



Cardiol Therapeutics Completes Patient Enrollment in its Phase II MAVERIC-Pilot Study Investigating CardiolRx™ for Recurrent Pericarditis

Topline Results Expected in Q2 2024

This is a Designated News Release.

Toronto, ON – February 21, 2024 – 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, today announced completion of patient enrollment in its Phase II open-label pilot study (“MAVERIC-Pilot”) investigating the safety, tolerability, and efficacy of CardiolRx™ in patients with recurrent pericarditis. In addition, the Company announced that it expects to report topline results from MAVERIC-Pilot in Q2 2024.

“Having achieved full patient enrollment, we are now positioned to announce high-level MAVERIC-Pilot clinical trial data in the second quarter of this year. These results are expected to inform the design of a pivotal Phase III clinical trial in recurrent pericarditis to underpin the potential regulatory approval of CardiolRx™, which has recently been granted Orphan Drug Designation by the United States FDA,” said Andrew Hamer, Cardiol Therapeutics’ Chief Medical Officer and Head of Research & Development. “We thank our clinical collaborators and participating patients and families for their continued interest and commitment. Their support is contributing to our understanding of the therapeutic profile of CardiolRx™ in this debilitating inflammatory heart disease associated with symptoms that adversely affect quality of life and physical activity.”

MAVERIC-Pilot (NCT05494788) is a Phase II open-label pilot study investigating the tolerance, safety, and effect of CardiolRx™ administered to patients with recurrent pericarditis. The study has completed enrollment of the planned target of 25 patients in the United States, and subject to fulfilling eligibility criteria, any patient currently in the screening process who agrees to participate in the study will also be enrolled and included in the final cohort. In addition to standard safety assessments, MAVERIC-Pilot is designed to evaluate improvement in objective measures of this rare disease. The primary efficacy endpoint is the change, from baseline to 8 weeks, in patient-reported pericarditis pain using an 11-point numeric rating scale (“NRS”). The NRS is a validated clinical tool employed across multiple conditions with acute and chronic pain, including previous studies of recurrent pericarditis. Secondary endpoints include the NRS score after 26 weeks of treatment, and changes in circulating levels of C-reactive protein, a commonly used clinical marker of inflammation. Importantly, the study will also assess freedom from pericarditis recurrence.

Recurrent pericarditis refers to inflammation of the pericardium (the membrane or sac that surrounds the heart) that follows an initial episode (frequently resulting from a viral infection). Patients may have multiple recurrences. Symptoms include debilitating chest pain, shortness of breath, and fatigue, resulting in physical limitations, reduced quality of life, emergency department visits, and hospitalizations. Significant

accumulation of pericardial fluid and scarring can progress to life-threatening constriction of the heart. The only FDA-approved therapy for recurrent pericarditis, launched in 2021, is costly and is primarily used as a third-line intervention. On an annual basis, the number of patients in the United States having experienced at least one recurrence is estimated at 38,000. Approximately 60% of patients with multiple recurrences (>1) still suffer for longer than two years, and one third are still impacted at five years. Hospitalization due to recurrent pericarditis is often associated with a 6-8-day length of stay and cost per stay is estimated to range between \$20,000 and \$30,000 in the United States.

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 ("US FDA") 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. The US FDA has granted Orphan Drug Designation to CardiolRx™ for the treatment of pericarditis, which includes recurrent pericarditis.

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 studies and trial activities and timelines associated with such activities, including for primary efficacy endpoint and secondary endpoints, the Company's plan to advance the development of a novel subcutaneous formulation of CardiolRx™ for use in heart failure, and the Company's expectation to report topline results from MAVERIC-Pilot in Q2 2024 and that these results will inform the design of a pivotal Phase III clinical trial in recurrent pericarditis to underpin the potential regulatory approval of CardiolRx™. 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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