Cardio3 BioSciences Treats First Patients in World's First Phase III Clinical Trial Using Pre-Programmed Cells for the Treatment of Heart Failure

Mont-Saint-Guibert, Belgium, June 10, 2013 - 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, announces it has treated its first patients in its Congestive Heart failure Cardiopoietic Regenerative Therapy (CHART-1) European Phase III trial for C-Cure®. The patients, who have been randomly allocated to either the treatment or sham arm of the trial, were treated at the CHU Charleroi, Belgium.

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

The Cardio3 BioSciences' most advanced therapy C-Cure®, involves taking cells from a patient's bone marrow and through a proprietary process called Cardiopoiesis, re-programming those cells so that they become heart precursor cells with the aim of replicating the normal process of cardiac development in the embryo and healing the failing heart. The cells, known as cardiopoietic cells, are then injected back into the patient's heart through a minimally invasive procedure using a proprietary catheter called C-Cath®$_{ez}$®, with the goal of repairing damaged tissue and improving heart function, clinical outcomes and quality of life. C-Cure® builds on research conducted at Mayo Clinic (Rochester, Minnesota, USA), Cardio3 BioSciences (Mont-Saint-Guibert, Belgium) and Cardiovascular Centre Aalst (Aalst, Belgium). This Phase III trial builds on the successful outcome of the Phase II trial of which the results were recently published in the Journal of the American College of Cardiology (JACC)[1].

Dr Christian Homsy, CEO of Cardio3 BioSciences, said: "Heart failure remains a significant burden to patients, families and society in general. It is associated with high morbidity, mortality and escalating healthcare costs. We believe C-Cure® has the potential to become a treatment which goes beyond symptom relief towards healing heart tissue. It is a huge step for us to have the first patients undergo their cardiac injection in the Phase III trial and we are confident that we will be able to confirm the promising results we have already seen in our Phase II study."

Dr Dariouch Dolatabadi, the physician that performed the first two procedures added: "Regenerative therapies have the potential to revolutionize the treatment of heart disease and other conditions and we are excited to be working with Cardio3 BioSciences on what is a ground breaking study. The results seen in the earlier trial were encouraging as was reflected in the recent publication in JACC. If repeated in this larger study, those results would bring nearer a potentially disruptive treatment for the expanding epidemic of heart failure."

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[1] Bartunek J, Behfar A, Dolatabadi D, Vanderheyden M, Ostojic M, Dens J, El Nakadi B, Banovic M, Branko B, Vrolix M, Legrand V, Vrints C, Vanoverschelde J-L, Crespo-Diaz R, Homsy C, Tendera M, Waldman S, Wijns W, Terzic A. Cardiopoietic stem cell therapy in heart failure. The C-CURE multicenter randomized trial with lineage-specified biologics. Journal of the American College of Cardiology 2013.

Prof. Jozef Bartunek, CHART-1 Study Principal Investigator, said: "Heart failure is a very common and very serious condition. A person living to age 40 years has a one in five risk of developing heart failure and, once the disorder is apparent, a one in three chance of dying within a year of diagnosis. Regenerative medicines offer the potential, for the first time, of repairing the failing heart. C-Cure® could therefore mark a significant step forward in treatment."

The Phase III trial is a prospective, multi-centre, randomized, sham-controlled, blinded study (patients and evaluators) comparing treatment with C-Cure® to a sham treatment. The trial will recruit a minimum of 240 patients with chronic advanced heart failure of ischemic origin. The primary endpoint of the trial is a composite endpoint including mortality, morbidity, Six Minute Walk Test, quality of life and left ventricular structure and function at 9 months post-procedure.

Studies in additional countries will commence once national regulatory approvals have been received and sites selected and engaged.

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About Cardio3 BioSciences

Cardio3 BioSciences is a leading Belgian 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. Cardio3 BioSciences leverages research collaborations in the US and in Europe with, amongst other, 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 cardiac progenitor cells that behave like those cells lost to heart disease. This reprogramming 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.

In accordance with the Bayh-Dole Act, Mayo Clinic has licensed the technology underlying C-Cure® to Cardio3 BioSciences and received an equity position in the company in the context of the license. Mayo Clinic and the inventors of the technology, Drs. Andre Terzic and Atta Behfar, have a financial interest associated with the technology related to this research. While no royalties have accrued to date, Mayo Clinic has rights to receive future royalties which will be shared with Drs. Terzic and Behfar in accordance with the Mayo Clinic Royalty sharing policy.