ALLAY-HF

INVESTIGATORS	**Mazen Albaghdadi, MD Principal Investigator** **Viviana Navas, MD Sub-Investigator** **Robert Cubeddu, MD Sub-Investigator** **Adam Frank, MD Sub-Investigator**
Trial Objective	• **To evaluate the safety and efficacy of the Alleviant ALV1 System in patients with chronic heart failure (HF) and preserved ejection fraction (HFpEF) or mildly reduced ejection fraction (HFmrEF), who remain symptomatic despite appropriate guideline directed medical therapy (GDMT).**
Randomization	• **Patients will be randomized in a 1:1 ratio to undergo the investigational device procedure or a sham control procedure**
Key Inclusion	• **Chronic symptomatic HF documented by each of the following** a. History of HF for at least 6 months prior to enrollment **AND** b. Symptoms of HF requiring current treatment with diuretics for ≥ 30 days **AND** c. NYHA class II or III; **OR** ambulatory NYHA class IV symptoms (paroxysmal nocturnal dyspnea, orthopnea, dyspnea on mild or moderate exertion) at screening visit; d. At least one HF hospital admission (with HF as the primary or secondary diagnosis) **OR** treatment with IV diuretics within 12 months of enrollment; **OR** an NT-proBNP value > 150 pg/ml in normal sinus rhythm/> 450 pg/ml in atrial fibrillation, **OR** a BNP value > 50 pg/ml in normal sinus rhythm/> 150 pg/ml in atrial fibrillation at screening visit • Ongoing Stable GDMT managemt

	• **Subject is ≥ 40 years of age** • **LVEF ≥ 40%** • **Subject is able to perform supine ergometer exercise test**
Key Exclusion	Advanced HF documented in the medical history, defined as **one or more** of the following: ACC/AHA/ESC Stage D HF, non-ambulatory NYHA Class IV Patient is on the cardiac transplant waiting list Inotropic infusion (continuous or intermittent) within 6 months of screening visit Prior history of EF < 40% • Hypertrophic obstructive cardiomyopathy, restrictive cardiomyopathy, constrictive pericarditis, cardiac amyloidosis or other infiltrative cardiomyopathy such as hemochromatosis or sarcoidosis. Additional testing is suggested for patients with LV wall thickness > 1.5 cm to rule out amyloidosis • Chronic pulmonary disease documented in the medical history, defined as one or more of the following: a.home oxygen use dependent b. Hospitalization for treatment of chronic pulmonary disease within 12 months of enrollment c. Significant chronic pulmonary disease defined as forced-expiratory volume-1 (FEV1) < 50% of predicted d. If severe chronic obstructive pulmonary disease (COPD) is documented in the medical history, a spirometry test is to be performed and the patient excluded if FEV1 < 50% • **Subject is currently requiring dialysis** • Uncorrected valve disease documented in the medical history or measured by the studyspecific • TTE performed during screening. Uncorrected valve disease includes one or more • of the following: Greater than moderate mitral regurgitation Greater than mild mitral stenosis Moderate or greater tricuspid regurgitation Moderate or greater aortic stenosis e. Greater than moderate aortic regurgitation