Celyad Announces Third Quarter 2018 Business Update

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 provided an update on key clinical and operational developments for the third quarter ended September 30, 2018.

THIRD QUARTER 2018 HIGHLIGHTS

- FDA permitted the IND application for CYAD-101 to go into effect
- No toxicity observed in the initial patient treated in the THINK CyFlu cohort evaluating the safety and anti-tumor activity of CYAD-01 after standard preconditioning chemotherapy
- Key additions to the Board of Directors and Senior Leadership Team
- Cash position of €55.9 million as of September 30, 2018

Dr. Christian Homsy, CEO of Celyad, commented: “We continue to be pleased with the flow of data from our clinical programs for CYAD-01. The data to date for CYAD-01 add to a growing body of evidence showing that our cell therapy has encouraging clinical activity across several indications, including acute myeloid leukemia and metastatic colorectal cancer, and is well-tolerated. In addition, we are excited for our lead allogeneic candidate, CYAD-101, which leverages our understanding of NKG2D biology, to enter the clinic for the treatment of metastatic colorectal cancer by year-end.”

THIRD QUARTER 2018 OPERATIONAL AND FINANCIAL REVIEW

Updates to Allogeneic CYAD-101 Program and CYAD-01 THINK CyFlu Cohort

In July 2018, the U.S. Food and Drug Administration (FDA) accepted the Investigational New Drug (IND) application for CYAD-101, the world’s first non-gene edited, allogeneic CAR-T clinical candidate, and permitted it to go into effect. CYAD-101 will initially be evaluated in the alloSHRINK trial. Enrollment in the trial is expected to begin by year-end 2018. In September, Celyad announced the successful injection of the first patient under the amended protocol of the THINK trial, referred to as THINK CyFlu, in patients with metastatic colorectal cancer.
Strengthening our Management Team

In August, the Company announced that Dr. Margo Roberts, former Chief Scientific Officer of Kite Pharma Inc., joined Celyad’s Board of Directors and scientific committee. During the quarter, the Company also announced the appointment of Filippo Petti as Chief Financial Officer and Carri Duncan, PhD, as Vice President Corporate Development & Communications.

Financial review

The Company ended the quarter with €55.9 million in cash, cash equivalents and short-term investments. Use of cash over the third quarter of 2018 amounted to €6.7 million, in line with expectations. The Company confirms its previous guidance that existing cash, cash equivalents and short-term investments should be sufficient to fund operating expenses and capital expenditure requirements, based on the current scope of activities, until mid-2020.

HIGHLIGHTS SUBSEQUENT TO QUARTER-END

In October, Celyad announced an exclusive agreement with Horizon Discovery Group plc (LSE: HZD), for the use of its shRNA technology to generate Celyad’s second non-gene-edited allogeneic platform. Details of the agreement can be found on our website.

In early November, Celyad presented updated clinical results for the CYAD-01 program in solid tumors as well as translational research data at the Society for Immunotherapy of Cancer (SITC) 33rd Annual Meeting. Press release highlighting our advancing clinical and technological platforms can be found here.

Celyad is scheduled to present two abstracts detailing updated clinical results from the Phase 1 THINK dose-escalation trial and upcoming clinical trials for the CYAD-01 program at the American Society of Hematology (ASH) Annual Meeting in San Diego, December 1-4, 2018. Details can be found on our website here.

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About Celyad

Celyad is a clinical-stage biopharmaceutical company focused on the development of specialized CAR-T cell-based therapies. Celyad 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. Its lead oncology candidate, CYAD-01 (CAR-T NKG2D), is currently being evaluated in a Phase I dose escalation clinical trial to assess the safety and clinical activity of multiple administrations of autologous CYAD-01 cells in seven refractory cancers including five solid tumors (colorectal, ovarian, bladder, triple-negative breast and pancreatic cancers) and two hematological tumors (acute myeloid leukemia and multiple myeloma). The safety and clinical activity of the CYAD-01 therapy concurrently administered with standard-of-care treatments or preconditioning chemotherapy is also being assessed in a full clinical development program focused on acute myeloid leukemia and 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 efficacy of CYAD-01 and CYAD-101; statements concerning the ongoing and planned clinical development of CYAD-01 and CYAD-101, including the timing of trials, enrollment, data readouts and presentations; the clinical and commercial potential of CYAD-01 and CYAD-101 and the adequacy of Celyad’s financial resources; statements concerning Celyad’s exclusive agreement with Horizon Discovery Group; the clinical and commercial potential of its shRNA technology; Celyad’s financial condition, results of operation and business outlook; and Celyad’s expected cash burn. 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 and CYAD-101 drug product candidates. These results may not be repeated or observed in ongoing or future 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 mAb 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 and CYAD-101 in the United States and Europe and subsequent commercial success of CYAD-01 and CYAD-101, 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 6, 2018 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.