

15 SEPTEMBER 2014, 12:00PM CET

CARDIO3 BIOSCIENCES RECEIVES APPROVAL FOR THE CONTINUATION OF ITS CHART-1 PHASE III CLINICAL TRIAL FROM THE DSMB

The DSMB (Data Safety and Monitoring Board), a committee composed of international independent experts, unanimously recommends continuing the study according to the original protocol, after having analyzed safety data relating to C-Cure[®] and C-Cath_{ez}[®] in the ongoing Phase III clinical trial conducted in Europe and Israel

Mont-Saint-Guibert, Belgium - Cardio3 BioSciences SA (C3BS) (*NYSE Euronext Brussels* and *NYSE Euronext Paris: CARD*), leader in the discovery and development of regenerative, protective and reconstructive therapies for the treatment of cardiac diseases, today announces it has received the recommendation of the Data Safety and Monitoring Board (DSMB) to continue the CHART-1 clinical trial according to the original protocol. The recommendation is based on a planned analysis performed on all patient safety data available as per mid-August 2014.

The Data Safety and Monitoring Board is an independent committee composed of independent international experts in charge of safety evaluation of C-Cure[®] and C-Cath_{ez}[®] in the CHART-1 Phase III clinical trial currently underway in several countries in Europe and in Israel. The DSMB analyzed safety data 1-month post treatment of all patients randomized in the trial.

The CHART-1 (Congestive Heart failure Cardiopoietic Regenerative Therapy) trial represents the world's first Phase III trial for a pre-programmed cellular therapy for the treatment of heart failure.

The members of the DSMB approved unanimously the continuation of the trial having concluded that one month post treatment, C-Cure[®] and C-Cath_{ez}[®] shows no safety issue that compromises the continuation of the CHART-1 Phase III study.

Dr Christian Homsy, CEO of Cardio3 BioSciences, said: *"We are very pleased by the unanimous recommendation of the DSMB to continue to pursue CHART-1. This planned analysis is a significant step in our Phase III program and the positive outcome confirms all the confidence placed in the trial by our partners and investors. CHART-1 continues to progress well and the positive view of the DSMB will add further impetus to recruitment which we look forward to completing on schedule by the end of 2014."*

The Phase III trial is a prospective, multi-centre, randomized, sham-controlled, patient-and evaluator-blinded study comparing treatment with C-Cure[®] to a sham treatment. The trial will recruit a minimum of 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.

***** END *****

15 SEPTEMBER 2014, 12:00PM CET

For more information contact:

Cardio3 BioScienceswww.c3bs.com

Dr Christian Homsy, CEO

Julie Grade, Corporate Communication Manager

Tel : +32 10 39 41 00

Citigate Dewe Rogerson

Tel : +44 (0) 207 638 9571

Chris Gardner

If you want to subscribe to the company newsletter, please fill in the subscription form on the website www.c3bs.com

About Cardio3 BioSciences

Cardio3 BioSciences is a Belgian leading biotechnology company focused on the discovery and development of regenerative and protective therapies for the treatment of cardiac diseases. The company was founded in 2007 and is based in the Walloon region of Belgium. Cardio3 BioSciences leverages research collaborations in the US and in Europe with Mayo Clinic and the Cardiovascular Centre Aalst, Belgium.

The Company's lead product candidate C-Cure[®] is an innovative pharmaceutical product that is being developed for heart failure indication. C-Cure[®] consists of a patient's own cells that are harvested from the patient's bone marrow and engineered to become new heart muscle. This process is known as Cardiopoiesis.

Cardio3 BioSciences has also developed C-Cath^{®ez}, the most technologically advanced injection catheter with superior efficiency of delivery of bio therapeutic agents into the myocardium.

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

C3BS-CQR-1, C-Cure, C-Cath^{ez}, Cardio3 BioSciences and the Cardio3 BioSciences and C-Cath^{ez} 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. 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 required Phase III studies; additional clinical results validating the use of adult autologous stem cells to treat heart failure; satisfaction of regulatory and other requirements; and actions of regulatory bodies and other governmental authorities. As a result, of these factors investors and prospective investors are cautioned not to rely on any forward-looking statements. We disclaim any intention or obligation to update or review any forward-looking statement, whether as a result of new information, future events or otherwise.
