Final Results for THE ATHENA TRIALS: Autologous Adipose Derived Regenerative Cells (ADRCs) for Refractory Chronic Myocardial Ischemia with Left Ventricular (LV) Dysfunction

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Background
Based on the Phase I PRECISE trial, the automated on-site cell processing and IM delivery of Autologous Adipose-Derived Regenerative Cells (ADRCs), shows promise for treatment of refractory ischemia pts.

Methods
Two prospective, randomized (2:1, active: placebo), double-blind, parallel group trials (ATHENA and ATHENA II, N=45 each) were designed to enroll pts on max med management with EF 20-45%, multi-vessel CAD not amenable to revasc, inducible ischemia, and CCS Angina Class II-IV and/or NYHA Class II-III. Pts underwent liposuction (<450 mL adipose), followed by cell processing (Celution® System, Cytori Therapeutics), and injection of ADRC [ATHENA: 20x10^6 cells, ATHENA 2: 40x10^6 cells] into viable myocardium.

Results
Enrollment was terminated prematurely due to 3 neurological events which prolonged trial enrollment but were not cell related. 31 pts were enrolled (17 ADRCs, 14 placebo), with mean age 65+8 yrs and baseline LVEF 31.6%. Changes from baseline to 6 months are shown in Table 1, with improvement trends for V02 max and symptoms. Several SF-36 domains were sig improved. At 1 year improvement in MLHFQ -21.6 +/-13.9 vs. -5.5 +/- 23.8 (P=0.038) and fewer heart failure hospitalizations 3/17 (17.6%) vs 5/14 (35.7%) occurred in cell treated pts.

Conclusion
A small volume fat harvest, followed by automated local processing, and IM delivery of autologous ADRCs was associated with improvement in symptoms, quality of life and heart failure hospitalizations despite no improvement in LVEF. With PRECISE, this trial should provide the foundation for a large Phase 3 trial.
Other Information

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