

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 August 2022

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

As previously disclosed, on March 1, 2022, the Company received notification from the U.S. Food and Drug Administration (the “FDA”) that the CYAD-101-002 (KEYNOTE-B79) trial had been placed on clinical hold due to insufficient information to assess risk to study subjects. On August 1, 2022, the Company announced that the FDA had lifted the clinical hold on the CYAD-101-002 trial after the Company made changes to the eligibility criteria for the trial. A copy of the Company’s press release announcing the lifting of the clinical hold 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 Dr. Charles Morris 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).

EXHIBITS

<u>Exhibit</u>	<u>Description</u>
99.1	Press release issued by the Company on August 1, 2022

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: August 1, 2022

By: /s/ Michel Lussier

Michel Lussier

Interim Chief Executive Officer



Celyad Oncology Announces FDA Lifts Clinical Hold of CYAD-101-002 Phase 1b Trial

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 the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the CYAD-101-002 (KEYNOTE-B79) Phase 1b trial after the Company made changes to the eligibility criteria for the trial.

“We are pleased that the FDA lifted the clinical hold on this trial. We remain confident in the potential development of not only the candidate itself, but the continued development with our proprietary TIM technology. CYAD-101 is currently our only clinical candidate co-expressing NKG2D and TIM, and we hope to continue to showcase our expertise with our non-gene edited technologies and explore additional opportunities to utilize NKG2D in allogeneic CAR T,” said Dr. Charles Morris, Chief Medical Officer of Celyad Oncology.

As previously disclosed, on February 28, 2022, the Company announced that it was voluntarily pausing the CYAD-101-002 trial to investigate reports of two fatalities in the study. The trial was subsequently put on clinical hold in March 2022 by the FDA.

The CYAD-101-002 Phase 1b trial evaluates the TCR Inhibitory Molecule (TIM)-based allogeneic NKG2D CAR T cell investigational therapy CYAD-101 with MSD’s anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with refractory metastatic colorectal cancer (mCRC) with microsatellite stable (MSS) / mismatch-repair proficient disease.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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 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 include statements regarding: the continued development of the KEYNOTE-B79 trial and Celyad Oncology’s ability to engage in future opportunities using non-gene edited technologies. 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 risks and uncertainties can be found in Celyad Oncology’s U.S. Securities and Exchange Commission (SEC) filings and reports, including in the latest Annual Report on Form 20-F filed with the SEC 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.

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Source: Celyad Oncology SA