SDF-1 Plasmid Treatment for Patients with Heart Failure (STOP-HF)

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Background

- Alan known as CXCR4
- 6 kDa chemokine, receptor is CXCR4
- Upregulated in damaged tissue, including skin
- Improves cardiac function after acute myocardial infarction
- Mobilizes/recruits hematopoietic stem cells to injured tissues
- SDF-1 is increased in wounds after trauma
- SDF-1 therapy in diabetic wounds increased healing

Hypothesis:

- Re-introducing SDF-1 expression in a chronically damaged heart using plasmid DNA may increase cardiac function.

Phase I Results

NYHA Improvements (Cohorts 2 & 3)

Phase I Adverse Event Summary

- Overall, JVS-100 was safe and well-tolerated.
- 26 SAEs were reported in subjects that received study drug. Only 1 SAE (worsening heart failure) was thought to be "possibly" related to JVS-100. No other subjects had any serious adverse events reported as "related" or "possibly related" to JVS-100.

Phase II Trial Design

- 90 Person randomized, double blind, placebo controlled trial
- 60%/40% change in MLWHFQ score at 4 months
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- 15 injections of 1 ml for each patient

Endpoints:

- Secondary: NYHA class, functional echocardiography parameters at 4 and 12 months, additional mortality and morbidity endpoints

Major Inclusion/Exclusion

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  - NYHA class III 65%
  - NYHA class II 29%
  - NYHA class I 10%

- Major Exclusion Criteria
  - EF < 40%
  - 3 contiguous LV segments w/ abnormal WMSI

Recruitment Dates

The study began enrolling in August 2012 and will end recruitment in October 2013

Inquiries on Future Trials

- Experience with cardiovascular and/or gene therapy trials
- Historical recruitment rates for similar trials
- Strength of relationship between interventional cardiology and heart failure research programs at your site
- Advanced echocardiography capabilities

Centers Participating

- Cardiology PC (Birmingham, AL)
- Columbia University Medical Center (New York, NY)
- Minneapolis Heart Institute Foundation (Minneapolis, MN)
- University of Utah (Salt Lake City, UT)
- The Linder Center for Research (Cincinnati, OH)
- Pepin Heart Institute (Tampa, FL)
- Montefiore Medical Center (Bronx, NY)
- SUMMA Health System (Akron, OH)
- University of Pennsylvania (Philadelphia, PA)
- University of Florida (Gainesville, FL)
- Michigan Cardiovascular Institute (Saginaw, MI)
- Baylor Health (Dallas, TX)
- Johns Hopkins University (Baltimore, MD)
- Spectrum Health (Grand Rapids, MI)
- Iowa Heart Center (Des Moines, IA)
- Washington University in St. Louis (St. Louis, MO)