One Year Follow-up Results From AUGMENT-HF: A Multicenter Randomized Controlled Clinical Trial of the Efficacy of Left Ventricular Augmentation With Algisyl-LVR in the Treatment of Heart Failure

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Background: Therapeutic options for patients with advanced HF are quite limited. The AUGMENT-HF randomized, controlled study tested the hypothesis that LV augmentation with Algisyl (injectable Calcium-Alginate hydrogel) is superior to standard medical therapy (SMT) for treatment of patients with moderate to severe HF. Results were previously reported for the 6 month primary endpoint analysis. This report presents the results from 1 year of extended follow up for this clinical study.

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: AUGMENT-HF is an international, multi-centre, prospective, randomized, controlled evaluation of Algisyl-LVR in patients with advanced heart failure (HF). Patients inclusion criteria were LVEF ≤ 35%, peak VO2 of 9.0-14.5 mL/min/kg and LVEDD 30-40mm/m2 (LVEDD/BSA). Patients must have been on stable, evidence-based therapy for HF.

Results: A total of 58 patients completed the 12 month follow-up. 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 (81% NYHA class III or IV) 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. Treatment with Algisyl was associated with improved peak VO2 at 12 months with a treatment effect vs. Control of +2.10 mL/kg/min (95% confidence interval 0.96-3.24, P<0.001). Statistically significant improvements vs. Control at 12 months were observed for VO2 at Anaerobic Threshold (p<0.001), Peak Watts (p=0.003), Total Exercise Time (p=0.002), 6MWT distance (p<0.001), NYHA functional class (p<0.001) and Kansas City Cardiomyopathy Questionnaire (KCCQ) Clinical (p=0.018) and Overall (p=0.016) scores.

Conclusions: Prior clinical results for Algisyl demonstrated both safety and potentially important clinical benefits for patient with advanced heart failure refractory to SMT. These results demonstrate that Algisyl in addition to standard medical therapy was more effective than standard medical therapy alone for providing sustained 1-year benefits in exercise capacity, symptoms and clinical status for patients with advanced chronic HF.

Disclosure:
D.L. Mann: Consultant/Advisory Board; Modest; Scientific Advisory Board. S.D. Anker: Consultant/Advisory Board; Modest; Scientific Advisory Board. A. Coats: Consultant/Advisory Board; Modest; Scientific Advisory Board. M. Volterrani: Research Grant; Modest; research grants. H.N. Sabbah: Consultant/Advisory Board; Modest; Scientific Advisory Board. R. Dowling: Consultant/Advisory Board; Modest; Scientific Advisory Board. R.J. Lee: Consultant/Advisory Board; Modest; Scientific Advisory Board. A. Hinson: Employment; Modest; LoneStar Heart.