



**NEWS RELEASE**

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**Tissue Genesis Begins FDA-Approved  
Clinical Trial**

*First FDA Cell Therapy Trial Using Adipose Tissue, Collected at Point of Care with an Automated System*

HONOLULU, HAWAII – Tissue Genesis, Inc., an emerging leader in adult stem cell and regenerative medicine, announced today that it has begun clinical trials for peripheral vascular disease (PVD) with adipose (fat) derived adult stem cell-coated vascular grafts at the University of Louisville Hospital. Tissue Genesis is the first to initiate a FDA-approved trial using the patient’s own adipose-derived adult stem cells (ASCs) prepared at the point-of-care. The clinical trial commenced enrollment in April and is led by Dr. Charles B. Ross, a board-certified vascular surgeon and Chief of the Division of Vascular Surgery and Endovascular Therapeutics at the University of Louisville Hospital.

Peripheral vascular disease affects over eight million people in the United States. By 2020, the number is expected to increase by 43 percent. PVD includes damage to or blockage in the blood vessels of the peripheral arteries and veins, causing pain and weakness. Approximately 25 percent of patients progress to critical limb ischemia (CLI), oftentimes leading to amputation. In the United States, 130,000 amputations are performed annually due to PVD.

Researchers have been actively seeking a way to coat the inside of synthetic grafts used to treat PVD so that they more closely resemble native vessels and increase long-term graft survival. The stromal vascular fraction of adipose tissue contains millions of regenerative cells, which can be used to coat the inner surface of vascular grafts. “Based on previous studies, the potential of ASCs to increase the patency and life of the graft is tremendous,” states Dr. Stuart Williams, Chief Science Officer for Tissue Genesis and Executive and Scientific Director of the Cardiovascular Innovation Institute in Louisville, Kentucky.

ASCs are being increasingly looked to as a readily available source abundant in adult stem cells. Compared to bone marrow derived stem cells, ASCs can be obtained via a quick and simple liposuction procedure with minimal down time and without the need for prolonged cell culturing. ASCs are reported to contain 100 – 1000 times more mesenchymal stem cells than bone marrow derived stem cells.

“We are committed to using our research to help people suffering from painful diseases like PVD and CLI,” noted Anton Krucky, President and CEO of Tissue Genesis. “As the first company to conduct an FDA-approved clinical trial for PVD in the U.S. utilizing ASCs recovered at the point-of-care with an automated device, we are proud to be on the frontier of new therapies that can change the lives of millions. Our ground-breaking research and clinical translation continues to push us to the front of regenerative medicine in many aspects of the medical field. Our strategy is to expand clinical trial validation into other therapeutic areas. This vascular therapy has the potential to be applied to coronary artery bypass grafts (CABG),” added Krucky. An estimated 250,000 CABG procedures are performed annually.

Tissue Genesis’ Cell Isolation System is a compact, automated desktop unit that utilizes liposuctioned adipose tissue to isolate millions of adult stem cells in about an hour. This proprietary enabling platform technology averages approximately 35 to 50 million stromal cells per 60 cc of adipose, which then can be potentially applied to a variety of unmet medical needs. The point-of-care Cell Isolation System, manufactured to the highest standards, is CE-marked and GMP-certified.

### **About Tissue Genesis, Inc.**

An emerging leader in adipose-derived cell therapy and regenerative medicine, Tissue Genesis, Inc. is a high-growth, clinical-stage company based in Honolulu, Hawai‘i. Industry leading physicians, engineers and scientists have developed a proprietary therapy for Tissue Genesis that may deliver innovative medical solutions for a wide range of existing medical problems, including: cardiac and peripheral vascular disease; orthopedic injuries; cosmetic and soft tissue defects; and many other applications. For more information, visit [www.tissuegenesis.com](http://www.tissuegenesis.com).

### **Safe Harbor Statement**

This press release contains statements, which may constitute "forward-looking statements" within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, as amended by the Private Securities Litigation Reform Act of 1995. Those statements include statements regarding the intent, belief or current expectations of Tissue Genesis, Inc., and members of its management as well as the assumptions on which such statements are based. There can be no assurance that Tissue Genesis will be able to commercially develop its therapeutic cell technology or products, that necessary regulatory approval will be obtained, that any clinical trials will be successful, or that the proposed

treatments will prove to be safe and/or effective. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those contemplated by such forward-looking statements. Important factors currently known to management that could cause actual results to differ materially from those in forward-statements include fluctuation of operating results, the ability to compete successfully and the ability to complete before-mentioned transactions. The company undertakes no obligation to update or revise forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events, or changes to future operating results.