

## Celyad Successfully Doses First Patient with CYAD-02 in CYCLE-1 Trial for r/r AML and MDS

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- Preliminary data from the Phase 1 CYCLE-1 trial are expected during second half 2020

**Mont-Saint-Guibert, Belgium** - Celyad (Euronext Brussels and Paris, and Nasdaq: CYAD), a clinical-stage biopharmaceutical company focused on the development of CAR-T cell-based therapies, today announced the successful administration of the next-generation, NKG2D-based candidate CYAD-02 to a relapsed/refractory acute myeloid leukemia (r/r AML) patient enrolled in the Phase 1 CYCLE-1 trial.

Dr. Dries Deeren, Head of Clinical Hematology at AZ Delta Hospital Roeselare said, *"We are proud to be participating in the CYCLE-1 trial evaluating the novel CAR-T cell therapy, CYAD-02, for the treatment of patients with advanced acute myeloid leukemia. Initial clinical results from Celyad's AML and MDS program look encouraging. Based on preclinical data, where CYAD-02 has shown a differentiated and more potent profile to the first-generation approach, we're excited to clinically evaluate the next-generation NKG2D construct in such an extremely challenging patient population."*

Frédéric Lehmann, VP of Clinical Development & Medical Affairs at Celyad, added, *"Dosing the first patient with CYAD-02 marks another major milestone to systematically advance our pipeline of proprietary autologous product candidates in our relapsed/refractory acute myeloid leukemia program. We look forward to investigating this next-generation approach which combines our NKG2D receptor, shRNA technology and OptimAb manufacturing process. Enrollment in the CYCLE-1 trial will continue over the coming months and we expect to report preliminary data from the study during the second half of 2020."*

### Background on CYAD-02

CYAD-02 is an investigational CAR-T therapy that engineers an all-in-one vector approach in patient's T-cells to express both (i) the NKG2D chimeric antigen receptor (CAR), a receptor expressed on natural killer cells that binds to eight stress-induced ligands expressed on tumor cells, and (ii) short hairpin RNA (shRNA) SMARTvector technology licensed from Horizon Discovery to knockdown the expression of NKG2D ligands MICA and MICB on the CAR-T cells. In preclinical models, shRNA-mediated knockdown of MICA and MICB expression on NKG2D CAR-T cells has shown enhanced *in vitro* expansion, as well as enhanced *in vivo* engraftment and persistence, of the CAR-T cells, as compared to first-generation NKG2D-based CAR-T cells.

### Background on CYCLE-1 Phase 1 Trial

In November 2019, the Company initiated the Phase 1 CYCLE-1 trial (NCT04167696). The open-label, dose-escalation trial will evaluate the safety and clinical activity of a single infusion of CYAD-02 produced with the OptimAb manufacturing process following preconditioning chemotherapy

cyclophosphamide (300 mg/m<sup>2</sup>) and fludarabine (30 mg/m<sup>2</sup>), or CyFlu, in patients with r/r AML and myelodysplastic syndromes (MDS). In addition, patients are also eligible to receive bridging therapy, based on physician's choice, in advance of treatment with CYAD-02. The trial will evaluate three dose levels of CYAD-02, at 100 million, 300 million and one billion cells per infusion.

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#### **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. Celyad has received funding from the Walloon Region (Belgium) to support the advancement of its CAR-T cell therapy programs.

#### **For more information, please contact:**

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#### **Forward-looking statements**

This release may contain forward-looking statements, including statements regarding: the safety and clinical activity of CYAD-02; statements regarding the ongoing and planned clinical development of CYAD-02, including the timing of trials, enrolment, data readouts and presentations; the clinical and commercial potential of CYAD-02; and the OptimAb manufacturing processes. Forward-looking 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-02 drug product candidate. 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 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-02 in the United States and Europe and subsequent commercial success of 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



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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.