Celyad dient eerste AML-patiënt met einddosis toe in CYAD-01 THINK-studie en start behandeling eerste patiënt met tweede behandelingscyclus

- Celyad dient derde en laatste dosisniveau toe in bloedkankergroep van THINK-onderzoek
- Tweede behandelingscyclus met CYAD-01 in THINK-onderzoek goedgekeurd en eerste patiënt gedoseerd

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, heeft vandaag aangekondigd dat de eerste injecties op het derde, en laatste, dosisniveau van CYAD-01 bij een eerste patiënt met acute myeloïde leukemie (AML) in het fase 1 THINK-onderzoek werden toegediend.

"*De tolerantie van CYAD-01 tot op heden waargenomen als mono-therapie, samen met de eerste waargenomen tekenen van klinische activiteit in recidiverende en refractaire AML, benadrukken het ontwikkelingspotentieel van ons product voor zowel hematologische kankers als solide tumoren*", verklaarde Dr. Christian Homsy, CEO van Celyad. "*We zijn begonnen met het toedienen van de eerste injecties op het derde dosisniveau van CYAD-01 bij een recidiverende refractaire AML-patiënt van de THINK-studie zonder toxiciteitsproblemen te hebben waargenomen. We kijken uit naar het beëindigen van de dosis-escalatiefase, mogelijks naar een expansiefase, en naar het rapporteren van interimresultaten van het THINK-onderzoek op medische congressen later dit jaar. Daarenboven zijn we verheugd mee te delen dat het toedienen van een tweede cyclus van CYAD-01 bij een eerste patiënt eerder deze maand begonnen is.* "

De open-label fase 1 THINK-studie wordt in de VS en in Europa uitgevoerd. De dosisescalatiefase, gelijktijdig uitgevoerd in solide tumoren en in bloedkankers, omvat drie dosisniveaus: tot $3x10^8$, $1x10^9$ en $3x10^9$ CYAD-01-cellen per dosis. Bij elke dosisniveau ontvangen de patiënten drie opeenvolgende toedieningen, telkens om de twee weken, met de vermelde dosis CYAD-01.

Verwacht wordt dat in totaal 3 AML-patiënten het derde en laatste, hoogste dosisniveau toegediend zullen krijgen. Tot op heden werden met CYAD-01 reeds, aan lagere doses, tekenen van klinische activiteit waargenomen in de THINK-studie bij AML-patiënten die één complete cyclus CYAD-01-behandeling voltooid hebben aan de per protocool-dosis gaande van volledige

repons tot "Stable Disease" (ziekte-stabilisatie). Celyad rapporteerde eerder 's werelds eerste volledige respons na een CAR-T-celtherapie bij een patiënt met refractaire en recidiverende AML, zonder dat beroep gedaan werd op preconditioneringstherapie.

Op basis van de veelbelovende tekenen van activiteit die tot op heden werden waargenomen, evalueert Celyad nu of een tweede toedieningscyclus van CYAD-01 de klinische respons zou kunnen verbeteren of verlengen. Een eerste patiënt op het tweede dosisniveau is met succes aan zijn tweede behandelingscyclus begonnen zonder enige tot nu toe gemelde toxiciteitsproblemen.

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 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, CYAD-01 (CAR-T NKG2D), has been evaluated in a single dose escalation Phase 1 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 Boston, Massachusetts. 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 the new mAb manufacturing method used to manufacture this drug product candidate; statements concerning the ongoing and planned clinical development of CYAD-01. 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. The THINK trial is not complete. 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.