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**PRESS RELEASE**

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# Cardio3 BioSciences Receives Authorization to Begin World's First Phase III Clinical Trial in Regenerative Medicine for Heart Failure in Spain

- **To date, six countries have granted authorization for Cardio3 BioSciences' Phase III (CHART-1)**
- **CHART-1 trial represents the world's first Phase III trial for a pre-programmed cellular therapy targeting heart failure**

**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 Spanish Agency for Medicines and Health Products (AEMPS) to begin its Congestive Heart failure Cardiopoietic Regenerative Therapy (CHART-1) European Phase III trial for C-Cure® in Spain.

Spain is the sixth country to have authorized this unique study after the United Kingdom, Belgium, Israel, Serbia and Hungary.

To date, 11 internationally-renowned centers have begun recruiting patients in those countries. First patients were treated in June 2013.

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

**Professor Francesco Aviles, the Principal Investigator in Spain commented:** *"This approval allows Spanish medical institutions to start enrolling patients in the CHART-1 trial and join the group of other distinguished investigators that are already active in the trial. Six clinical centers are ready to start. 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. The Phase II data published in JACC earlier this year provide a strong scientific rationale for this technology and the potential it has to change the standard of care for our patients."*

**Dr Christian Homsy, CEO of Cardio3 BioSciences, said:** "*The authorization by the Spanish authorities is another important step in our development plan. We believe our unique therapy offers the potential to revolutionize treatment for heart failure, a common and severe illness."*

The Phase III trial is a prospective, multi-centre, randomized, sham-controlled, patient-and evaluator-blinded study comparing treatment with C3BS-CQR-1 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.

Studies in additional countries will commence once national regulatory approvals have been received.

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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 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.

*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.*