



PRESS RELEASE

DalCor Announces Opening of International Trial Sites for Its Dal-GenE Phase 3 Cardiovascular Outcomes Trial

Sites open in Europe and New Zealand

Enrollment on schedule in trial of dalcetrapib in genetically distinct patients with acute coronary syndrome (ACS)

Recently published data showing genotype-dependent effects on cholesterol efflux supports the rationale for the Phase 3 trial

Trial steering committee meeting at 2016 ESC Congress

LONDON, August 23, 2016 – DalCor Pharmaceuticals today announced the opening of multiple international clinical trial sites in New Zealand and Europe for its Phase 3 dal-GenE clinical trial, a cardiovascular outcomes study of dalcetrapib in patients with acute coronary syndrome (ACS) and the AA genotype in the ADCY9 gene. DalCor will also be assembling the dal-GenE study's steering committee at the European Society Cardiology's ESC Congress taking place in Rome on Aug. 27-31, 2016. The study was initiated in April 2016 in North America and top-line data are expected in 2020.

The dal-GenE study will enroll a total of 5000 patients across 1000 centers in 33 countries including the U.S., Canada, New Zealand, the United Kingdom, France, Spain, Sweden, Finland, Belgium, Netherlands, Switzerland, Austria, Slovenia, Slovakia, Bulgaria, Israel and others. These centers will be activated and begin enrolling patients throughout 2016.

DalCor Pharmaceuticals and The Montreal Heart Institute have also [recently announced](#) the publication in *Circulation Cardiovascular Genetics* of data demonstrating dalcetrapib's AA genotype-dependent beneficial effects on inflammation marker C-reactive protein as well as cholesterol efflux in patients with ACS.

Quotes

Donald Black, M.D., FACC, chief medical officer of DalCor, said "Based on the multiple, consistent results of the dal-Outcomes and dal-Plaque 2 genetic analyses, we are optimistic that dalcetrapib will reduce the risk of cardiovascular events in patients with the AA genotype in the dal-GenE Phase 3 study. Opening these additional clinical sites is an important step in ensuring that we complete this trial, and we are confident that we will be in a position to share top-line data in 2020."

Harvey D. White, M.D., director of coronary care and cardiovascular research at the Green Lane Cardiovascular Service, Auckland City Hospital, New Zealand and a study investigator, said "We look forward to participating in this first-of-its kind Phase 3 clinical trial. We believe this study represents significant progress in our ability to employ precision medicine to improve outcomes in patients with high risk

cardiovascular disease. The AA genotype is as prevalent in New Zealand as it is in the U.S. and Europe so we expect to support the trial with strong enrollment from our institution.”

About the dal-GenE Clinical Trial

The double-blind, randomized, placebo-controlled, multicenter Phase 3 clinical trial will enroll 5,000 patients recently hospitalized with ACS and who express the AA genotype at variant rs1967309 in the ADCY9 gene, determined by an investigational companion diagnostic test developed by Roche Molecular Systems (RMS). The primary endpoint of the study is the time to first occurrence of any component of the composite of cardiovascular death, myocardial infarction (heart attack) and stroke. The trial will be conducted at 1,000 sites in 33 countries.

About Dalcetrapib

In 2012, investigators at the Montreal Heart Institute led by Professors Jean-Claude Tardif and Marie-Pierre Dubé found a significant association between the effects of dalcetrapib in altering CV events and the polymorphism at the rs1967309 location in the adenylate cyclase type 9 (ADCY9) gene. Patients with the AA genotype had a 39% reduction in CV events when treated with dalcetrapib compared to placebo, while GG patients had a 27% increase and AG patients had a neutral effect. This analysis was conducted in 5749 patients. Subsequent prospective analyses of other studies also demonstrated reduced atherosclerosis and improvement in confirming biomarkers in the AA population when treated with dalcetrapib.

DalCor secured a worldwide exclusive license for dalcetrapib together with rights to the genetic marker for use with dalcetrapib and all other CETP inhibitors. DalCor is sponsoring the dal-GenE study, which is planned to include 5,000 patients to prospectively confirm the results of the pharmacogenomic analysis in the dal-Outcomes study in a patient population with the AA genotype at the rs1967309 location in the ADCY9 gene.

About DalCor Pharmaceuticals

DalCor is developing precision treatments by genetically targeting patients that will derive clinical benefits. By integrating clinical and genetic insights, DalCor intends to deliver superior clinical cardiovascular outcomes. The company’s first development program, dalcetrapib, is intended to reduce cardiovascular events in a specific genetic subset of patients. DalCor Pharmaceuticals has offices in Montreal, San Mateo, Calif., Zug, Switzerland and Stockport, U.K. For more information, visit www.dalcorpharma.com

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