Seraxis Announces FDA IND Allowance for Clinical Study of SR-02 Replacement Islets for Type 1 Diabetes

A Phase I/II Clinical Study to assess safety, potency and durability of SR-02 implanted to the abdominal omentum of patients with difficult-to-control T1D

October 15, 2024, Germantown, MD. Seraxis Inc., a clinical stage regenerative medicine company, has received FDA's allowance of an Investigational New Drug (IND) application for a Phase I/II clinical study of its novel islet replacement therapy SR-02. SR-02 is the first reprogrammed stem cell-derived pancreatic product candidate allowed by FDA for testing in humans as a potential functional cure for insulin-requiring diabetes.

"It is established that replacement islets can free a patient of diabetes from insulin dependency. Our goal is to make a highly allocompatible and off-the-shelf product available to the millions of patients in need," said Will Rust, PhD, Seraxis President and CEO.

The SR-02 therapeutic candidate is comprised of allogeneic pancreatic endocrine cell clusters that, when implanted to the omentum, form a functional endocrine pancreas outside of the native pancreas. SR-02 is manufactured at clinical scale in the company's cGMP manufacturing facility from a proprietary stem cell line reprogrammed from healthy donor pancreas tissue.

"Seraxis is making an important contribution in the effort to relieve patients with diabetes from insulin injections and long-term health complications. This route of administration may offer a safer option for the development of these treatments," said James Markmann, MD PhD, Vice President of Transplant Services, Penn Transplant Institute.

About Seraxis

Seraxis is bringing transformative therapies to the millions of people worldwide struggling with the management of insulin-requiring diabetes and the associated life-threatening complications. Seraxis' lead program, SR-02, is a novel islet replacement therapy for patients of insulin-requiring diabetes with concurrent immunosuppression therapy. This therapy is the foundation of Seraxis follow-on therapies for patients without immune suppression. Frazier Life Sciences, Polaris Partners, Eli Lilly and Company, the T1D Fund and others are investors in Seraxis. Visit www.seraxis.com.