Juventas Therapeutics doses first patient in Phase II STOP-HF trial

CLEVELAND, Aug. 20, 2012 /PRNewswire-USNewswire/ -- Juventas Therapeutics, a privately-held clinical-stage company developing novel regenerative therapies for treatment of cardiovascular disease, reports treating the first patient in its STOP-HF trial. The 90-patient, placebo-controlled, randomized double-blinded Phase II study is evaluating the safety and efficacy for JVS-100 in patients with late stage heart failure. Dr. Amit Patel, the Director of Clinical Regenerative Medicine at University of Utah Medical Center, treated the patient.

JVS-100, the Company's lead product, encodes Stromal cell-Derived Factor 1 (SDF-1) which has been shown to repair damaged tissue through recruitment of circulating stem cells to the site of injury, prevention of ongoing cell death, and restoration of blood flow.

Earlier this year, Juventas reported 12-month results from a Phase I clinical trial in New York Heart Association (NYHA) Class III heart failure patients. In addition to meeting the primary safety endpoint, patients receiving target therapeutic doses demonstrated clinically significant improvements at 12 months in 6 minute walk distance (6MWD) and the Minnesota Living with Heart Failure Questionnaire (MLHFQ). Nearly half of the patients improved a full NYHA class, with multiple patients improving two full classes.

The product will be delivered to patients using the BioCardia Helical Infusion System. BioCardia is a leading provider of cardiovascular catheter systems designed to deliver biologic therapies for cardiac regeneration. The Helical Infusion System is a CE Marked steerable two catheter system that enables delivery of biologic therapies to the heart muscle from within the chamber of the heart. It requires no external capital equipment and has an excellent clinical safety profile. The Helical Infusion System is commercially available in the European Union and is under investigation in the United States in ongoing clinical trials.

"The initiation of this trial marks an important step forward for Juventas Therapeutics," states Marc Penn, M.D., Ph.D. Founder of Juventas and the Director of the Summa Cardiovascular Institute at Summa Health Systems. "We established the Company based on a hypothesis that cell therapy could be distilled down to factor-based approaches, which would be clinically-beneficial while reducing cost and complexity associated with producing and delivering adult stem cells. It is exciting to see those early scientific discoveries translate into potential therapeutics."

About Juventas Therapeutics

Juventas Therapeutics, headquartered in Cleveland, OH, is a privately held clinical-stage biotechnology company developing a pipeline of regenerative therapies to treat life–threatening diseases. Founded in 2007 with an exclusive license from Cleveland Clinic, Juventas has transitioned its therapeutic platform from concept to initiation of mid-stage clinical trials for treatment of heart failure and critical limb ischemia. Investors include New Science Ventures, Takeda Ventures, Triathlon Medical Venture Partners, Venture Investors, Early Stage Partners, Fletcher Spaght Ventures, Reservoir Venture Partners, Glengary, The Global Cardiovascular Innovation Center, Tri-State Growth Fund, North Coast Angel Fund, X Gen Ltd., JumpStart Inc., and Blue Chip Venture Co. The company has received

non-dilutive grant support through the Ohio Third Frontier-funded Cleveland Clinic Ohio BioValidation Fund, Global Cardiovascular Innovation Center and Center for Stem Cell & Regenerative Medicine.

About BioCardia

BioCardia, Inc. (San Carlos, Calif.) was incorporated in 2002 to design, develop, manufacture, and market innovative devices to enable percutaneous delivery of biologics to treat cardiovascular disease. The company's initial products are intended to provide new therapeutic options for patients with heart failure and chronic myocardial ischemia.

About STOP-HF

The STOP-HF Trial (Sdf-1 plasmid Treatment fOr Patients with Heart Failure) is a multi-center, randomized, double-blind, placebo-controlled study to assess the safety and efficacy of JVS-100 treatment in patients with late-stage heart failure. The trial is scheduled to enroll at up to 12 centers in the United States. Co-Principal Investigators for the trial are Dr. Leslie Miller, the Chair for the College of Medicine Cardiovascular at USF Health and Dr. Warren Sherman, the Director of Cardiac Cell-Based Endovascualar Therapies at Columbia University Medical Center.

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