ARRY-371797, a p38 MAP Kinase Inhibitor for LMNA-related Genetic (Familial) Dilated Cardiomyopathy

ARRY-797-231 (http://clinicaltrials.gov/ct2/show/NCT02057341)
Array BioPharma Inc., Boulder, CO

Key Inclusion Criteria:
- Patients with ischemic dilated cardiomyopathy and stable New York Heart Association (NYHA) Class II - IIIa congestive heart failure (CHF).
- Stable, guidelines-based medical and device therapy, without any CHF hospitalizations or change in heart failure drug dose with ≥ 50% reduction in dose or ≥ 100% increase in dose in the past 3 months.
- Left ventricular (LV) and diastolic diameter by trans-thoracic echocardiography of > 3.3 cm (for females) or 3.4 cm (for males) and/or LV ejection fraction ≤ 45%.
- Gene positive for a pathogenic mutation in the LMNA gene, as determined by a CLIA-certified clinical laboratory (mutations including but not limited to: splice-site, non-sense, deletion mutations, a mis-sense mutation in a highly conserved codon, a mis-sense mutation involving a major charge change, a mis-sense mutation previously associated with genetic dilated cardiomyopathy).
- Completed distance during six minute walk test of ≥ 100 m and ≤ 350 m within 3 weeks prior to first dose of study drug, and ≤ 100 m and ≥ 400 m on the day before and day of first dose of study drug.

Key Exclusion Criteria:
- Unstable clinical cardiac symptoms requiring unscheduled hospitalization within 60 days prior to study start.
- Clinically significant coronary artery disease, as per Investigator judgment.
- Currently receiving continuous intravenous (IV) inotropic infusion, or presence of a ventricular assist device, or history of prior heart transplantation.
- Any of the following within 60 days prior to study start: Myocardial infarction, cardiac surgical procedures, acute coronary syndrome, hemodynamically destabilizing cardiac arrhythmia, serious systemic infection with evidence of sepsis, any major surgical procedure requiring general anesthesia.
- Uncontrolled, hemodynamically significant primary valvular disease, initiation of cardiac resynchronization therapy within 180 days prior to study start.
- Likelihood, in the Investigator's opinion, of undergoing cardiac transplantation, left ventricular assist device or other device implantation, or other cardiac surgery within the next 6 months; or of requiring continuous IV inotropic treatment, or referral for hospice or end-of-life treatment.
- Active malignancy (except surgically-curative basal cell carcinoma, squamous cell carcinoma, or cervical carcinoma).
- Participation in any other investigational study of drugs or devices within 30 days prior to study start.
- Additional criteria exist.

How to Become a Study Center
Sponsor: Array BioPharma Inc
Array BioPharma Clinical Trial Cell Center 303-381-6604
Additional Contact: Robert T. Hopkins, MS
Phone: 303-867-5659; Mobile: 303-330-7264
Fax: 303-867-5659; Mobile: 303-330-7264
e-mail: roberthopkins@arraybiopharma.com

References