



Cardio3 BioSciences Announces Positive Outcome of the C-Cure® Phase II Clinical Trial in Heart Failure Patients

Mont-Saint-Guibert, Belgium, November 17, 2010 – The Belgian biotechnology company, Cardio3 BioSciences - a leader in discovery and development of regenerative and protective therapies for the treatment of cardiovascular diseases - today announces positive six-month results, including significant functional and clinical benefit, from the Phase II clinical trial of its development programme C-Cure®, designed as a novel stem cell therapy for heart failure based on breakthrough technology.

Forty-five patients with severe heart failure of ischemic origin participated in the C-Cure multicenter Clinical Trial in Belgium, Serbia and Switzerland, and were randomized to optimal standard of care (control group; n=24) or optimal standard of care plus C-Cure treatment (treatment group; n=21). The primary objective of this trial was to assess the safety and feasibility of C-Cure, a stem cell product candidate derived from the patient's own bone marrow and guided to cardiac lineage cells.

Beyond meeting the safety objective as assessed by an independent safety board, the trial revealed that six months after receiving C-Cure, patients in the treatment group showed significant improvements in a number of measures of their heart function.

Patients receiving the trial drug C-Cure saw an 18.1% increase in left ventricular ejection fraction (LVEF) over baseline at the six month follow-up point, as measured by echocardiography, while the mean LVEF increased only by 3.6% in patients enrolled in the control group. This difference in LVEF between the C-Cure treated and control patients was highly significant ($p < 0.0001$).

The trial also generated data that suggest favorable remodelling of heart muscle and improved heart muscle performance in the treatment versus control group. Signs of functional improvement were supported by improved fitness, shown by a significant mean difference in the 6-minute walking distance test between the treatment and control groups.

In terms of feasibility, the bone marrow of 70% of the attempted 30 patients was successfully processed into C-Cure. The company is targeting even further increasing this successful rate to 80% in its Phase III clinical program.

Dr. Christian Homsy, CEO of Cardio3 BioSciences said: "The highly promising data we report today build on the favourable safety profile we have observed through this Phase II trial and documents in patients our belief that we have with C-Cure a product candidate with the potential to make a real difference in the treatment of heart failure. It is important to note that the improvements in heart function suggested by the trial, were identified in the context of a Phase II trial aimed at assessing the safety and feasibility of C-Cure therapy. It is all the more encouraging to have seen significant differences in some key efficacy indicators despite the fact that the study was not powered, in terms of the number of patients, to demonstrate efficacy."

CARDIO3 BIOSCIENCES S.A.

Axisparc Business Center – Rue Edouard Belin 12 – 1435 Mont-Saint-Guibert – Belgium
Tel +32 (10) 39 41 00 – Fax +32 (10) 39 41 41 – Email info@c3bs.com – www.c3bs.com



“As noted in the company’s press release of 29 June 2010, with the Phase II stage completed and to allow for potential modifications to the trial protocol, Cardio3 BioSciences has not proceeded to Phase III recruitment into the trial but has continued to gather all data for the six month analysis.”

“Through the Phase II trial, we gained significant experience in working with a highly innovative stem cell therapy in a clinical setting, and we are using this acquired knowledge in the design of our planned Phase III programme. Cardio3 BioSciences is committed in taking the steps needed to bring to patients a new treatment for a condition where current therapies do not address the underlying cause of the disease.”

Dr. Jozef Bartunek, Associate Director of the Cardiovascular Center in Aalst, Belgium and Co-Principal Investigator of the C-Cure Clinical Trial added: “The data reported today are very positive for this ‘first in man’ trial using stem cells ‘directed’ to become heart cells. Early efficacy signals are impressive as they come on top of the optimal therapy currently available for patients with heart failure. The only difference between the two groups was the administration of C-Cure in the treatment group. C-Cure could ultimately represent a major step in advancing cardiac regenerative medicine, potentially offering a revolutionary treatment in patients suffering from heart failure, a devastating disease.”

