

FDA grants Fast Track Designation for Celyad's ischemic heart failure therapy, C-Cure[®]

- Celyad intends to leverage this designation to accelerate the search for a strategic partner
- Designation granted on the strength of the evidence in the subset of patients that were responders at 9 month, further confirmed by the 12 months data recently presented

Mont-Saint-Guibert, Belgium - Celyad (Euronext Brussels and Paris, and NASDAQ:CYAD), a leader in the discovery and development of engineered cell-based therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its C-Cure[®] therapy.

FDA granted Fast Track designation for reduction in mortality, hospitalization and improvement of quality of life in patients with chronic heart failure secondary to ischemic cardiomyopathy with baseline Left Ventricular End-Diastolic Volumes (LVEDV) between 200 and 370ml as Fast Track Development Program.

Celyad's C-Cure[®] therapy is one of the most advanced cell therapies in the heart failure segment. The CHART-1 trial has identified a sizeable patient population with a positive response to C-Cure[®], and a better defined optimal dosing.

This was further validated by the 12 months data recently presented by Prof. John Teerlink at the late breaking session of the European Heart Failure Society meeting (Paris, Mays 1st, 2017), and accepted for publication in the European Journal of Heart Failure.

In December 2015 Celyad received clearance from the FDA for CHART-2, a prospective multi-centre, randomized, sham-controlled, Phase III pivotal study for C-Cure[®]. The company is in the process of identifying strategic partners to initiate the CHART-2 clinical trial.

Dr. Christian Homsy, CEO of Celyad: "While Celyad focuses its resources in the development of our immuno-oncology platform, receiving Fast Track Designation is an important milestone for C-Cure[®] and is a testimony to the quality of the science and the strength of the 9 and 12 months CHART-1 data. We hope, with the support of Piper Jaffray, to be able to identify a partner to carry the C-Cure program forward."

The FDA's Fast Track Drug Development Program is designed to expedite clinical development and submission of New Drug Applications (NDA) for medicines with the potential to treat serious or life-threatening conditions and address unmet medical needs. Specifically, Fast Track designation facilitates frequent interactions with the FDA review team, including meetings to discuss all aspects of development to support approval, and also provides the opportunity to submit sections of an NDA on a rolling basis as data become available.

For more information on Fast Track, visit the FDA website (<http://www.fda.gov>).



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About Celyad

Celyad is a clinical-stage biopharmaceutical company focused on the development of specialized cell-based therapies. The Company utilizes its expertise in cell engineering to target cancer. Celyad's Natural Killer Receptor based T-Cell (NKR-T) platform has the potential to treat a broad range of solid and hematologic tumors. Its lead oncology candidate, the CAR-T NKR-2, has been evaluated in a single dose - escalation Phase I clinical trial to assess the safety and feasibility of CAR-T NKR-2 cells in patients suffering from AML or MM. This Phase I study was successfully completed in September 2016. Celyad was founded in 2007 and is based in Mont-Saint Guibert, Belgium, and Boston, Massachusetts. Celyad's ordinary shares are listed on the Euronext Brussels and Euronext Paris exchanges, and its American Depository Shares are listed on NASDAQ Global Market, all under the ticker symbol CYAD.

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**ardiopoietic **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.



Press Release

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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 CAR-T NKR-2 cell therapy, 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 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 I clinical trial for CAR-T 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 Annual Report on Form 20-F filed with the SEC on April 8, 2016 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.