

23 OCTOBER 2013, 11:00 AM CET

Cardio3 BioSciences Receives Authorization to Enroll Patients in Italy in its Phase III Clinical Trial CHART-1

- CHART-1 trial represents the world's first Phase III trial in regenerative medicine for a pre-programmed cellular therapy targeting heart failure
- To date, seven countries have granted authorization for Cardio3 BioSciences' Phase III (CHART-1)
- Six leading clinical centers will participate in CHART-1 in Italy

Mont-Saint-Guibert, Belgium - The Belgian biotechnology company, Cardio3 BioSciences (C3BS), a leader in the discovery and development of regenerative, protective and reconstructive therapies for the treatment of cardiac diseases, today announces it has received authorization from the Italian Medicines Agency (AIFA) to begin its Congestive Heart failure Cardiopoietic Regenerative Therapy (CHART-1) European Phase III trial for C-Cure® in Italy.

After the recent authorization in Spain, and earlier in United Kingdom, Belgium, Israel, Serbia and Hungary, Italy is the seventh country to have authorized this unique study. There will be six leading clinical centers participating to the trial in Italy.

The CHART-1 trial represents the world's first Phase III trial for a pre-programmed cellular therapy targeting heart failure.

Professor Marco Metra, the Principal Investigator in Italy commented: *"We are proud to participate in this Phase III trial evaluating the benefit of C-Cure® cardiopoietic cells for the treatment of severe heart failure. We believe that the CHART-1 study is one of the most important current studies on improving the treatment of chronic heart failure. We hope that this innovative treatment will improve the quality of life of patients suffering from this progressive and debilitating disease, one of the most important unmet medical needs today. E' tempo d'iniziare! Anche nel nostro paese! "*

Dr Christian Homsy, CEO of Cardio3 BioSciences, said: *"We are very pleased with the progress of our Phase III clinical study. Adding another big European country like Italy, which will open six sites, will enable us to pursue the study according to our development plan."*

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 9 months post-procedure.

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Upcoming financial events

12 November 2013 : Business Update Q3 2013

22-23 November 2013 : Actionaria –Listed companies & financial products Fair – Palais des Congrès Paris

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 cells that behave identically to those lost to heart disease. This process is known as Cardiopoiesis.

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

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

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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.