

CELYAD S.A.

FORM 6-K (Report of Foreign Issuer)

Filed 07/09/19 for the Period Ending 07/09/19

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 July 2019

Commission File Number: 001-37452

CELYAD 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 SA

On June 17th, 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 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).

EXHIBITS

<u>Exhibit</u>	<u>Description</u>
99.1	Press release issued by the registrant on June 17 th , 2019

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 9th, 2019

By: /s/ Filippo Petti

Filippo Petti
Chief Executive Officer



Press Release
17 June 2019
7:00 am CEST

**Celyad Presents Clinical Update for CYAD-01 at
24th Congress of the European Hematology Association**

- *Results from the ongoing Phase 1 THINK and DEPLETHINK trials evaluating CYAD-01 for the treatment of relapsed or refractory (r/r) acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) continue to support the therapeutic clinical development of the NKG2D-based CAR-T therapy product candidate*
- *Preliminary data from Cohort 10 of the THINK trial evaluating a denser schedule of infusions of CYAD-01 without preconditioning showed better cell engraftment compared to biweekly injections of CYAD-01 without preconditioning*
- *Initial results from the DEPLETHINK trial evaluating a single infusion of CYAD-01 following preconditioning chemotherapy demonstrated the regimen was well-tolerated with a better time-averaged engraftment of the CAR-T cells compared to the dose-escalation segment of the THINK trial with a cycle of three injections of CYAD-01*

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 therapies, today announced that updated clinical data for the CYAD-01 program in r/r AML and MDS was presented in a poster presentation session on Saturday, June 15 at the 24th Congress of the European Hematology Association (EHA) in Amsterdam, Netherlands.

Dr. Frédéric Lehmann, VP of Clinical Development & Medical Affairs at Celyad, commented, “*Our observations from the Phase 1 THINK clinical trial evaluating CYAD-01 without prior lymphodepletion in relapsed/refractory acute myeloid leukemia and myelodysplastic syndrome patients show the cell therapy is generally well tolerated. Encouragingly, this safety and tolerability profile was also demonstrated during the early stages of CYAD-01 treatment intensification where an increased systemic persistence of CAR-T cells is obtained after reduced interval dosing or in combination with preconditioning chemotherapy. As such, we continue to focus our efforts on increasing the aggressiveness of CYAD-01 to potentially deepen the breadth, frequency and duration of clinical responses in this refractory patient population.*”

THINK Phase 1 Trial in Hematological Malignancies Update

- As of May 23, 2019, preliminary anti-leukemic activity has been observed in six out of thirteen patients (46%) evaluable per protocol in the THINK Phase 1 trial with four out of thirteen patients (31%) exhibiting objective responses, including one out of the four patients experiencing a duration of response of over 90 days.
- Overall, multiple infusions of CYAD-01 without any prior preconditioning chemotherapy continues to show an encouraging tolerability profile with eight patients from over twenty treated experiencing grade 3/4 treatment-related adverse events (AEs). No neurotoxicity AEs have been observed in any patient receiving CYAD-01.

- The denser schedule of infusions in the absence of any bridging or preconditioning chemotherapy without preconditioning chemotherapy evaluated in Cohort 10 showed that of three r/r AML or MDS patients evaluable, one patient experienced disease stabilization and two patients had disease progression following treatment with up to six doses of 1 billion cells of CYAD-01.
- The denser dosing schedule was generally reported to be well-tolerated. Three patients of four patients evaluable for safety in Cohort 10 experienced grade 1/2 cytokine release syndrome (CRS), which showed rapid resolution following the appropriate treatment, including tocilizumab. One patient experienced a grade 4 infusion reaction, which was not considered to be a dose-limiting toxicity of the therapy.
- Overall, better time-averaged engraftment (area under the curve) was observed with a reduced interval dosing (Cohort 10) as compared to the equivalent dose of the THINK trial evaluating a cycle of three injections of CYAD-01 administered every two weeks.
- Recruitment in Cohort 11 of the THINK trial evaluating the denser schedule of up to six infusions of three billion cells of CYAD-01 without preconditioning chemotherapy is ongoing and results are expected by the end of 2019.

