

# Celyad to Present Update to r/r AML and MDS Program at 2019 ASH Annual Meeting

 Management to host an analyst and investor event to review data from American Society of Hematology (ASH) on Monday, Dec. 9, at 8:30 p.m. ET

Mont-Saint-Guibert, Belgium - Celyad (Euronext Brussels and Paris, and Nasdaq: CYAD), a clinicalstage biopharmaceutical company focused on the development of CAR-T cell therapies, today announced that three abstracts related to the company's autologous NKG2D-based CAR-T candidates for the treatment of relapsed/refractory acute myeloid leukemia (r/r AML) and myelodysplastic syndromes (MDS) have been accepted for presentation at the 61st American Society of Hematology (ASH) Annual Meeting, which will be held from December 7-10, 2019, in Orlando, Florida. In addition, management will host a live event at ASH for analysts and investors on Monday, December 9, to review the data from the three posters, as well as updates to the company's development program for r/r AML and MDS and proprietary OptimAb manufacturing process.

Filippo Petti, chief executive officer of Celyad, noted, "We look forward to providing an update at next month's ASH Annual Meeting on our autologous CAR-T program focused on the treatment of acute myeloid leukemia and myelodysplastic syndromes, including the latest clinical results from the CYAD-01 Phase 1 THINK and DEPLETHINK trials. In addition, we are excited to highlight the latest preclinical data from our next-generation NKG2D-based candidate CYAD-02 and our OptimAb manufacturing process, which underpins both autologous CAR-T assets within the program."

# ASH Investor/Analyst Event and Webcast Information

Celyad will host an event at ASH for investors and analysts on Monday, December 9, 2019, beginning at 8:30 p.m. ET to review data presented, as well as to provide updates on the company's development program for r/r AML and MDS and its proprietary OptimAb manufacturing process. The event will also be webcast live and can be accessed under Events & Webcasts in the Investors section of the company's website.

#### Poster Presentation Details:

The following abstracts published today are now available on the ASH website. Following presentation at the meeting, the posters will be available in the <u>library</u> section of Celyad's website.

Publication #3826: Results from the Completed Dose-Escalation of the Hematological Arm of

> the Phase I Think Study Evaluating Multiple Infusions of NKG2D-Based CAR T-Cells as Standalone Therapy in Relapse/Refractory Acute Myeloid

Leukemia and Myelodysplastic Syndrome Patients

Date & Time: Monday, December 9, 2019, 6 p.m. - 8 p.m. ET





Publication #3844: Interim Results from the Phase I Deplethink Trial Evaluating the Infusion of a

> NKG2D CAR T-Cell Therapy Post a Non-Myeloablative Conditioning in Relapse or Refractory Acute Myeloid Leukemia and Myelodysplastic

Syndrome Patients

Date & Time: Monday, December 9, 2019, 6 p.m. – 8 p.m. ET

Publication #3931: Next Generation NKG2D-based CAR T-cells (CYAD-02): Co-expression of a

Single shRNA Targeting MICA and MICB Improves Cell Persistence and Anti-

Tumor Efficacy in vivo

Date & Time: Monday, December 9, 2019, 6 p.m. - 8 p.m. ET

### Background on THINK Phase 1 Trial

The THINK trial (NCT03018405) is an open-label, dose-escalation Phase 1 trial assessing the safety and clinical activity of multiple CYAD-01 administrations without prior preconditioning. The dose escalation segment of the trial evaluated three dose levels (300 million, 1 billion and 3 billion cells per infusion) of one cycle of three CYAD-01 administrations with two-week intervals. In 2018, the THINK trial was amended to add two cohorts to assess a more frequent dosing schedule of CYAD-01 for the treatment of r/r AML. The cohorts will evaluate six injections of CYAD-01 without preconditioning over two months of administration. The first cycle includes three infusions of CYAD-01 separated by one-week intervals. The second cycle includes three infusions of CYAD-01 separated by two-week intervals. Patients will either receive 1 billion cells per infusion (Cohort 10) or 3 billion cells per infusion (Cohort 11). The primary endpoint of the trial is safety and secondary endpoints include clinical activity and pharmacokinetics.

# Background on DEPLETHINK Phase 1 Trial

In October 2018, Celyad initiated the DEPLETHINK Phase 1 trial (NCT03466320). The open-label, dose-escalation trial will evaluate a single infusion of CYAD-01 following treatment with the standard preconditioning regimen of cyclophosphamide (300 mg/m²) and fludarabine (30 mg/m²), or CyFlu. The trial includes two different intervals between lymphodepletion and administration of CYAD-01. In addition, the trial will evaluate three dose levels of CYAD-01 including 100 million, 300 million and 1 billion cells per infusion, respectively. The primary endpoint of the trial is safety and secondary endpoints include clinical activity and pharmacokinetics.

## Background on OptimAb Manufacturing Process

Celyad's proprietary OptimAb manufacturing process utilizes a shortened cell culture and incorporates a selective PI3K inhibitor. This results in a product that is enriched for T cells with a memory-like phenotype. Preclinical data demonstrate that NKG2D-based CAR-T cell therapies produced using the OptimAb manufacturing process drive improved anti-tumor activity in an aggressive AML model compared to alternative manufacturing process.



