



Cardio3 BioSciences Publishes the Science Basis for C-Cure® in JACC

Article described a landmark process generating cardiac precursor cells to rebuild heart tissue

Mont-Saint-Guibert, Belgium, 16 August, 2010 ... Cardio3 BioSciences, a leading Belgian biotechnology company specialising in regenerative therapies for the treatment of cardiovascular disease, today announces that the key scientific work underlying its lead pharmaceutical product C-Cure®, a revolutionary stem cell treatment for heart failure, has been published in the Journal of the American College of Cardiology (JACC). The findings were described as “landmark work” in the accompanying editorial in today’s publication¹.

The research, carried out at Mayo Clinic in Rochester, Minnesota, USA, and in collaboration with the Cardiovascular Center in Aalst, Belgium led to the development of Cardio3 BioSciences’ technological platform designed to reprogram the patient’s own stem cells to rebuild the heart.

In this ground-breaking work, researchers were able to identify a process involving a cocktail of growth factors to successfully reprogram mesenchymal (connective tissue) stem cells (MSCs) harvested from the bone marrow of heart failure patients into cardiac precursor cells.

Injected into an animal model of heart disease, these cardiac precursor cells improved heart function by repopulating scar tissue and generating new blood vessels, effectively eliminating the scar and rebuilding the heart with new functional human heart tissue. Treated animals demonstrated improved heart function and were cured from their heart failure.

In their editorial, Eduardo Marban, M.D., Ph.D., and Konstantinos Malliaras, M.D., of Cedars-Sinai Heart Institute, describe the Mayo approach as a “boot camp” for stem cells and that the study “...provides the first convincing evidence that MSCs, at least *in vitro*, can in fact become functional cardiomyocytes (heart cells)...”

Cardio3 BioSciences has advanced the development of this technology with the recent conclusion of a Phase II clinical trial that recruited 45 heart failure patients in Europe. The Company recently announced that its lead compound C-Cure had an excellent safety profile and observed positive trends in both physiological and clinical heart function, as was anticipated from the animal model data published in JACC. C-Cure’s unique repair action on heart muscle is projected to yield clinical benefits in a Phase III trial setting.

Dr Christian Homsy, CEO of Cardio3 BioSciences said: “Publication of this research in a journal as prestigious as JACC highlights the quality of the science underlying our lead product. This trans-Atlantic effort involving leading edge science in both the US and Belgium

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served to dramatically increase the potency of human stem cells to repair heart tissue and provides the basis for C-Cure, a therapy that could revolutionize the treatment of this devastating disease.

“Based on this world-class science and the insights and confidence we have gained from our first clinical trial, we are now finalising the design of our pivotal clinical program for C-Cure and look forward to continuing to steps needed to bring this much needed treatment to patients.”

The research was supported by the National Institutes of Health, the American Heart Association, the Marriott Heart Disease Research Program, Cardio3 BioSciences, the Ted Nash Long Life Foundation, the Ralph Wilson Medical Research Foundation, the Mayo Clinic General Mills Clinician-Investigator Fellowship, and Mayo Clinic.

The paper’s authors include Atta Behfar, M.D., Ph.D., Satsuki Yamada, M.D., Ph.D., Ruben Crespo-Diaz, Jonathan Nesbitt, Lois Rowe, Carmen Perez-Terzic, M.D., Ph.D., of Mayo Clinic; Vinciane Gaussin, Ph.D. and Christian Homsy, M.D., Cardio3 BioSciences, Mont-Saint-Guibert, Belgium; and Jozef Bartunek, M.D., Cardiovascular Center, Aalst, Belgium.

Mayo Clinic and two of the investigators involved in this research have a financial interest associated with technology related to this research. That technology has been licensed to Cardio3 BioSciences in exchange for equity.

1: Behfar A, Yamada S, Crespo-Diaz R, Nesbitt J, Rowe L, Perez-Terzic C, Gaussin V, Homsy C, Bartunek J, Terzic A. Guided Cardiopoiesis Enhances Therapeutic Benefit of Bone Marrow Human Mesenchymal Stem Cells in Chronic Myocardial Infarction. Journal of the American College of Cardiology 2010.

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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 heart tissue.

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).

Disclosures

Mayo Clinic holds equity in Cardio3 BioSciences as a result of intellectual property licensed to the company.