EVALUATION OF CARDIAC FUNCTION IN SYMPTOMATIC HEART FAILURE PATIENTS IN A SINGLE INFUSION, PHASE 1, DOSE ESCALATION STUDY OF GLIAL GROWTH FACTOR 2

Oral Contributions
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Background: Glial Growth Factor 2 (GGF2) is a neuregulin peptide critical for myocardial function. GGF2 improves left ventricular function (LVF) in animal models of cardiac injury. We report echocardiographic findings in a first-in-man, double-blind, placebo controlled, escalating single dose study of tolerability of GGF2 in patients with systolic HF.

Methods: Patients with LV ejection fraction (EF) <40% and symptomatic HF (NYHA Class II-III) received a single IV dose of GGF2 (0.007-1.5 mg/kg) or placebo (4:2) in 7 cohorts. Echocardiography was performed at baseline, days 8, 14, 28 and 90.

Results: 40 patients (mean age 57 years, 82% male) were enrolled. EF at screening in the placebo and treatment groups was 29±3 and 27±1%, respectively. The change in EF (mean±SD) at D8, D14, and D28 was [(EF at Day) - (Baseline EF)] for the placebo group compared to 2.3±8, 11.6±10 and 12±5.1% for the cohort receiving the maximally tolerated dose (0.75 mg/kg). Figure 1.

Conclusions: Single dose GGF2 in patients with symptomatic HF showed a trend towards improving LVF over 28 days compared to placebo. Further studies will determine safety and possible therapeutic effect of repeat dosing of GGF2 on LVF and other cardiac outcomes.

Figure 1. Mean Change In Ejection Fraction Following Single Dose of GGF2 (mg/kg) Or Placebo