

Press Release

SERAXIS Inc. announces novel method and cell line that generate highly pure populations of insulin-producing cells capable of reversing diabetes in rodents.

Germantown, United States, September 5, 2018 – SERAXIS Inc., a privately held regenerative medicine company today announced the successful production of stem cell derived pancreatic cells capable of regulating blood glucose in rodent models of insulin dependent diabetes.

The results of a preclinical study describing the development of a new and efficient method for the production of insulin-secreting beta cells in pancreatic islet-like clusters was published this week in PLOS ONE (Southard et al, doi 10.1371/journal.pone. 0203126). The SERAXIS investigators further showed that the islet clusters functioned like mature pancreatic islets, secreting insulin shortly after transplantation in response to fluctuations in glucose in a rodent model of diabetes. The patented SERAXIS stem cells were derived from human pancreatic islets using induced pluripotent stem cell (iPSC) technology, and selected for their ability to regain pancreatic identity. The proprietary cells were generated using (chromosomally) non-integrating reprogramming factors to create a stem cell line, SR1423, that uniquely generates islet-like clusters when exposed to the SERAXIS differentiation protocol. According to Marie Csete, M.D., Ph.D, on SERAXIS' Scientific Advisory Board, the purity of SERAXIS islet-like cells is important in facilitating the application to clinical studies, and the production of glucagon by the cells suggests that the complex machinery for controlling glucose in a physiologically relevant way is present in SR1423 cells.

The cells were created using procedures that are Good Manufacturing Practice (GMP)-

compliant to speed translation to the clinic. In parallel, SERAXIS successfully developed

an immune-protective retrievable device to encase the islet-like clusters.

studies, this patented biocompatible device enabled long-term glycemic control in

immune-competent rat and mouse models of diabetes, preventing rejection of the encased

cells. "We are very proud of the progress of SERAXIS towards the development of an

allogeneic therapy for insulin-dependent diabetes" said William Rust, Ph.D., chief

executive officer, SERAXIS, "and we are actively working with SERAXIS scientific

advisors and clinical domain experts to develop the remaining data necessary to complete

an IND filing for clinical trial testing of the encapsulated cells".

About SERAXIS INC.

SERAXIS is a privately held biotechnology company, incorporated in Singapore and the

United States. Its U.S. headquarters are located in Germantown, Maryland in the heart of

the I-270 Technology Corridor. SERAXIS used proprietary technologies to develop: (1) a

cell therapy that functions shortly after transplantation in diabetic animals and; (2) a

device that safely protects these human pancreas cells from the immune system of animal

hosts without need for pharmacologic immunosuppression. Further information can be

found at www.seraxis.com

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