
A Phase 3 Study Comparing the Utility of Human Acellular Vessels to Arteriovenous Fistula in Subjects with End-Stage Renal Disease (California Sites)

Grant Award Details

A Phase 3 Study Comparing the Utility of Human Acellular Vessels to Arteriovenous Fistula in Subjects with End-Stage Renal Disease (California Sites)

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-09688

Project Objective: Completion of Phase III Clinical Program Comparing the Utility of Human Acellular Vessels to Arteriovenous Fistula in Subjects with End-Stage Renal Disease

Investigator:

Name: Jeffrey Lawson

Institution: Humacyte, Inc.

Type: PI

Disease Focus: Kidney Disease, Kidney Failure

Human Stem Cell Use: Adult Stem Cell

Award Value: \$3,525,000

Status: Closed

Grant Application Details

Application Title: A Phase 3 Study Comparing the Utility of Human Acellular Vessels to Arteriovenous Fistula in Subjects with End-Stage Renal Disease (California Sites)

Public Abstract: **Therapeutic Candidate or Device**

Human Acellular Vessel (HAV)

Indication

Conduit for Vascular Access for Hemodialysis

Therapeutic Mechanism

Mechanism of action: the HAV is comprised of intact extracellular matrix constructed by human smooth muscle cells (SMC) in a biomimetic bioreactor system. The manufacturing process is designed to create a biologic matrix similar in protein composition and 3 dimensional structure with biomechanical properties that are observed with native tissue. Once implanted, the HAV is remodeled by the host resulting in a vascular structure more similar in histological appearance to native vascular tissue.

Unmet Medical Need

Current vascular access technologies for hemodialysis are fraught with complications associated with thrombosis, infection and abandonment. Compared to conventional vascular access treatments for dialysis the HAV has the potential for less frequent clotting, abandonment and infection

Project Objective

Completion of Phase III Clinical Program

Major Proposed Activities

- Manufacturing & Distribution of the HAV for clinical testing in dialysis patients
- Enrollment in Phase III Clinical Trial and Implantation of HAV into patients requiring vascular access for hemodialysis
- Longitudinal test subject follow-up, data collection and analysis, regulatory approval of HAV for widespread clinical use

Statement of Benefit to California:

The research proposed in this application will directly benefit California citizens by advancing medical/surgical therapies in the area of vascular access for hemodialysis. Further, through this clinical program widespread clinical experience will be developed with the HAV for a broader application of vascular reconstruction in all anatomic areas. Finally, this work will economically benefit citizens in California by pursuing clinical research activities and manufacturing processes within CA.

Source URL: <https://www.cirm.ca.gov/our-progress/awards/phase-3-study-comparing-utility-human-acellular-vessels-arteriovenous-fistula>