



Press Release
01 November 2018
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Celyad to Present New CYAD-01 Data from THINK Study in Relapsed/Refractory Acute Myeloid Leukemia at 2018 ASH Annual Meeting

- *Oral presentation highlighting updated THINK study data evaluating CYAD-01 without preconditioning chemotherapy in relapsed or refractory (r/r) acute myeloid leukemia (AML)*
- *As of July 2018, three out of seven (42%) r/r AML patients evaluable for response achieved a complete response (CRh/CRi) following treatment with the per-protocol dose of CYAD-01*
- *Overall, five out of seven (71%) patients achieved meaningful decrease in bone marrow blasts*
- *Company to host Analyst/Investor event on Monday, December 3, 2018*

Mont-Saint-Guibert, Belgium - Celyad (Euronext Brussels and Paris, and Nasdaq: CYAD), a clinical-stage biopharmaceutical company focused on the development of specialized CAR-T cell-based therapies, today announced that two abstracts detailing updated clinical results from the Phase 1 THINK dose-escalation trial and anticipated clinical trials for the CYAD-01 program will be presented at the 60th American Society of Hematology (ASH) Annual Meeting in San Diego, December 1-4, 2018. Company management will also review the results of the THINK trial and provide an update on Celyad's clinical development program for CYAD-01 at an Analyst/Investor event, which will also be available via webcast on December 3, 2018.

"We are encouraged by the preliminary THINK study data evaluating CYAD-01, without preconditioning chemotherapy in patients with relapsed or refractory acute myeloid leukemia," said Dr. Christian Homsy, CEO of Celyad. "The data supplement a growing body of evidence that CYAD-01 shows encouraging clinical activity and is well-tolerated and suggests its potential for the treatment of acute myeloid leukemia, a challenging disease with limited therapeutic options. In addition to this important milestone, we continue to investigate CYAD-01 in alternative protocols to further optimize its clinical benefit."

Updated data from the THINK trial of CYAD-01 in patients with r/r AML will be presented by Principal Investigator David A. Sallman, M.D., of the Moffitt Cancer Center, on December 3, 2018. The presentation will include new information on safety, activity and correlative science data of the complete dose-escalation segment of the trial.

Top-line data from the abstract as of a data cut-off date of July 31, 2018, included:

- Of the seven response-evaluable r/r AML patients enrolled in the trial who received the per-protocol dose of CYAD-01, the best overall response rate was 42% (three patients). Two additional patients experienced important clinical benefit with hematologic improvement and bone marrow blasts decrease, leading to clinical activity of 71% (five patients).
- One patient experienced a complete remission with partial hematologic recovery (CRh) and two patients experienced a complete remission with incomplete marrow recovery (CRi). One CRh and one CRi occurred at dose level 1 (DL1) with an additional CRi at dose level 3. All three responders achieved a response by day 29 (i.e., prior to the third administration of CYAD-01).
- The patient with CRh from DL1 was bridged to allogeneic hematopoietic stem cell transplantation (allo-HSCT) on day +97 post treatment with CYAD-01. This patient remains in durable complete molecular remission (CR_{MRD}-) for more than one year (ongoing). A detailed case report of this patient was published in *Haematologica* in April 2018.
- Of the two additional r/r AML patients who experienced a clinical benefit, one patient had a decrease in blast counts from 24% to 10%, while a second patient had a decrease from 9.8% to 5.5%. Disease stabilization in these patients were observed for three months and over four months (ongoing), respectively. Both patients were treated in dose level 2 of the study.
- Overall, 12 patients with hematological malignancies (AML, myelodysplastic syndrome and multiple myeloma) treated with CYAD-01 in the cohort had reached the safety follow-up. The most common treatment-related adverse events (AEs) included pyrexia, cytokine release syndrome (CRS), hypoxia, lymphopenia, fatigue and nausea. CRS occurred in five patients (three grade 1/2 AEs and two grade 3 AEs), with rapid resolution following the appropriate treatment, including tocilizumab. Overall, five patients experienced grade 3/4 treatment-related AEs. No neurotoxicity AEs were observed in patients treated with CYAD-01.

[CYAD-01 and THINK Trial Design](#)



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

The THINK trial (NCT03018405) is an open-label, dose-escalation Phase 1 trial assessing the safety and clinical activity of multiple CYAD-01 administrations without prior preconditioning in two parallel cohorts: i) patients with hematological malignancies, including r/r AML, and ii) patients with metastatic solid tumors. The dose escalation segment of the study evaluates three dose levels (300 million, 1 billion and 3 billion cells per injection) of one cycle of three CYAD-01 administrations with two-week intervals.

ASH Analyst/Investor Event and Webcast Information

Celyad will host an Analyst/Investor event on Monday, December 3, 2018, beginning at 8:30 p.m. PT to review data presented at ASH. The event will be webcast live and can be accessed under Events & Webcasts in the Investors section of the Company's website.

A complete list of Celyad and collaborator presentations to be made at ASH appears below:

Oral Presentation

Remissions in Relapse/Refractory Acute Myeloid Leukemia Patients Following Treatment with NKG2D CAR-T Therapy Without a Prior Preconditioning Chemotherapy (Abstract #111326 – Publication Number 902)

Presenter: David A. Sallman, M.D., Moffitt Cancer Center

Date: Monday, December 3, 2018, 4:45 p.m. Pacific Time

Location: Manchester Grand Hyatt San Diego, Seaport Ballroom F

Poster Presentation

Phase 1 Studies Assessing the Safety and Clinical Activity of Multiple Doses of a NKG2D-based CAR-T Therapy, CYAD-01, in Acute Myeloid Leukemia (Abstract #114747 – Publication Number 1398)

Presenter: Jason B Brayer, MD, Moffitt Cancer Center

Date: Saturday, December 1, 2018, 6:15 PM - 8:15 PM

Location: San Diego Convention Center, Hall GH

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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 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 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 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 efficacy of CYAD-01 and the mAb manufacturing method used to manufacture this drug product candidate; statements concerning the ongoing and planned clinical development of CYAD-01, including the timing of data readouts and presentations; the clinical and commercial potential of CYAD-01 and the adequacy of Celyad's financial resources; 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



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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 drug product candidate. These results may not be repeated or observed in ongoing or future studies involving the CYAD-01 drug product candidate. 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 in the United States and Europe and subsequent commercial success of CYAD-01, 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 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.