

## Cardiol Therapeutics Announces Clinical Steering Committee for Phase 2 International Trial in Acute Myocarditis Using CardiolRx™ 100

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Cardiol Therapeutics Inc. (TSX: **CRDL**; OTCQX: **CRTPF**) (“**Cardiol**” or the “**Company**”), a leader in the production of pharmaceutical cannabidiol (CBD) products and in the development of innovative cannabidiol medicines for heart disease, is pleased to announce the formation of the Clinical Steering Committee (“CSC”) for a Phase 2 international trial in acute myocarditis using the Company’s CardiolRx™ 100 cannabidiol formulation.

The CSC, which comprises key opinion leaders in acute myocarditis from North America and Europe, recently met during the American Heart Association’s Scientific Sessions in Philadelphia held November 16<sup>th</sup> to 18<sup>th</sup>. The role of the CSC is to advise on the trial design, provide overall supervision of the trial, and ensure that it is being conducted in accordance with the principles of Good Clinical Practice. The CSC has oversight of the protocol, any protocol amendments, and provides advice to the investigators on all aspects of the trial.

Acute myocarditis is characterized by inflammation of the heart muscle (myocardium). The most common cause is viral infection of the heart tissue which is initially responsible for the inflammation. In a significant number of cases, perhaps due to an autoimmune process, the inflammation persists with ongoing myocardial damage and depressed heart function. Although the symptoms are often mild, myocarditis remains an important cause of acute and fulminant heart failure and is the most common 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. Symptoms include chest pain, fatigue, shortness of breath, and arrhythmias. Because of the progressive damage to heart cells, heart failure develops (defined as the inability of the heart to pump sufficient blood to meet the needs of the body). The study will use left ventricular ejection fraction (LVEF) as one measure of heart function.

CardiolRx™ 100 is Cardiol Therapeutics’ pure pharmaceutically (cGMP) produced high concentration cannabidiol formulation that is THC free (<10ppm). Based on the large body of experimental evidence of the anti-inflammatory and cardioprotective properties of cannabidiol in models of cardiovascular disease, Cardiol believes there is an opportunity to develop a potential breakthrough therapy for acute myocarditis that would be eligible for designation as an orphan drug. In the United States, an orphan drug designation is granted for pharmaceuticals being developed to treat medical conditions affecting fewer than 200,000 people. These conditions are referred to as orphan diseases. In the U.S. and the European Union, orphan drugs are eligible for accelerated marketing approvals and companies developing orphan drugs typically receive other incentives, including a prolonged period of market exclusivity that can extend over seven years, during which the drug developer has sole rights to market the drug.

“Cardiol has assembled eight highly distinguished thought leaders in cardiology from North America and Europe to oversee and guide our acute myocarditis trial that is being planned at world leading heart institutes, including the Cleveland Clinic, the Mayo Clinic, the Houston Methodist DeBakey Heart and Vascular Center, the University of Ottawa Heart Institute, and Charité University Medicine Berlin,” stated David Elsley, President and CEO of Cardiol Therapeutics. “The U.S. orphan drug program was successfully utilized to accelerate the first FDA approval of cannabidiol for the treatment of two pediatric epilepsy orphan diseases. We see a similar opportunity with our international trial in acute myocarditis to fast track the development of our CardiolRx formulation for a serious cardiovascular orphan disease for which there is currently no accepted standard of care.”

Members of Cardiol’s Acute Myocarditis CSC include:

**Dennis M. McNamara, MD (Chair)**

Dr. Dennis McNamara is a Professor of Medicine at the University of Pittsburgh. He is also the Director of the Heart Failure/Transplantation Program at the University of Pittsburgh Medical Center. Dr. McNamara received his undergraduate/graduate education at Yale University, New Haven, Connecticut, and Harvard Medical School, Boston, Massachusetts, respectively. He completed his internship, residency, and cardiology fellowship at Massachusetts General Hospital in Boston. McNamara’s current research interests include etiology and pathogenesis of dilated cardiomyopathies; inflammatory syndromes of cardiovascular disease; myocardial recovery in recent onset non-ischemic primary cardiomyopathy; etiology and management of peripartum cardiomyopathy; and genetic modulation of outcomes in cardiovascular disease.

