

# **Regulated information**

PRESS RELEASE

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### CARDIO3 BIOSCIENCES ANNOUNCES Q1 2014 BUSINESS UPDATE

#### AND CONFIRMS PREVIOUS OPERATIONAL AND FINANCIAL GUIDANCE

**Mont-Saint-Guibert, Belgium,** – Cardio3 BioSciences SA (C3BS) (*NYSE Euronext Brussels and Paris: CARD*), a leader in the discovery and development of advanced regenerative therapies for heart disease, today announces its business update for the three-month period ending 31 March 2014.

## Highlights

- IND Clearance from the FDA for its CHART-2 Phase III Heart Failure Clinical Trial
- Appointment of Hanspeter Spek, former senior Executive of Sanofi to its Board of Directors
- Cardio3 BioSciences' Advanced Regenerative Technology Featured in Nature Reviews and European Heart Journal
- Strengthening of IP Portfolio with new US Patent
- Continued progress with the CHART-1 clinical trial of its lead product candidate, C-Cure<sup>®</sup>. To date, nine countries have granted authorization for CHART-1
- Strong cash position with €19.2 million in cash and short-term investments at 31 March 2014, sufficient to finance the Company's existing clinical development program

**Dr Christian Homsy, CEO of Cardio3 BioSciences, said:** "Cardio3 BioSciences continued the momentum seen last year into the start of 2014. CHART-1, our European Phase III, remains on track with more countries and centres being added to the study. During the first quarter we also made significant progress towards a second Phase III with FDA approval for our CHART-2 trial. Our science remains at the forefront of the field of regenerative medicine, as evidenced by high profile references in major journals, and we look forward to delivering on that potential in the clinic and ultimately to benefit patients."

#### Operational and financial review

In January, the U.S. Food and Drug Administration (FDA) authorized the Company's Investigational New Drug (IND) application for clinical testing of the Company's proprietary regenerative medicine product C-Cure<sup>®</sup> as a treatment targeting heart failure. CHART-2, the Company's second Phase III clinical trial, is intended to assess, in the US, the efficacy of C-Cure. The primary endpoint of the trial is the "Six Minute Walk Test" nine months post-procedure, a commonly used index of cardiovascular performance. C3BS showed a 20% improvement for treated patients versus the control group on that specific endpoint during its Phase II trial.

At the end of March 2014, the Company announced the appointment of Hanspeter Spek, a significant new addition to the Board expected to contribute significantly to implementation of Cardio3

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BioSciences' business development strategy. Hanspeter was past President Global Operations of Sanofi, prior to his retirement from the Company in mid-2013.

Also in the period, Cardio3 BioSciences' lineage-specified cardiac progenitor (Cardiopoietic) technology was referenced in the journal Nature Reviews Cardiology and European Heart Journal as a next generation advancement in the science of regeneration.

In February Cardio3 BioSciences announced it had strengthened its IP portfolio following the United States Patent and Trademark Office ("USPTO") issuing of a Notice of Allowance for patent application number US 12/994,626. The patent application covers compositions and methods for obtaining cells to treat heart tissue and specific parts of the Cardiopoiesis process by which Cardio3 BioSciences reprograms stem cells into cardiac progenitor cells during manufacturing.

As of 31 March 2014, the Company was on target for its goal to complete patient enrolment into CHART-1 by the end of 2014 and therefore confirms the guidance given at the end of 2013. At the date of this press release we have 28 centers active or ready to enroll.

The Company continues to exercise tight cash management and ended the period to 31 March 2014 with €19.2 million in cash on hand and short term investment. Management confirms that it anticipates the CHART-1 trial to be fully financed until the availability of the read-out of the primary endpoint which is expected at the end of 2015.

## Post the period end, C3BS obtained EMA certification on C-Cure® quality data

At the beginning of May, the European Medicines Agency (EMA) issued a certification of quality data for C-Cure<sup>®</sup>, the Company's lead product. The Advanced Therapy Medicinal Products (ATMP) certification recognizes the quality data generated for C-Cure<sup>®</sup> in its development program so far as meeting the rigorous standards imposed by the EMA. The ATMPs certification for quality data will facilitate the appraisal of the application for marketing authorization for C-Cure which will be submitted once the clinical data is available from the CHART-1 Phase III clinical trial, anticipated as around the end of 2015.

\*\*\* END \*\*\*

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## 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 USA and in Europe with Mayo Clinic and the Cardiovascular Centre Aalst, Belgium.

The Company's lead product candidate C-Cure<sup>®</sup> is an innovative pharmaceutical product that is being developed for heart failure indication. C-Cure<sup>®</sup> 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<sup>®</sup><sub>ez</sub>, a technologically advanced injection catheter with superior efficiency of delivery of biotherapeutic agents into the myocardium.

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

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