# CELYAD ONCOLOGY SA

## FORM 6-K

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

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

# FORM 6-K

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

**For the Month of December 2020**

**Commission File Number: 001-37452**

# CELYAD ONCOLOGY SA

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

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

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): ☐

**Celyad Oncology SA**

On December 7, 2020, Celyad Oncology SA (the "Company") issued a press release, a copy of which is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

*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 Forms F-3 (File No. 333-248464) and S-8 (File No. 333-220737).*

**EXHIBITS**

| Exhibit | Description |
| --- | --- |
| 99.1 | Press release issued by the registrant on December 7, 2020 |

**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: December 7, 2020

By: /s/ Filippo Petti
Filippo Petti
*Chief Executive Officer and Financial Officer*

**Exhibit 99.1**

Regulated Information
Inside Information

**Celyad Oncology Provides Updates on Allogeneic and Autologous CAR T Programs at 62nd ASH Annual Meeting and Exposition**

- *First patient dosed in the CYAD-211 Phase 1 IMMUNICY-1 trial. Preclinical results for CYAD-211 for multiple myeloma showed robust antitumor activity with no demonstrable evidence of Graft-versus-Host Disease*
- *Company discontinues the development of first-generation, autologous CAR T candidate CYAD-01 based on clinical futility observed to date from the Phase 1 THINK trial*
- *Preliminary data from CYCLE-1 trial evaluating next-generation autologous CYAD-02 in r/r AML / MDS patients showed encouraging clinical signals, including a high-risk MDS patient treated at dose level 3 who achieved an objective marrow complete response; dose level 3 cohort of the CYCLE-1 trial is ongoing*
- *Management to hold a conference call later today, December 7, at 1 p.m. CET/ 7 a.m. ET*

December 7, 2020 07:00 a.m. CET

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 updates from the company's shRNA-based anti-B cell maturation antigen (BCMA) allogeneic CAR T candidate, CYAD-211, and autologous NKG2D receptor-based CAR T candidates, CYAD-01 and CYAD-02. These updates were virtually presented at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition, held from December 5-8, 2020.

"The recent announcement of the dosing of our first patient with CYAD-211 in the IMMUNICY-1 trial was a major milestone for the organization as we continue to strategically focus on next-generation allogeneic CAR T cell therapies underpinned by our innovative shRNA technology platform that we took from concept to clinic in just two years," said Filippo Petti, Chief Executive Officer of Celyad Oncology. "With IMMUNICY-1, we're not only looking to offer patients with refractory multiple myeloma an option where few exist, but also to use this as an opportunity to validate the use of our shRNA platform as a novel allogeneic technology in what we believe could greatly expand our potential to develop best-in-class, off-the-shelf CAR T cell therapies."

Mr. Petti added, "While we are disappointed by the latest update from the Phase 1 THINK trial for CYAD-01, we are encouraged by the initial clinical results from our next-generation CYAD-02 candidate for the treatment of patients with relapsed or refractory AML and MDS and look forward to future updates from the CYCLE-1 trial. With greater perspective on our autologous programs, the organization will remain steadfast in our commitment to patients with cancer by continuing to concentrate on the discovery and development of novel, allogeneic CAR T candidates."

CYAD-211 and IMMUNICY-1 Phase 1 Trial Update

*Background*

- CYAD-211 is a first-in-class, allogeneic CAR T candidate engineered to co-express a BCMA targeting chimeric antigen receptor and a single shRNA, which interferes with the expression of the CD3ζ component of the T cell receptor complex.
- IMMUNICY-1 will evaluate the safety and clinical activity of a single infusion of CYAD-211 following preconditioning chemotherapy cyclophosphamide and fludarabine in patients with relapsed/refractory multiple myeloma (r/r MM).
- The trial seeks to determine the recommended dose of CYAD-211 in r/r MM patients for further development as well as to establish proof-of-principle that single shRNA-mediated knockdown can generate allogeneic CAR T cells in humans without inducing Graft-versus-Host Disease (GvHD).
- On December 4, 2020, the company announced dosing of the first patient in the CYAD-211 Phase 1 IMMUNICY-1 trial.

*Preclinical Results*

- CYAD-211 demonstrated robust anti-tumor activity *in vitro* and *in vivo* concurrent with lack of alloreactivity in preclinical MM models.
- No demonstrable evidence of GvHD was observed with CYAD-211 in preclinical models confirming efficient inhibition of alloreactivity.

*Study Design*

- The IMMUNICY-1 trial is a first-in-human, open-label dose-finding study evaluating three dose levels of CYAD-211, including $3x10^7$, $1x10^8$ and $3x10^8$ cells per infusion, in patients with r/r MM.

*Next Steps*

- Proof-of-principle data from the initial dose cohorts are expected during first half 2021.
- Clinical activity data from the full dose-escalation trial are expected during second half 2021.

CYAD-01 and THINK Phase 1 Trial Update

*Background*

- The company's first generation NKG2D receptor-based CAR T clinical candidate CYAD-01 was evaluated for the treatment of patients with r/r acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) in the Phase 1 THINK trial.
- In 2019, the company implemented the OptimAb manufacturing process within the CYAD-01 program, to be evaluated in the study expansion cohort of the THINK trial. The trial intended to assess the safety and clinical activity of CYAD-01 when produced with the OptimAb process following no preconditioning chemotherapy.

