Persbericht
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Haematologica publiceert rapport over volledige remissie van patiënt met gerecidiveerde refractaire AML na behandeling met Celyad's CYAD-01

Casus detailleert allereerste complete morfologische remissie bij gerecidiveerde refractaire AML patiënt na behandeling met genetisch gemanipuleerde T cellen zonder preconditionering

Mont-Saint-Guibert, België - Celyad (Euronext Brussel en Parijs, en NASDAQ: CYAD), een klinisch biofarmaceutisch bedrijf dat zich richt op de ontwikkeling van CAR-T-cel therapieën, kondigt aan dat het tijdschrift *Haematologica*[1] later vandaag een patiëntcasus uit het THINK Phase I-onderzoek publiceert. De auteurs van deze publicatie, getiteld "*NKG2D-based Chimeric Antigen Receptor Therapy Induced Remission in a Relapsed/Refractory Acute Myeloid Leukemia Patient*" zijn onderzoekers van het Moffitt Cancer Center en Research Institute uit Florida (VS) en leden van het wetenschappelijke team van Celyad.

Het tijdschrift geeft details vrij over de eerste objectieve respons verkregen na een CAR-T behandeling bij recidiverende en refractaire acute myeloïde leukemie (AML) na toediening van CYAD-01, Celyad's Natural Killer Group 2D (NKG2D) chimere antigeenreceptor T-celtherapie, zonder voorafgaande lymfodepletie. De patiënt kreeg driemaal het aanvangsdosisniveau van CYAD-01 toegediend ($3x10^8$-cellen), met een periode van twee weken tussen elke dosis. Na drie maanden bereikte de patiënt een morfologische leukemie-vrije toestand[2] wat de patiënt toeliet een allo-hematopoietische stamceltransplantatie (allo-HSCT) te ondergaan. Deze leidde tot een volledige moleculaire remissie van de patiënt die, tot op heden, 9 maanden na zijn registratie in de THINK-studie, nog steeds in remissie is. De CYAD-01 behandeling werd goed verdragen zonder significante toxiciteiten.

De aangetoonde eerste objectieve respons na een CAR-T behandeling in recidiverende en refractaire AML zonder chemotherapeutische preconditionering benadrukt het potentieel van CYAD-01 als behandeling voor AML.

"Onze resultaten demonstreren de validiteit van NKG2D als target, vooral in de context van refractaire AML en zonder andere behandelingen noch preconditionering", verklaarde ***Frédéric Lehmann,*** **vicepresident klinische ontwikkeling en medische zaken bij Celyad**. *"We kijken*

[1] http://www.haematologica.org/content/early/recent

[2] MLFS : Morphologic Leukemia-Free State

ernaar uit om het klinisch ontwikkelingsplan voor ons NKG2D CAR-T gebaseerd platform verder te zetten en de verschillende voorwaarden te onderzoeken waarbinnen deze therapie oplossingen kan bieden aan kankerpatiënten in een eindstadium."

Dr. David Sallman, Assistant Member in het Malignant Hematology Department van het Moffitt Cancer Center: *"Deze THINK-casus biedt de eerste klinische validiteit voor CYAD-01 als een tumorspecifieke antigenreceptor en AML als ziekte gevoelig voor genetisch gemanipuleerde celtherapieën. Daar antigeen-targeting belangrijke uitdagingen biedt in AML, biedt dit resultaat hoop voor het verdere gebruik van genetisch gemanipuleerde T-cellen voor patiënten met AML die alle medische mogelijkheden hebben uitgeput. Het is des te opvallender dat dit resultaat werd vastgesteld zonder voorafgaande lymfodepletie, wat het potentieel benadrukt van het gebruik van een fysiologische antigenreceptor ."*

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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), 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 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.

About the THINK Trial

THINK (**TH**erapeutic **I**mmunotherapy with **NK**G2D) is a multinational (EU/US) open-label Phase I study 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 trial test three dose levels: up to $3x10^8$, $1x10^9$, and $3x10^9$ CYAD-01 cells per injection. At each dose-level, the patients will receive three successive adminitrations of CYAD-01 cells, two weeks apart. The dose-escalation part of the study will enroll up to 24 patients while the extension phase would enroll up to 86 additional patients.

About Celyad's CAR-T cell Platform

Celyad is developing a unique CAR T-cell platform, transducing Natural Killer Receptors (NKR) onto T lymphocytes. Unlike traditional CAR T-cell therapy, which targets only one tumor antigen, each natural killer (NK) cell receptor recognizes multiple antigens.

Celyad's lead candidate, CYAD-01, is a CAR T-cell engineered to express the human NK receptor, NKG2D, which is an activating receptor. CYAD-01 triggers cell killing through the binding of NKG2D to any of its eight naturally occurring ligands, which are known to be overexpressed on more than 80% of tumors. Preclinical results indicate that CYAD-01 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, enabling the development of long-term immune memory against specific tumor antigens.

Celyad is developing both autologous and allogeneic CAR T-cell NKG2D approaches. CYAD-01 is an autologous therapy where 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 (CYAD-101) engineers the T cells of healthy donors, to express NKG2D as well as TCR Inhibitory Molecules (TIMs), to avoid having the donor cells rejected by the patient's immune system (Graft vs. Host Disease). The preclinical research underlying this technology was originally conducted at Dartmouth College by Dr. Charles Sentman and has been described extensively in peer-reviewed publications.

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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, activity, efficacy and feasibility of CYAD-01 cell therapy and other product candidates, including current and planned preclinical studies and clinical trials and regulatory filings for Celyad's product candidates; the clinical and commercial potential of these product candidates and the adequacy of Celyad's financial resources; the strength of Celyad's intellectual property portfolio and 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, including anticipated milestones and royalties and the timing thereof; Celyad's expected cash burn, which reflect Celyad's current expectations and projections about future events; and the anticipating timing of Celyad's 2017 annual report, 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 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 successful manufacture of drug product for its clinical trials; 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.