Celyad Successfully Doses First Patient with CYAD-01 Produced with OptimAb Manufacturing Process

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 CYAD-01 produced with the OptimAb manufacturing process to a patient enrolled in cohort 3 (300 million cells) of the Phase 1 DEPLETHINK trial.

Jean-Pierre Latere, Chief Operating Officer of Celyad said “The dosing of the first patient with CYAD-01 manufactured with the OptimAb process marks another important milestone for our company. The OptimAb manufacturing process has shown exciting activity in preclinical models and we believe that the integration of the manufacturing process into our autologous relapsed/refractory acute myeloid leukemia program should help us to improve upon the initial signals we have observed to date with CYAD-01. We look forward to reporting preliminary data from patients enrolled in the DEPLETHINK trial treated with CYAD-01 produced with the OptimAb process by the end of the year.”

Background on CYAD-01
CYAD-01 is an investigational CAR-T therapy in which a patient's T cells are engineered to express a chimeric antigen receptor (CAR) based on NKG2D, a receptor expressed on natural killer (NK) cells that binds to eight stress-induced ligands expressed on tumor cells.

Background on OptimAb Manufacturing Process
The 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 CYAD-01 produced using the OptimAb manufacturing process drives improved anti-tumor activity in an aggressive acute myeloid leukemia (AML) model compared to CYAD-01 produced with the previous mAb manufacturing process.

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 for the treatment of relapsed/refractory AML and myelodysplastic syndromes (MDS) following preconditioning chemotherapy (cyclophosphamide [300 mg/m²] and fludarabine [30 mg/m²]). 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.

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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 Depositary Shares are listed on the Nasdaq Global Market, all under the ticker symbol CYAD.

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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-01, 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. 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-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.