*Latest Clinical Data*

- Overall, eight of the eleven patients planned per protocol in the THINK trial were treated with OptimAb-produced CYAD-01 cells.
- No dose-limiting toxicities were reported from patients treated with OptimAb-produced CYAD-01 cells.
- Stable disease (SD) was achieved in two of eight patients treated with OptimAb-produced CYAD-01 cells (one MDS and one AML patient); an additional MDS patient became eligible for an allogeneic stem cell transplantation after treatment with CYAD-01 and achieved a complete response. No objective responses were observed following treatment with OptimAb-produced CYAD-01 cells.

*Next Steps*

- Based on clinical futility observed to date of CYAD-01 from the Phase 1 THINK trial the company has decided to discontinue the development of CYAD-01 for the treatment of r/r AML / MDS. No additional patients will be enrolled in the CYAD-01 program.

CYAD-02 and CYCLE-1 Phase 1 Trial Update

*Background*

- In November 2019, the company initiated the dose-escalation Phase 1 CYCLE-1 trial, evaluating the safety and clinical activity of the next-generation, autologous NKG2D receptor-based CAR T candidate CYAD-02 following preconditioning chemotherapy in patients with r/r AML / MDS.
- The next-generation, NKG2D receptor-based CAR T candidate CYAD-02 incorporates shRNA to target the NKG2D ligands MICA and MICB. In preclinical models, shRNA-mediated knockdown of MICA and MICB expression on NKG2D receptor-based CAR T cells has shown enhanced *in vitro* expansion, as well as enhanced *in vivo* engraftment and persistence of the CAR T cells, as compared to first-generation NKG2D receptor-based CAR T cells.

*Preliminary Clinical Data*

- To date, nine patients have received treatment with CYAD-02: three patients at dose level 1, three patients at dose level 2 and three patients at dose level 3.
- CYAD-02 was generally well-tolerated, with one grade 4 infusion reaction (dose level 1) and one grade 3 cytokine release syndrome (dose level 3). Both patients recovered rapidly following the appropriate treatment.
- To date, seven patients were evaluable for clinical activity:
    - Of the five very high-risk MDS patients: (i) three patients demonstrated anti-leukemic activity (at least 50% bone marrow blasts decrease) with the single patient evaluated at dose level 3 achieved a marrow complete response (mCR) at first assessment (ongoing); (ii) two additional patients exhibited a durable SD of more than five months (one of two ongoing).
    - Of the two adverse AML patients, one patient demonstrated anti-leukemic activity with a SD of four months (ongoing).

*Next Steps*

- The dose level 3 cohort of the CYCLE-1 trial is ongoing. Additional safety and efficacy data from the trial are expected during the first half of 2021.

Conference Call and Webcast Details

Celyad Oncology will host a conference call to discuss the update from ASH on Monday, December 7, 2020 at 1 p.m. CET / 7 a.m. ET. The conference call can be accessed through the following numbers:

United States: +1 877 407 9716
International: +1 201 493 6779

The conference call will be webcast live and can be accessed here. The event will also be archived and available on the "Events " section of the company's website. Please visit the website several minutes prior to the start of the broadcast to ensure adequate time for registration to the webcast.

**About CYAD-211**

CYAD-211 is an investigational, short hairpin RNA (shRNA)-based allogeneic CAR T candidate for the treatment of relapsed or refractory multiple myeloma (r/r MM). CYAD-211 is engineered to co-express a BCMA targeting chimeric antigen receptor and a single shRNA, which interferes with the expression of the CD3ζ component of the T cell receptor (TCR) complex. In July 2020, Celyad Oncology announced FDA Clearance of its IND application for CYAD-211.

**About CYAD-01**

CYAD-01 is an investigational CAR T therapy in which a patient's T cells are engineered to express a chimeric antigen receptor (CAR) based on NKG2D, a receptor expressed on natural killer (NK) cells that binds to eight stress-induced ligands expressed on tumor cells.

**About CYAD-02**

CYAD-02 is an investigational CAR T therapy that engineers an all-in-one vector approach in patient's T cells to express both (i) the NKG2D chimeric antigen receptor (CAR), a receptor expressed on natural killer cells that binds to eight stress-induced ligands expressed on tumor cells, and (ii) short hairpin RNA (shRNA) SMARTvector technology licensed from Horizon Discovery to knockdown the expression of NKG2D ligands MICA and MICB on the CAR T cells. In preclinical models, shRNA-mediated knockdown of MICA and MICB expression on NKG2D CAR T cells has shown enhanced in vitro expansion, as well as enhanced in vivo engraftment and persistence, of the CAR T cells, as compared to first-generation NKG2D receptor based CAR T cells.

**About Celyad Oncology**

Celyad Oncology is a clinical-stage biotechnology company focused on the discovery and development of chimeric antigen receptor T cell (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.

**Forward-looking statements**

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 clinical and preclinical activity of CYAD-02 and CYAD-211. 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 include the duration and severity of the COVID-19 pandemic and government measures implemented in response thereto. 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 25, 2020 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:**

Sara Zelkovic
Communications & Investor Relations Director
Celyad Oncology
investors@celyad.com
Daniel Ferry
Managing Director
LifeSci Advisors, LLC
daniel@lifesciadvisors.com

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