

Seraxis' manufacturing suite completes GMP quality system audit ahead of SR-02 IND filing and transplantation of pancreatic clusters to patients with Type 1 Diabetes

GMP-compliant manufacturing puts SR-02 on track to be industry's second clinical-stage stem cell derived pancreatic islet transplant program.

The third-party auditor's FDA six-system approach yielded no critical nor major observations of Seraxis' quality system for the production of GMP-grade organs from pancreas-derived stem cells.

Dr. William Rust, CEO, will present further data on the development of SR-02 and follow-on immune-cloaked SR-03 on Monday, January 8 at 10:30am PST at Biotech Showcase in San Francisco.

Germantown, MD, January 4, 2024. Seraxis, Inc., a regenerative medicine company developing a pancreatic islet replacement therapy to transform the lives of patients with Type 1 and insulin-requiring Type 2 diabetes, today announced the completion of a comprehensive third-party on-site Good Manufacturing Practice (GMP) audit of Seraxis' QMS, cleanroom, cell growing production process and QC laboratory, conducted in advance of Seraxis' planned IND submission of the pancreatic clusters candidate SR-02 for the intended treatment of insulin-dependent diabetes. The independent audit followed the FDA six-system approach and concluded that Seraxis' proprietary manufacturing process is in compliance with GMP audit standards, regulations and internal written procedures.

"The manufacturing of an exquisite cluster of living cells – essentially the production of a replacement human organ – is a tremendously nuanced and intricate feat of biological engineering," said Seraxis' Chief Operating Officer, Carole Welsch, PhD. "We are proud that our team has created a clinical-scale cleanroom production facility and quality system that pass muster with a rigorous audit comparable to a possible future FDA inspection associated with our upcoming IND filings."

"Seraxis' stem cell line SR1423 was derived from pancreatic cells and retain the epigenetic fingerprint of islets so, by design, they efficiently expand and generate replacement islet clusters. This characteristic eliminates purification steps, enabling Seraxis to manufacture product on a clinical scale for both the SR-02 program and the follow-on immune-cloaked SR-03 program in our Germantown facility," added CEO Will Rust.

Dr. Rust will be presenting Seraxis' recent candidate development data in a presentation at Biotech Showcase on Monday, January 8, in a 10:30am (PST) session. The presentation will be posted to www.seraxis.com shortly thereafter.

ABOUT SERAXIS

Seraxis is bringing transformative cures to the millions of people worldwide struggling with the management and life-threatening complications of T1D and insulin-requiring T2D.

Seraxis' lead program, SR-02, is a novel, off-the-shelf islet replacement therapy slated to enter clinical testing with immunosuppressive therapy in 2024 in patients with severe recurrent hypoglycemia. A follow-on diabetes program, SR-03, is a version of the Seraxis pancreatic clusters altered to be unrecognized by the immune system for use without chronic immune suppression by the broader population of T1D and insulin-requiring T2D.

Seraxis' underlying proprietary technology enables the creation of a pipeline of novel stem cell-derived therapies originating from single donated organs for other indications. The company's lead therapeutic program, SR-02, is manufactured from a stem cell line derived from a human donor pancreas. These cells preferentially re-differentiate into pancreatic clusters containing all the endocrine cells of the native pancreatic islet, and with safety, potency, and manufacturing advantages over embryonic and induced pluripotent stem cells.

Seraxis is backed by Frazier Life Sciences, Polaris Partners, Eli Lilly, the JDRF T1D Fund and independent investors. Seraxis manufactures its best-in-class therapeutic pancreatic clusters using scalable, clinically compliant processes in its cGMP facility located in Maryland's I-270 Biotech Corridor.

For more information, please visit www.seraxis.com.