

# CELYAD S.A.

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

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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 November 2018**

**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 November 30<sup>th</sup>, 2018, 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 Christian Homsy and Frédéric Lehmann 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>	Description
99.1	Press release issued by the registrant on November 30, 2018

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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: November 30, 2018

By: /s/ Christian Homsy

Christian Homsy

*Chief Executive Officer*



Press Release  
30 November 2018  
07:00 am CET

Celyad Doses First mCRC Patient in the Phase 1  
alloSHRINK Trial Evaluating Non-Gene Edited  
Allogeneic CAR-T Candidate, CYAD-101

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- *Topline data from alloSHRINK trial are expected in second half of 2019*
- *Company regains full development and commercialization rights to CYAD-101 from ONO Pharmaceutical for Japan, Korea and Taiwan*

**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 the injection of the first patient in the Phase 1 alloSHRINK trial evaluating the Company's non-gene edited allogeneic CAR-T therapy, CYAD-101, administered concurrently with FOLFOX chemotherapy in the treatment of patients with unresectable metastatic colorectal cancer (mCRC).

*"The initiation of the alloSHRINK trial marks a critical milestone for our organization,"* said Dr. Christian Homsy, CEO of Celyad. *"CYAD-101 represents a potential first-in-class approach to allogeneic CAR-T therapy and continues to build up Celyad's leadership position in the allogeneic field, which is anchored by the Company's robust allogeneic patent estate in the United States and complemented by our novel shRNA-based non-gene edited platform."*

Dr. Frédéric Lehmann, VP of Clinical Development & Medical Affairs at Celyad, commented, *"CYAD-101 represents Celyad's second oncology program to enter the clinic for the treatment of metastatic colorectal cancer and balances the Company's autologous clinical candidate CYAD-01, which has demonstrated encouraging preliminary results in the Phase 1 SHRINK trial. We believe investigating CYAD-101 in the alloSHRINK trial will leverage our clinical experience to date in the treatment of metastatic colorectal cancer as we look to develop novel therapies for this devastating disease."*

Celyad also announced that ONO Pharmaceutical Co., Ltd. has given notice to the Company that it will no longer pursue development of CYAD-101 in Japan, Korea and Taiwan. Celyad and ONO Pharmaceutical entered into an exclusive license agreement for the development and commercialization of CYAD-101 in these specified territories in July 2016. Based on the agreement, ONO Pharmaceutical was required to exercise an option following the initiation of the Phase 1 trial for CYAD-101. The agreement has now expired and Celyad controls worldwide development and commercialization rights to CYAD-101.

#### CYAD-101 and alloSHRINK Trial Design

CYAD-101 is an investigational, non-gene edited, allogeneic (donor derived) CAR-T therapy that co-expresses the chimeric antigen receptor NKG2D, a receptor expressed on natural killer (NK) cells that binds to eight stress-induced ligands expressed on tumor cells and the novel inhibitory peptide TIM (T cell receptor [TCR] Inhibiting Molecule). TCR signaling is responsible for Graft versus Host Disease (GvHD). The expression of TIM reduces signaling of the TCR complex and could therefore reduce or eliminate GvHD in patients treated with CYAD-101.

The alloSHRINK trial (NCT03692429) is an open-label, dose-escalation trial that will assess the safety and clinical activity of CYAD-101 administered concurrently with FOLFOX chemotherapy in patients with unresectable mCRC. Patients will receive six cycles of FOLFOX chemotherapy every two weeks and three administrations of CYAD-101 every two weeks 48 hours after the initiation of chemotherapy cycles one, two and three. The three dose levels to be evaluated are 100 million, 300 million and 1 billion cells per injection, respectively.

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#### About Celyad

Celyad is a clinical-stage biopharmaceutical company focused on the development of specialized CAR-T cell-based therapies. Celyad 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. Its lead oncology candidate, CYAD-01 (CAR-T NKG2D), is currently being evaluated in a Phase I dose escalation clinical trial to assess the safety and clinical activity of multiple administrations of autologous CYAD-01 cells in seven refractory cancers including five solid tumors (colorectal, ovarian, bladder, triple-negative breast and pancreatic cancers) and two hematological tumors (acute myeloid leukemia and multiple myeloma). The safety and clinical activity of the CYAD-01 therapy concurrently administered with standard-of-care treatments or preconditioning chemotherapy is also being assessed in a full clinical development program focused on acute myeloid leukemia and 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 efficacy of CYAD-01 and CYAD-101; statements concerning the ongoing and planned clinical development of CYAD-01 and CYAD-101, including the timing of trials, enrollment, data readouts and presentations; the clinical and commercial potential of CYAD-01 and CYAD-101 and the adequacy of Celyad's financial resources; statements concerning Celyad's exclusive agreement with Horizon Discovery Group; Celyad's worldwide development and commercialization rights to CYAD-101; the clinical and commercial potential of its shRNA technology; Celyad's financial condition, results of operation and business outlook; and Celyad's expected cash burn. 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. These results may not be repeated or observed in ongoing or future studies involving the CYAD-01 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 and CYAD-101 in the United States and Europe and subsequent commercial success of CYAD-01 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 6, 2018 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.