

## Celyad initiates the certification by the EMA of the non-clinical data of C-Cure<sup>®</sup>

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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, today announced the initiation of the certification procedure by the European Medicines Agency (EMA) of the non-clinical data of its lead product, C-Cure<sup>®</sup>, currently in the follow-up period of its CHART-1 Phase III clinical trial in Europe and Israel.

The certification procedure involves the scientific evaluation by the European Medicines Agency's Committee for Advanced Therapies (CAT) of non-clinical data generated for C-Cure<sup>®</sup>. It aims to prepare the submission of a marketing-authorization application.

**Dr Christian Homsy, CEO of Celyad, commented:** "This is another great step in the preparation of the marketing authorization dossier of our lead product C-Cure<sup>®</sup>. In April 2014, we obtained the certification of the quality part of the dossier. If granted in spring next year, this other certification should enable us to file for marketing authorization only a few months after the readout of the CHART-1 data, expected mid 2016".

C-Cure<sup>®</sup> is Celyad's most advanced product candidate based on its cardiopoiesis platform and is being developed for heart failure indications. The Company expects to release the full clinical data set for CHART-1, its Phase III trial in Europe and Israel, in the middle of 2016. The research underlying this technology was originally conducted at Mayo Clinic by the research team of Professor André Terzic and Atta Behfar, and has been published in numerous peer-reviewed publications. C-Cure<sup>®</sup> consists of a patient's own cells harvested from bone marrow, treated with cardiopoietic growth factors and then re-injected into the heart. It is designed to produce new autologous heart muscle cells which behave identically to those lost as a result of infarction, without the risk of rejection.

C-Cure<sup>®</sup>'s potential has been demonstrated in a multi-centre randomized controlled Phase II trial conducted in Europe. The results of the C-Cure<sup>®</sup> Phase II trial were published in April 2013 in the *Journal of American College of Cardiology*.

### ***ATMPs and European Regulation on ATMPs***

The European Regulation (EC) No 1394/2007 provides a consolidated framework for this innovative class of products, including a procedure allowing SMEs to voluntarily apply for the certification of the pharmaceutical quality and the pre-clinical data of an ATMP (Advanced Therapy Medicinal Product). The aim is to offer an early dialogue with the Agency, to clarify regulatory requirements and provide feedback on the quality and completeness of data submitted.

While the certification procedure is independent from a Marketing Authorization Application (MAA), it follows the scientific and technical requirements necessary to facilitate the preparation, filing and evaluation of a future MAA. The issuance of a certificate by the EMA, expected in spring 2016, will confirm that the data submitted for an ATMP meet the scientific and technical standards that apply to other pharmaceutical and biotechnology products.

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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<sup>®</sup>, 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 coverage of the US Patent No 9,181,527, the safety and efficacy of Celyad's product candidates, the potential clinical and commercial potential of these product candidates, potential future product candidates 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 there are risks and uncertainties associated with strength of the Company's intellectual property portfolio, including the US Patent No 9,181,527. Third parties may challenge the validity, enforceability, or scope of our patents, including the US Patent No 9,181,527, which may result in such patents being narrowed, invalidated, or held unenforceable. Furthermore, even if these patents are unchallenged, our patents may not adequately cover our products or prevent others from designing their products to avoid being covered by our claims.

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 DSMB's

determination not to discontinue the Phase III clinical trials for C-Cure<sup>®</sup> on the basis of non-futility is not a determination as to the likelihood of success and is not a guarantee that the trial will be successful; the risk that safety, bioactivity and 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<sup>®</sup> 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 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<sup>®</sup>, NKG2D CAR T-cell, C-Cath<sub>ez</sub><sup>™</sup>, OnCyte, Celyad, Cardio3 BioSciences and the Cardio3 BioSciences, Celyad, C-Cath<sub>ez</sub><sup>™</sup>, 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.