**Leslie T. Cooper, Jr., MD (Co-Chair)**

Dr. Leslie T. Cooper, Jr., is a general cardiologist and the chair of the Mayo Clinic Enterprise Department of Cardiovascular Medicine, as well as chair of the Department of Cardiovascular Medicine at the Mayo Clinic in Florida. Dr. Cooper's clinical interests and research focus on clinical and translational studies of rare and undiagnosed cardiomyopathies, myocarditis, and inflammatory cardiac and vascular diseases, such as giant cell myocarditis, cardiac sarcoidosis, eosinophilic myocarditis, and Takayasu's arteritis. He has published over 130 original peer-reviewed papers, as well as contributing to and editing books on myocarditis. In addition to his clinical and research work, Dr. Cooper is a fellow of the American College of Cardiology, the American Heart Association, the European Society of Cardiology Heart Failure Association, the International Society for Heart and Lung Transplantation, and the Society for Vascular Medicine and Biology. He is also the founder and former president of the Myocarditis Foundation and continues to serve on its Board of Directors.

**Arvind Bhimaraj, MD**

Dr. Arvind Bhimaraj is a specialist in Heart Failure and Transplantation Cardiology and is Assistant Professor of Cardiology, Institute for Academic Medicine, at Houston Methodist and at Weill Cornell Medical College, NYC. He has been Co-Director of the Heart Failure Research Laboratory at Houston Methodist since 2016. His area of focus is anti-fibrotic mechanisms and how to promote recovery of a damaged heart. Dr. Bhimaraj was a Heart Failure Fellow at the Cleveland Clinic from July 2010 to September 2011. Dr. Bhimaraj also specializes in Interventional Cardiology, is board certified in Cardiovascular Disease, and the author of numerous cardiovascular publications.

**Matthias Friedrich, MD**

Dr. Matthias Friedrich is Full Professor with the Departments of Medicine and Diagnostic Radiology at the McGill University in Montreal and Chief, Cardiovascular Imaging at the McGill University Health Centre. He is also Professor of Medicine at Heidelberg University in Germany. Dr. Friedrich earned his MD at the Friedrich-Alexander-University Erlangen-Nürnberg, Germany. He completed his training as an internist and cardiologist at the Charité University Medicine Center, Humboldt University in Berlin. Dr. Friedrich founded one of the first large Cardiovascular Magnetic Resonance centres in Germany at the Charité University Hospital in Berlin. After his move to Canada, from 2004 to 2011, he was Director of the Stephenson Cardiovascular MR Centre at the Libin Cardiovascular Institute of Alberta and Professor of Medicine within the Departments of Cardiac Sciences and Radiology at the University of Calgary, Canada. From 2011 to 2015, he directed the Philippa and Marvin Carsley Cardiovascular MR Centre at the Montreal Heart Institute and was Michel and Renata Hornstein Chair in Cardiac Imaging at the Université de Montréal.

**Peter Liu, MD**

Dr. Peter Liu is the Chief Scientific Officer and Vice President, Research, of the University of Ottawa Heart Institute, and Professor of Medicine and Physiology at the University of Toronto and University of Ottawa. He was the former Scientific Director of the Institute of Circulatory and Respiratory Health at the Canadian Institutes of Health Research, the major federal funding agency for health research in Canada. Prior to that role, he was the inaugural Director of the Heart & Stroke/Lewar Centre of Excellence in Cardiovascular Research at University of Toronto. Dr. Liu received his MD from the University of Toronto, and postgraduate training at Harvard University. His laboratory investigates the causes and treatments of heart failure, the role of inflammation, and the identification of novel biomarkers and interventions in cardiovascular disease. Dr. Liu has published over 300 peer-reviewed articles in high impact journals and received numerous awards in recognition of his research and scientific accomplishments.

**Wai Hong Wilson Tang, MD**

Dr. Wai Hong Wilson Tang is the Advanced Heart Failure and Transplant Cardiology specialist at the Cleveland Clinic in Cleveland, Ohio. Dr. Tang is also the Director of the Cleveland Clinic's Center for Clinical Genomics; Research Director, and staff cardiologist in the Section of Heart Failure and Cardiac Transplantation Medicine in the Sydeff and Arnold Miller Family Heart & Vascular Institute at the Cleveland Clinic. He attended and graduated from Harvard Medical School in 1996, having over 23 years of diverse experience, especially in Advanced Heart Failure and Transplant Cardiology. Dr. Tang is affiliated with many hospitals including the Cleveland Clinic and cooperates with other doctors and physicians in medical groups including The Cleveland Clinic Foundation.

**Barry Trachtenberg, MD**

Dr. Barry H. Trachtenberg is a cardiologist specializing in heart failure and cardiac transplantation. He is also the director of the Michael DeBakey Cardiology Associates Cardio-Oncology program, an evolving field devoted to prevention and management of cardiovascular complications of cancer therapies such as chemotherapy and radiation. His clinical experience includes heart failure and heart transplantation, mechanical support pumps, and cardio-oncology. He has contributed to multiple publications related to advanced heart failure, cardiac transplantation, regenerative therapies, and ventricular assist devices. Dr. Trachtenberg is a member of the American Heart Association, the International Society for Heart and Lung Transplantation, the Heart Failure Society of America, and the International CardioOncology Society of North America.

