Celyad Announces Third Quarter 2019 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 its operational developments for the third quarter ended September 30, 2019.

Filippo Petti, CEO of Celyad stated, “We have reported a steady stream of encouraging news from our pipeline throughout the third quarter and subsequent weeks, including preliminary Phase 1 data for our first-in-class, non-gene edited allogeneic CYAD-101 CAR-T product candidate, the introduction of our proprietary OptimAb manufacturing process to our autologous relapsed/refractory acute myeloid leukemia program led by CYAD-01, and CYAD-02, the acceptance of the IND application for our next-generation candidate CYAD-02, and the advancement of our shRNA technology platform related to our CYAD-200 series of allogeneic product candidates. We continue to establish our position as innovative leaders in the industry as we focus on our core mission of developing innovative CAR-T therapies for cancer patients.”

“In addition, with the closing of our global equity offering in September, we believe the company has sufficient capital resources to enable it to complete its next major clinical milestones, including the upcoming data releases from the CYAD-01 program in relapsed/refractory acute myeloid leukemia,” continued Filippo Petti.

Third Quarter 2019 and Recent Business Highlights

- Successfully dosed the first relapsed/refractory (r/r) acute myeloid leukemia (AML) patient in the DEPLETHINK Phase 1 trial with CYAD-01 produced with OptimAb manufacturing process.
- Presented preliminary data from the ongoing dose-escalation Phase 1 alloSHRINK trial evaluating CYAD-101 at the Society for Immunotherapy of Cancer (SITC) 34th Annual meeting.
  - Results from the trial demonstrated a favorable tolerability profile for CYAD-101, with encouraging anti-tumor activity in the refectory metastatic colorectal cancer (mCRC). Two patients experienced a confirmed partial response, and five patients experienced stable disease for a period of three months or more. In addition, there was no clinical or laboratory evidence of graft-versus-host disease (GvHD).
  - Completed enrollment in the dose-escalation segment of the alloSHRINK trial with additional results from the trial anticipated during first half 2020.
- Continued advancement of proprietary non-gene edited allogeneic short hairpin RNA (shRNA) platform related to the CYAD-200 series of shRNA-based allogeneic CAR-T candidates.
- Closed global equity offering with gross proceeds of $20.0 million (approximately €18.2 million) in September 2019.
Third Quarter 2019 Financial Review

As of September 30, 2019, the Company ended the quarter with a treasury position of €44.6 million ($48.8 million), which includes net proceeds of €17.0 million from the global equity offering in September 2019. Net cash burn over the third quarter of 2019 amounted to €6.1 million, in line with expectations. The Company confirms its previous guidance that its treasury position should be sufficient, based on the current scope of activities, to fund operating expenses and capital expenditure requirements into first half 2021.

Pipeline Updates

CYAD-01 – Autologous NKG2D-based CAR-T

CYAD-01 continues to advance the Phase 1 THINK and DEPLETHINK clinical trials for the treatment of patients with relapsed/refractory (r/r) acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). In September, the Company successfully administered CYAD-01 produced with the OptimAb manufacturing process to a patient enrolled in cohort 3 (300 million cells) of the Phase 1 DEPLETHINK trial. The 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 CYAD-01 produced using the OptimAb manufacturing process drives improved anti-tumor activity in an aggressive AML model compared to CYAD-01 produced with the mAb manufacturing process.

The Company is scheduled to present the latest clinical results from the Phase 1 THINK and DEPLETHINK trials, which utilized CYAD-01 produced with the previous mAb manufacturing process, as well as provide updates on the development program for r/r AML and MDS and proprietary OptimAb manufacturing process at the 61st American Society of Hematology (ASH) Annual Meeting being held on December 7-10 in Orlando, Florida.

CYAD-02 – Autologous NKG2D-based CAR-T

In June, the U.S. Food & Drug Administration accepted the Investigational New Drug (IND) application for CYAD-02, a next-generation, autologous NKG2D-based CAR-T candidate. CYAD-02 incorporates short hairpin RNA (shRNA) technology to target the NKG2D ligands MICA and MICB. The single shRNA modulates the expression of both ligands, which translates to encouraging increases in vivo engraftment and anti-tumor activity in preclinical studies.

