

## Celyad receives clearance from the US FDA on its CHART-2 Phase III IND

The US FDA determined that the C-Cure<sup>®</sup>/C-Cath<sub>ez</sub><sup>™</sup> combination safety profile obtained from the CHART-1 trial allows the initiation of the CHART-2 Heart Failure Clinical Trial in the US

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**Mont-Saint-Guibert, Belgium** - Celyad (Euronext Brussels and Paris, and NASDAQ: CYAD), a leader in the discovery and development of engineered cell therapies, with clinical programs in cardiovascular disease and immuno-oncology, today announced that the U.S. Food and Drug Administration (FDA) has authorized the Company's Investigational New Drug (IND) application to proceed thus allowing for the clinical testing of Celyad's lead cardiology candidate (C-Cure cardiopoietic cells) delivered via the proprietary catheter (C-Cath<sub>ez</sub>) in the Phase III Heart Failure Trial (CHART-2) in the US.

CHART-2 is intended to assess, the efficacy of C-Cure as a treatment for heart failure of ischemic origin. CHART-2 is designed as a prospective, multi-centre, randomized, sham-controlled, patient- and evaluator-blinded Phase III study comparing treatment with C-Cure to a sham treatment. The trial is aimed to recruit a minimum of 240 patients with chronic advanced symptomatic heart failure.

**Dr. Christian Homsy, Chief Executive Officer of Celyad:** "CHART-2 study using Celyad's lead cardiology candidate (C-Cure cardiopoietic cells) delivered via our proprietary catheter (C-Cath<sub>ez</sub>) will allow us to expand our Phase III clinical program and allow US clinical sites and patients to participate in our trials. We also expect that our fully proprietary approach will give us an innovative value added proposition when it comes to the potential commercialization of the treatment".

**Dr. Warren Sherman, Chief Medical Officer of Celyad:** "Celyad's patient centric approach is served by providing potentially the best possible combination of C-Cure with C-Cath<sub>ez</sub> for the treatment of ischemic heart failure. C-Cath<sub>ez</sub> best in class catheter provides more than three times higher retention of viable cells one hour after the injection than other designs, and hence potentially optimizes the effect of C-Cure."

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## About Celyad

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

Celyad's ordinary shares are listed on Euronext Brussels and Euronext Paris under the ticker symbol CYAD and Celyad's American Depositary Shares are listed on the NASDAQ Global Market under the ticker symbol CYAD.

To learn more about Celyad, please visit [www.celyad.com](http://www.celyad.com)

## Forward looking statements

In addition to historical facts or statements of current condition, this press release contains forward-looking statements, including statements about the potential safety and feasibility of NKG2D CAR T-cell therapy and C-Cure and the clinical potential of the Company's technology platform generally and the timing of future clinical trials, 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 30-day safety data described in the release are preliminary in nature and the Phase 1 trial is not completed. There is limited data concerning safety and feasibility of NKG2D CAR T-cell therapy. These data may not continue for these subjects or be repeated or observed in ongoing or future studies involving our NKG2D CAR T-cell therapy, C-Cure or other product candidates. It is possible that safety issues or adverse events may arise in the future.

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 risks associated with conducting clinical trials; the risk that safety, bioactivity, feasibility and/or efficacy demonstrated in earlier clinical or pre-clinical studies may not be replicated in subsequent studies; risk associated with the 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; risks associated with the satisfaction of regulatory and other requirements; risks associated with the actions of regulatory bodies and other governmental authorities; risks associated with obtaining, maintaining and protecting intellectual property, our ability to enforce our patents against infringers and defend our patent portfolio against challenges from third parties; risks associated with competition from others developing products for similar uses; risks associated with our ability to manage operating expenses; and risks associated with our ability to obtain additional funding to support our business activities and establish and maintain strategic business alliances and business initiatives. A further list and description of these risks, uncertainties and other risks can be found in the Company's Securities and Exchange Commission filings and reports, including in the Company's prospectus filed with the SEC on June 19, 2015 and future filings and reports by the Company. Given these uncertainties, the reader is advised not to place any



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undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. The Company expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless required by law or regulation.

C3BS-CQR-1, C-Cure, NKG2D CAR T-cell, C-Cath<sub>ez</sub>, OnCyte, Celyad, Cardio3 BioSciences and the Cardio3 BioSciences, Celyad, C-Cath<sub>ez</sub>, CHART-1, CHART-2 and OnCyte logos are signs internationally protected under applicable Intellectual Property Laws. Mayo Clinic holds equity in Celyad as a result of intellectual property licensed to the Company.