Persbericht
20 juli 2017
7u00 CEST

Celyad kondigt start van het SHRINK-onderzoek aan

- **De SHRINK-studie evalueert het synergetisch effect van gelijktijdige toediening van CYAD-01 (CAR-T NKG2D) en standaardchemotherapie bij patiënten met gemetastaseerde colorectale kanker**

Mont-Saint-Guibert, België - Celyad SA/NV (Euronext Brussel en Parijs, en NASDAQ: CYAD), een leider op het gebied van de ontdekking en ontwikkeling van gespecialiseerde celgebaseerde CAR-T behandelingen, kondigt vandaag de start aan van het SHRINK-onderzoek, de derde klinische studie met zijn toonaangevende productkandidaat CYAD-01 (CAR-T NKG2D) dat zich richt op patiënten met gemetastaseerde colorectale kanker.

SHRINK (**S**tandard C**h**emotherapy **R**egimen and **I**mmunotherapy with **NK**R-2) is een open-label fase I-studie die de veiligheid en klinische activiteit evalueert van meerdere doses CYAD-01, samen toegediend met de neoadjuvante FOLFOX-behandeling bij patiënten met potentieel resecteerbare levermetastasen van colorectale kanker.

Dr. Christian Homsy, CEO van Celyad, lichtte toe: "We zijn verheugd dat we met het SHRINK-onderzoek starten omdat het ons toelaat om de doeltreffendheid te evalueren van onze veelbelovende CYAD-01-therapie in combinatie met chemotherapie. We zijn ervan overtuigd dat ons partnerschap met belangrijke Belgische kankerinstituten ons nieuwe inzichten in de behandeling van gemetastaseerde colorectale kanker zal bieden. De aankondiging van vandaag, samen met ons, nog lopende, THINK-onderzoek en de verwachte LINK-studie, bevestigt nogmaals onze inzet en toewijding om kanker, vooral dan solide tumoren, te verslaan."

Dr. Frédéric Lehmann, Vice-President klinische ontwikkeling en medische zaken bij Celyad voegde daaraan toe: "Als koploper in dit domein is het onze taak om het potentieel van de CAR-T-behandelingen verder te ontwikkelen. De start van het SHRINK-onderzoek is een volgende belangrijke mijlpaal voor ons en voor patiënten wereldwijd. Dit onderzoek evalueert het synergetisch effect van gelijktijdige toediening van onze toonaangevende productkandidaat CYAD-01 en standaardchemotherapie als eerstelijnbehandeling voor gemetastaseerde colorectale kanker. We kijken uit naar de eerste infusie bij deze patiënt met colorectale kanker die in de volgende weken zal plaats hebben alsook naar de registratie van de andere patiënten. De SHRINK-studie is een van de nieuwe studies van Celyad die in 2017 van start gaan, en maakt deel uit van een uitgebreid internationaal klinisch programma dat de ontwikkeling van ons productkandidaat CYAD-01 ondersteunt."

SHRINK zal in belangrijke Belgische oncologiecentra worden uitgevoerd. De studie omvat een dosisescalatiefase en een uitbreidingsfase. De studie-opzet voor de dosisescalatie zal drie

dosisniveaus omvatten telkens aangepast in functie van het lichaamsgewicht: tot $3x10^8$, $1x10^9$ en $3x10^9$ CYAD-01. Bij elk dosisniveau krijgen de patiënten drie opeenvolgende toedieningen, telkens om de twee weken, met de vermelde dosis CYAD-01. Aan de dosisescalatiefase van de studie zullen hoogstens 18 patiënten deelnemen, aan de uitbreidingsfase zouden 21 extra patiënten deelnemen.
De indicatie van colorectale kanker die in het SHRINK-onderzoek wordt geëvalueerd, werd geselecteerd op basis van bewijs afkomstig van de preklinische settings en de nog lopende THINK-studie.