The Company is scheduled to present preclinical data for CYAD-02 at the upcoming ASH conference. In addition, the company plans to initiate the Phase 1 CYCLE-01 study evaluating the CYAD-02 following preconditioning chemotherapy in r/r AML in early 2020.

CYAD-101 – TIM-based Allogeneic NKG2D-based CAR-T

Celyad’s first-in-class, non-gene edited allogeneic clinical candidate CYAD-101 continues to advance in the alloSHRINK Phase 1 trial. At the SITC 34th Annual Meeting, the Company presented
preliminary data from the ongoing alloSHRINK trial assessing safety and clinical activity of CYAD-101 in patients with relapsed or refractory metastatic colorectal cancer (mCRC) who had progressed beyond second line metastatic chemotherapy. Preliminary data showed no clinical evidence of GvHD has been observed following 35 injections of CYAD-101, supporting the ability of the company’s novel inhibitory peptide T cell receptor (TCR) inhibiting molecule (TIM) to reduce signaling of the TCR complex through a non-gene edited approach. Treatment with CYAD-101 with prior FOLFOX preconditioning chemotherapy to control the host-versus-graft (HvG) reaction was well-tolerated, with no report of dose-limiting toxicity. No patients discontinued treatment due to adverse events. In addition, the regimen demonstrated encouraging anti-tumor activity, with two patients experiencing a confirmed partial response according to RECIST 1.1 criteria, and five patients experiencing stable disease of more than or equal to three months of duration. Tumor burden decrease was observed in six out of 12 patients in total.

Preliminary results from the completed dose-escalation segment of the alloSHRINK trial are expected in the first half of 2020. This will include three additional patients at dose level three (one billion cells per infusion) of the trial, for a total of nine patients in the cohort, as planned per the protocol.

Based on the data presented to date, the Company plans to expand the trial to further evaluate CYAD-101 with prior FOLFOX chemotherapy in refractory mCRC patients. Enrollment in the expansion segment of the trial is expected to begin in mid-2020 following the production of additional CYAD-101 cells.

**CYAD-200 Series – shRNA-based Allogeneic CAR-Ts**

The Company continues to pursue the development of the proprietary non-gene edited allogeneic shRNA SMARTvertex platform and progress towards filing IND applications for the CYAD-200 series of shRNA-based allogeneic CAR-T candidates, including CYAD-211, the Company’s CAR-T therapy targeting B-cell maturation antigen (BCMA) for the treatment of multiple myeloma.

**Key Upcoming Milestones**

- Poster presentations of THINK Phase 1 trial and DEPLETHINK Phase 1 trial evaluating CYAD-01 produced with the mAb manufacturing process for the treatment of r/r AML and MDS at the 61st ASH Annual Meeting, which will be accompanied by an investor and analyst event (live and webcast) hosted by company on Monday, December 9th.
- Initiation of the Phase 1 dose-escalation CYCLE-01 trial evaluating CYAD-02, following preconditioning chemotherapy, for the treatment of r/r AML and MDS is expected in early 2020.
- Anticipated completion of enrollment of the DEPLETHINK Phase 1 trial evaluating CYAD-01 produced with the OptimAb manufacturing process during first half 2020.
- Updated results from the completed dose-escalation segment of the alloSHRINK trial are expected in first half 2020, including an additional three patients at dose level three (one billion cells per infusion) of the trial.
• Submission of IND application for CYAD-211 (shRNA-based allogeneic BCMA CAR-T candidate) for the treatment of patients with multiple myeloma is anticipated during first half 2020.
• Initiation of the dose-expansion segment of the alloSHRINK trial is anticipated to begin in mid-2020.

Upcoming Conferences

Celyad’s management team is scheduled to participate in the following conferences during the remainder of 2019:

• Jefferies London Healthcare Conference, November 20 - 21
• Evercore ISI HealthCONx Conference, December 3 - 5
• 61st ASH Annual Meeting, December 7-10

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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.

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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.