



Innovative Heart-Specified Stem Cell Therapy Improves Heart Function and Fitness in Heart Failure Patients

Cardio3 BioSciences Announces International C-Cure® Phase II Clinical Trial at the 60th Annual American College of Cardiology Meeting

- *C-Cure is the next generation heart-specified regenerative product developed from the patients' own bone marrow cells to enable heart repair*
- *At 6 months post-therapy, C-Cure treated heart failure patients walked 73 meters more than patients that received optimal standard of care*
- *C-Cure therapy improved heart function with an increase in left ventricular ejection fraction of 18.1%*

Mont-Saint-Guibert, Belgium, April 5, 2011 – The Belgian biotechnology company, Cardio3 BioSciences, a leader in discovery and development of regenerative and protective therapies for the treatment of cardiovascular diseases, today revealed detailed data from the Phase II clinical trial of its novel stem cell therapy for heart failure, C3BS-CQR-1 (C-Cure®), at the 60th annual American College of Cardiology in New Orleans, USA. This newest innovation builds on a proprietary “cardiopoietic platform”, and the ongoing collaborations with investigators at Mayo Clinic and Aalst Cardiovascular Center.

The clinical study was presented by Dr. Jozef Bartunek, Associate Director of the Cardiovascular Center in Aalst, Belgium and Co-Principal Investigator of the C-Cure trial. The results show that, beyond existing best standard of care, patients saw improvements in heart function and exercise capacity when treated with C-Cure. This novel stem cell therapy involves taking a patient’s own bone marrow stem cells and guides them to repair heart tissue when introduced into a damaged heart area.

Heart failure affects over 117 million people worldwide, and cannot be cured today by currently available therapies. Regenerative therapies, such as C-Cure, offer the potential of a lifesaving treatment providing choice to patients with limited options and potentially avoiding the need for heart transplantation.

The Phase II trial recruited 45 patients with severe heart failure of ischemic origin in Belgium and Serbia who were treated with optimal standard of care (Control group) or optimal standard of care plus C-Cure (C-Cure group).

Patients receiving C-Cure saw an 18.1% increase in left ventricular ejection fraction (LVEF), a measure of heart function, over baseline, as measured by echocardiography, while the mean LVEF improved only marginally in patients enrolled in the control group. This difference in LVEF between the C-Cure treated and control patients was significant ($p < 0.01$) suggesting that C-Cure treatment leads to heart tissue repair.

Importantly, signs of functional heart improvement were supported by improved fitness, shown by a clinically meaningful mean difference in the 6-minute walking distance test between the C-Cure treatment and control groups. After 6 months, patients treated with C-Cure were able to walk an average of 52 metres further in six minutes whereas control patients treated with current optimal standard of care were able to walk 21 metres less on average. The difference of 73 meters between both groups suggests heart failure



patients treated with C-Cure could expect to return to a more active lifestyle, as they recover their ability to perform daily activities.

Dr. Jozef Bartunek explained: “Data presented today strongly suggest that C-Cure is a promising treatment for heart failure, one of the world’s greatest unmet medical needs. A person living to the age of 40 has a one-in-five risk of developing heart failure and, once the disorder is apparent, a one-in-three chances of dying within a year of diagnosis. With the C-Cure trial, we show improved left ventricular and clinical performance consistent with a generalized therapeutic benefit. Moreover, we proved feasibility and safety of the C-Cure treatment regimen. The overall signs of efficacy in C-Cure treated patients are indeed encouraging and open a new chapter in cardiovascular regenerative medicine.”

Dr. Christian Homsy, CEO of Cardio3 BioSciences, added: “We are very pleased to be presenting this important data at one of the most prestigious cardiology conferences. The positive outcome of the C-Cure study reiterates our belief that C-Cure treatment using heart-specified stem cells can make a real difference to patients suffering from heart failure. We are currently planning the next stages of product development, and are committed to taking the steps needed to successfully bring this new and important treatment to patients with heart failure, a condition where current therapies do not address the underlying cause of disease.”

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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 cardiovascular disease.

The Company’s lead product candidate, C3BS-CQR-1 (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.

Disclosures

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.

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.