Celyad
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Press Release
Regulated Information
Inside Information
June 28, 2016
12:00 pm CET

Celyad Announces Results for the CHART-1 Phase III Clinical Trial Evaluating C-Cure® Cell Therapy

- A statistically-significant difference on the primary endpoint was not reached; however, a positive trend was seen across all treatment groups, and the primary endpoint was met (p=0.015) for a subset representing 60% of the population of the CHART-1 study (baseline End Diastolic Volume (EDV) segmentation).
- Based on the positive subgroup analysis, Celyad will contact the European Medicines Agency concerning a marketing authorization application.
- Prof. Jozef Bartunek will present the full 39 weeks' data at the "Hot Line Heart Failure and Innovative Approaches" Late Breaking Clinical Trial Session at ESC on Sunday, August 28, 2016.
- Celyad will seek a partner to accelerate further development and commercialization of C-Cure®.

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 diseases and immuno-oncology, today announced headline results for CHART-1, its European Phase III clinical trial for its lead cardiovascular disease product candidate.

Across the complete trial population, a positive trend was clearly identifiable. However, a statistically-significant difference between treatment and control (sham procedure) was not reached.

For patients representing 60% of the overall study population and categorized by their End Diastolic Volume (EDV) at inclusion, significance was met for the primary endpoint (p = 0.015). Most importantly, in this subgroup, a strong trend or a statistical significant positive difference was seen in all individual elements of the composite primary endpoint (Mortality, Worsening Heart Failure Events, Quality of Life, 6 minutes Walking Test, End Systolic Volume and Ejection Fraction).

The study procedure was well tolerated with no safety concerns.

The CHART-1 trial has been selected by the European Society of Cardiology to be presented at the "Hot Line Heart Failure and Innovative Approaches" Late Breaking Clinical Trial session of the ESC congress in Rome on Sunday, August 28, 2016, at 11:54 am CEST. The European Society of Cardiology has organized a press conference scheduled at 8 am CEST on the same day.

Based on the positive results seen in this highly clinically relevant group of patients for whom treatment options are currently limited, Celyad will contact the European Medicine Agency concerning a marketing authorization application.

The Company will use the CHART-1 results as a foundation to optimize the design of the pivotal CHART-2 US trial. In line with this, Celyad confirms it is seeking partnerships to accelerate further development and commercialization of C-Cure®.

At the Company's request, trading in Celyad stock (CYAD.BR) will be suspended on June 28, 2016, until the completion of the conference call scheduled at 2:00pm CEST (see details below).

Dr. Christian Homsy, CEO of Celyad, commented: "*For the first time in a randomized, double-blind, controlled, Phase III cell therapy study, a positive effect, consistent across all parameters tested, was observed for a substantial, clearly definable, group of heart failure patients.*

CHART-1 has allowed us to better define the patient population that would benefit from C-Cure®. We are excited by the prospects for C-Cure® as a new potential treatment option for a highly relevant heart failure population. We are confident that the results will generate interest from potential partners that could accelerate the development and commercialization of C-Cure®."

Prof. Jozef Bartunek, CHART-1 principal co-investigator, said: "*This pioneering study has contributed greatly to our understanding of heart failure disease and the place of regenerative medicine in its management. The results seen for a large clinically relevant number of the patients are ground breaking. We look forward to completing the full analysis and making the data available to the medical community at ESC.*

On behalf of the CHART 1 steering committee we wish to thank the patients and families who were enrolled in the study as well as all the physicians and medical teams that made this study possible."

Prof. Gerasimos Filippatos, Immediate Past-President of the Heart Failure Association of the European Society of Cardiology, member of the CHART-1 dissemination committee, said, *"The CHART-1 results have identified a well-defined group of patients with symptomatic heart failure despite optimal therapy. Those patients are a large subset of the heart failure population and present specific therapeutic challenges. The outcome of CHART-1 indicate those patients could benefit from this therapy".*

Conference Call Details

A conference all will be held on Tuesday, June 28, 2016 at 2:00pm (CEST) / 8:00am (EDT) to review the topline results of the CHART 1 study. Christian Homsy, Chief Executive Officer, will deliver a brief presentation followed by a Q+A session.

Participants are asked to call the assigned numbers approximately five minutes before the conference call begins.

The call can be accessed by dialing the numbers below and using the conference ID: 41106485

International:	+44 (0) 1452 560304
Belgium:	024017052
France:	0800918149
UK:	08000738965
US:	18669265708

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About C-Cure®

C-Cure® is Celyad's product candidate based on its cardiopoiesis platform being evaluated for heart failure. The research underlying this technology was originally conducted at Mayo Clinic by the research team of Professor André Terzic and Doctor Atta Behfar, and has been published in numerous peer-reviewed publications. C-Cure® consists of a patient's own cells harvested from bone marrow, treated with a combination of cytokines and growth factors and then re-injected into the heart. It is designed to enhance reparative capabilities in the failing heart.

About CHART-1

The CHART-1 (**C**ongestive **H**eart failure C**a**rdiopoietic **R**egenerative **T**herapy) trial is a Phase III clinical trial to evaluate C-Cure® for the treatment of heart failure. CHART-1 is a prospective, controlled multi-center, randomized, double-blinded Phase III clinical trial comparing treatment with C-Cure® to a sham treatment. The trial recruited 271 evaluable patients with chronic advanced symptomatic heart failure in 12 countries in Europe and Israel. The trial is designed to

assess the safety and efficacy of C-Cure®. The primary endpoint of the trial was a composite endpoint including mortality, morbidity, quality of life, Six Minute Walk Test and left ventricular structure and function at nine-month post-procedure.

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 next generation 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, NKR-2 (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

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 NKR-2-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 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 NKR-2. These data may not continue for these subjects or be repeated or observed in ongoing or future studies involving our NKR-2 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 NKR-2; 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 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, NKR-2, OnCyte, Celyad, Celyad, C-Cath$_{ez}$™, 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.