

CELYAD ONCOLOGY SA

FORM 6-K

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

Filed 11/12/20 for the Period Ending 11/12/20

Telephone	32 10 394 100
CIK	0001637890
Symbol	CYAD
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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 November 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 November 10, 2020, Celyad Oncology SA (the “Company”) issued a press release, announcing that the third quarter 2020 financial results of the company as well as an update on its operational developments.

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 Forms F-3 (File No. 333-220285) and S-8 (File No. 333-220737).

EXHIBITS

<u>Exhibit</u>	<u>Description</u>
99.1	Press release issued by the registrant on November 10, 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: November 12, 2020

By: /s/ Filippo Petti

Filippo Petti

Chief Executive Officer and Financial Officer



Celyad Oncology Announces Third Quarter 2020 Financial Results and Recent Business Highlights

November 10, 2020 10:01 p.m. CET

- *Established a clinical trial collaboration with MSD to evaluate CYAD-101 with KEYTRUDA® in patients with microsatellite stable mCRC*
- *Expect to initiate the expansion cohort of the Phase 1 alloSHRINK trial for CYAD-101 in mCRC patients following FOLFIRI preconditioning chemotherapy by year-end 2020*
- *Phase 1 dose-escalation trial for lead shRNA-based allogeneic CAR T candidate, CYAD-211, for r/r MM on track to begin by year-end 2020*

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 an update on its operational developments for the third quarter ended September 30, 2020.

“We are pleased with the continued momentum seen across our allogeneic clinical programs over the past few months,” commented Filippo Petti, Chief Executive Officer of Celyad Oncology. “Major milestones during third quarter 2020 include expanding the CYAD-101 clinical program for the treatment of metastatic colorectal cancer through our recent clinical trial agreement with MSD to conduct the KEYNOTE-B79 study which will evaluate the potential synergy of pairing CYAD-101 with KEYTRUDA. We are also steadily progressing towards the initiation of the Phase 1 IMMUNICY-1 study by end of year for our anti-BCMA shRNA-based candidate CYAD-211 for the treatment of relapsed/refractory multiple myeloma. In addition, upcoming data from our autologous NKG2D receptor-based CAR T candidates, which we plan to announce at the annual ASH congress, will help guide next steps for our AML franchise.”

Third Quarter 2020 and Recent Business Highlights

- Announced plans to conduct a Phase 1b KEYNOTE-B79 clinical study of non-gene edited allogeneic CAR T therapy CYAD- 101 following FOLFIRI (combination of 5-fluorouracil, leucovorin and irinotecan) preconditioning chemotherapy, with MSD’s, a tradename of Merck, anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in refractory metastatic colorectal cancer (mCRC) patients with microsatellite stable (MSS) / mismatch-repair proficient (pMMR) disease.
- Hosted a Research & Development webinar for investors and analysts on September 29th, with a replay currently available on the [Events page](#) of the Company’s website. Topics covered during the event included:
 - Presentation by Dr. Richard Kim, M.D., Professor of Oncology, Moffitt Cancer Center, on the immuno-oncology and treatment landscapes for mCRC and,
 - Overview of Celyad Oncology’s candidate CYAD-101 for mCRC and CYAD-211 for relapsed / refractory multiple myeloma (r/r MM), and the company’s short hairpin RNA (shRNA) platform and All-in-One vector approach.
- Announced U.S. Food and Drug Administration (FDA) clearance of the Investigational New Drug (IND) application and approval of the Clinical Trial Application (CTA) by the Federal Agency for Medicines and Health Products (FAMHP) of Belgium for the Company’s lead shRNA-based allogeneic candidate CYAD-211, clearing the way to initiate the Phase 1 IMMUNICY-1 clinical trial by the end of 2020.
- Established an Open Market Sale AgreementSM with Jefferies LLC, pursuant to which the Company may from time to time sell through “an at the market offering” up to \$25,000,000 of new American Depositary Shares.

Third Quarter 2020 Financial Review

As of September 30, 2020, the Company ended the quarter with a treasury position of €20.0 million (\$23.4 million). Net cash burn during the third quarter of 2020 amounted to €6.7 million (\$7.8 million), in line with expectations. The Company confirms its previous guidance that its existing treasury position should be sufficient, based on the current scope of activities, to fund operating expenses and capital expenditure requirements into the third quarter of 2021.

