22.04.2021 – GBC Managementinterview with David Elsley, CEO of Cardiol Therapeutics Inc.

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The Company announced topline results from its Phase I Single and Multiple Ascending Dose Clinical Trial of CardiolRx™. CardiolRx is a pharmaceutically produced oral cannabidiol formulation being developed for the treatment of acute and chronic inflammation associated with heart disease. These results positively support Cardiol Therapeutics' proposed treatment dosage for their upcoming CardiolRx Phase II and Phase II/III trials. David Elsley, President and CEO of Cardiol Therapeutics, stated: "Cardiol is initiating a Phase II/III clinical trial in the U.S. investigating the cardioprotective properties of CardiolRx in 422 hospitalized patients with COVID-19 with a prior history of, or risk factors for, cardiovascular disease, and we are planning to file an Investigational New Drug application with the FDA for a Phase II international trial in acute myocarditis, an inflammatory condition of the heart which remains a leading cause of sudden cardiac death in children and young adults."

GBC AG: Mr. Elsley, first, we congratulate you for this achievement. To our knowledge no other studies have incorporated such a high number of subjects for single and multiple ascending dosing of high concentration cannabidiol. Can you explain your decision to include over 52 participants?

David Elsley: To date, the clinical trials conducted with cannabidiol in support of FDA approvals for the treatment of rare childhood epilepsies have only involved children. It is therefore important to note that Cardiol's study is one of the most comprehensive Phase I clinical trials ever conducted in adults. Cardiol's study included fifty-two adult subjects who received one of two doses of drug (5 mg/kg or 15 mg/kg of CardiolRx) in both a non fed and fed state. Our study results demonstrated that when the drug was taken with food, the blood levels of the drug were six to seven times higher than when the drug was taken without food. This is an important confirmatory finding as it supports our long-standing recommendation that cannabidiol should be taken with food to optimize its therapeutic potential. Cannabidiol is fat soluble, and when taken with food, more drug reaches the blood circulation and becomes available to target sites of disease. Furthermore, even at the very high doses administered during our study, CardiolRx was shown to be safe and well tolerated with no adverse impact on cardiac status or liver function.

GBC AG: These results allow Cardiol Therapeutics to move one step further in the process of drug approval by the FDA. Can you give us more details on the timeline for your two major clinical development programs?

David Elsley: We are currently initiating a landmark Phase II/III clinical study in the United States in patients with cardiovascular disease (CVD), or risk factors for CVD, who are hospitalized with COVID-19. In this study we are investigating the anti-inflammatory and cardioprotective properties of CardiolRx in these high-risk patients, who experience markedly elevated risk for mortality and major cardiovascular complications, such as heart attack or stroke. This potentially registrational trial will enroll 422 patients at clinical research centers throughout the U.S. We are also preparing to explore the cardioprotective properties of CardiolRx in a second inflammatory heart condition called acute myocarditis. Acute myocarditis is a devasting disease that represents a leading cause of sudden cardiac death in young healthy adults and children and for which there is currently no recognized standard of care. Based on the successful results of the Company's Phase I program, we are now preparing to file an IND application with the FDA for a Phase II study in acute myocarditis; a disease that is eligible for orphan drug fast-track designation in the U.S., as it represents a life-threatening disease that affects less than 200,000 people in the United States. Importantly, GW Pharmaceuticals utilized the U.S. orphan drug program to fast track the development of cannabidiol for rare forms of pediatric epilepsy, and in 3.5 years increased shareholder value by over US $6 billion.

GBC AG: When GW Pharmaceuticals, developer of the leading cannabidiol epilepsies treatment Epidiolex, got acquired by Jazz Pharmaceutical for over 7.2B USD, it served as a stamp of approval for new treatments based on high dosages of cannabidiol. Do you believe that if CardiolRx got approval for commercial production by the FDA to treat acute myocarditis, the company could expect the same range of valuation or even higher?

David Elsley: The acute myocarditis market opportunity is essentially twice the size of the market for rare epilepsies. The prevalence of the rare pediatric epilepsies is about 37,000 each year, whereas the prevalence of acute myocarditis is over 70,000 people. It is also important to note that other treatments being investigated for acute myocarditis are extremely expensive, with potential treatment costs in the range of USD $60,000. In this context, the potential value of CardiolRx as a new drug for the treatment of acute myocarditis is incredibly significant, as not only would we have the opportunity to improve outcomes and quality of life for these young patients, but we would also have an opportunity to save the healthcare system the enormous expenses of treating patients in the hospital.

