Results from Cardio3BioSciences C-CURE® Trial Published in the Journal of the American College of Cardiology

Regulated information – Inside information

Trial Demonstrates Statistically Significant Improvements in Heart Function and Exercise Tolerance with Cardiopoietic Stem Cell Therapy

Mont-Saint-Guibert, Belgium, 11 April, 2013 - Cardio3 BioSciences (C3BS) announces today the advanced publication of C-CURE (Phase II) trial results in the on-line edition of the Journal of the American College of Cardiology (JACC).[1]

The publication reported:

- Statistically significant improvement in cardiac function for the treated patients,
- Statistically significant improvement in 6-minute walk distance for the treated patients.

The publication concluded that the therapy with C3BS-CQR-1 (previously C-Cure) was feasible and safe with signals of benefit in chronic heart failure, meriting further definitive clinical evaluation.

The C-Cure trial was a prospective, multicenter, randomized study to evaluate the feasibility, safety, and efficacy of CQR-1 in the treatment of patients with chronic heart failure secondary to ischemic cardiomyopathy. CQR-1 consists of the patient's own stem cells harvested from the bone marrow and engineered to become progenitors of new functional cardiac cells. Those cells behave identically to the cells lost to heart disease. In the C-Cure trial, all patients received optimal standard-of-care for heart failure, while treated group also received an intra-myocardial injection of CQR-1.

On the basis of these outcomes, C3BS has initiated a Phase III trial for CQR-1, called CHART-1 for **C**ongestive **H**eart failure C**a**rdiopoietic **R**egenerative **T**herapy. This is the first Phase III trial using organ specified cells for the treatment of ischemic heart failure and will recruit approximately 240 patients, with chronic advanced symptomatic heart failure underlining Cardio3 BioSciences' dedication and leadership in bringing regenerative therapies to patients. The primary endpoint of the trial integrates cardiac and clinical endpoints as recommended by the European Medicines Agency.

Dr Jozef Bartunek, Principal Investigator, said: "The Phase II trial demonstrates that cardiopoietic stem cell therapy is feasible, safe and with strong signals of efficacy. These results highlight the promise of such novel technology for optimized regenerative intervention in heart failure, bringing next generation therapies to patients. With Cardio3 BioSciences having started the follow-up Phase III trial, the cardiopoietic approach is at the forefront of this exciting field."

Dr Christian Homsy, CEO of Cardio3 BioSciences, added: "Publication of the C-Cure trial results in a journal as prestigious as JACC highlights the quality of the science underlying our lead product, CQR-1. We look forward to confirming the promising Phase II results, in our Phase III trial.

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.

Worldwide, this is the first pivotal Phase III study assessing such advanced regenerative product for the treatment of heart failure. We believe that the innovative science behind our product has the potential to revolutionize the treatment of this debilitating disease."

Prof. Dr. André Terzic, lead regenerative medicine specialist at Mayo Clinic in Rochester (MN), USA and Co-Principal Investigator of the C-Cure Clinical Trial, commented: "Heart failure is a major global challenge with the aging of the population and the shortage of donor organs. By introducing lineage guidance into the cell therapy protocol, the C-CURE trial provides initial clinical evidence for a new approach in cardiovascular regenerative medicine. Clinical translation of cardiopoietic stem cell therapy indicates favorable impact on myocardial remodeling, left ventricular ejection fraction, and global wellness. The C-CURE trial thus advances the paradigm of stem cell therapy, providing a rationale for further clinical validation."

***** END *****

For more information contact:

Cardio3 BioSciences
Dr Christian Homsy, CEO
Anne Portzenheim, Communication Manager

www.c3bs.com
Tel : +32 10 39 41 00
aportzenheim@c3bs.com

Citigate Dewe Rogerson
Chris Gardner/Nina Enegren

Tel : +44 (0) 207 638 9571
nina.enegren@citigatedr.co.uk

Hill & Knowlton
Katia Delvaille

Tel : +32 2 737 95 00
katia.delvaille@hkstrategies.com

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 close research collaborations in the US with Mayo Clinic and in Europe with the Cardiovascular Centre Aalst, Belgium.

The Company's lead product candidate C3BS-CQR-1 is the most advanced autologous cellular therapy product for the treatment of heart failure, one of the world's most pressing unmet medical needs. The product consists of patient's own stem cells harvested from the bone marrow and engineered to become progenitors of new functional cardiac cells that behave identically to those lost to heart disease with a goal to rebuild the heart. This process of cardiac-linage commitment is known as Cardiopoiesis. CQR-1 is currently the first product in a Phase III trial worldwide using organ specified cells for the treatment of ischemic heart failure.

Cardio3 BioSciences has also developed C-Cath®$_{ez}$, the technologically most advanced intra-myocardial injection catheter with superior performance for delivery of biotherapeutics into the

myocardium. The proprietary steerable percutaneous catheter has been developed to elevate the standard of care to clinicians and patients. C-Cath$_{ez}$® is CE marked and is now available for commercial use in the EU and many other countries where the CE mark allows commercialization.

Disclosures

In accordance with the Bayh-Dole Act, Mayo Clinic has licensed the technology underlying C3BS-CQR-1 (formerly 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.

 In addition to historical facts or statements of current condition, this press release contains forward-looking statements, which reflect our current expectations and projections about future events, and involve certain known and unknown 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. These forward-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.