Update on Clinical and Preclinical Programs

CYAD-101 – Allogeneic TIM-based, NKG2D receptor-based CAR T for mCRC

Celyad Oncology's first-in-class, non-gene edited clinical candidate CYAD-101 continues to advance in the alloSHRINK Phase 1 trial for the treatment of mCRC. CYAD-101 co-expresses the NKG2D receptor and the novel inhibitory peptide TIM (TCR Inhibitory Molecule), whose expression reduces signaling of the TCR complex by interfering with the CD3 ζ component of the TCR complex. The Company plans to initiate the expansion cohort of the alloSHRINK trial which will evaluate CYAD-101 following FOLFIRI preconditioning chemotherapy in refractory mCRC patients, at the recommended dose of one billion cells per infusion. Enrollment in this expansion cohort is expected to start by year-end 2020.

Planning is also ongoing to initiate the Phase 1b KEYNOTE-B79 study of CYAD-101, following FOLFIRI preconditioning chemotherapy, with MSD's KEYTRUDA® in refractory mCRC patients with MSS / pMMR disease during the first half of 2021. The Company believes the mechanism of actions between CYAD-101 and KEYTRUDA® are highly complementary and could help to drive meaningful clinical benefit in patients with advanced mCRC.

CYAD-211 – Allogeneic shRNA-based, anti-BCMA CAR T for r/r MM

CYAD-211 is an investigational, short hairpin RNA (shRNA)-based allogeneic CAR T candidate for the treatment of 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 CD3 ζ component of the T-cell receptor (TCR) complex. In July 2020, Celyad Oncology announced FDA clearance of its IND application for CYAD-211 and subsequently received CTA approval for CYAD-211 by the FAMHP. The Company plans to initiate the Phase 1 IMMUNICY-1 trial evaluating CYAD-211 following preconditioning chemotherapy in r/r MM by year-end 2020.

CYAD-01 – Autologous NKG2D receptor-based CAR T for r/r AML and MDS

The Company's first-in-class NKG2D receptor-based CAR T clinical candidate CYAD-01 continues to advance in the ongoing Phase 1 THINK trial for the treatment of patients with r/r acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). The Company is scheduled to announce preliminary data from CYAD-01 produced with the OptimAb manufacturing process from the expansion cohort of the Phase 1 THINK trial at the American Society of Hematology (ASH) conference in December 2020.

CYAD-02 – Next-Generation Autologous NKG2D receptor-based CAR T for r/r AML and MDS

CYAD-02 is an investigational CAR T therapy that engineers an All-in-One vector approach in patient's T cells to express the NKG2D receptor CAR and shRNA to knockdown the expression of NKG2D ligands MICA and MICB on the CAR T cells. The Company is currently conducting the Phase 1 dose-escalation CYCLE-1 trial evaluating CYAD-02 for the treatment of r/r AML and MDS. During the third quarter, the Company initiated the third dose cohort of the trial. The CYCLE-1 trial is assessing the safety and clinical activity of a single infusion of CYAD-02 produced with the OptimAb manufacturing process following preconditioning chemotherapy with cyclophosphamide and fludarabine. Preliminary data from CYCLE-1 trial are expected at the ASH conference in December 2020.

Upcoming Milestones

- Plan to begin enrollment in the expansion cohort of the Phase 1 alloSHRINK trial evaluating CYAD-101 following FOLFIRI preconditioning chemotherapy in refractory mCRC patients by year-end 2020.
- Expect to initiate the dose-escalation Phase 1 IMMUNICY-1 trial evaluating CYAD-211 in r/r MM by year-end 2020.
- Expect to initiate the Phase 1b KEYNOTE-B79 clinical study of CYAD-101 following FOLFIRI preconditioning chemotherapy, with KEYTRUDA® in refractory mCRC patients in first half of 2021.
- Three abstracts accepted for presentation at the annual ASH Meeting & Exposition, being held December 5–8, including:
 - Poster presentation of the Company's anti-BCMA allogeneic CAR T candidate, CYAD-211
 - Poster presentations of the Company's autologous NKG2D receptor-based CAR T candidates, CYAD-01 and CYAD-02

Upcoming Conferences

Celyad Oncology's management team is scheduled to participate in the following conferences during the remainder of 2020:

- Bryan, Garnier & Co. Virtual European Healthcare Conference, November 16, 2020
- Jefferies Virtual London Healthcare Conference, November 17, 2020
- SVB Leerink Oncology 1x1 Day, November 19, 2020
- 62nd American Society of Hematology Annual Meeting & Exposition, December 5 – 8, 2020

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 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 the expected date of the Phase 1 IMMUNICY-1 trial initiation by year-end 2020, and 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



Source: Celyad Oncology SA