GBC AG: When GW Pharmaceuticals conducted their Phase III trial for Epidiolex, they had a total of 224 patients. Once again, your CardiolRx Phase II/III Trial for patients with COVID-19 who have a prior history of, or risk factors for cardiovascular disease will count twice as many patients. Can you explain why you are embarking on such an important clinical program?

David Elsley: Our Phase II/III trial has been designed to investigate the impact of CardiolRx on the risk of mortality, major cardiovascular complications, such as heart attack or stroke, and risk of progression to intensive care or requirement for ventilatory support. In this context, we have a unique opportunity to study a large patient population to determine the ability of CardiolRx to affect the end result of disease, in addition to studying the impact of our drug on a patient's symptoms, quality of life, and other markers of disease progression. To demonstrate the impact of a new medicine on significant clinical endpoints such as mortality or morbidity, typically larger patient numbers are required and that is why our U.S. study design includes more patients than the previous studies in epilepsy you are referring to. The other benefit of using a larger number of patients in our study is the potential for the trial results to support both an emergency use authorization

and an application for marketing authorization for the treatment of high-risk COVID-19 patients.

GBC AG: How fast after the approval from the FDA could you commercialise CardiolRx regarding COVID-19?

David Elsley: The FDA has provided emergency use authorization in a matter of weeks after positive data for other treatments. To the extent that we continue to see outbreaks around the world of COVID-19, we believe that positive results form our Phase II/III program would also support an emergency use authorization by the FDA and possibly other jurisdictions around the world. Positive results from this study may also support a new drug application for the treatment of patients with a prior history of cardiovascular diseases who become COVID-19 positive as notwithstanding the roll out of vaccines, we believe there will be a need for effective therapies for high-risk COVID-19 patients well into the future.

GBC AG: Lastly, you surround yourself with a team of leading practicians in the cardiovascular field. More specifically, one fact caught our attention: Dr. Matthias Friedrich and Dr. Carsten Tschöpe both have strong links to Germany and more precisely Berlin. Dr. Tschöpe is the Vice Director of the Department of Internal Medicine and Cardiology at the University Medicine Berlin and was awarded the prestigious Arthur Weber Prize by the German Cardiac Society for his cardiovascular research. Dr. Friedrich founded one of the first large Cardiovascular Magnetic Resonance centres in Germany at the Charité University Hospital in Berlin. Can you explain us how Cardiol Therapeutics and you personally came to have such strong ties with Germany?

David Elsley: Dr. Tschöpe is world renowned for his work in acute myocarditis. At the Charité hospital in Berlin, he oversees one of the largest myocarditis practices in all of Europe. Patients with acute myocarditis are referred from all over Germany and Europe to the Charité. Dr. Friedrich, who is now at McGill University Hospital in Montreal, also spent many years in heart failure medicine at the Charité and he is also internationally recognized for his work in electrophysiology in heart disease. Inflammation increases your risk for abnormal heart rhythms which can lead to ventricular tachycardia which can in turn result in sudden cardiac death. Dr. Friedrich is an expert in looking at this aspect of cardiac disease. In this regard, as heart disease does not respect borders and affects people all around the world, we are extremely pleased that our Steering Committee, which oversees the design of our clinical trial programs, is made up of international specialists from Europe, the United States, Canada, and Latin America.

GBC AG: CardiolRx's treatment of acute myocarditis would not fight the cause, usually a virus infection, but would limit the direct damages inflicted to the patient heart tissue. It could therefore limit the possible cardiac failure and irreversible damage to the ventricular function due to the myocardial tissue inflammation caused by the infection. What is your treatment trying to achieve?

David Elsley: We developed CardiolRx for patients that need cardio protection during the acute phase of disease. We envisage providing patients with high doses of cannabidiol over a relatively short period of time (30-60 days) to provide rapid onset cardio protection during the acute or dangerous phase of the disease. In short, we believe this therapeutic strategy can help protect heart tissue from the damage caused by inflammation and therefore reduce the consequences of this disease and significantly improve patients' quality of life.

GBC AG: Mr. Elsley, thank you very much for the interview.

ANNEX

I.

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