



PRESS RELEASE

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## CARDIO3 BIOSCIENCES ANNOUNCES THE ENROLMENT OF THE 240<sup>TH</sup> PATIENT FOR ITS CHART-1 PHASE III CLINICAL TRIAL FOR THE TREATMENT OF HEART FAILURE

**Mont-Saint-Guibert, Belgium** - Cardio3 BioSciences (C3BS) (*Euronext Brussels and Paris: CARD*), a leader in the discovery and development of regenerative, protective and reconstructive therapies, announces today the enrolment of the 240<sup>th</sup> patient in its CHART-1 European trial for C-Cure<sup>®</sup>, the first and only stem cell therapeutic using guided stem cells for the treatment of congestive heart failure.

With recruitment that started in mid-2013, Cardio3 BioSciences has enrolled 240 patients in less than 18 months, ahead of schedule. As usual in clinical trials targeting severe indications, the Company will continue to recruit additional patients in anticipation of patient dropouts. The CHART-1 trial is currently ongoing in 12 countries in Europe and Israel.

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.

**Dr Christian Homsy, CEO of Cardio3 BioSciences, said:** *"We are extremely pleased to have enrolled the 240<sup>th</sup> patient of CHART-1, ahead of schedule. This represents a major achievement for the entire team involved in this trial and I am proud we succeeded in achieving this key operational objective this year. The CHART-1 trial remains solidly on track, with the interim futility readout scheduled for the end of March 2015 and the readout of the full dataset a year later. This accomplishment demonstrates our clinical expertise and gives us confidence for the upcoming CHART-2 trial, to be initiated soon in the U.S."*

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### About CHART-1

CHART-1 is the Company's first Phase III clinical trial, intended to assess in Europe, the efficacy of C-Cure<sup>®</sup> as a treatment for heart failure of ischemic origin. The CHART-1 Phase III trial is a prospective, multi-centre, randomized, sham-controlled, patient-and evaluator-blinded study comparing treatment with C-Cure<sup>®</sup> 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 mortality, morbidity, quality of life, Six Minute Walk Test and left ventricular structure and function at nine months post-procedure. The CHART-1 trial is currently ongoing in 11 countries in Europe (Sweden, Ireland, the United Kingdom, Belgium, Serbia, Bulgaria, Hungary, Spain, Italy, Poland, Switzerland) and Israël.

### About C-Cure<sup>®</sup>

Cardio3 BioSciences' C-Cure<sup>®</sup> 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



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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).

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**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<sub>ez</sub>®, 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.

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*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.*