

# Potential new treatment to reduce the burden of atherosclerosis in acute coronary syndrome patients

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The Montreal Heart Institute today announced the start of the Phase 2 CHI-SQUARE (Can HDL Infusions Significantly QUICKen Atherosclerosis REgression?) study of CER-001 in patients with acute coronary syndrome (ACS), in collaboration with Cerenis Therapeutics, a biopharmaceutical company developing novel high-density lipoprotein (HDL) therapies to treat cardiovascular and metabolic diseases.

CER-001 is an innovative complex of recombinant human ApoA-I, the major structural protein of HDL, and phospholipids. It has been designed to mimic the structure and function of natural, nascent HDL, also known as pre-beta HDL, which is believed to be protective against atherosclerosis. It is hoped that CER-001 will further reduce [cardiovascular events](#) in high-risk patients by promoting removal of cholesterol from the vessel wall.

The double-blind, randomized, placebo-controlled, safety and efficacy study will assess the ability of CER-001 to regress coronary atherosclerotic plaque as measured by intravascular ultrasound (IVUS). The study will include over 500 patients at fifty centers in the US, Canada and Europe, and will evaluate three different dose levels given in six weekly intravenous infusions.

The study is being done in collaboration with the Global

Atherothrombotic Investigative Network (GAIN). Dr. Jean-Claude Tardif, Director of the Research Centre at the Montreal Heart Institute, is serving as the principal investigator. "We are excited to be conducting the CHI-SQUARE study, which aims to show benefits of CER-001 on atherosclerotic plaque following a short course of therapy." said Dr. Tardif. "This is the largest IVUS study conducted with a pre-beta HDL mimetic, and represents a potential new treatment paradigm to reduce the burden of atherosclerosis."

Pre-beta HDL is believed to protect against cardiovascular disease by removing cholesterol and other lipids from tissues including the arterial wall and transporting them to the liver for elimination. The aim for the clinical use of a recombinant ApoA-I HDL mimetic is to stimulate cholesterol removal in a process known as reverse lipid transport.

"Following the excellent safety and tolerability Phase I results with CER-001, this trial will evaluate the efficacy in ACS patients," said Jean-Louis Dasseux, CEO of Cerenis. "The potential of HDL therapy is well recognized and CER-001, as a first in class pre-beta HDL mimetic, could have great therapeutic value to patients with ACS."

Provided by Montreal Heart Institute

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