

## Celyad successfully administers CYAD-01 in first patients in SHRINK and LINK trials

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*Celyad achieves important milestone in CYAD-01 treatment evaluation of metastatic colorectal cancer:*

- *No toxicity observed to date in first patient enrolled in the SHRINK<sup>1</sup> trial (concurrent administration of CYAD-01 with standard chemotherapy)*
- *No toxicity observed to date in first patient enrolled in the LINK<sup>2</sup> trial (hepatic transarterial administrations)*

**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 the successful injection of the first patients in the SHRINK trial and the LINK trial, both targeting metastatic colorectal patients.

**Dr. Christian Homsy, CEO of Celyad commented:** *“The infusion of a first patient in a new trial is always an important moment. CYAD-01, concurrently administered with standard chemotherapy FOLFOX in SHRINK, or administered through hepatic transarterial injections in LINK appears to have been well-tolerated to date. We are particularly satisfied with the lack of on target/off tumor toxicity observed to date in the context of the combination of CYAD-01 with chemotherapy. This bolstered our belief that, based on a careful and exhaustive clinical development plan, our product candidate will lead the path towards a therapy for cancer patients.”*

After the promising signals of clinical activity of CYAD-01 reported in 2017 and validation of the use of the NKG2D receptor, Celyad designed a clinical development plan which aims at defining the best of the following approaches for CYAD-01 in patients with Acute Myeloid Leukemia (AML) and colorectal (CRC) cancers:

- CYAD-01 as a stand-alone investigational therapy, currently being evaluated in the THINK trial with relapsed refractory AML and CRC patients. Results have already been reported: the world's first complete response by a CAR-T cell therapy in a patient with refractory and relapsed AML as well as stable diseases reported in colorectal and ovarian cancer patients.

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<sup>1</sup> Standard CHemotherapy Regimen and Immunotherapy with NKG2D

<sup>2</sup> Loco-regional Immunotherapy with NKG2D

- CYAD-01 administered concurrently with standard of care treatments. The SHRINK trial was initiated with CRC patients earlier in 2018. We expect that the EPITHINK trial will be initiated soon with AML patients.
- CYAD-01 administered after preconditioning of the patients using lymphodepletion. We expect trials in AML (DEPLETHINK AML) and CRC (DEPLETHINK CRC) patients to be initiated in the coming weeks.

Our objective is to continue with the above approach that offers the best observed safety/efficacy profile and to move forward in later phase clinical trials in both AML and CRC indications.

**Dr. Frédéric Lehmann, VP Clinical Development and Medical Affairs at Celyad added:**  
*“Today’s announcement reflects Celyad’s commitment to develop the potential of CYAD-01 and is the result of our strong collaborations with key academic institutions in both the USA and Europe. Our clinical strategy aims to build on the favorable tolerability profile of CYAD-01 observed to date, and evaluate CYAD-01 in multiple settings to find the best approach for cancer patients. We are making good progress and look forward to sharing further results on SHRINK, LINK and other trials.”*

SHRINK is an open-label Phase I trial evaluating the safety and clinical activity of multiple doses of CYAD-01, administered concurrently with the neoadjuvant FOLFOX treatment in patients with resectable liver metastases from colorectal cancer. The dose escalation design of SHRINK includes three dose levels:  $1 \times 10^8$ ,  $3 \times 10^8$  and  $1 \times 10^9$  of CYAD-01. At each dose, the patients will receive three successive administrations, two weeks apart at the specified dose. No adverse events have been reported in the first injection of the first patient enrolled.

LINK is an open-label Phase I trial evaluating the safety and clinical activity of CYAD-01, adopting a loco-regional approach in treating patients with multiple CYAD-01 administration through hepatic transarterial injections to colorectal cancer patients diagnosed with unresectable liver metastases. The dose escalation design of LINK includes three dose levels:  $3 \times 10^8$ ,  $1 \times 10^9$  and  $3 \times 10^9$  of CYAD-01. At each dose, the patients will receive three successive administrations, two weeks apart at the specified dose. No adverse events have been reported in the first patient enrolled, who has received his three consecutive CYAD-01 administrations.

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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), has been evaluated in a single dose escalation Phase I 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). 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

In addition to historical facts or statements of current condition, this press release contains forward-looking statements, including statements about the potential safety, activity, efficacy and feasibility of CYAD-01 cell therapy and other product candidates; including current and planned preclinical studies and clinical trials and regulatory filings for Celyad's product candidates; the clinical and commercial potential of these product candidates and the adequacy of Celyad's financial resources; the strength of Celyad's intellectual property portfolio and plans related thereto; Celyad's expectations regarding its strategic collaborations and license agreements with third parties, including Novartis, Celdara Medical, and Dartmouth College, and the potential impact of such collaborations on Celyad's future financial condition, including anticipated milestones and royalties and the timing thereof; Celyad's expected cash burn, which reflect Celyad's current expectations and projections about future events; and the anticipating timing of Celyad's 2017 annual report, and involve certain known and unknown risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. 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 risks associated with conducting clinical trials; the risk that safety, bioactivity, feasibility and/or efficacy demonstrated in earlier clinical trials or preclinical studies may not be replicated in subsequent trials or studies; risks



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associated with the timely submission and approval of anticipated regulatory filings; the successful initiation and completion of clinical trials, including its clinical trials for CYAD-01; risks associated with the successful manufacture of drug product for its clinical trials; risks associated with the satisfaction of regulatory and other requirements; risks associated with the actions of regulatory bodies and other governmental authorities; risks associated with obtaining, maintaining and protecting intellectual property, Celyad's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; risks associated with competition from others developing products for similar uses; risks associated with Celyad's ability to manage operating expenses; and risks associated with Celyad's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and business initiatives. 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 4, 2017 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. 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.