Press release
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EMA Grants Certification of Quality Data for C-Cure® to Cardio3 BioSciences

Mont-Saint-Guibert, Belgium, - Cardio3 BioSciences (C3BS) (*NYSE Euronext Brussels and Paris: CARD*), a leader in the discovery and development of advanced regenerative therapies for heart disease, announces today that the European Medicines Agency (EMA) has issued a certification of quality data for C-Cure®, the Company's lead product.

C-Cure® is a cardiovascular lineage-committed cell therapy product developed for the treatment of heart failure, currently in a pivotal phase III clinical trial in Europe and Israel. Obtaining the certification is an important step towards marketing authorization in Europe. The Advanced Therapy Medicinal Products (ATMP) certification recognizes quality of data generated for C-Cure® in its development programme so far as meeting the rigorous standards imposed by the EMA for successful development and submission of a marketing application.

Dr Christian Homsy, CEO of Cardio3 BioSciences, said: "We are proud that the data we have generated around our lead product has been confirmed as meeting the rigorous quality requirements set by the EMA, the regulatory body which would be responsible for the European marketing authorization of C-Cure®. The ATMPs certification for quality data will facilitate the appraisal of our application for marketing authorization for C-Cure which we will submit once the clinical data is available from our Phase III trial, anticipated as around the end of 2015, and we have completed our analyses. This is thus another important step towards a potential market approval of C-Cure in Europe."

ATMPs and European Regulation on ATMPs

ATMPs are at the forefront of biotechnology and medical innovation. Because of their novelty and complexity, evaluating the quality, safety, and efficacy of ATMPs often requires the development of alternative approaches that go beyond what is needed for conventional medicines.

The European Regulation (EC) No 1394/2007 provides a consolidated framework for this innovative class of products, including a procedure allowing SMEs to voluntarily apply for the certification of the pharmaceutical quality and the pre-clinical data of an ATMP. The aim is to offer an early dialogue with the Agency, to clarify regulatory requirements and provide feedback on the quality and completeness of data submitted.

While the certification procedure is independent from a Marketing Authorization Application (MAA), it follows the scientific and technical requirements necessary to facilitate the preparation, filing and evaluation of a future MAA. The issuance of a certificate by the EMA confirms that the data submitted for an ATMP meet the scientific and technical standards that apply to other pharmaceutical and biotechnology products, including among others requirements regarding GMP and stability.

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For more information contact:

Cardio3 BioSciences **www.c3bs.com**
Dr Christian Homsy, CEO Tel : +32 10 39 41 00
Anne Portzenheim, Communication Manager aportzenheim@c3bs.com

Citigate Dewe Rogerson Tel : +44 (0) 207 638 9571
Chris Gardner

About Cardio3 BioSciences

Cardio3 BioSciences is a Belgian leading biotechnology company focused on the discovery and development of regenerative and protective therapies for the treatment of cardiac diseases. The company was founded in 2007 and is based in the Walloon region of Belgium. Cardio3 BioSciences leverages research collaborations in the US and in Europe with Mayo Clinic and the Cardiovascular Centre Aalst, Belgium.

The Company's lead product candidate C-Cure® is an innovative pharmaceutical product that is being developed for heart failure indication. C-Cure® consists of a patient's own cells that are harvested from the patient's bone marrow and engineered to regenerate the heart. This process is known as Cardiopoiesis.

Cardio3 BioSciences has also developed C-Cath$_{ez}$®, the most technologically advanced injection catheter with superior efficiency of delivery of bio therapeutic agents into the myocardium.

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