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# Cardiol Therapeutics Announces Formation of Data Safety Monitoring and Clinical Endpoint Committees for Phase II/III Outcomes Trial in High-Risk Patients Hospitalized with COVID-19

***Trial designed to investigate the cardioprotective properties of CardiolRx™ in patients hospitalized with COVID-19 who have a prior history of, or risk factors for, cardiovascular disease***

**Oakville, ON – January 21, 2021 – Cardiol Therapeutics Inc.** (**TSX: CRDL**)(**OTCQX: CRTPF**) ("**Cardiol**" or the "**Company**"), a clinical-stage biotechnology company focused on the research and clinical development of anti-inflammatory therapies for the treatment of cardiovascular disease, today announced the formation of the Data Safety Monitoring Committee ("DSMC") and the Clinical Endpoint Committee ("CEC") for the Company's Phase II/III trial in high-risk patients hospitalized with COVID-19 at clinical centers throughout the United States.

The DSMC comprises independent experts who will assess the patient safety data, and, if needed, critical efficacy endpoints of the trial. In order to do so, the DSMC may review unblinded study information (on a patient level or treatment group level) during the conduct of the trial. After each data review, the DSMC will advise the study Steering Committee with recommendations for protocol modifications, if concerns over safety have developed, or that the study should continue according to the protocol if no concerns are identified. The DSMC will also perform an interim analysis after 200 patients have completed the study, to determine if the study is likely to enroll enough patients to achieve statistical significance or if additional patients should be recruited.

The DSMC currently consists of three members:

- **Chair: Dr. Jean Lucien Rouleau** – Professor and Former Dean, University of Montreal and Cardiologist, Montreal Heart Institute. Dr. Rouleau has an international reputation in cardiovascular research, particularly in the field of both basic mechanisms and improving the clinical care of patients with heart failure. His publication list includes more than 475 articles and 7 book chapters.
- **Statistician: Dr. George Wells** – Professor, School of Epidemiology, Public Health and Preventive Medicine, University of Ottawa and Director, Cardiovascular Research Methods Centre, University of Ottawa Heart Institute. Dr. Wells has worked extensively with governments and non-government research organizations, as well as private pharmaceutical and biotechnology companies. He has been an Investigator in over 240

research projects with research funding exceeding $120 million. Dr. Wells is the author or co-author of over 400 published articles.

- **Dr. John Teerlink** – Professor of Medicine, University of California, San Francisco and Director of Heart Failure and the Echocardiographic Laboratory at the San Francisco Veterans Affairs Center. Dr. Teerlink is actively involved in many acute and chronic heart failure clinical trials, serving on endpoint, data safety monitoring, and steering committees for numerous international cardiovascular studies. He currently serves on the Acute Heart Failure Committee of the European Society of Cardiology Heart Failure Association and has served on the National Committee on Heart Failure and Transplantation of the American Heart Association. Dr. Teerlink was profiled in *The Lancet* as an internationally recognized leader in heart failure.

The CEC comprises clinical experts in cardiology and Intensive Care and has been established to ensure accurate and consistent assessment of the trial endpoints and/or serious adverse events. In order to ensure an unbiased endpoint assessment, members of the CEC are blinded to treatment assignment. The goal of the CEC is to standardize endpoints and optimize data quality.

The CEC currently consists of three members:

- **Chair: Dr. Brent Mitchell** – Professor of Cardiac Sciences and Former Director of the Libin Cardiovascular Institute, University of Calgary. After a Fellowship in Clinical Cardiology at Dalhousie University in Halifax, Dr. Mitchell undertook a Fellowship in clinical electrophysiology at Stanford University Medical Centre, California. Dr. Michell's clinical practice and research interests are in the area of cardiac electrophysiology, particularly in the diagnosis and management of tachyarrhythmias. Dr. Mitchell has published several sentinel papers in the diagnosis and management of serious cardiac arrhythmias.
- **Dr. Maria Rosa Costanzo** – Professor, Rush Medical College and Cardiologist, Advocate Health, Naperville, IL. Dr. Costanzo is Board Certified in Advanced Heart Failure and Cardiac Transplantation. Dr. Costanzo is currently the Medical Director of the Midwest Heart Specialists – Advocate Medical Group Heart Failure and Pulmonary Arterial Hypertension Programs, and Medical Director of the Edward Hospital Center for Advanced Heart Failure. Dr. Costanzo has published nearly 200 peer-reviewed manuscripts and is the author of numerous review papers, monographs and book chapters.
- **Dr. Courtney Bennett** – Cardiologist and Intensive Care Physician, Director of Quality Improvement in the Cardiac Intensive Care Unit, Mayo Clinic, Rochester, MN. Dr. Bennett is a board-certified cardiologist and board-eligible in critical care medicine. Her clinical interests include cardiac critical care and contrast echocardiography. Dr. Bennett is Mayo Quality Academy gold-certified and serves as the Director of Quality Improvement in the Cardiac Intensive Care Unit.

Cardiol's double-blind, placebo-controlled Phase II/III clinical trial is designed to investigate the efficacy and safety of CardiolRx™, a pharmaceutically produced extra strength cannabidiol formulation, in 422 hospitalized COVID-19 patients with a prior history of, or risk factors for, cardiovascular disease. This patient population is at significant risk of developing cardiovascular complications, which are frequently fatal, during their illness.

**About Cardiol Therapeutics**

Cardiol Therapeutics Inc. (**TSX: CRDL**)(**OTCQX: CRTPF**) is a clinical-stage biotechnology company focused on the research and clinical development of 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 currently entering a Phase II/III outcomes study in hospitalized patients testing positive for the COVID-19 virus. This potentially registrational trial is designed to evaluate the efficacy and safety of CardiolRx as a cardioprotective therapy to reduce mortality and major cardiovascular events in COVID-19 patients 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 is also planning to file an IND 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 the most common 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.

Cardiol recently commercialized Cortalex™ (cortalex.com) in the Canadian market. Cortalex is a pharmaceutically produced cannabidiol formulation, developed for patients who wish to avoid THC or for whom THC exposure is not recommended. For more information about Cardiol Therapeutics, please visit cardiolrx.com.

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***Cautionary statement regarding forward-looking information:***

*This news release contains "forward-looking information" within the meaning of applicable Canadian securities laws. All statements, other than statements of historical fact, that address activities, events, or developments that Cardiol Therapeutics Inc. ("Cardiol" or the "Company") 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 that our Phase II/III study is potentially a registrational trial and is expected to provide invaluable data with respect to the therapeutic potential of CardiolRx in the treatment of inflammatory heart disease, including heart failure, the Company's plans for a Phase II international trial of CardiolRx™ in acute myocarditis and to develop a subcutaneous formulation of CardiolRx and other anti-inflammatory therapies for the treatment of chronic heart failure. Forward-looking information contained herein reflects the current expectations or beliefs of Cardiol based on information currently available to it 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. These risks and uncertainties and other factors include the risks and uncertainties referred to in the Company's Annual Information Form dated March 30, 2020, including the risks and uncertainties associated with product commercialization and clinical studies, and uncertainties in predicting treatment outcomes. These 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. Although Cardiol believes that the expectations reflected in the forward-looking information are reasonable, they do involve certain assumptions, risks, and uncertainties and are not (and should not be considered to be) guarantees of future performance. It is important that each person reviewing this news release understands the significant risks attendant to the operations of Cardiol.*