Efficacy of Left Ventricular Augmentation With Algisyl-LVR in the Treatment of Advanced Heart Failure Patients With Ischemic and Non-Ischemic Cardiomyopathy: Results of the AUGMENT-HF Multicenter Randomized Controlled Trial

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Introduction: Therapeutic options for patients with severe heart failure (HF), refractory to pharmacological therapies, are limited. Given the significant morbidity and mortality associated with this stage of the disease, a novel and effective therapeutic approach is greatly needed. Clinically relevant large animal models and computer simulations have suggested that the addition of non-contractile material to the failing myocardium can reduce elevated myofiber stress. Algisyl-LVR is a proprietary biopolymer gel that is injected into strategic areas of the LV free wall, where it remains as a permanent implant. A prior clinical trial suggested Algisyl-LVR to be safe and potentially efficacious in patients with advanced HF.

Hypothesis: Algisyl LVR is superior to standard medical therapy in the management of chronic HF with a reduced ejection fraction (EF) secondary to ischemic or non-ischemic etiologies.

Methods: Multi-center, prospective, randomized, controlled evaluation of Algisyl-LVR in patients with HF secondary to either ischemic or non-ischemic etiology. Seventy-eight patients were randomized (1:1) to Algisyl-LVR (n=40) and standard medical therapy (n=38). Patients were mean age 62.3 (± 9.6) with ischemic (57.7%) or non-ischemic (42.3%) HF, a mean EF of 25.8 (± 5.5), and symptomatic HF (mean NYHA class of 2.9 ± 0.5) with a mean Peak VO2 of 12.2 (± 1.8) ml/min/kg, and a mean 6 MWT distance of 293.6 (± 81.3) m. Patients must have been on stable, evidence-based therapy for HF.

Results: The results of the primary endpoint analysis will be presented including 6 month change in Peak VO2, 6 MWT, NYHA class, KCCQ score, biochemical analysis, and electrocardiographic evaluations.

Conclusions: The results of the AUGMENT-HF clinical trial will provide the first insights into the potential for this novel concept of LV augmentation with Algisyl-LVR in the
failing heart as an effective strategy for improving functional capacity and clinical outcomes in patients with advanced HF.

Disclosure:

S.D. Anker: Consultant/Advisory Board; Significant; Scientific Advisory Board. A. Coats: Consultant/Advisory Board; Significant; Scientific Advisory Board. G. Cristian: None. D. Dragomir: None. E. Pusineri: None. L. Bettari: Research Grant; Modest; Research Support. M. Volterrani: None. R.J. Lee: Consultant/Advisory Board; Modest; Scientific Advisory Board. H.N. Sabbah: Consultant/Advisory Board; Modest; Scientific Advisory Board. A. Hinson: Employment; Significant; Employee of LoneStar Heart. D.L. Mann: Consultant/Advisory Board; Modest; Scientific Advisory Board.