DEPLETHINK Phase 1 Trial Update

- The initial cohorts of the DEPLETHINK trial enrolled six r/r AML or MDS patients who received a single administration of a safety-precaution low-dose CYAD-01 (100 million cells per infusion) following preconditioning chemotherapy consisting of cyclophosphamide and fludarabine, or CyFlu, at two different time-intervals (three or seven days) between the preconditioning regimen and administration of CYAD-01.
- As of May 23, 2019, three patients experienced grade 1/2 CRS, which showed rapid resolution following the appropriate treatment, including tocilizumab. One patient experienced a grade 4 infusion reaction, which was not considered to be a dose-limiting toxicity of the therapy, during the consolidation cycle without preconditioning.
- Of the five patients evaluable per protocol, two patients experienced disease stabilization following treatment with CYAD-01.
- Better time-averaged engraftment was observed after a single infusion of low-dose CYAD-01 with prior preconditioning compared to the dose-escalation segment of the THINK trial evaluating a cycle of three injections of CYAD-01.
- Evaluation of higher dose-levels comparable to the Phase 1 THINK trial, including 300 million and 1 billion cells, are ongoing in the dose-escalation trial and preliminary results from these cohorts are expected by year-end 2019.

Background on THINK Phase 1 Trial

The THINK trial (NCT03018405) is an open-label, dose-escalation Phase 1 trial assessing the safety and clinical activity of multiple CYAD-01 administrations without prior preconditioning. The dose escalation segment of the trial evaluated three dose levels (300 million, 1 billion and 3 billion cells per infusion) of one cycle of three CYAD-01 administrations with two-week intervals.

In 2018, the THINK trial was amended to add two cohorts to assess a more frequent dosing schedule of CYAD-01 for the treatment of r/r AML. The cohorts will evaluate six injections of CYAD-01 without preconditioning over two months of administration. The first cycle includes three infusions of CYAD-01 separated by one-week intervals. The second cycle includes three infusions of CYAD-01 separated by two-week intervals. Patients will either receive 1 billion cells per infusion (Cohort 10) or 3 billion cells per infusion (Cohort 11). The primary endpoint of the trial is safety and secondary endpoints include clinical activity and pharmacokinetics.

Background on DEPLETHINK Phase 1 Trial

In October 2018, Celyad initiated the DEPLETHINK Phase 1 trial (NCT03466320). The open-label, dose-escalation trial will evaluate a single infusion of CYAD-01 following treatment with the standard preconditioning regimen of cyclophosphamide (300 mg/m²) and fludarabine (30 mg/m²), or CyFlu. The trial includes two different intervals between lymphodepletion and administration of CYAD-01. In addition, the trial will evaluate three dose levels of CYAD-01 including 100 million, 300 million and 1 billion cells per infusion, respectively. The primary endpoint of the trial is safety and secondary endpoints include clinical activity and pharmacokinetics.

*****END*****

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 Depositary Shares are listed on the Nasdaq Global Market, all under the ticker symbol CYAD.

For more information, please contact:

Celyad

Filippo Petti, Chief Executive Officer – investors@celyad.com

Anne Moore, Vice President Corporate Strategy – T: +32(0) 10 39 41 87 – communications@celyad.com

For Europe: Ulysse Communication

Bruno Arabian – T.: +33 (0)6 87 88 47 26 – barabian@ulyse-communication.com

For the U.S.: LifeSci Advisors

Investor Relations: Daniel Ferry – T.: +1 (617) 535 7746 – daniel@lifesciadvisors.com

Public Relations: Sara Zelkovic – T: +1 (646) 876 4933 – sara@lifescipublicrelations.com

Forward-looking statements

This release may contain forward-looking statements, including statements regarding the safety and efficacy of CYAD-01 and CYAD-101; 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; Celyad's worldwide development and commercialization rights to CYAD-101; the ongoing and planned clinical and commercial potential and development of its shRNA technology; Celyad's financial condition, results of operation and business outlook; and the planned presentation of clinical data at the 24th Congress of the European Hematology Association (EHA). 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 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.