory factors in response to blood glucose levels. The VC-01 product is being developed as a potential long-term diabetes treatment without immune suppression, and without risk of hypoglycemia or other diabetes-related complications.

ViaCyte is headquartered in San Diego, California with additional operations in Athens, Georgia. The Company is funded in part by the California Institute for Regenerative Medicine (CIRM) and JDRF.

For more information please visit www.viacyte.com. Connect with ViaCyte here: http://www.twitter.com/viacyte