



## **Cardio3 BioSciences Establishes US Subsidiary in Rochester, MN**

**Rochester, MN, USA and Mont-Saint-Guibert, Belgium, September 22, 2011** – The Belgian biotechnology company, Cardio3 BioSciences, a leader in the discovery and development of regenerative and protective therapies for the treatment of cardiovascular diseases, announced today that it has established a subsidiary, Cardio3 BioSciences, Inc. in Rochester, Minnesota.

Cardio3 BioSciences has advanced the development of its core revolutionary technology of adult autologous stem cell commitment to cardiac lineage C3BS-CQR-1 (C-Cure®) for the treatment of heart failure. The new subsidiary has been set up to support the expansion of the company's clinical and regulatory activities in the US and substantiate the early evidence of the feasibility, safety and efficacy of C3BS-CQR-1 (C-Cure®) in a larger scale setting as well as to strengthen its research and commercialization efforts with Mayo Clinic and other collaborators in the US.

Cardio3 BioSciences has strong links with Rochester, MN. The key scientific work underlying the Company's Cardiopoiesis technology platform, which is designed to reprogram patient's own stem cells to rebuild the heart, originated at Mayo Clinic, MN. In this ground-breaking work, researchers were able to identify a process involving a combination of growth factors to reprogram mesenchymal stem cells harvested from the bone marrow of heart failure patients into cardiac precursor cells. In 2007, Mayo Clinic entered into a technology license agreement with Cardio3 BioSciences, giving them an exclusive worldwide license to use the inventions related to the cardiopoiesis platform. Since then, Cardio3 BioSciences successfully transferred the technology to a fully compliant pharmaceutical manufacturing environment and conducted a Phase II clinical trial showing the promise of this technology.

Cardio3 BioSciences aims for C3BS-CQR-1 (C-Cure®) to be the first approved regenerative product for ischemic heart failure. In a prospective, randomized, multi-national, Phase II clinical trial, ischemic heart failure patients treated with C-Cure showed after 6 months a significant 18.1% relative improvement of Left Ventricular Ejection Fraction (a measure of heart function) versus baseline whereas the control group had a relative improvement of 3.6% versus baseline. Patients in the C-Cure treated group also showed a significantly improved exercise capacity as measured by a standard test called the "six-minute walk distance test". There was no evidence of complications related to the use of cardiopoietic stem cells. Cardio3 BioSciences plans to discuss the phase II results with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) before finalizing the protocol for the phase III trials.

**Dr Christian Homsy, CEO of Cardio3 BioSciences says:** "Today is a very significant day for Cardio3 BioSciences. In establishing our US subsidiary in Rochester, we are reinforcing our historical link with Mayo Clinic and strengthening our US presence before the start of the Phase III trials of C-Cure. We expect these phase III trials to start in 2012 and include centers in the US to confirm the encouraging Phase II results. Rochester is an acknowledged medical center of excellence that we very much look forward to being a part of."

**Ardell Brede, Mayor, City of Rochester:** "I'm quite pleased and excited that Cardio3 BioSciences has decided to locate their US subsidiary in Rochester. Gary Smith President of Rochester Area Economic Development Inc. and I met with Christian Homsy on a number of occasions most recently at the Bio 2011 June meeting in Washington DC. While this will start out as a small operation we believe Cardio3 BioSciences has the potential to one day be a major employer, contributing to Rochester's



growth as the world's premier Destination Medical Community. I look forward to providing them a warm Rochester welcome."

**Gary Smith, President Rochester Area Economic Development Inc:** "We started courting Cardio3 BioSciences shortly after they signed their license agreement with Mayo. We are pleased Christian and his team see the value in locating their business here. Their early results of applying Mayo developed technology look promising. Hopefully one day soon Cardio3 BioSciences' products will be improving outcomes for thousands of patients. Following that success there should also be lots of jobs created for Rochester Area residents."

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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 cardiac 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 program 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 commercializing 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. In addition to its relationship with Mayo Clinic, Cardio3 BioSciences draws on clinical expertise from the renowned Cardiovascular Center Aalst, Belgium.



## **About Heart Failure**

Heart failure, also known as congestive heart failure, is characterized as the inability of the heart to pump sufficient blood supply to the body. Leading causes of heart failure include coronary artery diseases, high blood pressure and diabetes. Heart failure is a common, costly, disabling, and potentially deadly condition affecting 5.8 million people in the US and more than 11 million people in the European Union. With the exception of heart transplant, there isn't a cure for heart failure at the moment.

## **Disclosures**

C-Cure, Cardio3 BioSciences and the Cardio3 BioSciences logo are trademarks or registered trademarks of Cardio3 BioSciences SA, in Belgium, other countries, or both.

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

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