ALLSTAR PHASE II

Design: randomized, double-blind, placebo-controlled

- Subject participation lasts ~13 months and includes screening, treatment, and a 12 month follow-up period
    - Single intracoronary infusion with either CAP-1002 or placebo (randomized 2:1 favoring CAP-1002)
- Safety Endpoint: the proportion of patients receiving CAP-1002 that experience active myocarditis possibly attributable to treatment accompanied by the presence of circulating antibodies specific to the CAP-1002, death due to ventricular tachycardia or ventricular fibrillation, sudden unexpected death, or a major adverse cardiac event (MACE) one month post-infusion as compared to the placebo group
- Primary Efficacy Endpoint: relative change in MRI assessment of infarct size from baseline to 12 months between the CAP-1002 and placebo groups
    - MRI performed at investigative imaging sites; central Core Lab assessments
    - Require ≥ 15% infarct scar size at baseline

Subject population: ischemic left ventricular dysfunction and a previous MI

Key inclusion criteria:

- History of MI within the prior 12 months due to coronary artery event and evidenced by typical ischemic symptoms
- Stent placement in the coronary artery supplying the infarcted territory
- At least one historical assessment of left ventricular ejection function (LVEF) ≤45%
- Left ventricular infarct size of ≥ 15% of left ventricular mass as determined by screening MRI
- No further revascularization clinically indicated at the time the subject is assessed for participation in ALLSTAR

Key exclusion criteria:

- Subjects with a history of coronary artery bypass surgery, and a graft (arterial or saphenous vein graft) attached to coronary artery to be infused
- Diagnosed or suspected myocarditis
- History of cardiac tumor, or cardiac tumor demonstrated on screening MRI
- History of previous stem cell therapy
- History of radiation treatment to the central or left side of thorax
- Participation in an on-going protocol studying an experimental drug or device, or participation in an interventional clinical trial within the last 30 days
- Uncontrolled diabetes (HbA1c>9%)
- Abnormal liver function (SGPT > 3 times the upper reference range) and/or abnormal hematology (hematocrit < 25%, WBC < 3000 µl, platelets < 100,000 µl) studies without a reversible, identifiable cause
- New York Heart Association (NYHA) Class IV congestive heart failure
- Evidence of tumor on screening chest/abdominal/pelvic (body) CT scan

ClinicalTrials.gov: NCT01458405