

## Celyad Outlines Key 2019 Priorities Including the Acceleration of the CYAD-01 Program in r/r AML and MDS

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- *Lead candidate CYAD-01 continues to demonstrate encouraging clinical activity in THINK Phase 1 trial with a new complete response (CR) observed in patient with myelodysplastic syndrome (MDS)*
- *Key focus to accelerate the development of CYAD-01 for the treatment of patients with relapsed or refractory (r/r) acute myeloid leukemia (AML) or MDS, including the initiation of a Phase 2 clinical trial during second half 2019*

**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 that it is accelerating its clinical development strategy for AML and MDS and provided updates on clinical candidates CYAD-01 and CYAD-101 with key upcoming milestones for 2019.

*"We made progress in 2018 with our CAR-T clinical programs and we believe the Company is poised to achieve a number of important milestones in 2019,"* noted Dr. Christian Homsy, CEO of Celyad. *"We continue to be encouraged by the clinical data observed with CYAD-01 for the treatment of hematological indications. As a result, we are prioritizing the clinical development program of CYAD-01 for the treatment of relapsed or refractory acute myeloid leukemia or myelodysplastic syndrome towards Phase 2 trials."*

### 2019 Milestones

Building upon its 2018 accomplishments, the Company intends to achieve the following key milestones over the next 12 months:

- Report additional data from the Phase 1 dose-escalation THINK trial for CYAD-01 in r/r AML or MDS patients, including initial data from the schedule optimization portion of the trial;
- Complete enrollment for and report initial data from the Phase 1 dose-escalation DEPLETHINK trial evaluating CYAD-01 with preconditioning chemotherapy in r/r AML or MDS patients;
- Accelerate the development strategy and refine the regulatory pathway plan for CYAD-01 for the treatment of r/r AML or MDS patients, including the initiation of a Phase 2 clinical trial;
- Present *in vivo* preclinical data for our proprietary non-gene edited allogeneic shRNA platform and progress towards an Investigational New Drug (IND) application for the program; and
- Further evaluate the potential for next-generation autologous and allogeneic NKG2D-based CAR-T therapies in the treatment of solid tumors.



## Clinical Update for CYAD-01 in Hematological Malignancies

Celyad's lead clinical candidate, CYAD-01, is currently being evaluated in multiple clinical trials for the treatment of patients with hematological malignancies, including r/r AML and MDS.

### THINK Phase 1 Trial

- In December 2018 at the 60<sup>th</sup> Annual American Society of Hematology meeting, Celyad reported an encouraging objective response rate in r/r AML patients of 38% (three out of eight) from the THINK Phase 1 trial, evaluating CYAD-01 without preconditioning chemotherapy.
- Preliminary data for the last two patients enrolled and treated at dose level 3 show one patient with relapsing MDS with refractory anemia with excess blasts achieved a marrow complete response after two injections of CYAD-01, while the second patient with r/r AML experienced disease stabilization after the first cycle of CYAD-01. Both patients plan to receive a second (consolidation) cycle of therapy.
- Additional results from the THINK Phase 1 trial are expected to be announced during the first half of 2019.

Dr. Frédéric Lehmann, Vice President of Clinical Development and Medical Affairs at Celyad, commented, "*Current clinical data for the last two patients treated at dose level 3 of the THINK trial provide additional support for the further development of CYAD-01 as a potential treatment of r/r AML and MDS and our decision to rapidly identify the best clinical path forward for the investigational therapy.*"

### DEPLETHINK Phase 1 Trial

- In December 2018, Celyad reported initial data from Cohort 1 of the trial, in which the administration of CYAD-01 following the preconditioning regimen of cyclophosphamide and fludarabine was well-tolerated, with no dose-limiting toxicity or treatment-related grade 3 or above adverse events observed. Based on these preliminary safety data from Cohort 1, enrollment has been initiated in Cohort 2 of the trial. Preliminary data from the DEPLETHINK Phase 1 trial are expected in mid-2019.

### EPITHINK Phase 1 Trial

- Based on the data generated to date for CYAD-01 from the THINK trial and the recent update in the treatment landscape for newly diagnosed AML patients, the Company has put the EPITHINK trial on hold to focus its efforts on the development of CYAD-01 for the treatment of r/r AML patients. Celyad plans to reassess the opportunity for CYAD-01 in newly diagnosed AML patients after the optimal treatment design for the therapy is determined. The EPITHINK Phase 1 dose-escalation trial planned to assess the administration of CYAD-01 concurrently with 5-azacytidine in treatment-naïve and/or elderly AML patients ineligible for intensive treatment.



## Solid Tumor Clinical Program Update

- In November 2018 at the Society for Immunotherapy of Cancer 33<sup>rd</sup> Annual Meeting, the Company reported an interim analysis from the Phase 1 dose-escalation SHRINK trial evaluating the safety and activity of CYAD-01 administered concurrently with FOLFOX chemotherapy (a combination of 5-fluorouracil, leucovorin and oxaliplatin) in patients with metastatic colorectal cancer (mCRC). Follow-up assessment of patients based on response evaluation criteria in solid tumors (RECIST) from dose level 1 of the trial confirmed one patient achieved a partial response and two patients experienced disease stabilization. Full data from the SHRINK Phase 1 trial are expected in 2019.
- In December 2018, Celyad initiated the alloSHRINK trial evaluating the non-gene edited allogeneic CAR-T therapy, CYAD-101, administered concurrently with FOLFOX chemotherapy in the treatment of patients with unresectable mCRC. To date, no relevant treatment related toxicity has been observed in the first subject enrolled in the trial. Topline data from alloSHRINK trial are expected in the second half of 2019.

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## About CYAD-01 and CYAD-101

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. CYAD-101 is an investigational, non-gene edited, allogeneic (donor derived) CAR-T therapy that co-expresses the chimeric antigen receptor NKG2D of CYAD-01 and the novel inhibitory peptide TIM (T cell receptor [TCR] Inhibiting Molecule). The expression of TIM reduces signaling of the TCR complex, which is responsible for Graft versus Host Disease (GvHD) and could therefore reduce or eliminate GvHD in patients treated with CYAD-101.

## 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 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 CYAD-101; 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; Celyad's worldwide development and commercialization rights to CYAD-101; the ongoing and planned clinical and commercial potential and development 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



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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.