SHRINK is de derde klinische studie van Ceylad met zijn productkandidaat CYAD-01, een CAR-T-celtherapie die NKG2D-liganden viseert, om de veiligheid en werking bij gemetastaseerde colorectale kanker te evalueren. De twee andere onderzoeken zijn CM-CS1 (voltooid) en THINK (nog lopend).

EINDE

About Celyad

Celyad is a clinical-stage biopharmaceutical company focused on the development of specialized CAR-T cell based therapies. The company 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, the CAR-T NKR-2, has been evaluated in a single dose escalation Phase I clinical trial to assess the safety and feasibility of CAR-T NKR-2 cells in patients suffering from AML or MM. This Phase I study was successfully completed in September 2016. 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 NASDAQ Global Market, all under the ticker symbol CYAD.

For more information about Celyad, please visit: www.celyad.com

About Celyad's NKR-T Cell Platform

Celyad is developing a unique CAR-T cell platform, using Natural Killer Receptor (NKR) transduced on to T lymphocytes. The platform targets a wide range of solid and hematological tumors. Unlike traditional CAR-T cell therapy, which target only one tumor antigen, Natural Killer (NK) cell receptors enable a single receptor to recognize multiple tumor antigens.
Celyad's lead candidate, CAR-T NKR-2, is a CAR-T-Cell engineered to express the human NK receptor, NKG2D, which is an activating receptor. CAR-T NKR-2 triggers cell killing through the binding of NKG2D to any of eight naturally occurring ligands that are known to be overexpressed on more than 80% of tumors.
Preclinical results indicate that CAR-T NKR-2 has multiple mechanisms of actions and goes beyond direct cancer cell killing. It inhibits the mechanisms that enable tumors to evade the immune system, activates and recruit anti-tumor immune cells and disrupts the blood supply to the tumor. These mechanisms promote the induction of adaptive immunity, meaning the development of a long-term immune memory against specific tumor antigens of the targeted tumor.
In contrast to traditional CAR-T therapeutic approaches, and based on strong preclinical evidence, Celyad's current CAR-T NKR-2 program does not use patient lymphodepleting pre-conditioning, thereby avoiding the toxicities associated with chemotherapy and allowing the immune system to remain intact.
Celyad is developing both autologous and allogeneic CAR-T NKR-2 approaches. For autologous CAR-T NKR-2, Celyad collects the patient's own T-Cells and engineers them to express NKG2D in order to target cancer cells effectively. Celyad's allogeneic

platform engineers the T-Cells of healthy donors, to also express TCR Inhibitory Molecules (TIMs), to avoid having the donor cells rejected by the patient's normal tissues (also called Graft vs. Host Disease).
The preclinical research underlying this technology was originally conducted at Dartmouth College by Dr. Charles Sentman and has been published extensively in peer-reviewed publications.

For more information, please contact:

For Europe: Consilium Strategic Communications
Chris Gardner and **Chris Welsh -** T: +44 (0)20 3709 5700 – celyad@consilium-comms.com

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

For Belgium: Comfi
Gunther De Backer and **Sabine Leclercq -** T.: +32 (0)2 290 90 90 – celyad@comfi.be

For the U.S.: Stern Investor Relations
Will O'Connor and **Michael Schaffzin –** T.: +1 212.362.1200 **–** celyad@sternir.com

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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 CAR-T NKR-2 cell therapy, which reflect our 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, 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 or pre-clinical studies may not be replicated in subsequent studies; risk associated with the timely submission and approval of anticipated regulatory filings; the successful initiation and completion of clinical trials, including Phase I clinical trial for CAR-T NKR-2; 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, our ability to enforce our patents against infringers and defend our patent portfolio against challenges from third parties; risks associated with competition from others developing products for similar uses; risks associated with our ability to manage operating expenses; and risks associated with our ability to obtain additional funding to support our 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 the Company's Securities and Exchange Commission filings and reports, including in the Company's Annual Report on Form 20-F filed with the SEC on April 8, 2016 and future filings and reports by the Company. 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. The Company 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.