Cardiol Therapeutics Announces Topline Results from the Phase II ARCHER Trial of CardiolRx(TM) in Acute Myocarditis

written by Raj Shah | August 6, 2025

- *Change in the primary endpoint of left ventricular (LV) extracellular volume (ECV) showed a notable improvement (p = 0.0538) favouring CardiolRx™ over placebo.*
- *Reduction in ECV was associated with improvements across multiple pre-specified cardiac magnetic resonance imaging (CMR) endpoints, including a significant reduction in LV mass.*
- *The ARCHER trial results provide compelling clinical proof of concept for CardiolRx™ and strongly support advancing the clinical development of CardiolRx™ and CRD-38 in cardiomyopathies, heart failure, and myocarditis.*
- *The ARCHER results have been submitted for presentation at an upcoming scientific meeting and will be submitted for publication.*

August 6, 2025 (Source) – Cardiol Therapeutics Inc. **(NASDAQ: CRDL) (TSX: CRDL)** (“**Cardiol**” or the “**Company**“), a clinical-stage life sciences company focused on developing anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease, today announced topline results from ARCHER, the Company’s Phase II clinical trial in patients with acute myocarditis. In the two primary endpoints—extracellular volume (“ECV”) and global

longitudinal strain ("GLS")—CardiolRx™ showed a notable improvement in ECV (p = 0.0538) compared to placebo following 12 weeks of double-blind therapy, with no significant difference observed in GLS in a population that had preserved left ventricular ("LV") function at baseline. The reduction in ECV was associated with improvements over placebo in multiple pre-specified cardiac magnetic resonance imaging ("CMR") endpoints, including a significant reduction in LV mass. The ARCHER trial results provide compelling clinical proof of concept for CardiolRx™ and strongly support advancing the clinical development of CardiolRx™ and CRD-38 in cardiomyopathies, heart failure, and myocarditis. Consistent with findings from Cardiol's Phase II MAvERIC trial in recurrent pericarditis, CardiolRx™ was shown to be safe and well tolerated. The ARCHER results have been submitted for presentation at an upcoming scientific meeting and will be submitted for publication.

"On behalf of the ARCHER Steering Committee, I would like to extend our sincere gratitude to the patients who participated in the study; to their families and caregivers for their invaluable support; and to the clinical trial site investigators and staff, members of the international Steering Committee, and the Data and Safety Monitoring Committee, whose exemplary efforts in patient recruitment, clinical care, trial execution, monitoring, and oversight were instrumental in achieving the compelling findings of the ARCHER trial," said Dr. Dennis M. McNamara, Professor of Medicine at the University of Pittsburgh, Director of the Center for Heart Failure Research at the University of Pittsburgh Medical Center, and Chair of the ARCHER Steering Committee. "I commend Cardiol for undertaking this important trial that investigated the biological effects of pharmaceutically manufactured cannabidiol in acute myocarditis. The results offer exciting new insights into the treatment of acute myocarditis and strongly support advancing the clinical

development of this novel therapeutic approach for inflammatory cardiac conditions, including myocarditis and heart failure. I look forward to collaborating with my colleagues on the Steering Committee as we prepare for the presentation and publication of the comprehensive ARCHER trial data."

Dr. Leslie T. Cooper, Jr., the Elizabeth C. Lane, Ph.D. and M. Nadine Zimmerman, Ph.D. Professor of Internal Medicine at the Mayo Clinic in Jacksonville, Florida, and Co-Chair of the Steering Committee for the ARCHER trial, added, "ARCHER was an important, well-designed, and well-executed clinical trial. The intriguing findings reinforce our original hypothesis that pharmaceutically manufactured cannabidiol can attenuate myocardial inflammation and edema. ARCHER's results provide sound rationale for advancing the clinical development of this novel therapy in conditions of the myocardium characterized by edema, fibrosis, and remodeling, including the growing challenge of immune checkpoint inhibitor-induced myocarditis which can be fatal."

"We are delighted with the ARCHER trial results," said David Elsley, President and Chief Executive Officer of Cardiol Therapeutics. "We initiated this ambitious study—focused on a potentially life-threatening cardiac disorder for which there is no established standard of care—to further investigate the therapeutic potential of CardiolRx in inflammatory heart disease. We are thrilled to observe improvements in multiple CMR measures associated with diagnosis, prognosis, and clinical outcomes. As we continue to advance our lead clinical program, the pivotal Phase III MAVERIC trial in recurrent pericarditis, we now look forward to integrating the ARCHER findings into our broader clinical development strategy and business development initiatives—supporting the continued advancement of CardiolRx and CRD-38 as potential treatments for inflammatory cardiac disorders."

ARCHER is a Phase II multi-national, randomized, double-blind, placebo-controlled trial investigating the safety, tolerability, and impact of CardiolRx™ on myocardial recovery in patients presenting with acute myocarditis. The design and rationale for ARCHER were published on June 27, 2024, in the journal *ESC Heart Failure*. The study enrolled 109 patients from leading cardiovascular research centers in the United States, France, Brazil, and Israel. The two primary outcome measures of the trial, which were evaluated following 12 weeks of double-blind therapy, consist of cardiac magnetic resonance imaging parameters: extra-cellular volume and global longitudinal strain, which assess myocardial function and tissue characteristics associated with fibrosis and inflammation.

Acute Myocarditis

Acute myocarditis is an 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 the feeling one might faint. The disease 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. Viral infection is the most common cause of myocarditis; however, it can also result from bacterial infection, 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 drug therapies for acute myocarditis. Patients hospitalized with the condition experience an average seven-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.

About Cardiol Therapeutics

Cardiol Therapeutics Inc. **(NASDAQ: CRDL) (TSX: CRDL)** is a clinical-stage life sciences company focused on developing 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 pericarditis, myocarditis, and heart failure.

Cardiol has received Investigational New Drug Application authorization from the United States Food and Drug Administration ("US FDA") to conduct clinical studies to evaluate the efficacy and safety of CardiolRx™ in two diseases affecting the heart: recurrent pericarditis and acute myocarditis. The MAVERIC Program in recurrent pericarditis, 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, comprises the completed Phase II MAvERIC-Pilot study (NCT05494788) and the ongoing Phase III MAVERIC trial (NCT06708299). The completed ARCHER trial (NCT05180240) is a Phase II study 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. The US FDA has granted Orphan Drug Designation to CardiolRx™ for the treatment of pericarditis, which includes recurrent pericarditis.

Cardiol is also developing CRD-38, a novel subcutaneously administered drug formulation 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 regarding the Company's focus on developing anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease, the Company's intended clinical studies and trial activities and timelines associated with such activities, including the Company's plan to complete the Phase III study in recurrent pericarditis with CardiolRx™, the Company's plan to advance the development of CRD-38, a novel subcutaneous formulation of cannabidiol intended for use in heart failure, the Company's presentation and publication of the comprehensive ARCHER trial data, and the Company's belief that results from the ARCHER trial provide compelling clinical proof of concept for CardiolRx™ and strongly support advancing the clinical development of CardiolRx™ and CRD-38 for the treatment of inflammatory cardiac disorders including cardiomyopathies, heart failure, and myocarditis. 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 Information Form filed with the Canadian securities administrators and U.S. Securities and Exchange Commission on March 31, 2025, available on SEDAR+ at sedarplus.ca and EDGAR at sec.gov, 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. Investors are cautioned not to rely on these forward-looking statements.

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