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Cardiol Therapeutics Inc

OAKVILLE, ONTARIO, CANADA, October 18, 2021 /EINPresswire.com/ -- Cardiol Therapeutics Inc. (NASDAQ: CRDL) (TSX: CRDL) ("Cardiol" or the "Company"), a clinical-stage biotechnology company focused on developing innovative anti-inflammatory therapies for the treatment of cardiovascular disease (CVD), announced today that it is expanding its LANCER trial to include several hospital centers in Brazil, Mexico, and Canada. LANCER is a Phase II/III randomized, double-blind, placebo-controlled trial designed to assess the efficacy and safety of CardiolRx™ in preventing cardiovascular complications in hospitalized patients with a confirmed diagnosis of COVID-19, and who have pre-existing, or significant risk factors for, cardiovascular disease (CVD).

The LANCER trial is currently enrolling patients at hospital centers in the United States under an Investigational New Drug (IND) application cleared by the U.S. Food and Drug Administration (FDA). Cardiol has now received requisite government approvals from health regulators in Brazil, Mexico, and Canada to initiate several additional hospital centers in these countries. Clinical site activation is underway in Brazil and Mexico and the first hospital centers are initiating patient enrollment. Clinical site selection is also in progress in Canada.

"COVID-19 remains an international crisis and there remains an urgent need to develop new therapeutics to address the immune-mediated inflammation that results from the virus, particularly in high-risk patients with cardiovascular disease," stated Dr. Guillermo Torre-Amione, Chairman of Cardiol Therapeutics. "With the expansion of the LANCER trial to include prominent clinical research centers in Brazil, Mexico, and Canada, we are now positioned to accelerate patient recruitment into the trial and expedite the path towards our goal of determining the cardioprotective properties of CardiolRx in COVID patients with pre-existing, or significant risk factors for, cardiovascular disease."

The composite primary efficacy endpoint of the LANCER trial is the difference between the active and placebo groups in the percentage of patients who develop, during the first 28 days following randomization and first dose of study medication, one or more of several common outcomes in this high-risk patient population. These include all-cause mortality, requirement for ICU admission and/or ventilatory support, as well as cardiovascular complications, including the development of heart failure, acute myocardial infarction, myocarditis, stroke, or new sustained or symptomatic arrhythmia.

Patients with COVID-19 primarily present with respiratory symptoms which can progress to bilateral pneumonia and serious pulmonary complications. It is now recognized that the impact of COVID-19 is not limited to the pulmonary system. Individuals with pre-existing CVD or who have risk factors for CVD (such as diabetes, hypertension, obesity, abnormal serum lipids, or age greater than 64) are at significantly greater risk of developing serious disease from COVID-19 and experience greater morbidity. Moreover, such COVID-19 patients are at significant risk of developing cardiovascular complications (such as acute myocardial infarction, cardiac arrhythmias, myocarditis, stroke, and heart failure) during the course of their illness, which are frequently fatal. A therapeutic strategy to prevent or limit the number or severity of both pulmonary and cardiovascular complications is likely to considerably improve outcomes from this disease.

The LANCER trial was designed and is being overseen by an independent Steering Committee, consisting of international thought leaders in inflammatory heart disease. In addition to investigating the pulmonary and cardioprotective properties of CardiolRx in high-risk COVID-19 patients, the trial is expected to generate invaluable clinical data with respect to the therapeutic potential of CardiolRx in the treatment of other inflammatory cardiac disorders, including acute myocarditis and heart failure.

About Cardiol Therapeutics

Cardiol Therapeutics Inc. (NASDAQ: CRDL) (TSX: CRDL) is a clinical-stage biotechnology company focused on the research and clinical development of innovative anti-inflammatory therapies for the treatment of cardiovascular disease (“CVD”). The Company’s lead product, CardiolRx™, is a pharmaceutically produced oral cannabidiol formulation that is being investigated in a Phase II/III outcomes study (the LANCER trial). The LANCER trial is designed to evaluate the efficacy and safety of CardiolRx as a cardioprotective therapy to reduce mortality and major cardiovascular events in patients hospitalized with COVID-19 who have a prior history of, or risk factors for, CVD, and to investigate the influence CardiolRx has on key markers of inflammatory heart disease.

Cardiol has also received clearance from the FDA for its investigational new drug (“IND”) application for a Phase II international trial that will investigate the anti-inflammatory and anti-fibrotic properties of CardiolRx in patients with acute myocarditis, which remains a leading cause of sudden cardiac death in people under 35 years of age. In addition, Cardiol is developing a subcutaneous formulation of CardiolRx and other anti-inflammatory therapies for the treatment

of chronic heart failure – a leading cause of death and hospitalization in North America, with associated annual healthcare costs in the U.S. alone exceeding $30 billion.

For more information about Cardiol Therapeutics, please visit cardiolrx.com.

Cautionary statement regarding forward-looking information:

This news release contains "forward-looking information" within the meaning of applicable securities laws. All statements, other than statements of historical fact, that address activities, events, or developments that Cardiol believes, expects, or anticipates will, may, could, or might occur in the future are "forward-looking information". Forward looking information contained herein may include, but is not limited to, statements relating to the expansion of the LANCER trial to include several additional clinical research centers in Brazil, Mexico, and Canada, enabling the Company to accelerate patient recruitment into the trial, and the Company's focus on developing innovative anti-inflammatory therapies for the treatment of CVD. Forward-looking information contained herein reflects the current expectations or beliefs of Cardiol based on information currently available to it and is based on certain assumptions, and is subject to a variety of known and unknown risks and uncertainties and other factors that could cause the actual events or results to differ materially from any future results, performance, or achievements expressed or implied by the forward-looking information, and are not (and should not be considered to be) guarantees of future performance. These risks and uncertainties and other factors include the risks and uncertainties referred to in the Company's Annual Information Form dated March 31, 2021, as well as the risks and uncertainties associated with product commercialization and clinical studies. These assumptions, risks, uncertainties, and other factors should be considered carefully, and investors should not place undue reliance on the forward-looking information. Any forward-looking information speaks only as of the date on which it is made and, except as may be required by applicable securities laws, Cardiol disclaims any intent or obligation to update or revise such forward-looking information, whether as a result of new information, future events, or results, or otherwise.

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