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Cardiol Therapeutics Receives Health Canada Approval for Phase II Clinical Trial of CardiolRx™ for Acute Myocarditis

Oakville, ON – October 25, 2021 – 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, is pleased to announce that it has received approval from Health Canada to proceed with the Company's Phase II, multi-center, double-blind, randomized, placebo-controlled trial designed to study the safety and tolerability of CardiolRx™ as well as its impact on myocardial recovery in patients presenting with acute myocarditis. The approval follows the U.S. Food and Drug Administration (FDA) providing clearance to proceed with the Company's Investigational New Drug (IND) application to commence this trial, as announced by the Company on August 24th, 2021.

Myocarditis is an acute inflammatory condition of the myocardium, characterized by inflammation of the heart muscle, which may result in chest pain, impaired cardiac function, atrial and ventricular arrhythmias, and conduction disturbances. Although the symptoms are often mild, myocarditis remains an important cause of acute and fulminant heart failure and is a leading cause of sudden cardiac death in people less than 35 years old. In addition, some patients proceed to develop chronic dilated cardiomyopathy which continues to be the leading indication for cardiac transplantation. Although viral causes of myocarditis are the most common, myocarditis can result from a broad range of infections and can be caused by certain drugs, including chemo-therapeutic agents used to treat several common cancers. Myocarditis has also been described as a complication of COVID-19 and, more recently, has been reported as a rare complication associated with certain vaccines for COVID-19.

Cardiol's acute myocarditis study is expected to enroll 100 patients at clinical centers in the United States, Canada, and Europe. The primary endpoints of the trial, which will be evaluated after 12 weeks of double-blind therapy, consist of the following cardiac magnetic resonance measures: left ventricular function (ejection fraction and longitudinal strain) and myocardial edema (extra-cellular volume), each of which has been shown to predict long-term prognosis of patients with acute myocarditis.

The study has been designed by an independent steering committee comprising distinguished thought leaders in heart failure and myocarditis from international centers of excellence, including: the Cleveland Clinic, the Mayo Clinic, the Houston Methodist DeBakey Heart and Vascular Center, the University of Ottawa Heart Institute, McGill University Health Centre, University of Pittsburgh Medical Center, Charité Hospital Berlin, and the University of South Florida Health Morsani College of Medicine/Tampa General Hospital Heart and Vascular Institute.

Given the risk of significant heart failure associated with acute myocarditis, current intervention includes drugs commonly administered for heart failure. However, no generally accepted treatment exists for acute myocarditis. Some patients respond to immunosuppressive therapy in combination with steroids, or immune-modulation therapy using immune globulin. Nevertheless, the evidence for these therapies is insufficient to support their adoption as the standard of care and they carry high risk for significant adverse effects.

Based on the large body of experimental evidence of the anti-inflammatory and cardioprotective properties of cannabidiol in models of cardiovascular disease, the Company believes there is a significant opportunity to develop an important new therapy for acute myocarditis that would be eligible for designation as an orphan drug in the United States. The U.S. Orphan Drug Designation program was created to offer companies significant incentives, including accelerated regulatory review and approval, to develop treatments for diseases that affect fewer than 200,000 people in the U.S. The program was successfully utilized to support the first FDA approval of cannabidiol for the treatment of rare child-onset epilepsy syndromes. Cardiol believes there is a similar opportunity to develop its CardiolRx formulation as an orphan drug for the treatment of acute myocarditis, for which there is currently no accepted standard of care.

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 a significant opportunity to develop an important new therapy for acute myocarditis that would be eligible for designation as an orphan drug, 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, including the

assumption that, subject to positive outcomes of its clinical trials, the Company's CardiolRx™ formulation is eligible for designation as an orphan drug, and is also 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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