

Cardio3 BioSciences Completes Patient Enrolment in First Stage of Pivotal Trial of C-Cure® in Heart Failure

45 patients enrolled in study designed to evaluate the ability of cardiopoietic cells to restore cardiac function

Mont-Saint-Guibert, Belgium, December 15, 2009 ... Cardio3 BioSciences, a leading Belgian biotechnology company specialising in cell-based therapies for the treatment of cardiovascular diseases, announced today that it has completed, two months ahead of schedule, enrolment in the first stage of its pivotal Phase II/III trial of C-Cure, a unique stem cell therapy for heart failure. Forty-five patients have now enrolled in the study which is being conducted at centres in Belgium and Serbia. The C-Cure trial will ultimately enroll 240 patients making it one of the largest randomized trials in regenerative therapies for heart failure.

C-Cure is produced by taking a patient's own bone marrow 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).

Safety data from this stage of the trial is expected to be available in May 2010. The second stage, which will recruit 195 further patients is expected to start in the third quarter of 2010 and involve further sites in Europe and in the United States. The trial design is a randomized, prospective, multi-center trial, to evaluate the safety and efficacy of C-Cure beyond optimal clinical care in patients with heart failure. The trial will also evaluate socio-economic implications of therapy.

Dr Christian Homsy, CEO of Cardio3 BioSciences said: "We believe C-Cure holds the promise for a treatment that could fundamentally change the future of heart failure patients, one of the world's greatest medical needs. The fact that we have been able to fully enroll the first stage of the trial two months ahead of schedule speaks to the interest physicians have in this potential new therapy and brings us a step nearer a new treatment for a condition where at present current therapy does not address the underlying cause of the disease."

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 20 million patients in Europe, US and Japan 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.

Dr. Jozef Bartunek, Associate Director of the Cardiovascular Center in Aalst, Belgium and Co-Principal Investigator of the C-Cure trial commented: “C-Cure represents a major breakthrough in the field of cardiac regenerative medicine offering the potential of a curative treatment which could save lives and avoid the need for heart transplants. The trial is progressing very well and we look forward to seeing the safety data next year and to beginning the larger second stage to fully examine the efficacy of C-Cure for these patients.”

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For more information contact:

Cardio3 BioSciences

Dr Christian Homsy, CEO

Tel: +32 10 39 41 00

Mayra Beydoun, Brand & Communication
Manager

Tel : +32 10 39 41 00

mbeydoun@c3bs.com

www.c3bs.com

Citigate Dewe Rogerson

Chris Gardner/Nina Enegren

Tel : +44 (0) 207 638 9571

chris.gardner@citigatedr.co.uk

About Cardio3 BioSciences

Cardio3 BioSciences is a leading Belgian biotechnology company specialising in stem cell-based 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 from Mayo Clinic, C-Cure allows the differentiation of a patient's own cells into cardiopoeitic cells which grow into new heart cells and repair heart muscle.

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.

Cardio3BioSciences was founded in July 2007 and is based in Mont-Saint-Guibert in the Walloon region of Belgium.

Disclosures

Mayo Clinic has a financial interest in technology related to this research and may stand to gain from the successful outcome of the research. Mayo Clinic holds equity in Cardio3 BioSciences as a result of intellectual property licensed to the company.