**Carsten Tschöpe, MD**

Dr. Carsten Tschöpe is Professor of Medicine and Cardiology and Vice Director of the Department of Internal Medicine and Cardiology, Charité University Medicine Berlin. He received his doctorate in medicine in 1993 and has over 140 peer-

reviewed publications, including overview and book articles, and 120 international original articles. His research interests include inflammatory cardiomyopathy, diabetic cardiopathy, and ischemic cardiopathy. He also includes diastolic dysfunction, endothelial dysfunction, peptide systems, and experimental and clinical studies in cardiology and stem cells in his research studies. For his outstanding research work, Dr. Tschöpe was awarded the prestigious Arthur Weber Prize by the German Cardiac Society – Cardiovascular Research.

## About Cardiol Therapeutics

Cardiol Therapeutics Inc. (TSX: CRDL; OTCQX: CRTPF) is focused on producing pharmaceutical cannabidiol (CBD) products and developing innovative therapies for heart disease, including acute myocarditis and other causes of heart failure. The Company's lead product, CardiolRx™, is designed to be one of the safest and most consistent CBD formulations on the market. CardiolRx is pharmaceutically produced, cGMP certified, and is THC free. The Company plans to commercialize CardiolRx in the billion-dollar market for medicinal cannabinoids in Canada and is also pursuing distribution opportunities in Europe and Latin America.

In heart failure, Cardiol is planning an international clinical study of CardiolRx in acute myocarditis, a condition caused by inflammation in heart tissue, which remains the most common cause of sudden cardiac death in people less than 35 years of age. The Company is also developing proprietary nanotechnology to uniquely deliver pharmaceutical CBD and other anti-inflammatory drugs directly to sites of inflammation in the heart that are associated with heart failure. Heart failure is the leading cause of death and hospitalization in North America with associated healthcare costs in the U.S. alone exceeding \$30 billion. For further information about Cardiol Therapeutics, please visit [www.cardiolrx.com](http://www.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") believes, expects or anticipates will, may, could or might occur in the future are "forward-looking information". Forward-looking information is frequently identified by the use of words such as "plans", "expects", "projects", "intends", "believes", "anticipates", "forecasts", and other similar words and phrases, including variations (and negative variations) of such words and phrases, or may be identified by statements to the effect that certain actions, events or conditions "may", "could", "should", "would", or "will" be taken, occur or be achieved. Forward-looking information contained herein may include, but is not limited to, statements with respect to: future events; the future performance or the intended business strategy of Cardiol, including, but not limited to, the plan to commercialize CardiolRx™ 100 and the planning of an international clinical study of CardiolRx in acute myocarditis; the potential for Cardiol's licensed drug encapsulation and delivery technologies to enhance the bioavailability of pharmaceuticals; management's expectations regarding estimated future pharmaceutical research and development opportunities, collaborations and prospects; the success and proposed timing of Cardiol's product development activities; the ability of Cardiol to develop its product candidates; Cardiol's plans to research, discover, evaluate and develop additional products; Cardiol's proposed future collaborations to advance Cardiol's lead nanoformulations into clinical development; and the potential for Cardiol's cannabinoid-based products to provide sources of future revenue. 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 that the success of Cardiol's product candidates will require significant capital resources and years of clinical development efforts; the results of clinical testing and trial activities of Cardiol's products; Cardiol's ability to obtain regulatory approval and market acceptance of its products; Cardiol's ability to raise capital and the availability of future financing; Cardiol's lack of operating history; unforeseeable deficiencies in the development of Cardiol's product candidates; uncertainties relating to the availability and costs of financing needed in the future for Cardiol's research and development initiatives; Cardiol's ability to manage its research, development, growth and operating expenses; the potential failure of clinical trials to demonstrate acceptable levels of safety and efficacy of Cardiol's product candidates; Cardiol's ability to retain key management and other personnel; risks related to fluctuations in medicinal cannabinoid markets in Canada and worldwide; uncertainties regarding Cardiol's ongoing collaborative and manufacturing partnerships; uncertainties regarding results of researching and developing products for human use; Cardiol competes in a highly competitive and evolving industry; Cardiol's ability to obtain and maintain current and future*

*intellectual property protection; and other risks and uncertainties and factors. 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.*