

# CELYAD ONCOLOGY SA

## FORM 6-K

(Report of Foreign Issuer Pursuant to Rule 13a-16 or 15d-16)

Filed 05/12/21 for the Period Ending 05/12/21

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 6-K**

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**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16  
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

**For the Month of May 2021**

**Commission File Number: 001-37452**

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**CELYAD ONCOLOGY SA**

**(Translation of registrant's name into English)**

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**Rue Edouard Belin 2  
1435 Mont-Saint-Guibert, Belgium  
(Address of principal executive offices)**

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F       Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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**Celyad Oncology SA**

On May 12, 2021, Celyad Oncology SA (the “Company”) issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

*The information contained in this Current Report on Form 6-K, including Exhibit 99.1, except for the quote of Filippo Petti contained in Exhibit 99.1, is hereby incorporated by reference into the Company’s Registration Statements on Form F-3 (File No. 333-248464) and Form S-8 (File No. 333-220737).*

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**EXHIBITS**

Exhibit

Description

99.1 [Press release issued by the Company on May 12, 2021](#)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**CELYAD ONCOLOGY SA**

Date: May 12, 2021

By: /s/ Filippo Petti

Filippo Petti

*Chief Executive Officer and Financial Officer*



**Celyad Oncology to Present Data from Phase 1 IMMUNICY-1 Trial of Non-Genetically Edited Allogeneic CAR T Candidate CYAD-211 in Relapsed/Refractory Multiple Myeloma at the European Hematology Association Virtual Congress**

May 12th, 2021 10:01 p.m. CEST

- *No Grade  $\geq$  3 treatment-related adverse events nor evidence of Graft-versus-Host disease reported from the completed first dose-level (DL1) cohort of Phase 1 dose-escalation IMMUNICY-1 trial evaluating the shRNA-based anti-BCMA CAR T candidate, CYAD-211, for relapsed/refractory (r/r) multiple myeloma*
- *Initial clinical activity observed, with one confirmed partial response (PR) observed in this low dose ( $30 \times 10^6$  cells per infusion)*

Mont-Saint-Guibert, Belgium – Celyad Oncology SA (Euronext & Nasdaq: CYAD), a clinical-stage biotechnology company focused on the discovery and development of chimeric antigen receptor T-cell (CAR T) therapies for cancer, today announced that an abstract highlighting initial clinical data from the Phase 1 IMMUNICY-1 trial of CYAD-211 has been accepted for e-poster presentation at the upcoming European Hematology Association (EHA) Virtual Congress 2021

Filippo Petti, Chief Executive Officer at Celyad Oncology, commented, “We are very pleased with the initial results from the low dose cohort of our first shRNA-based allogeneic candidate, CYAD-211, which has showed preliminary signs of clinical activity, including a confirmed partial response, with no evidence of Graft-versus-Host-Disease. We are encouraged by the observed clinical activity at such a low dose level and the overall steady progress of the trial to date. Our team is intently focused on further assessing whether shRNA-mediated knockdown can generate safe, functional and clinically relevant allogeneic CAR T-cells for the treatment of cancer while offering an alternative technology platform with key advantages over gene-editing. We are excited for the opportunity to present the latest safety, clinical activity and cell kinetic data for the program next month at EHA and look forward to future updates for the program throughout 2021 as we move towards our goal of establishing proof-of-concept for this dynamic platform.”

CYAD-211 is an investigational, non-gene edited allogeneic CAR T candidate engineered to co-express a single hairpin RNA (shRNA) and a BCMA-targeting chimeric antigen receptor in development for the treatment of relapsed/refractory multiple myeloma (r/r MM). This non-gene editing technology, which does not permanently alter the genome integrity, is intended to decrease the potential safety risk associated with “off-target” genome modifications. This “All-in-One” Vector approach with one single transduction step avoids multiple genetic modifications and cost associated with additional GMP grade materials.

**EHA 2021 ePoster Presentation Details:**

The following abstract published today is now available on the EHA 2021 [website](#). Following the presentation at the meeting, the posters will be available in the [Scientific Publications](#) section of Celyad Oncology’s website.

**Title:** Objective response at low dose in the first-in-human IMMUNICY-1 trial evaluating non-gene edited allogeneic CYAD-211 anti-BCMA CAR T product in relapsed or refractory multiple myeloma

**Presenter:** Dr. Sébastien Anguille, Antwerp University Hospital (UZA), Edegem, Belgium

**Topic:** Gene therapy, cellular immunotherapy and vaccination—Clinical

**Date and Time:** e-Poster available starting Friday, June 11, 2021 at 9:00 a.m. CEST

**Abstract Number:** EP739

**About CYAD-211**

CYAD-211 is an investigational, shRNA-based allogeneic CAR T candidate for the treatment of r/r MM. CYAD-211 is engineered to co-express an anti-BCMA targeting chimeric antigen receptor and a single shRNA to knockdown the CD3zeta component of the T cell receptor complex.

**About IMMUNICY-1 Phase 1 trial**

The open-label, dose-escalation trial will evaluate the safety and clinical activity of CYAD-211 following cyclophosphamide and fludarabine preconditioning chemotherapy in patients with relapsed or refractory multiple myeloma. The trial will evaluate multiple dose levels of CYAD-211:  $30 \times 10^6$ ,  $100 \times 10^6$  and  $300 \times 10^6$  cells per infusion. For more information, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov), study identifier number [NCT04613557](#).

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## **About Celyad Oncology SA**

Celyad Oncology SA is a clinical-stage biotechnology company focused on the discovery and development of CAR T therapies for cancer. The Company is developing a pipeline of allogeneic (off-the-shelf) and autologous (personalized) CAR T cell therapy candidates for the treatment of both hematological malignancies and solid tumors. Celyad Oncology was founded in 2007 and is based in Mont-Saint-Guibert, Belgium and New York, NY. The Company has received funding from the Walloon Region (Belgium) to support the advancement of its CAR T cell therapy programs. For more information, please visit [www.celyad.com](http://www.celyad.com).

## **Forward-Looking Statement**

This release may contain forward-looking statements, within the meaning of applicable securities laws, including the Private Securities Litigation Reform Act of 1995. Forward-looking statements may include statements regarding: the safety and clinical activity of Celyad Oncology's pipelines and financial condition, results of operation and business outlook. Forward-looking statements may involve known and unknown risks and uncertainties which might cause actual results, financial condition, performance or achievements of Celyad Oncology to differ materially from those expressed or implied by such forward-looking statements. Such risk and uncertainty includes outcomes of the Phase 1 IMMUNICY-1 trial of CYAD-211. A further list and description of these risks, uncertainties and other risks can be found in Celyad Oncology'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 March 24, 2021 and subsequent filings and reports by Celyad Oncology. These forward-looking statements speak only as of the date of publication of this document and Celyad Oncology's actual results may differ materially from those expressed or implied by these forward-looking statements. Celyad Oncology 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.

## **Investor and Media Contacts:**

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Source: Celyad Oncology SA