

## **CARDIO3 BIOSCIENCES RECEIVES AUTHORIZATION TO ENROLL PATIENTS IN SWITZERLAND 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, 12 countries have granted authorization for Cardio3 BioSciences' Phase III (CHART-1)**
- **The progress of CHART-1 is in line with objectives**

**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 it has received authorization from Swissmedic, the Swiss agency for the authorisation and supervision of therapeutic products, to begin its Congestive Heart failure Cardiopoietic Regenerative Therapy (CHART-1) European Phase III trial for C-Cure® in Switzerland.

After the recent authorization in Bulgaria, and earlier in Sweden, Ireland, the United Kingdom, Belgium, Israel, Serbia, Hungary, Spain, Italy, and Poland, Switzerland is the 12<sup>th</sup> country to have authorized this unique study, which aims to treat ischemic congestive heart failure.

The CHART-1 trial (Congestive Heart failure Cardiopoietic Regenerative Therapy) represents the world's first Phase III trial for a pre-programmed cellular therapy for the treatment of heart failure. Earlier this year, the Company received approval from the DSMB (Data Safety and Monitoring Board) to continue CHART-1 without any changes to the original protocol. The members of the DSMB analyzed safety data 1-month post treatment and unanimously concluded that C-Cure® and C-Cath<sub>ez</sub>® show no safety issue. Now in the final stages of this clinical trial, and with recruitment continuing to be strong, Cardio3 BioSciences is expected to finalize the recruitment of the last patients towards end of 2014. In parallel, CHART-2, the FDA-approved Phase III clinical trial, will also start around the end of the year.

**Dr Christian Homsy, CEO of Cardio3 BioSciences, said:** *"We are approaching the final recruitment phase of our Phase III clinical study for C-Cure® and remain on schedule to finalize recruitment towards end of 2014. The addition of Switzerland in our clinical study is a very positive sign. It is yet another demonstration that ischemic heart failure is an indication for which there is an urgent need for a truly curative therapy. Our hope that C-Cure® will become that therapy is growing every day."*

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.

**\*\*\* END \*\*\***

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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<sup>®</sup> is an innovative pharmaceutical product that is being developed for heart failure indication. C-Cure<sup>®</sup> 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><sup>®</sup>, 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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