



PRESS RELEASE

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Cardio3 BioSciences Enrolls First Patient in Phase I Trial for NKG2D CAR T-Cell

Mont-Saint-Guibert, Belgium - Cardio3 BioSciences (C3BS) (*Euronext Brussels and Paris: CARD*), a leader in engineered cell-therapy treatments with clinical programs initially targeting indications in cardiovascular disease and oncology, today announced the enrollment of the first patient in a Phase I clinical trial evaluating the Company's lead CAR T-Cell therapy, NKG2D CAR T-Cell, in blood cancer patients with acute myeloid leukemia (AML) or multiple myeloma (MM). Cell engineering and processing will be followed in the coming days by the infusion of NKG2D CAR T-Cells into the patients.

NKG2D CAR T-Cell is an autologous chimeric antigen receptor T lymphocyte (CAR T-cell) therapy constructed using the native sequence of non-engineered natural killer cell (NK cell) receptors which, unlike traditional CAR technologies such as those targeting the CD19 antigen, have the potential to target a broad range of solid tumors and blood cancers by targeting ligands present on numerous cancer types. We believe that NKG2D CAR T-Cell is a potential new treatment option for patients with solid tumors such as breast, colorectal, lung, liver, ovarian and bladder cancer, in addition to the blood cancers targeted in this trial. The research underlying this technology was originally conducted at Dartmouth College by Professor Charles Sentman, and has been published in numerous peer-reviewed publications such as [Journal of Immunology](#), [Cancer Research](#) and [Blood](#).

NKG2D CAR T-Cell received an Investigational New Drug (IND) clearance, under the name *CM-CS1*, from the U.S. Food and Drug Administration (FDA) in July 2014 for the Phase I clinical trial in hematologic cancers.

Dr. Christian Homsy, CEO of Cardio3 BioSciences, commented: *"We are extremely pleased to initiate enrollment of the first Phase I trial of our CAR T-Cell therapy program with lead product candidate NKG2D CAR T-Cell, in-line with our previously disclosed clinical development plan. As AML and MM are two underserved blood cancer subtypes, there is a clear need for new, viable treatment options. To date, NKG2D CAR T-Cell therapies have demonstrated the prevention of tumor development and increased survival in preclinical animal models, suggesting that NKG2D CAR T-Cell has the potential to be one such therapy."*

This trial is assessing the safety and feasibility of NKG2D CAR T-Cell as primary endpoints, with secondary endpoints including clinical efficacy. Cardio3 BioSciences expects to complete the study in mid-2016 and will provide updates as the trial advances.

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About NKG2D CAR T-Cell

Cardio3 BioSciences' lead product candidate in its oncology platform, NKG2D CAR T-Cell, is a chimeric antigen receptor (CAR) T-cell autologous therapy intended to treat cancer. The CAR technology developed by Cardio3 BioSciences uses human natural killer cell (NK cell) receptors which target ligands present on numerous cancer cells. The research underlying this technology was originally conducted by Dartmouth College Professor Charles Sentman, and has been published in numerous peer-reviewed publications such as [*Journal of Immunology*](#) in 2009, [*Cancer Research*](#) in 2006, and [*Blood*](#) in 2005. NKG2D CAR T-Cell has an active Investigational New Drug (IND) application with the FDA for a Phase I clinical trial in certain hematologic cancers. The primary objective of this dose escalation trial is to assess safety and feasibility in certain acute myeloid leukemia (AML) or multiple myeloma (MM) patients.

About Cardio3 BioSciences

Cardio3 BioSciences is a leader in engineered cell therapy with clinical programs initially targeting indications in cardiology and oncology. Founded in 2007 and based in the Walloon region of Belgium, Cardio3 BioSciences leverages research collaborations in the USA 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 ischemic heart failure. The Company's lead product candidate in oncology is NKG2D CAR T-Cell, an autologous CAR T-cell product candidate using NKG2D, a natural killer cell receptor designed to target ligands present on numerous cancer cells, including ovarian, bladder, breast, lung and liver cancers, as well as leukemia, lymphoma and myeloma. 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

Reference

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Forward looking statements

In addition to historical facts or statements of current condition, this press release contains forward-looking statements, which reflect our current expectations and projections about future events, and involve certain known and unknown risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. These forward-looking statements are further qualified by important factors, which could cause actual results to differ materially from those in the forward-looking statements, including timely submission and approval of anticipated regulatory filings; the successful initiation and completion of clinical trials, including Phase III clinical trials for C-Cure[®] and Phase I clinical trial for CAR-NKG2D, additional clinical results validating the use of adult autologous stem cells to treat heart failure and CAR T-cell autologous therapy to treat cancer; satisfaction of regulatory and other requirements; actions



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of regulatory bodies and other governmental authorities; obtaining, maintaining and protecting intellectual property, our ability to enforce our patents against infringers and defend our patent portfolio against challenges from third parties, competition from others developing products for similar uses, our ability to manage operating expenses, and our ability to obtain additional funding to support our business activities and establish and maintain strategic business alliances and new business initiatives. In addition, any forward-looking statements represent our views only as of today and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

C3BS-CQR-1, C-Cure, NKG2D CAR T-Cell, C-Cath_{ez}, OnCyte, Cardio3 BioSciences and the Cardio3 BioSciences, C-Cath_{ez}, CHART-1, CHART-2 and OnCyte logos 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.