Prof. André Terzic, lead regenerative medicine specialist at Mayo Clinic in Rochester (MN), USA and Co-Principal Investigator of the C-Cure Clinical Trial commented: “Use of stem cells to seek to promote tissue repair in diseased hearts has the potential to transform medicine by providing curative solutions for the unmet needs of our patients. The C-Cure multicenter trial, which involved integrated teams on two continents, has introduced in the clinic the newest innovation under development in the field - namely the application of heart-prespecified stem cells in the treatment of heart failure. By translating a smart stem cell technology, known as “guided cardiopoiesis”, into a first-in-class regenerative product candidate designed to be tailored to the individual patient, this study provides a critical step in our understanding of the feasibility, safety and efficacy of next generation cardiovascular medicine.”

Using the insights from the trial and input from regulatory agencies in Europe and the United States, Cardio3 BioSciences is now designing a clinical trial programme for C-Cure expected to start in 2011.

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For more information contact:

Cardio3 BioSciences

Dr. Christian Homsy, CEO

Tel: +32 10 39 41 00

Anne Portzenheim, Communication Manager

Tel : +32 10 39 41 00

aportzenheim@c3bs.com



Citigate Dewe Rogerson
Chris Gardner/Nina Enegren

Hill & Knowlton
Katia Delvaille

www.c3bs.com

Tel : +44 (0) 207 638 9571
chris.gardner@citigatedr.co.uk
Tel : +32 2 737 95 00
kdelvail@hillandknowlton.com

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 cardiovascular disease.

The Company's lead product candidate, C-Cure[®], is a highly innovative stem cell approach for the treatment of heart failure, one of the world's most pressing unmet medical needs. Based on a comprehensive strategy developed by Cardio3 BioSciences and leveraging technology licensed from Mayo Clinic, the C-Cure development programme is designed to direct the patient's own stem cells into new heart cells with the potential to rebuild the heart.

The Cardio3 BioSciences team has extensive experience in developing and commercialising new pharmaceutical products and medical technologies and the Company's current strategy is to drive the clinical development of C-Cure and to market the product itself, if marketing authorisation is obtained, on a wide geographical scale.

Cardio3 BioSciences was founded in July 2007 and is based in Mont-Saint-Guibert (near Louvain-la-Neuve) in the Walloon region of Belgium.

About C-Cure and Heart Failure

Heart failure is a life-threatening and increasingly common condition in which the heart cannot pump enough blood through the body, leaving the patient debilitated and significantly decreasing quality of life. It can result from heart attacks or a number of other causes. Patients suffering from the condition can experience shortness of breath and extreme exhaustion. Based on available data, the company estimates that 84 million people suffer from heart failure and that this number will double by 2020. Therapies available for chronic heart failure aim at slowing disease progression, but with the exception of heart transplant, existing drugs or devices do not cure the underlying disease.

C-Cure is produced by taking a patient's own stem cells and, through a proprietary process, differentiating them into cardiac lineage ("cardiopoietic") cells designed to regenerate damaged heart muscle. Cardiopoietic cells are injected into the heart of the patient with heart failure where they aim to replace damaged tissue and promote repair without carrying the risk of rejection. This is the first product candidate of its kind offering the potential for heart muscle regeneration. C-Cure is being developed on the basis of multiple years of research conducted at Mayo Clinic (Rochester, Minnesota, USA) and clinical expertise gained at the Cardiovascular Center in Aalst (Aalst, Belgium).



In accordance with the Bayh-Dole Act, Mayo Clinic has licensed the technology underlying C-Cure to Cardio 3 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 Mayo Clinic Royalty Sharing policy.

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company's directors' current expectations and projections about future events. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking statements contained in this press release regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, the Company expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its or their parent or subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. No undue reliance should be placed on forward-looking statements, which speak only as of the date of this press release.