Persbericht
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Celyad dient CYAD-01 met success toe bij eerste darmkanker-patiënt na preconditionerende chemotherapie

- *Geen toxiciteit waargenomen tot op heden bij eerste patiënt in aangepast THINK-onderzoek ter beoordeling van de veiligheid en antitumor-respons van CYAD-01 na preconditionerende chemotherapie bij patiënten met darmkanker*

Mont-Saint-Guibert, Belgium - Celyad (Euronext Brussel en Parijs, en NASDAQ: CYAD), een klinisch biofarmaceutisch bedrijf dat zich richt op de ontwikkeling van celgebaseerde CAR-T behandelingen, kondigde vandaag de succesvolle toediening aan bij de eerste patiënt onder het aangepaste protocol van het THINK-onderzoek. Deze aangepaste studie evalueert de CYAD-01-behandeling na een niet-myeloablatieve preconditionerende chemotherapie (cyclofosfamide en fludarabine) bij refractaire patiënten met metastatische darmkanker (CRC).

"De eerste dosering van CYAD-01 in deze toepassing is een nieuwe belangrijke stap voor ons bedrijf", zei Dr. Christian Homsy, CEO van Celyad. "CYAD-01 heeft veelbelovende tekenen van klinische activiteit aangetoond als stand-alone therapie; we doen er nu ook alles aan om het klinisch voordeel voor patiënten te maximaliseren door verder onderzoek te doen naar CYAD-01 in een reeks verschillende aanpakken. We wensen de antitumoractiviteit van CYAD-01 niet alleen als stand-alone therapie te evalueren maar ook met preconditionering en standaard chemotherapie, in zowel solide tumoren als in bloedkankers. Deze aanvullende onderzoeken zullen duidelijk maken welke de beste klinische aanpakken zijn voor een patiëntenpopulatie die echt behoefte heeft aan nieuwe therapeutische opties."

Het aangepaste THINK-onderzoek is een open-label, single arm Fase I-onderzoek, ontworpen om de veiligheid en antitumoractiviteit van CYAD-01 te evalueren enkel bij patiënten met metastatische CRC na toediening van cyclofosfamide (300 mg / m²) en fludarabine (30 mg / m2). Op basis van de eerste gegevens van het onderzoek zou een per-protocol-uitbreidingsfase kunnen worden gestart.

CYAD-01 is een onderzoekstherapie waarbij de T-cellen van een patiënt bewerkt worden om de chimere antigeenreceptor NKG2D tot expressie te brengen. NKG2D is een receptor die tot expressie wordt gebracht op natuurlijke killercellen (NK)-cellen die zich binden aan acht door stress geïnduceerde ligands die zich op tumorcellen bevinden. CYAD-01, door middel van een aantal onderzoeken, is momenteel in klinische ontwikkeling voor solide tumoren en bloedkankers.

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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.

For more information, please contact:

Celyad

Christian Homsy, CEO and Filippo Petti CFO
Nicolas Van Hoecke, Director, Investor Relations & Communications - T: +32(0) 10 39 41 84 – investors@celyad.com

For Belgium: Comfi

Sabine Leclercq - T.: +32 (0)2 290 90 90 – celyad@comfi.be

For France: NewCap

Pierre Laurent and Nicolas Mérigeau - T: + 33(0)1 44 71 94 94 - **celyad@newcap.eu**

For the U.S.: LifeSci Advisors

Daniel Ferry – T.: +1 (617) 535 7746 **– daniel@lifesciadvisors.com**
Public Relations: Allison Blum – T:+1 (646) 627 8383 - **allison@lifescipublicrelations.com**

Forward-looking statements

This release may contain forward-looking statements, including statements regarding the safety and efficacy of CYAD-01 and the new 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 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 interim 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 new 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.