Cardiol Therapeutics Announces it has Exceeded 50% Enrollment in its Phase II ARCHER Trial in Acute Myocarditis

written by Raj Shah | January 9, 2024

January 9, 2024 (Source) – Cardiol Therapeutics Inc. **(NASDAQ: CRDL) (TSX: CRDL)** ("**Cardiol**" or the "**Company**"), a clinical-stage life sciences company focused on the research and clinical development of anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease, is pleased to announce that it has exceeded 50% patient enrollment for ARCHER, the Company's Phase II, multi-center, international, double-blind, randomized, placebo-controlled trial investigating the safety, tolerability, and impact of CardiolRx™ on myocardial recovery in patients presenting with acute myocarditis.

"Achieving this milestone reflects the commitment and interest demonstrated by our clinical collaborators and participating patients, and we thank them for their contribution to the progress being made in this important clinical trial," said David Elsley, Cardiol Therapeutics' President and Chief Executive Officer. "Acute myocarditis is an inflammatory heart disease that impairs heart function, is associated with symptoms that can seem like a heart attack, is an important cause of acute and fulminant heart failure and is a leading cause of sudden cardiac death in people under 35 years of age. Results from the ARCHER trial will assist in further understanding the therapeutic potential of CardiolRx™ and will complement the important clinical data from our ongoing MAvERIC-Pilot Phase II study in patients presenting with recurrent pericarditis."

The ARCHER trial has been designed in collaboration with an independent steering committee comprising distinguished thought leaders in heart failure and myocarditis from international centers of excellence. The trial is expected to enroll 100 patients at pre-eminent cardiovascular research centers in North America, France, Brazil, and Israel. The primary outcome measures of the trial, which will be evaluated following 12 weeks of double-blind therapy, consist of two cardiac magnetic resonance imaging measures: left ventricular function (longitudinal strain) and myocardial edema/fibrosis (extra-cellular volume), each of which has been shown to predict long-term prognosis of patients with acute myocarditis. Additional efficacy outcome measurements include survival, freedom from major cardiovascular events, resolution of clinical symptoms, and change in biomarkers associated with cardiac function and inflammation.

Myocarditis is an acute inflammatory condition of the heart muscle (myocardium) characterized by chest pain, shortness of breath at rest or during activity, fatigue, rapid or irregular heartbeat (arrhythmias), and light-headedness or feeling one might faint. Although the symptoms are often mild, many patients will also report flu-like symptoms such as headache, body aches, joint pain, fever or sore throat prior to disease onset. Viral infection is the most common cause of myocarditis; however, this disease can also result from bacterial infection and commonly used drugs and mRNA vaccines, as well as therapies used to treat several common cancers, including chemo-therapeutic agents and immune checkpoint inhibitors.

There are no FDA-approved therapies for acute myocarditis. Patients hospitalized with the condition experience an average 7-day length of stay and a 4 – 6% risk of in-hospital mortality, with average hospital charge per stay estimated at $110,000 in the United States. Cardiol believes there is a significant

opportunity to develop an important new therapy for acute myocarditis that would also be eligible for designation as an orphan drug in the United States and the European Union. Orphan drug designation programs were established to provide life sciences companies with incentives to develop new therapies for rare diseases. These incentives include periods of prolonged marketing exclusivity and exemptions from certain fees. Products with orphan drug designation also frequently qualify for accelerated regulatory review.

About Cardiol Therapeutics

Cardiol Therapeutics Inc. **(NASDAQ: CRDL) (TSX: CRDL)** is a clinical-stage life sciences company focused on the research and clinical development of anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease. The Company's lead small molecule drug candidate, CardiolRx™ (cannabidiol) oral solution, is pharmaceutically manufactured and in clinical development for use in the treatment of heart disease. It is recognized that cannabidiol inhibits activation of the inflammasome pathway, an intracellular process known to play an important role in the development and progression of inflammation and fibrosis associated with myocarditis, pericarditis, and heart failure.

Cardiol has received Investigational New Drug Application authorization from the United States Food and Drug Administration to conduct clinical studies to evaluate the efficacy and safety of CardiolRx™ in two diseases affecting the heart: (i) a Phase II multi-center open-label pilot study in recurrent pericarditis (the MAvERIC-Pilot study; NCT05494788), an inflammatory disease of the pericardium which is associated with symptoms including debilitating chest pain, shortness of breath, and fatigue, and results in physical limitations, reduced quality of life, emergency department visits, and

hospitalizations; and (ii) a Phase II multi-national, randomized, double-blind, placebo-controlled trial (the ARCHER trial; NCT05180240) in acute myocarditis, an important cause of acute and fulminant heart failure in young adults and a leading cause of sudden cardiac death in people less than 35 years of age.

Cardiol is also developing a novel subcutaneously administered drug formulation of cannabidiol intended for use in heart failure – a leading cause of death and hospitalization in the developed world, with associated healthcare costs in the United States exceeding $30 billion annually.

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 Company's focus on developing anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease, the molecular targets and mechanism of action of the Company's product candidates, the Company's intended clinical study and trial activities and timelines associated with such activities, the Company's plan to advance the development of a novel subcutaneous formulation of CardiolRx™ for use in heart failure, and details as to how the results of the ARCHER Trial and MAvERIC Pilot Study will be used going forward. 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 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 Report on Form 20-F dated March 28, 2023, 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, and such information may not be appropriate for other purposes. Any forward-looking information speaks only as of the date of this press release 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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