

## PRESS RELEASE

### **DalCor Achieves 50 percent Enrollment Milestone for Phase 3 Cardiovascular Trial** **-- *Dalcetrapib Studied in Genetically Targeted Patients with Acute Coronary Syndrome* --**

**LONDON and MONTREAL**, August 28, 2017 – DalCor Pharmaceuticals today announced it has exceeded its enrollment schedule with 50 percent of patients randomized in its Phase 3 “dal-GenE” clinical trial. More than 2,500 out of 5,000 expected patients with acute coronary syndrome (ACS) and the AA genotype at variant rs1967309 in the ADCY9 gene have entered into this cardiovascular outcomes study of dalcetrapib. In 2012, investigators at The Montreal Heart Institute observed a significant association of dalcetrapib in altering cardiovascular events (CV) for the AA genotype patients who had a 39 percent reduction in cardiovascular events when compared with placebo.

Approximately 1 in 5 people worldwide have the AA genotype at this single-nucleotide polymorphism (SNP), an important genetic marker that distinguishes which patients may be most likely to benefit from treatment by dalcetrapib and possibly similar drugs. DalCor is the first company to apply precision medicine to this field by studying dalcetrapib’s promising effects on atherosclerosis in a specific genetically-defined population.

Dal-GenE is an international clinical trial led by the Montreal Health Innovations Coordinating Center (MHICC), the lead Academic Research Organization (ARO) and Medpace, a leading Clinical Research Organization (CRO). The patients have been accrued from over 700 centers in 31 countries, including the U.S., covering six continents.

“We are encouraged by recent developments in the industry that show positive trial results with cholesteryl ester transfer protein (CETP) inhibitors. While statins have earned a pivotal place as the standard of care for reducing some of the adverse consequences of elevated cholesterol, we believe, to continue this progress and address continuing unmet medical needs, new therapies targeting non-LDL mechanism will be needed,” said Robert McNeil, CEO of DalCor. “There are now a number of studies that may indicate that dalcetrapib, through a ‘CETP’ mediated, non-LDL mechanism, may significantly reduce atherosclerosis in genetically defined patients who experienced an ACS event while treated with standard of care. The implications of these findings are that when employing genetically targeted medicines, such as dalcetrapib, to treat patients along with standard of care, they may experience marked clinical benefit compared to placebo. In this light, we are very excited to announce this enrollment milestone ahead of schedule.”

“The rapid enrollment of patients may enable us to report topline data ahead of our timeline projections,” Dr. McNeil added. “Importantly, we continue to target 2020 for dalcetrapib regulatory submissions.”

Donald M. Black, Chief Medical Officer said, “We believe the peaked interest in this trial highlights the need for a therapeutic alternative, which we anticipate providing with our targeted compound, dalcetrapib. Our precise focus on a genetically-defined group is a first in cardiovascular medicine, and supports an individualized approach to treatment for better outcomes. We are motivated to make dal-GenE the first major test that uses precision medicine to improve prognosis following a recent acute coronary syndrome. We are looking forward to learning more about the other CETP inhibitor studies recently completed.”

“Our clinical team has partnered with a strong network of investigators and other groups, such as ANMCO in Italy, Green Lane Coordinating Center in New Zealand and ECLA in Argentina and Chile, which enables us to significantly progress the study’s recruitment rate,” commented Dr. Therese Heinonen, the Global Project Director for the dal-GenE study speaking for the Montreal Health Innovations Coordinating Center (MHICC). “We expect to stay on this accelerated path toward meeting the worldwide demand for cardiovascular treatment with dalcetrapib.”

### **About Dalcetrapib**

Dalcetrapib is the first precision medicine in the cardiovascular space to have reached full-scale development with this Phase III clinical study. Over 17,000 patients have participated in dalcetrapib clinical trials to date.

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 5,749 patients. A prospective analysis of the dal-Plaque 2 study data has also demonstrated reduced atherosclerosis in the AA population when treated with dalcetrapib, but an increase in atherosclerosis in the GG population.

### **About the dal-GenE Study**

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 800 sites in 32 countries.

## **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 secured a worldwide exclusive license for dalcetrapib together with rights to the genetic marker for use with dalcetrapib and 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.

DalCor Pharmaceuticals has offices in Montreal, San Mateo, Calif., Zug, Switzerland and Stockport, U.K. For more information, visit [www.dalcorpharma.com](http://www.dalcorpharma.com)

## **About the Montreal Heart Institute**

Founded in 1954 by Dr. Paul David, the Montreal Heart Institute constantly aims for the highest standards of excellence in the cardiovascular field through its leadership in clinical and basic research, ultra-specialized care, professional training and prevention. It is part of the broad network of health excellence made up of Université de Montréal and its affiliated institutions. The Montreal Heart Institute ranks as the No. 1 research hospital in Canada for research intensity and research funds per researcher, according to Research Infosource. For more information, please visit [www.icm-mhi.org](http://www.icm-mhi.org)

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