

# CELYAD S.A.

## **FORM 6-K** (Report of Foreign Issuer)

Filed 07/08/19 for the Period Ending 07/08/19

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SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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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 July 2019**

**Commission File Number: 001-37452**

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**CELYAD 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 SA**

On July 2<sup>nd</sup>, 2019, Celyad 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 Forms F-3 (File No. 333-220285) and S-8 (File No. 333-220737).*

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**EXHIBITS**

<u>Exhibit</u>	<u>Description</u>
99.1	Press release issued by the registrant on July 2, 2019

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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 SA**

Date: July 8, 2019

By: /s/ Filippo Petti

Filippo Petti  
*Chief Executive Officer*



Celyad to Host Conference Call to Review Clinical  
Update from ESMO 21<sup>st</sup> World GI Congress

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**Mont-Saint-Guibert, Belgium** - Celyad (Euronext Brussels and Paris, and Nasdaq: CYAD), a clinical-stage biopharmaceutical company focused on the development of CAR-T cell-based therapies, today announced that Professor Dr. Eric Van Cutsem from Universitair Ziekenhuis Leuven ( *UZ Leuven* ) will present data from the NKG2D-based autologous and allogeneic CAR-T candidates, CYAD-01 and CYAD-101, respectively, at the upcoming European Society for Medical Oncology (ESMO) 21<sup>st</sup> World Congress on Gastrointestinal Cancer (WCGIC) to be held on July 3-6, 2019, in Barcelona, Spain. Following the oral and poster presentations at WCGIC, Celyad's management team will host a conference call to discuss the initial clinical results from the SHRINK and alloSHRINK trials.

Filippo Petti, CEO of Celyad noted *"We are honored to have Professor Dr. Van Cutsem present preliminary data from our SHRINK and alloSHRINK trials, including an initial glimpse of data from the industry's first off-the-shelf investigational non-gene edited CAR-T candidate, CYAD-101. The comparable trial designs investigating similar NKG2D-based CAR-T therapies should provide for a unique comparison of an autologous and allogeneic engineered cell therapy approach for the treatment of metastatic colorectal cancer."*

Poster Oral Presentation

**Title:** Phase 1 studies assessing the safety and clinical activity of autologous and allogeneic NKG2D-based CAR-T therapy in metastatic colorectal cancer

**Abstract:** SO-009

**Presenter:** Eric Van Cutsem, M.D., Universitair Ziekenhuis Leuven (UZ Leuven)

**Date:** Friday, July 5, 9:00 a.m. CEST

**Location:** Auditorium B, Level 0

The poster (same title, same number) will be presented in the Exhibit Hall, Level 0 on Friday, July 5, 2019 from 10:35am – 11:05am CEST and 04:35pm – 05:05pm CEST.

Conference Call / Webcast Details

A conference call including a Q&A session will be held by the Company on Friday July 5, 2019 at 2:00 pm CEST / 8:00 am EDT.

The conference call can be accessed using the details below:

United States: +1 877 407 9208

International: +1 201 493 6784

Conference ID: 13692101

Alternatively, participants may also access an audio webcast of the event using the link below: <http://public.viavid.com/index.php?id=135092>

#### Background on CYAD-01 and CYAD-101

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. CYAD-101 is an investigational, non-gene edited, allogeneic (donor derived) CAR-T therapy that co-expresses the NKG2D CAR of CYAD-01 and the novel inhibitory peptide TIM (T cell receptor [TCR] Inhibiting Molecule). The expression of TIM reduces signalling of the TCR complex, which is responsible for Graft versus Host Disease (GvHD).

#### Background on SHRINK and alloSHRINK Trials

SHRINK is an open-label, dose-escalation Phase 1 trial assessing the safety and activity of CYAD-01 administered concurrently with FOLFOX chemotherapy in patients with metastatic colorectal cancer (mCRC). Patients will receive six cycles of FOLFOX (combination of 5-fluorouracil, leucovorin and oxaliplatin) chemotherapy every two weeks and three administrations of CYAD-01 every two weeks.

alloSHRINK is an open-label, dose-escalation Phase 1 trial assessing the safety and clinical activity of CYAD-101 administered concurrently with FOLFOX chemotherapy in patients with unresectable mCRC. Similar to the SHRINK trial for CYAD-01, patients will receive six cycles of FOLFOX chemotherapy every two weeks and three administrations of CYAD-101 every two weeks.

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#### **About Celyad**

Celyad is a clinical-stage biopharmaceutical company focused on the development of specialized CAR-T cell-based product candidates and utilizes its expertise in cell engineering to target cancer. Celyad's CAR-T cell platform has the potential to treat a broad range of solid and hematologic tumors. The company's lead clinical candidate, CYAD-01, an autologous NKG2D-based CAR-T therapy, is currently being evaluated in several Phase 1 clinical trials to assess safety and clinical activity for the treatment of hematological malignancies, such as acute myeloid leukemia, and solid cancers, such as metastatic colorectal cancer. Celyad is also developing CYAD-101, an investigational, non-gene edited, allogeneic (donor derived) NKG2D-based CAR-T therapy, which is currently being evaluated in a Phase 1 trial for the treatment of patients with metastatic colorectal cancer. Celyad was founded in 2007 and is based in Mont-Saint-Guibert, Belgium, and New York, NY. 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.

For more information, please contact:

**Celyad**

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**Forward-looking statements**

This release may contain forward-looking statements, including statements regarding: the safety and clinical activity of CYAD-01, CYAD-02 and CYAD-101; the OptimAb manufacturing process; statements regarding the ongoing and planned clinical development of CYAD-01, CYAD-02 and CYAD-101, including the timing of trials, enrollment, data readouts and presentations; the clinical and commercial potential of CYAD-01, CYAD-02 and CYAD-101; the ongoing and planned clinical and commercial potential and development of its shRNA technology; and the planned presentation of clinical data at the upcoming European Society for Medical Oncology (ESMO) 21st World Congress on Gastrointestinal Cancer (WCGIC). 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 data summarized above are preliminary in nature. There is limited data concerning safety and clinical activity following treatment with the CYAD-01 and CYAD-101 drug product candidates and CYAD-02 has not yet been evaluated in clinical trials. Our therapeutic candidates manufactured using our OptimAb process have not yet been evaluated in clinical trials. Prior clinical and preclinical results may not be repeated or observed in ongoing or future clinical studies involving the CYAD-01, CYAD-02 and CYAD-101 drug product candidates. 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 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, CYAD-02 and CYAD-101 in the United States and Europe and subsequent commercial success of CYAD-01, CYAD-02 and CYAD-101, 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 maintain and 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 5, 2019 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.