Persbericht
30 november 2018
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Celyad dient eerste dosis toe aan mCRC Patient in de Fase 1 alloSHRINK klinische studie die niet-genbewerkte allogene CAR-T productkandidaat CYAD-101 evalueert

- *Topline data van de alloSHRINK studie worden verwacht in de tweede helft van 2019*
- *Het Bedrijf verwerft opnieuw de volle ontwikkelings- en commercialisatierechten voor CYAD-101 in Japan, Korea en Taiwan van ONO Pharmaceutical*

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 injectie aan van de eerste patient in de Fase I alloSHRINK klinische studie. Die studie evalueert de niet-genbewerkte allogene CAR-T therapie CYAD-101 van het Bedrijf, samen toegediend met FOLFOX chemotherapie in de behandeling van patiënten met niet resecteerbare metastatische colorectale kanker (mCRC).

"Het begin van de alloSHRINK studie markeert een belangrijke mijlpaal voor onze organizatie" zei Dr. Christian Homsy, CEO van Celyad. *"CYAD-101 vertegenwoordigt een mogelijke first-in-class benadering van allogene CAR-T therapie and draagt verder bij aan de sleutelpositie van Celyad in het allogene veld. Die wordt verankerd met de robuuste allogene octrooiportfolio van het Bedrijf in de V.S. en aangevuld door onze nieuwe shRNA-gebaseerde niet-genbewerkte platform."*

Dr. Frédéric Lehmann, VP Clinical Development & Medical Affairs bij Celyad, becommentarieerde: *"CYAD-101 is het tweede oncologieprogramma van Celyad dat in de kliniek start voor de behandeling van metastatische colorectale kanker en is een tegenhanger voor de autologe klinische productkandidaat CYAD-01 van het bedrijf, die bemoedigende preliminaire resultaten gaf in de Fase 1 SHRINK studie. We geloven dat het onderzoek van CYAD-101 in de alloSHRINK studie onze klinische ervaring in de behandeling van metastatische colorectale kanker tot nu verder ten goede zal komen, omdat we blijven uitkijken naar de ontwikkeling van nieuwe therapieën voor deze verschrikkelijke ziekte."*

Celyad kondigde ook aan dat ONO Pharmaceutical Co., Ltd. het Bedrijf heeft verwittigd dat het CYAD-101 niet verder zal ontwikkelen in Japan, Korea en Taiwan. Celyad en ONO Pharmaceutical gingen een exclusieve licentie-overeenkomst voor de ontwikkeling en commercializatie van CYAD-101 aan in deze specifieke gebieden in juli 2016. Op basis van deze overeenkomst moest ONO Pharmaceutical een optie lichten bij het begin van de Fase I studie

voor CYAD-101. De overeenkomst is nu beëindigd en Celyad heeft weer controle over de wereldwijde ontwikkelings- en commercializatierechten van CYAD-101.

CYAD-101 en het design van de alloSHRINK Studie
CYAD-101 is een experimentele, niet-genbewerkte, allogene (van een donor afkomstige) CAR-T-therapie die zowel de chimere antigen receptor NKG2D, een receptor die tot expressie komt op natural killer (NK) cellen en bindt aan acht stress-geïnduceerde liganden op tumorcellen, en het innovatieve inhiberende peptide TIM (T cel receptor [TCR] Inhibiting Molecule) tot expressie brengt. TCR-signalisatie is de oorzaak van de graft-versus-hostziekte (GvHD). De expressie van TIM vermindert de signalisatie van het TCR-complex en zou GvHD dus kunnen verminderen of uitschakelen bij patiënten die behandeld worden met CYAD-101.

De alloSHRINK studie (NCT03692429) is een open-label, dosisescalatieonderzoek dat de veiligheid en klinische activiteit zal nagaan van CYAD-101, samen toegediend met FOLFOX chemotherapie in patiënten met niet-resecteerbare mCRC. Patiënten zullen in totaal zes cycli FOLFOX chemotherapie ontvangen om de twee weken en drie toedieningen CYAD-101 om de twee weken 48 uur na de aanvang van chemotherapie cyclus een, twee en drie. De drie dosisniveaus die geëvalueerd worden zijn respectievelijk 100 miljoen, 300 miljoen, en 1 miljard cellen per injectie.

EINDE

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; statements concerning 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; statements concerning Celyad's exclusive agreement with Horizon Discovery Group; the clinical and commercial potential 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 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.