Clinical trial of directly vascularized islet cell replacement therapy for high-risk type 1 diabetes

Grant Award Details

Clinical trial of directly vascularized islet cell replacement therapy for high-risk type 1 diabetes

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-09672

Project Objective: A phase 1 trial of Clinical trial of directly vascularized islet cell replacement therapy for high-risk type 1 diabetes

Investigator:

Name:	Howard Foyt
Institution:	ViaCyte, Inc.
Type:	PI

Disease Focus: Diabetes, Metabolic Disorders, Type 1 diabetes

Human Stem Cell Use: Embryonic Stem Cell

Award Value: $19,752,463

Status: Active

Grant Application Details

Application Title: Clinical trial of directly vascularized islet cell replacement therapy for high-risk type 1 diabetes

Public Abstract:

Therapeutic Candidate or Device

pancreatic progenitor cells in a delivery device that allows direct vascularization

Indication

high-risk type 1 diabetes including "brittle" diabetes and hypoglycemia unawareness

Therapeutic Mechanism

People with type 1 diabetes have lost their pancreatic cells that make insulin, and therefore have to self-administer insulin. It is very difficult to manage blood sugar to safe levels by this method. Chronically too high can lead to blindness, kidney failure, nerve damage, and heart problems, and too low can cause coma or death. This product will replace the lost pancreatic cells and provide a natural biological ability to maintain stable healthy blood sugar levels.

Unmet Medical Need

There are over 100,000 people in the US with type 1 diabetes so severe that they are at constant risk of hospitalization and/or death. Within months after administration, this product could naturally restore those patients' blood sugar to normal healthy levels and save their lives.

Project Objective

Phase 1/2 trial completed

Major Proposed Activities

- Manufacture and quality control of the test article for clinical trial
- Launch and run clinical trial
- Assay development

Statement of Benefit to California:

The product will be available through clinical trials in California and if approved by the FDA for commercial use, will help many thousands of Californians with high-risk diabetes. The product will save lives and increase quality of life for patients/families, while significantly reducing the state's health care burden. Indeed the product could become the most significant stem cell-based medical treatment of the coming decade; a tremendous achievement for California, its taxpayers, and CIRM.

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