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# Celyad reports a first complete response in a relapsed refractory AML patient in the THINK trial

• First ever morphologic complete response (MLFS<sup>1</sup>) with gene-engineered T cells without prior pre-conditioning chemotherapy for a patient with relapsed refractory acute myeloid leukemia (AML).

**Mont-Saint-Guibert, Belgium** - Celyad (Euronext Brussels and Paris, and NASDAQ: CYAD), a pioneer in the discovery and development of CAR-T cell therapies, today announces exciting early clinical results of the first dose-level in the hematological arm of its THINK trial (**TH**erapeutic Immunotherapy with CAR-T **NK**G2D).

**Christian Homsy, CEO of Celyad** comments: "*We are pleased to have demonstrated the first objective clinical response of CYAD-01 (a.k.a. CAR-T NKG2D) as this is the very first time a relapsed, refractory AML patient has reached a MLFS with gene-engineered T cells without pre-conditioning lymphodepletion nor additional other concurrent treatment to CYAD-01 administration. This success further reinforces our confidence in our approach and the validity of NKG2D ligands as a target. We will now use the collected data to move forward with the next stage of our product development: reinforcing responses in as many clinical settings as possible.*"

At the first dose-level 3x10<sup>8</sup> CYAD-01 T cells were administered without any prior conditioning chemotherapy to a cohort of three patients with hematologic cancer (two with AML and one with Multiple Myeloma, MM). One AML patient has achieved a MLFS after administration with CYAD-01 at the H. Lee Moffitt Cancer Center and Research Institute (Florida, USA).

**Dr. David Sallman, Assistant Member in the Malignant Hematology Department of Moffitt Cancer Center, comments** " The results announced today regarding CYAD-01 provide the first clinical validity of CYAD-01 as a tumor-specific antigen-receptor and AML as a disease sensitive to gene-engineered cell therapies. As antigen targeting offers significant challenges in AML, this outcome brings hope for the further use of gene-engineered T cells for patients with AML that have run out of therapeutic options. It's all the more striking that this outcome was observed without any prior lymphodepletion highlighting the potential of using a physiologic antigenreceptor."

AML is a blood cancer characterized by a rapid increase of abnormal white blood cells in the bone marrow, which in turn affects the production of normal blood cells. More than 20,000 people in

<sup>• &</sup>lt;sup>1</sup> MLFS for Morphological Leukemia-Free Status



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the US and almost as many people in Europe are diagnosed every year with this type of blood cancer. As AML's incidence increases with age and as population ages, it is expected that a growing number of people might be affected by this type of cancer.

**Dr. Frédéric Lehmann, Vice President Clinical Development and Medical Affairs at Celyad adds:** "*With this first objective and ongoing response, obtained without additional treatments such as lymphodepletion, CYAD-01 confirms the potential to treat relapsed refractory AML, one of the deadliest cancers with a median overall survival of less than 4 months. The concept of CAR-T cells with the NKG2D receptor is now progressing to further validation.*"

The THINK trial, conducted in the US and in Europe, includes two stages: a dose escalation and an extension stage. The dose escalation is being conducted in parallel in solid cancers (colorectal, pancreatic, ovarian, triple negative breast and bladder) and in hematologic (AML and MM) cancer groups, while the extension phase will evaluate in parallel each tumor type independently. The dose escalation design includes three dose levels adjusted to body weight: up to  $3\times10^8$ ,  $1\times10^9$  and  $3\times10^9$  CYAD-01. At each dose, the patients receive three successive administrations, two weeks apart, of CYAD-01 at the specified dose. To date, 14 patients have been dosed in the THINK trial. One Grade Three and one Grade Four event have been observed, both resolved within 72 hours. No dose limiting toxicities (DLT) nor deaths related to the investigational product have been reported.

# Celyad's management will host a conference call at 2pm CEST/8am EDT on Friday October 6, 2017

## **Conference Call Details**

A conference call will be held on Friday October 6, 2017 at 2:00pm (CEST) / 8:00am (EDT) to provide an update on Celyad's clinical strategy. Christian Homsy, Chief Executive Officer, and Patrick Jeanmart, Chief Financial Officer, will deliver a brief presentation followed by a Q&A session.

Participants are asked to call the assigned numbers approximately five minutes before the conference call begins.

The call can be accessed by dialling the numbers below and using the passcode: 95148855

International:	+44 (0) 2071 928338
Belgium:	02 793 3847
France:	0170700781
UK:	0800 2796619
US:	1 877 8709135

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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 Natural Killer Receptor based T-Cell (NKR-T) 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 Boston, Massachusetts. 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.

For more information about Celyad, please visit: <u>www.celyad.com</u>

#### For more information, please contact:

#### Celyad

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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 and feasibility of CYAD-01 cell therapy, including current and planned preclinical and clinical trials for Celyad's product candidates; the clinical and commercial potential of these product candidates and the adequacy of Celyad's financial resources; Celyad's intellectual property portfolio, including 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; and Celyad's expected cash burn, which reflect Celyad's current expectations and projections about future events, 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 associated with



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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 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.