

Cardio3 BioSciences Receives IND Clearance from the FDA for its CHART-2 Phase III Heart Failure Clinical Trial

Mont-Saint-Guibert, Belgium, - Cardio3 BioSciences (C3BS) (NYSE Euronext Brussels and Paris: CARD), a leader in the discovery and development of regenerative, protective and reconstructive therapies for the treatment of cardiac diseases, announces today that the U.S. Food and Drug Administration (FDA) has authorized the Company's Investigational New Drug (IND) application for clinical testing of the Company's proprietary regenerative medicine product C3BS-CQR-1 (C-Cure®) as a treatment targeting heart failure.

CHART-2, the Company's second Phase III clinical trial, is intended to assess in the US, the efficacy of C3BS-CQR-1 as a treatment for heart failure of ischemic origin. CHART-2 is designed as a prospective, multi-centre, randomized, sham-controlled, patient- and evaluator-blinded study comparing treatment with C3BS-CQR-1 to a sham treatment. The trial is aimed to recruit a minimum of 240 patients with chronic advanced symptomatic heart failure. The primary endpoint of the trial is the Six Minute Walk Test post-procedure, a commonly used index of cardiovascular performance.

Phase II data published in JACC¹ showed C3BS-CQR-1 statistically significant improvement of 77m in six-minute walk distance for the treated patients compared to the control group ($p < 0.01$), which represented a 20% improvement for treated patients versus the control group.

Dr Christian Homsy, CEO of Cardio3 BioSciences, said: “IND Clearance from the FDA is a milestone in our progress towards the start of our US trial and in our overall development program for C3BS-CQR-1. The files approved by the FDA make us optimistic about our ability to reproduce and potentially amplify the results seen in our Phase II trial. In Europe, our first Phase III study, CHART-1, has been authorized in eight countries. We can now consider a potential start to the CHART-2 trial in the second half of 2014. When started, we anticipate that the CHART-2 study will follow a similar timeline to our current European study.”

About C3BS-CQR-1

Cardio3 BioSciences' C3BS-CQR-1 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 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. C3BS-CQR-1 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).

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.
<http://www.c3bs.com/en/references>

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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 advanced 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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