Celyad Announces First Quarter 2020 Financial Results and Recent Business Highlights

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 therapies, today announced an update on operational developments for the first quarter ended March 31, 2020.

“I am extremely proud of our team’s dedication and focus over the past few months in progressing the development of our exciting CAR-T therapies during the COVID-19 pandemic. As a result of their efforts, we’ve continued to advance our programs, bringing us closer to several key milestones associated with our clinical and preclinical programs over the course of 2020. Specifically, we anticipate announcing additional data from our CYAD-101 alloSHRINK Phase 1 trial at ASCO, and filing the IND application for our lead shRNA-based allogeneic candidate CYAD-211 over the next few months, as well as providing a clinical update on our relapsed/refractory AML and MDS program in the second half of the year,” commented Filippo Petti, CEO of Celyad.

First Quarter 2020 and Recent Business Updates

- Initiation of the Phase 1 CYCLE-1 trial evaluating the next-generation autologous NKG2D receptor CAR-T candidate, CYAD-02, for the treatment of relapsed/refractory (r/r) acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS);
- Appointment of Dr. Stephen Rubino as Chief Business Officer as part of the strategic evolution of the management team;
- Appointment of Dr. Maria Koehler and Mr. Dominic Piscitelli to Board of Directors;
- Scheduled to present an update on the allogeneic NKG2D receptor CAR-T candidate, CYAD-101, for the treatment of refractory metastatic colorectal cancer (mCRC) at 2020 American Society of Clinical Oncology (ASCO) Virtual Scientific Program on May 29 – 31.

First Quarter 2020 Financial Review

The Company ended first quarter 2020 with a treasury position of €33.8 million ($37.3 million). Net cash burn over the first quarter of 2020 amounted to €5.5 million, which is in line with expectations. The Company confirms its previous guidance that its treasury position should be sufficient to fund operating expenses and capital expenditure requirements, based on the current scope of activities, through first half 2021.

Update on Clinical and Preclinical Programs

CYAD-01 – Autologous NKG2D CAR-T for r/r AML and MDS

The Company’s first-in-class NKG2D CAR-T clinical candidate CYAD-01 continues to advance in Phase 1 trials for the treatment of patients with r/r AML and MDS. During the first quarter of 2020,
the Company began recruitment within the expansion cohort of the Phase 1 THINK trial evaluating monotherapy CYAD-01. As reported in March 2020, the Company expects to announce preliminary data from CYAD-01 produced with OptimAb manufacturing process, including the expansion cohort of the Phase 1 THINK trial and the dose-escalation Phase 1 DEPLETHINK trial in the second half of 2020.

CYAD-02 – Autologous NKG2D CAR-T for r/r AML and MDS
In January 2020, the Company announced the first patient was dosed in the Phase 1 dose-escalation CYCLE-1 trial evaluating CYAD-02 for the treatment of r/r AML and MDS. In April, the Company began enrollment in the second dose cohort of the trial. The CYCLE-1 trial is assessing the safety and clinical activity of a single infusion of CYAD-02 produced with the OptimAb manufacturing process following preconditioning chemotherapy with cyclophosphamide and fludarabine.

CYAD-101 – Allogeneic TIM-based, NKG2D CAR-T for mCRC
The Company’s allogeneic clinical candidate, CYAD-101, which incorporates the non-gene edited T-cell receptor inhibitory molecule (TIM) technology, continues to advance in the Phase 1 alloSHRINK trial. Preliminary data to date has demonstrated no evidence of graft-versus-host disease (GvHD), no dose-limiting toxicity and promising early signals of clinical activity. Based on the initial data, the Company plans to progress to an expansion cohort of the trial to further evaluate CYAD-101 in refractory mCRC patients. The Company expects to report additional data from the dose-escalation segment of the CYAD-101 alloSHRINK Phase 1 trial at the 2020 ASCO Virtual Scientific Program on May 29 – 31.

CYAD-211 – Allogeneic shRNA-based, BCMA CAR-T for r/r MM
CYAD-211 is the lead program from the Company’s CYAD-200 series of proprietary non-gene edited allogeneic short hairpin (shRNA)-based CAR-T candidates. CYAD-211 targets the B-cell maturation antigen (BCMA) for the treatment of relapsed/refractory multiple myeloma (r/r MM).

Upcoming Milestones
- Report additional data from dose-escalation segment of CYAD-101 Phase 1 alloSHRINK trial at ASCO Virtual Scientific Program;
- Submit Investigational New Drug (IND) application for shRNA-based allogeneic BCMA CAR-T candidate CYAD-211 for the treatment of patients with r/r MM by mid-2020;
- Begin expansion cohort of CYAD-101 alloSHRINK Phase 1 trial during second half 2020;
- Report preliminary data from CYAD-01 produced with OptimAb manufacturing process including expansion cohort of Phase 1 THINK and dose-escalation Phase 1 DEPLETHINK trials during second half of 2020; and
- Report preliminary data from dose-escalation Phase 1 CYCLE-1 trial for CYAD-02 by year-end 2020.

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

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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-02, CYAD-100 Series and CYAD-200 Series; statements regarding the ongoing and planned clinical development of CYAD-01, CYAD-02, CYAD-100 Series and CYAD-200 Series, including the timing of trials, enrolment, data readouts and presentations; the clinical and commercial potential of CYAD-01, CYAD-02, CYAD-100 Series and CYAD-200 Series; the success of the OptimAb manufacturing system; the ongoing and planned clinical and commercial potential and development of Celyad’s shRNA technology; Celyad’s financial condition, results of operation and business outlook. 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-02, CYAD-100 Series and CYAD-200 Series product candidates. These results may not be repeated or observed in ongoing or future studies involving the CYAD-01, CYAD-02, CYAD-100 Series and CYAD-200 Series 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-02, CYAD-100 Series and CYAD-200 Series in the United States and Europe and subsequent commercial success of CYAD-01, CYAD-02, CYAD-100 Series and CYAD-200 Series, 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 product candidates and statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance and the impact of the novel coronavirus, COVID-19, including potential effects on our business, clinical trials, supply chain and manufacturing capabilities. 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 March 25, 2020 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.