ViaCyte and W. L. Gore & Associates Announce Collaborative Research Agreement to Develop Novel Implantable Delivery Technologies for Cell Therapies

SAN DIEGO, California and NEWARK, Delaware, March 28, 2017 – ViaCyte, Inc., a privately-held regenerative medicine company, and W. L. Gore & Associates, Inc. ("Gore"), a global materials science company, today announced a collaborative research agreement whereby the two companies will work together to develop novel implantable cell therapy delivery device technologies that provide protection from immune rejection.

For more than a decade, ViaCyte has been developing innovative stem cell-derived cell replacement therapies with a focus on the treatment of insulin-requiring diabetes. In the case of patients with type 1 diabetes, ViaCyte's product candidates have the potential to provide a functional cure. The company was the first to describe directed differentiation of human pluripotent stem cells into pancreatic cells, and the first to demonstrate the differentiation of stem cell-derived pancreatic progenitor cells into glucose-responsive insulin-producing cells, both in vivo and in vitro. In addition, ViaCyte launched the first clinical trial for stem cell-derived islet replacement therapy for type 1 diabetes. An important aspect of the therapy is the effective delivery of the cells to the patient. To accomplish this, ViaCyte has been developing encapsulation technologies including devices that protect the cells from the host immune system.

For more than forty years, Gore has been applying its materials science expertise to a variety of specific challenges in the life science industry. "We have a proven track record of developing and commercializing innovative new materials and products to address challenging implantable medical device applications and solving difficult problems for biologics manufacturers. Gore and ViaCyte began exploring a collaboration in 2016 with early encouraging progress leading to this agreement, and it was clear to us that teaming up with ViaCyte provided a synergistic opportunity for both companies," said Edward Gunzel, Technical Leader for Gore PharmBIO Products. "The experience, expertise, and intellectual property that each of us bring to the table is highly complementary. We look forward to working with ViaCyte to develop novel implantable delivery technologies for cell therapies."

ViaCyte is developing the PEC-Encap™ (also known as VC-01™) product candidate designed to deliver stem cell-derived islet replacement therapies to patients with type 1 diabetes as well as patients with type 2 disease that require insulin. The PEC-Encap combination product comprises PEC-01 pancreatic progenitor cells delivered in an immune-protective device called the Encaptra® Cell Delivery System. Based upon early, preliminary clinical evaluation, the
PEC-Encap product appears safe, the Encaptra device is providing immune protection as designed, and evidence of vascularization, engraftment, and differentiation of the PEC-01 cells into insulin-producing beta cells has been observed. Further product development work remains to improve engraftment of PEC-Encap, and non-clinical results have indicated the potential for improvement through modifications to the Encaptra Device.

Building on the observations with the PEC-Encap product candidate, ViaCyte is initiating clinical development of the PEC-Direct product candidate. The PEC-Direct product also delivers PEC-01 cells, but in a device that allows for direct vascularization of the cells. Used with immunosuppression as with other transplants, PEC-Direct has the potential to be a functional cure for patients suffering with type 1 diabetes who are at high risk for life-threatening acute complications.

"Gore has expertise in medical device development and drug delivery technologies, as well as previous research and development experience on cell encapsulation and implant programs for diabetes. We believe this collaboration represents a mutually beneficial relationship as the two teams cooperatively establish new methods of effectively delivering cell therapy to those with major unmet medical needs," said Paul Laikind, PhD, President and CEO of ViaCyte. "As ViaCyte advances our next generation encapsulation technologies for cell therapies, Gore's

contribution to the material and design improvements of the Encaptra delivery system is expected to support the reliable and robust long-term engraftment that is required for the PEC-Encap product to be most effective. With Gore's help, we plan to improve on the results we have seen with PEC-Encap, which would then have the potential of benefiting all patients with insulin-requiring diabetes, both type 1 and type 2."

ViaCyte and Gore have established a joint development team with members from both companies. Other terms of the agreement were not disclosed.

About Gore
W. L. Gore & Associates is a global materials science company dedicated to transforming industries and improving lives. Founded in 1958, Gore has built a reputation for solving complex technical challenges in the most demanding environments — from revolutionizing the outerwear industry with GORE-TEX® fabric to creating medical devices that improve and save lives to enabling new levels of performance in the aerospace, pharmaceutical and mobile electronics markets, among other industries. The company is also known for its strong, team-oriented culture and continued recognition from the Great Place to Work® Institute. Headquartered in Newark, Delaware, Gore employs approximately 10,000 associates and generates annual revenues that exceed $3 billion. For more information on Gore, please visit www.gore.com

About ViaCyte
ViaCyte is a privately-held regenerative medicine company developing novel cell replacement therapies as potential long-term diabetes treatments to reduce the risk of hypoglycemia and diabetes-related complications. ViaCyte's product candidates are based on the derivation of pancreatic progenitor cells, which are then implanted in a durable and retrievable cell delivery device. Once implanted and matured, these cells are designed to secrete insulin and other pancreatic hormones in response to blood glucose levels. ViaCyte has two products in development. The PEC-Direct™ product candidate delivers the pancreatic progenitor cells in a non-immunoprotective device and is being developed for type 1 diabetes patients that have severe hypoglycemic episodes, extreme glycemic lability, and/or impaired awareness of hypoglycemia. The PEC-Encap™ (also known as VC-01) product candidate delivers pancreatic progenitor cells in an immunoprotective device and is currently being evaluated in a Phase 1/2 trial in patients with type 1 diabetes who have minimal to no insulin-producing beta cell function. 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 on ViaCyte, please visit www.viacyte.com and connect with ViaCyte on Twitter and Facebook.

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