\*\*\* END\*\*\*

#### **About Celyad**

Celyad is a clinical-stage biopharmaceutical company focused on the development of specialized CAR-T cell-based product candidates and utilizes its expertise in cell engineering to target cancer. Celyad's CAR-T cell platform has the potential to treat a broad range of solid and hematologic tumors. The company's lead clinical candidate, CYAD-01, an autologous NKG2D-based CAR-T therapy, is currently being evaluated in several Phase 1 clinical trials to assess safety and clinical activity for the treatment of hematological malignancies, such as acute myeloid leukemia, and solid cancers, such as metastatic colorectal cancer. Celyad is also developing CYAD-101, an investigational, non-gene edited, allogeneic (donor derived) NKG2D-based CAR-T therapy, which is currently being evaluated in a Phase 1 trial for the treatment of patients with metastatic colorectal cancer. Celyad was founded in 2007 and is based in Mont-Saint-Guibert, Belgium, and New York, NY. Celyad's ordinary shares are listed on the Euronext Brussels and Euronext Paris exchanges, and its American Depository Shares are listed on the Nasdaq Global Market, all under the ticker symbol CYAD.

#### For more information, please contact:

#### Celyad

Filippo Petti, Chief Executive Officer - investors@celyad.com Alexandrine Hazard, Communications Associate - T: +32(0) 10 39 41 58 - communications@celyad.com

#### For Europe: Ulysse Communication

Bruno Arabian - T.: +33 (0)6 87 88 47 26 - barabian@ulysse-communication.com

#### U.S.: LifeSci Advisors

Investor Relations: Daniel Ferry - T.: +1 (617) 535 7746 - daniel@lifesciadvisors.com Public Relations: Sara Zelkovic - T.: +1 (646) 876 4933 - sara@lifescipublicrelations.com

#### Forward-looking statements

This release may contain forward-looking statements, including statements regarding: the safety and clinical activity of CYAD-01, CYAD-101 and CYAD-02; statements regarding the ongoing and planned clinical development of CYAD-101 and CYAD-02; statements regarding the ongoing and planned clinical development of CYAD-101 and CYAD-101 and CYAD-102; statements regarding the ongoing and planned clinical development of CYAD-101 and CYAD-102 and CYAD-102 and CYAD-102 and CYAD-103 and CYA01, CYAD-101 and CYAD-02, including the timing of trials, enrolment, data readouts and presentations; the clinical and commercial potential of CYAD-01, CYAD-101 and CYAD-02; and our mAb manufacturing processes. Forwardlooking statements may involve known and unknown risks, uncertainties and other factors which might cause actual results, financial condition and liquidity, performance or achievements of Celyad, or industry results, to differ materially from those expressed or implied by such forward-looking statements. In particular it should be noted that the data summarized above are preliminary in nature. There is limited data concerning safety and clinical activity following treatment with the CYAD-01, CYAD-101 and CYAD-02 drug product candidates. Our therapeutic candidates manufactured using our OptimAb process have not yet been evaluated in clinical trials. Prior clinical and preclinical results may not be repeated or observed in ongoing or future clinical studies involving the CYAD-01 and CYAD-101 drug product candidates. These forward-looking statements are further qualified by important factors and risks, which could cause actual results to differ materially from those in the forward-looking statements, including statements about: the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs; our ability to advance drug product candidates into, and successfully complete, clinical trials; our ability to successfully manufacture drug product for our clinical trials, including with our OptimAb manufacturing process and with respect to manufacturing drug product with the desired number of T cells under our clinical trial protocols; our reliance on the success of our drug product candidates, including our dependence on the regulatory approval of CYAD-01, CYAD-101 and CYAD-02 in the United States and Europe and subsequent commercial success of CYAD-01, CYAD-101 and CYAD-02, both of which may never occur; the timing or likelihood of regulatory filings and approvals; our ability to develop sales and marketing capabilities; the commercialization of our drug product candidates, if approved; the pricing and reimbursement of our drug product candidates, if approved; the implementation of our business model, strategic plans for our business, drug product candidates and technology; the scope of protection we are able to establish and maintain for intellectual property rights covering our drug product candidates and technology; our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights and proprietary technology of third parties; cost associated with enforcing or





defending intellectual property infringement, misappropriation or violation; product liability; and other claims; regulatory development in the United States, the European Union, and other jurisdictions; estimates of our expenses, future revenues, capital requirements and our needs for additional financing; the potential benefits of strategic collaboration agreements and our ability to maintain and enter into strategic arrangements; our ability to maintain and establish collaborations or obtain additional grant funding; the rate and degree of market acceptance of our drug product candidates, if approved; our financial performance; developments relating to our competitors and our industry, including competing therapies and statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance. A further list and description of these risks, uncertainties and other risks can be found in Celyad's U.S. Securities and Exchange Commission (SEC) filings and reports, including in its Annual Report on Form 20-F filed with the SEC on April 5, 2019 and subsequent filings and reports by Celyad. 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 and Celyad's actual results may differ materially from those expressed or implied by these forward-looking statements. Celyad 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.