



PRESS RELEASE

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Cardio3 BioSciences marks first important milestone in regulatory path toward C-Cure® market registration with Paediatric Investigation Plan waiver from EMA

Mont-Saint-Guibert, Belgium - Cardio3 BioSciences (C3BS) (*Euronext Brussels and Paris: CARD*), a leader in the discovery and development of specialized cell therapies, today announced that it has received a Paediatric Investigation Plan (PIP) waiver from the European Medicines Agency (EMA) for C-Cure®, the Company's lead product-candidate currently in Phase III clinical development for the treatment of ischemic heart failure.

As part of the regulatory process for the registration of new medicines with the EMA, pharmaceutical companies are required to provide a Paediatric Investigation Plan (PIP) outlining the Company's strategy for investigation of the new medicinal product in the paediatric population. In some instances, a waiver from developing a PIP for certain conditions may be granted by the Agency.

Cardio3 BioSciences received from the EMA an official, product-specific paediatric waiver for C-Cure® across all subsets of the paediatric population for the treatment of ischemic heart disease. As medical and surgical treatments exist for this extremely rare condition among paediatric patients, Cardio3 BioSciences has focused its regulatory approach for C-Cure® regenerative therapy on the adult patient population. Today, the EMA delivered the waiver to Cardio3 BioSciences, hence making it official that the clinical studies would be restricted to the adult population.

Christian Homsy, CEO of Cardio3 BioSciences commented: *"The PIP waiver represents the first important milestone in the regulatory process in Europe and signifies the completion of one of the mandatory stages that must be completed before Cardio3 BioSciences is able to submit a marketing authorisation for C-Cure® to the EMA. Our company is now well positioned to continue the process toward market authorisation by focusing on the completion of our Phase III clinical trial in adult patients. C-Cure®'s progression toward regulatory approval continues steadily and we look forward to fulfilling additional regulatory requirements to achieve EMA market authorisation for our main cardiac product-candidate."*

***** END *****

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About C-Cure®

Cardio3 BioSciences' C-Cure® therapy involves taking stem cells from a patient's own bone marrow and through a proprietary process called Cardiopoiesis, re-programming those cells to become heart cells. The cells, known as cardiopoietic cells, are then injected back into the patient's heart through a minimally invasive procedure, with the aim of repairing damaged tissue and improving heart function and patient clinical outcomes. C-Cure® is the outcome of multiple years of research conducted at Mayo Clinic (Rochester, Minnesota, USA), Cardio3 BioSciences (Mont-Saint-Guibert, Belgium) and Cardiovascular Centre in Aalst (Aalst, Belgium). C-Cure® is currently in Phase III clinical trials (CHART-1, approved by the EMA and CHART-2, approved by the FDA). The results of the Phase II trial, completed in January 2012, were published in the [*Journal of the American College of Cardiology*](#) (JACC) in April 2013. The publication reported a significant improvement in treated patients.

About Cardio3 BioSciences

Cardio3 BioSciences is a leading biotechnology company focused on the discovery and development of cell therapies for the treatment of unmet medical needs in cardiology and oncology. Founded in 2007 and based in the Walloon region of Belgium, Cardio3 BioSciences leverages research collaborations in the USA and in Europe with the Mayo Clinic (MN, USA), and Dartmouth College (NH, USA). The Company's lead product candidate in cardiology is C-Cure®, an autologous stem cell therapeutic using adult guided stem cells for the condition of congestive heart failure. The Company's lead product candidate in oncology is CM-CS1, an autologous CAR T-Cell product candidate using NKG2D, a Natural Killer (NK) cell receptor designed to target ligands present on most tumor types, including hematologic cancers and solid tumors. Cardio3 BioSciences is also developing a portfolio of medical devices for enhancing the delivery of bio therapeutic agents into the myocardium (C-Cath_{ez}®) and for cardiac surgery involving mitral valve defects.

Cardio3 BioSciences' shares are listed on Euronext Brussels and Euronext Paris under the ticker symbol CARD.

To learn more about Cardio3 BioSciences, please visit www.c3bs.com

Forward Looking Statements

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