UPMC | HEART AND VASCULAR INSTITUTE

2019 Heart Failure and Pulmonary Hypertension Clinical Trials

Is your patient a candidate for a clinical trial?

Referring your patient

The UPMC Heart and Vascular Institute is a leader in conducting research studies and clinical trials to better understand and treat heart failure and pulmonary hypertension.

To refer a patient, please call **1-84-HVI-TRIAL (844-848-7425)** or email **HVIresearch@upmc.edu**.

For more information about the UPMC Heart and Vascular Institute, please call **1-855-UPMC-HVI (876-2484)** or visit **UPMC.com/HVI**.

Heart Failure

SERENADE

A study to evaluate how effective and safe macitentan is on subjects with heart failure with preserved ejection fraction.

Inclusion criteria: Male or female 18 years or older, Signs of heart failure (swelling in your feet or belly, Short of breath with activity), Preserved ejection fraction (Ejection fraction 40% or greater)

Primary Investigator: Marc Simon, MD

ALIVE: Clinical Study of the BioVentrix Revivent TC™ System for Treatment of Left Ventricular Aneurysms

A prospective, multicenter, dual-arm pivotal study of 126 patients with 2:1 study (84 patients treated with the investigational device) vs. active concurrent control group (42 patients). The Revivent TC™ System is indicated for patients referred for surgical treatment of left ventricular aneurysm or anterior scar that is contiguous, and includes both anterior and septal components.

Inclusion Criteria: Age 18–80; CHF patients suffering from heart failure symptoms as defined by NYHA Class > 2 not responsive to medical therapy, with LVEF < 45%, LVESV ≥ 50 mL/m2; presence of LV aneurysm or anterior scar: defined by a contiguous acontractile (akinetic and/or dyskinetic) scar involving the septum and anterior, apical, or anterolateral regions of the LV as evidenced by cardiac imaging and referred for surgical management; viability of myocardium in regions remote from area of intended scar exclusion as evidenced by cardiac imaging; patient is on adequate guideline-directed medical therapy; candidates allocated to active concurrent control group must meet all inclusion criteria (including LV aneurysm scar presence), with the exception of LV aneurysm scar location.

Principal Investigator: Catalin Toma, MD

Sub-Investigators: Marc Simon, MD
Christopher Sciortino, MD

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Attribute-CM

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of AG10 in Subjects with Symptomatic Transthyretin Amyloid Cardiomyopathy. The primary endpoint is to evaluate the change in distance walked during the 6MWT from baseline to Month 12 of treatment and to determine a hierarchical combination of All-Cause mortality and CV-related hospitalization over a 30-month period.

Inclusion Criteria: ages 18-90; diagnosis of ATTR-CM (wild-type TTR or variant TTR); history of HF or clinical evidence of HF; NYHA Class I-III due to ATTR-CM; (if applicable) must be on stable CV GDMT for at least two weeks; completed ≥ 150m on the 6MWT for two consecutive tests; NT-pro BNP levels ≥ 300pg/mL; LV wall thickness ≥ 13mm; WOCBP agree to use acceptable methods of contraception.

Exclusion Criteria: Acute MI, ACS, or coronary revascularization within 90 days; experienced stroke within 90 days; hemodynamic instability; likely to undergo OHTx within one year; diagnosis of light-chain amyloidosis; abnormal LFTs >3x ULN; NT-pro BNP levels ≥ 7000pg/mL; eGFR <15mL/min/1.73m2; current treatment for ATTR-CM with Tafamidis or with marketed drug products lacking a labeled indication for ATTR-CM, patisiran, inotersen, green tea extract, or any investigational agent within 14 days or 90 days for patisiran and 180 days for inotersen; requires treatment with calcium channel blockers or digitalis.

Principal Investigator: Prem Soman, MD

CARILLON

Assessment of the CARILLON® Mitral Contour System® in treating functional mitral regurgitation associated with heart failure.

Primary Inclusion Criteria: Diagnosis of ischemic or non-ischemic cardiomyopathy, LVEF less than or equal to 50%, NYHA Functional class II, III, or IV, functional mitral regurgitation : 2+ (Moderate), 3+ (Moderate/Severe), or 4+ (Severe), stable on HF medications.

Primary Exclusion Criteria: Patient on continuous positive inotropes, no device implanted in coronary sinus, no previous mitral valve interventions, severe aortic stenosis, expected need for additional cardiac intervention in the next 30 days.

Principal Investigator: Conrad Smith, MD

REDUCE LAP-HF II

Study to evaluate the clinical efficacy and safety of the investigational InterAtrial Shunt Device (IASD®) System II for patients with elevated left atrial pressure who remain symptomatic despite appropriate medical management. Placed by an interventional cardiologist during a standard catheter-based procedure, the IASD system II creates a very small opening between the left and right atria. This opening allows blood to flow from the high pressure left atrium to the low pressure right atrium. This redistribution of blood to the right side potentially reduces the pressure in the left side and in the lungs.

Primary Inclusion Criteria: Symptoms of HF requiring current treatment with diuretics for > 30 days, Age > 40 years old, LV ejection fraction (EF) >40% within the past 6 months, without previously documented EF <30% (within the past 5 years)

Primary Investigator: Marc Simon, MD

Pulmonary Hypertension

RAPAMYCIN

Phase 1 clinical trial of ABI-009, an mTOR inhibitor, for patients with severe pulmonary hypertension. Subjects will receive IV infusion weekly for 16 weeks to evaluate maximum tolerated dose and safety.

Inclusion criteria: WHO Group 1 PAH, functional class III, on two or more standard PAH therapies.

Principal Investigator: Marc Simon, MD

EXPEDITE

A 16-week, multicenter, open-label study of Remodulin induction followed by Orenitram optimization in subjects with pulmonary arterial hypertension.

Primary Inclusion Criteria: Male or female age 18-75 years old, Diagnosis of WHO Group 1 Pulmonary arterial hypertension, WHO Functional class II or III, Subjects who are either not receiving PAH therapy or are currently being treated with up to 2 oral FDA-approved PAH therapies.

Primary Exclusion Criteria: Receiving a prostacyclin therapy

Principal Investigator: Marc Simon, MD

PHASE-BIO

A randomized, double-blind, parallel group, phase 2 study to assess the safety, tolerability, and efficacy of once weekly subcutaneous injections of a sustained-release VIP analogue, PB1046, in adult subjects with symptomatic pulmonary arterial hypertension.

Primary Inclusion Criteria: Male or female age 18-79 years old, Diagnosis of WHO Group 1 Pulmonary arterial hypertension, WHO Functional class II or III, Subjects who currently being treated with up to 3 FDA-approved PAH therapies comprised of any combination of oral and/or inhaled or IV therapy.

Primary Exclusion Criteria: Chronic SQ prostanoid/prostacyclin therapy for PAH.

Principal Investigator: Marc Simon, MD

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