



Cardio3 BioSciences Reports Positive Three-Month Data from its Clinical Trial of C-Cure® in Heart Failure

Mont-Saint-Guibert, Belgium, June 29, 2010 ... Cardio3 BioSciences, a leading Belgian biotechnology company specialising in regenerative therapies for the treatment of cardiovascular diseases, today announces positive safety data and preliminary efficacy results from its clinical trial of C-Cure®, a breakthrough stem cell therapy for heart failure.

Results showed C-Cure to have a very good safety profile with no adverse events related to C-Cure, as assessed by an independent board. The study is also examining a number of measures of efficacy. With three month follow up data in-hand, Cardio3 BioSciences has observed positive and encouraging trends in a number of physiological and clinical parameters. Meaningful differences were seen in ventricular size, ejection fraction and other measures of heart muscle activity in C-Cure treated patients when compared to control and to baseline. Partial data from a paired analysis of patients at six-months follow-up is suggestive of these beneficial trends being reinforced over time. Cardio3 Biosciences intends to publish the study results once the full six month dataset is available and has been analysed.

Dr Christian Homsy, CEO of Cardio3 BioSciences said: “The data so far from our trial is very encouraging. We showed that C-Cure is safe at three months. We also saw positive trends in other measures that suggest that C-Cure, as anticipated from animal model data, is acting on heart muscle in a way that could yield important clinical benefits. We now look forward to seeing the full six-month follow-up data and completing the analysis of the trial.”

“With the confidence and experience gained from this trial, we are moving ahead with finalizing the design of our pivotal clinical program for C-Cure. Cardio3 BioSciences is continuing to take the steps to bring to patients this 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 trial commented: “C-Cure could represent a major breakthrough in the field of cardiac regenerative medicine offering the potential of a life-saving treatment potentially avoiding the need for heart transplants. This trial represents a “first-in-man” therapy using cells ‘programmed’ to become heart cells. The early stage data that we have seen are encouraging and provides us with very valuable insights that we can use in the design of larger studies to fully examine the efficacy of C-Cure in heart failure patients.”

The current C-Cure study is a randomised, prospective, multi-center trial to evaluate the safety and efficacy of C-Cure beyond optimal clinical care in patients with heart failure. It recruited 45 patients in Belgium and Serbia. The primary end point of the trial is change in

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left ventricular ejection fraction (a measure of how well the heart is functioning) at six months post treatment.

Using the insights from the trial and input from regulators in Europe and the US, Cardio3 BioSciences is now designing a pivotal clinical trial program for C-Cure expected to start in 2011. With the Phase II stage completed and to allow for potential modifications to the trial protocol, Cardio3 BioSciences will not continue recruitment into the existing trial but will continue to gather all data for the six month analysis.

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About Cardio3 BioSciences

Cardio3 BioSciences is a leading Belgian biotechnology company specialising in regenerative therapies for the treatment of cardiovascular disease. The Company's lead product, C-Cure[®], is a highly innovative approach to the treatment of heart failure, one of the world's most pressing unmet medical needs. Based on a strategy developed by Cardio3 BioSciences'



founders and leveraging technology licensed from Mayo Clinic, C-Cure is designed to reprogram the patient's own stem cells into new heart cells 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 strategy is to drive the clinical development of C-Cure and to market the product itself in major territories.

Cardio3 BioSciences was founded in July 2007 and is based in Mont-Saint-Guibert in the Walloon region of Belgium.

About C-Cure and Heart Failure

Heart failure is a serious and common condition in which the heart cannot pump enough blood through the body, leaving the patient debilitated and unable to conduct a normal 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. It affects 28 million patients worldwide and this number is predicted to double by 2020. Therapies available for chronic heart failure aim at slowing down the disease progression, but with the exception of heart transplant, existing drugs or devices do not cure chronic heart failure.

C-Cure is produced by taking a patient's own stem cells and, through a proprietary process, differentiating them into cardiopoietic cells that can regenerate damaged heart muscle. The cardiopoietic cells are injected into the heart of a patient with heart failure where they are designed to behave identically to those cells lost in heart failure without carrying the risk of rejection, something that has not been achieved with previous cell therapies for this indication. C-Cure is the outcome of multiple years of research conducted at Mayo Clinic (Rochester, Minnesota, USA) and at the Cardiovascular Center in Aalst (Aalst, Belgium).