

Cardio3 BioSciences successfully completes futility analysis of lead cardiac cell therapy, C-Cure®

Decision supports continuation of Phase III trial evaluating treatment for congestive heart failure

Mont-Saint-Guibert, Belgium - Cardio3 BioSciences (C3BS) (*Euronext Brussels and Paris: CARD*), a leader in engineered cell therapy treatments, today announced the successful completion of a futility analysis for C-Cure®, its lead cell therapy for congestive heart failure, currently being evaluated in a Phase III clinical trial in Europe and Israel (CHART-1).

The Data Safety and Monitoring Board (DSMB), an independent committee comprised of international experts, reviewed unblinded safety and efficacy data from CHART-1 and determined that such data did not support discontinuation of the trial on the basis of safety or futility and recommended that it continue without changes to the protocol.

A futility analysis tests the inability of a clinical trial to achieve its efficacy objective. Therefore, a conclusion that a trial is not futile suggests that a clinical trial has the potential to achieve its stated efficacy objective.

The DSMB analysis was performed after all patients were enrolled in the trial. Prior to this futility analysis, CHART-1 completed all safety data reviews by the DSMB, indicating that there is no major or unexpected safety concern with C-Cure® in the target patient population.

Dr Christian Homsy, CEO of Cardio3 BioSciences, said: *“The positive recommendation from the DSMB is an important milestone for our Phase III clinical trial of C-Cure®, and we are extremely pleased to see that interim data supports the continuation of the trial on its initial assumptions. With the successful completions of both patient recruitment and this futility analysis, Cardio3 BioSciences can focus on further advancing the CHART-1 trial and, pending successful primary endpoint readout expected in the middle of 2016, initiating the registration process for C-Cure® in Europe”.*

CHART-1 (**C**ongestive **H**eart failure **C**ardiopoietic **R**egenerative **T**herapy) is a patient prospective, controlled multi-centre, randomized, double-blinded Phase III clinical trial comparing treatment with C-Cure® to a sham treatment. The trial has recruited 240 patients with chronic advanced symptomatic heart failure. The primary endpoint of the trial is a composite endpoint including mortality, morbidity, quality of life, Six Minute Walk Test and left ventricular structure and function at nine months post-procedure. The next milestone in the clinical trial will be the release of the full clinical data set, anticipated for the middle of 2016.

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About Cardio3 BioSciences

Cardio3 BioSciences is a leader in engineered cell therapy treatments with clinical programs initially targeting indications in cardiovascular disease and oncology. Founded in 2007 and based in the Walloon region of Belgium, Cardio3 BioSciences leverages research collaborations in the USA with the Mayo Clinic (MN, USA) and Dartmouth College (NH, USA). The Company's lead product candidate in cardiology is C-Cure[®], an autologous stem cell therapy for the treatment of congestive heart failure. The Company's lead product candidate in oncology is CAR-NKG2D, an autologous CAR T-cell product candidate using NKG2D, a Natural Killer (NK) cell receptor designed to target ligands present on numerous cancer cells, including blood cancers and solid tumors. Cardio3 BioSciences is also developing medical devices for enhancing the delivery of bio therapeutic agents into the heart (C-Cath_{ez}[®]) and potentially for the treatment of mitral valve defects.

Cardio3 BioSciences' shares are listed on Euronext Brussels and Euronext Paris under the ticker symbol CARD.

To learn more about Cardio3 BioSciences, please visit www.c3bs.com

About C-Cure[®]

Cardio3 BioSciences' C-Cure[®] therapy involves taking stem cells from a patient's own bone marrow and through a proprietary process called Cardiopoiesis, re-programming those cells to become heart cells. The cells, known as cardiopoietic cells, are then injected back into the patient's heart through a minimally invasive procedure, with the aim of repairing damaged tissue and improving heart function and patient clinical outcomes. C-Cure[®] is the outcome of multiple years of research conducted at Mayo Clinic (Rochester, Minnesota, USA), Cardio3 BioSciences (Mont-Saint-Guibert, Belgium) and Cardiovascular Centre in Aalst (Aalst, Belgium). C-Cure[®] is currently in Phase III clinical trials (CHART-1, approved by the EMA and CHART-2, for which enrollment will begin once final approval is received from FDA). The results of the Phase II trial, completed in January 2012, were published in the [*Journal of the American College of Cardiology*](#) (JACC) in April 2013. The publication reported a significant improvement in treated patients.

About CHART-1

CHART-1 (Congestive Heart failure Cardiopoietic Regenerative Therapy) is a patient prospective, controlled multi-centre, randomized, patient-and evaluator-blinded Phase III clinical trial comparing treatment with C-Cure[®] to a sham treatment. The trial requires the recruitment of a minimum of 240 patients with chronic advanced symptomatic heart failure. The primary endpoint of the trial is a composite endpoint including



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mortality, morbidity, quality of life, Six Minute Walk Test and left ventricular structure and function at nine months post-procedure. CHART-1 is currently ongoing in 15 countries in Europe and Israel.

Forward looking statements

In addition to historical facts or statements of current condition, this press release contains forward-looking statements, which reflect our current expectations and projections about future events, and involve certain known and unknown risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. These forward-looking statements are further qualified by important factors, which could cause actual results to differ materially from those in the forward-looking statements, including timely submission and approval of anticipated regulatory filings; the successful initiation and completion of clinical trials, including Phase III clinical trials for C-Cure® and Phase I clinical trial for CAR-NKG2D additional clinical results validating the use of adult autologous stem cells to treat heart failure and CAR T-cell autologous therapy to treat cancer; satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; obtaining, maintaining and protecting intellectual property, our ability to enforce our patents against infringers and defend our patent portfolio against challenges from third parties, competition from others developing products for similar uses, our ability to manage operating expenses, and our ability to obtain additional funding to support our business activities and establish and maintain strategic business alliances and business initiatives. In particular, it should be noted that the successful completion of the futility analysis for the CHART-1 is not a determination that the trial will demonstrate efficacy and is not a guarantee of success. Any forward-looking statements represent our views only as of today and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

C3BS-CQR-1, C-Cure, CAR-NKG2D, C-Cathez, OnCyte, Cardio3 BioSciences and the Cardio3 BioSciences, C-Cathez, CHART-1, CHART-2 and OnCyte logos are trademarks or registered trademarks of Cardio3 BioSciences SA, in Belgium, other countries, or both. Mayo Clinic holds equity in Cardio3 BioSciences as a result of intellectual property licensed to the company.