Persbericht
13 januari 2019
7:00 am CET

Celyad Successfully Doses First Patient with CYAD-02 in CYCLE-1 Trial for r/r AML and MDS

- *Preliminaire data van de CYCLE-1 studie worden verwacht in de tweede jaarhelft van 2020*

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 aan dat een patiënt met recidief/refractaire acute myeloïde leukemie (r/r AML) in de CYCLE-1 fase I klinische studie succesvol toegediend werd met CYAD-02, een NKG2D-gebaseerd kandidaat medicijn van de volgende generatie.

Dr. Dries Deeren, Hoofd van de dienst Klinische Hematologie aan het AZ Delta Hospitaal Roeselare zei, *"We zijn trots om deel te nemen aan de CYCLE-1 klinische studie die de nieuwe CAR-T celtherapie CYAD-02 evalueert voor de behandeling van patiënten met gevorderde acute myeloïde leukemie. Initiële klinische resultaten van Celyads AML en MDS programma zien er bemoedigend uit. Gebaseerd op preklinische data waar CYAD-02 een gedifferentieerd en krachtiger profiel toonde in vergelijking met de eerste-generatie behandeling, zijn we enthousiast om deze volgende generatie van het NKG2D construct klinisch te evalueren in zo'n extreem moeilijk te behandelen patiëntenpopulatie."*

Frédéric Lehmann, VP Klinische Ontwikkeling & Medische Zaken bij Celyad, voegde daaraan toe, *"De eerste patiënt met CYAD-02 doseren markeert een volgende belangrijke mijlpaal om onze pijplijn van propriëtaire autologe productkandidaten systematisch vooruit te brengen in ons recidief/refractaire acute myeloïde leukemie programma. We kijken er naar uit om deze benadering van de volgende generatie te testen, die onze NKG2D receptor, shRNA technologie en OptimAb productieproces combineert. Patiëntregistratie in de CYCLE-1 studie zal verder gaan gedurende de volgende maanden en we verwachten om preliminaire data van deze studie te rapporteren in de tweede jaarhelft van 2020."*

Achtergrond over CYAD-02

CYAD-02 is een kandidaat CAR-T therapie die gebruik maakt van een alles-in-één vector in T cellen van patiënten om volgende elementen tot expressie te brengen: i) de NKG2D chimere antigen receptor (CAR), een receptor die tot expressie komt op natural killer cellen en acht stress-geïnduceerde liganden die tot expressie komen op tumorcellen kan binden, en ii) short hairpin RNA (shRNA) SMARTvector technologie onder licentie van Horizon Discovery, om de expressie van NKG2D liganden MICA en MICB op de CAR-T cellen te verlagen. In preklinische modellen leidde de shRNA-gemedieerde verlaging van MICA and MICB expressie op NKG2D CAR-T cellen tot toegenomen *in vitro* expansie alsook tot toegenomen *in vivo* innesteling en persistentie van de CAR-T cellen vergeleken met de eerste generatie NKG2D-gebaseerde CAR-T cellen.

Achtergrond over de CYCLE-1 Fase 1 Klinische Studie

In november 2019 begon het Bedrijf met de Fase 1 CYCLE-1 Klinische Studie (NCT04167696). Deze open-label, dosis-uitbreidingsstudie zal de veiligheid en klinische activiteit nagaan van een enkele infusie van CYAD-02 geproduceerd met het OptimAb productieproces, volgend op preconditionerende chemotherapie cyclophosphamide (300 mg/m²) en fludarabine (30 mg/m²), of CyFlu, in patiënten met r/r AML en MDS. Daarenboven kunnen patïenten ook overbruggende therapie ontvangen gebaseerd op de keuze van de behandelende arts voor de behandeling met CYAD-02. De studie zal drie dosislevels van CYAD-02 evalueren: respectievelijk 100 miljoen, 300 miljoen en 1 miljard cellen per infusie.

EINDE

About Celyad

Celyad is a clinical-stage biopharmaceutical company focused on the development of specialized CAR-T cell-based product candidates and 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. The company's lead clinical candidate, CYAD-01, an autologous NKG2D-based CAR-T therapy, is currently being evaluated in several Phase 1 clinical trials to assess safety and clinical activity for the treatment of hematological malignancies, such as acute myeloid leukemia, and solid cancers, such as metastatic colorectal cancer. Celyad is also developing CYAD-101, an investigational, non-gene edited, allogeneic (donor derived) NKG2D-based CAR-T therapy, which is currently being evaluated in a Phase 1 trial for the treatment of patients with metastatic 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. Celyad has received funding from the Walloon Region (Belgium) to support the advancement of its CAR-T cell therapy programs.

For more information, please contact:

Celyad
Filippo Petti, Chief Executive Officer – investors@celyad.com
Alexandrine Hazard, Communications & IR Associate – T: +32(0) 10 39 41 58 – communications@celyad.com

For Europe: Ulysse Communication
Bruno Arabian – T.: +33 (0)6 87 88 47 26 – barabian@ulysse-communication.com

U.S.: LifeSci Advisors
Investor Relations: Daniel Ferry – T.: +1 (617) 430 7576 – daniel@lifesciadvisors.com
Public Relations: Sara Zelkovic – T.: +1 (646) 876 4933 – sara@lifescipublicrelations.com

Forward-looking statements

This release may contain forward-looking statements, including statements regarding: the safety and clinical activity of CYAD-02; statements regarding the ongoing and planned clinical development of CYAD-02, including the timing of trials, enrolment, data readouts and presentations; the clinical and commercial potential of CYAD-02; and the OptimAb manufacturing processes. 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-02 drug product candidate. Our therapeutic candidates manufactured using our OptimAb process have not yet been evaluated in clinical trials. Prior clinical and preclinical results may not be repeated or observed in ongoing or future clinical studies involving the CYAD-01 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 OptimAb 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-02 in the United States and Europe and subsequent commercial success of CYAD-02, 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 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 5, 2019 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.