Clinical Trial To Test Safety of Stem Cell-Derived Therapy for Type 1 Diabetes

UC San Diego is initial site for first-in-human testing of implanted cell therapy

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Researchers at the University of California, San Diego School of Medicine, in partnership with ViaCyte, Inc., a San Diego-based biotechnology firm specializing in regenerative medicine, have launched the first-ever human Phase I/II clinical trial of a stem cell-derived therapy for patients with Type 1 diabetes.

The trial will assess the safety and efficacy of a new investigational drug called VC-01, which was recently approved for testing by the U.S. Food and Drug Administration. The 2-year trial will involve four to six testing sites, the first being at UC San Diego, and will recruit approximately 40 study participants.

"The goal, first and foremost, of this unprecedented human trial is to evaluate the safety, tolerability and efficacy of various doses of VC-01 among patients with type 1 diabetes mellitus," said principal investigator Robert R. Henry, MD, professor of medicine in the Division of Endocrinology and Metabolism at UC San Diego and chief of the Section of Endocrinology, Metabolism & Diabetes at the Veterans Affairs San Diego Healthcare System. "We will be implanting specially encapsulated stem cell-derived cells under the skin of patients where it's believed they will mature into pancreatic beta cells able to produce a continuous supply of needed insulin. Previous tests in animals showed promising results. We now need to determine that this approach is safe in people."

Development and testing of VC-01 is funded, in part, by the California Institute for Regenerative Medicine, the state's stem cell agency, the UC San Diego Sanford Stem Cell Clinical Center and JDRF, the leading research and advocacy organization funding type 1 diabetes research.

Type 1 diabetes mellitus is a life-threatening chronic condition in which the pancreas produces little or no insulin, a hormone needed to allow glucose to enter cells to produce energy. It is typically diagnosed during childhood or adolescence, though it can also begin in adults. Though far less common than Type 2 diabetes, which occurs when the body becomes resistant to insulin, Type 1 may affect up to 3 million Americans, according to the JDRF. Among Americans age 20 and

younger, prevalence rose 23 percent between 2000 and 2009 and continues to rise. Currently, there is no cure. Standard treatment involves daily injections of insulin and rigorous management of diet and lifestyle.

Phase I/II clinical trials are designed to assess basic safety and efficacy of therapies never before tested in humans, uncovering unforeseen risks or complications. Unpredictable outcomes are possible. Such testing is essential to ensure that the new therapy is developed responsibly with appropriate management of risks that all medical treatments may present.

"This is not yet a cure for diabetes," said Henry. "The hope, nonetheless, is that this approach will ultimately transform the way individuals with Type 1 diabetes manage their disease by providing an alternative source of insulin-producing cells, potentially freeing them from daily insulin injections or external pumps."

This clinical trial at UC San Diego Health System was launched and supported by the UC San Diego Sanford Stem Cell Clinical Center. The Center was recently created to advance leading-edge stem cell medicine and science, protect and counsel patients, and accelerate innovative stem cell research into patient diagnostics and therapy.

To learn more about eligibility for this clinical trial, call Todd May at 858-657-7039.

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