

Cardio3 BioSciences Announces Infusion of First Patient in NKG2D Phase I Trial with no short term adverse events

- *No short term on-target, off-tumor toxicity observed to date in first patient following single dose NKG2D CAR T-cell infusion; marks an important step in therapy evaluation.*
- *Staggered enrolment of 2 additional patients to be expected after a 30 day follow-up observation of the initial patient.*
- *The trial is a dose escalation study evaluating safety and feasibility of a CAR T-cell therapy in patients with acute myeloid leukemia or multiple myeloma.*

Mont-Saint-Guibert, Belgium - Cardio3 BioSciences (*Euronext Brussels and Paris: CARD*), soon to be renamed Celyad, a leader in engineered cell-therapy treatments today announced the infusion of the first patient enrolled in the Company's Phase I clinical trial evaluating the safety and feasibility of its NKG2D CAR T-cell therapy, in cancer patients suffering from acute myeloid leukemia (AML) or multiple myeloma (MM).

This Phase I trial is a dose escalating study. Following the infusion of the first dose of NKG2D CAR T-cell, there were no short term adverse events observed in that patient. A pre-defined, staggered enrolment of two additional patients at the same dose level is expected to occur after an additional 30-day safety assessment of the first infused patient.

Dr. Christian Homsy, CEO of Cardio3 BioSciences, commented: *"The infusion of the first patient enrolled in our initial Phase I trial evaluating NKG2D CAR T-cell marks a significant milestone in developing our immuno-oncology program. Once the preliminary 30 days safety evaluation will have been completed, we expect to continue enrolment in the study to further evaluate the therapy's safety and hopefully efficacy. We believe NKG2D CAR T-cell could emerge as a new and viable treatment option for patients with a broad range of cancer types, with potential application in patients with haematological malignancies and beyond."*

Dr. Vincent Brichard, Vice President Immuno-oncology of Cardio3 BioSciences, added: *"The absence of short term adverse events of NKG2D CAR T-cell observed in the first days following infusion of the first patient is an important step in the initial evaluation of the safety profile of the therapy. According to the trial design, this first patient will be monitored closely over the next 30 days before we expand enrolment to two additional patients at the same dose level, followed by the next dose level with a second cohort of patients. This dose-escalation trial is expected to enrol a total of approximately 24 patients and we look forward to providing updates as the trial advances."*

The Phase I trial, anticipated to be completed in mid-2016, is assessing the safety and feasibility of NKG2D CAR T-cell as primary endpoints, with secondary endpoints including clinical efficacy.

NKG2D CAR T-cell is an autologous chimeric antigen receptor T lymphocyte (CAR T-cell) therapy constructed using the native sequence of natural killer cell (NK cell) receptors which, unlike traditional CAR technologies such as those targeting the CD19 antigen, has the potential to target a



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broad range of solid tumors and blood cancers by targeting ligands present on numerous cancer types. 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](#).

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About NKG2D CAR T-Cell

Cardio3 BioSciences's 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

Founded in 2007, and based in Belgium, Cardio3 BioSciences is a leader in engineered cell therapy with clinical programs initially targeting indications in cardiology and oncology. Cardio3 BioSciences is developing its lead cardiovascular disease product candidate, C-Cure®, for the treatment of ischemic heart failure, and has completed enrolment of a Phase III trial in Europe and Israel. In addition, the Company is developing a portfolio of CAR T-cell therapies that utilize human Natural Killer cell receptors for the treatment of numerous solid tumors and blood cancers. Its lead oncology product candidate, NKG2D CAR T-cell, entered a Phase I clinical trial in April 2015.

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

On April 15, 2015, the Company announced its plan to use the name Celyad for commercial purposes and to seek shareholder approval of the new name for the legal entity at its annual general meeting of shareholders scheduled for May 5, 2015. The Company's ticker symbol will change from CARD to CYAD immediately following shareholder approval of the name change.



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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. In particular it should be noted that the Phase 1 clinical trial evaluating NKG2D CAR T-cell has not been completed. There is limited data concerning the safety and feasibility of NKG2D CAR T-cell therapy. These data may not be repeated or observed in ongoing or future studies involving evaluating NKG2D CAR T-cell or the Company's other product candidates. 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 NKG2D CAR T-cell additional clinical results validating the use of adult autologous stem cells to treat ischemic heart failure and CAR T-cell autologous therapy to treat cancer; satisfaction of regulatory and other requirements; actions 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 business initiatives. 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-Cathez, OnCyte, Celyad, Cardio3 BioSciences and the Cardio3 BioSciences, Celyad, C-Cathez, CHART-1, CHART-2 and OnCyte logos are signs internationally protected under applicable Intellectual Property Laws. Mayo Clinic holds equity in Cardio3 BioSciences as a result of intellectual property licensed to the Company.