PRESS RELEASE

DalCor Randomizes First Patient in the DalGenE Phase 3 Cardiovascular Outcomes Trial

--- Montreal Heart Institute Leads Worldwide Study ---

-- Dalcetrapib to be Studied in Genetically Distinct Patients with Acute Coronary Syndrome (ACS) --

- Global Study to be Conducted at 1,000 Sites in 33 Countries -

LONDON and MONTREAL, April 26, 2016 – DalCor Pharmaceuticals today announced it has randomized the first patient in the 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. The worldwide clinical trial will be led by the Montreal Heart Institute.

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.

Researchers at the Montreal Heart Institute (MHI), who will be leading the dal-GenE study, discovered the importance of the AA genotype in determining patients’ clinical response to treatment with dalcetrapib. MHI’s Biobank was also used in this pharmacogenomic research. Approximately 20 percent of the general population harbor the AA genotype.

Quotes

Robert McNeil, Ph.D., chief executive officer of DalCor, said, “We believe that targeting a genetically specific patient population with dalcetrapib has the potential to dramatically reduce cardiovascular risk in this select patient population. Success would represent a major breakthrough in an important therapeutic area that has seen a tremendous amount of interest. This trial represents a major step forward in cardiovascular medicine, opening new doors and creating therapeutic options for patients of specific genetic composition suffering from heart disease and who can benefit from the compound. We expect to complete the trial in the first half of 2020.”
André Desmarais, O.C., O.Q., deputy chairman, president and co-chief executive officer of Power Corporation, said, “I am extremely proud to have contributed to this advancement through the financing of the MHI BioBank and my involvement with DalCor. This is a perfect example of how making impact investments can have actual social effects. Individual success and collective welfare should be seen as two sides of the same coin, in the end creating value for all. I believe that the Montreal Heart Institute is underway to changing the lives of millions of people and further positioning itself globally in the world of science, which will continue to attract talent and investors in Montreal. I look forward to seeing the results of the trial.”

Jean-Claude Tardif, C.M., M.D., director of the Research Center at the Montreal Heart Institute and professor of medicine at the Université de Montréal, said, “We are thrilled to initiate this important clinical trial and prove the observation that patients with a specific genetic profile will respond favorably to dalcetrapib. This is a major step forward in our quest for precision cardiovascular medicine against atherosclerosis, the leading cause of mortality in the world.”

Donald Black, M.D., chief medical officer of DalCor, said, “We have established a strong network of investigators who are eager to assess a therapeutic mechanism that is distinct from lowering LDL-cholesterol. With the dal-GenE trial, we are expecting to demonstrate a very significant reduction in heart attacks, strokes and cardiovascular deaths with the addition of dalcetrapib to the standard of care including statins in patients with ACS.”

Didier Leconte, MBA, ASC, senior director, life sciences investments at Fonds de solidarité FTQ, said, “Our direct and indirect investments in DalCor are evidence of our strong support for the work they and the team at the Montreal Heart Institute are doing. We believe deeply in both teams’ ability to develop this treatment with the potential to help so many people who are at risk of heart attacks and strokes because of cardiovascular disease.”

About Dalcetrapib

Dalcetrapib is one of four CETP inhibitors to have reached full-scale development. Over 17,000 patients have participated in dalcetrapib clinical trials. A large, double blind cardiovascular (CV) study, dal-Outcomes, randomized over 15,000 patients already taking statins. The drug was well tolerated but the study results were globally neutral – there was no significant reduction in CV events in the dalcetrapib group.

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. Additional analyses of other studies also demonstrated reduced atherosclerosis 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 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

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

About the Fonds de solidarité FTQ

The Fonds de solidarité FTQ helps drive our economy. With net assets of $11.2 billion as at November 30, 2015, the Fonds is a development capital fund that channels the savings of Quebecers into investments in all sectors of the economy to help create and maintain jobs and further Québec’s development. The Fonds is a partner, either directly or through its network members, in more than 2,550 companies. With more than 600,000 shareholder-savers, the Fonds helps create, maintain and protect more than 176,000 jobs. For more information, visit www.fondsftq.com.

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