

# CELYAD S.A.

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

Filed 05/16/18 for the Period Ending 05/15/18

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|-------------|------------------------------------|
| Telephone   | 32 10 394 100                      |
| CIK         | 0001637890                         |
| Symbol      | CYAD                               |
| 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 May 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 May 15, 2018, 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 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 May 15, 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.

Date: May 15, 2018

**CELYAD SA**

By: /s/ Patrick Jeanmart

Patrick Jeanmart  
*Chief Financial Officer*



## Celyad Announces First Quarter 2018 Business Update

*Steady progress in THINK 1 , SHRINK 2 and LINK 3 trials*

**Mont-Saint-Guibert, Belgium** - Celyad (Euronext Brussels and Paris, and NASDAQ: CYAD) a clinical-stage biopharmaceutical company focused on the development of specialized CAR-T cell based therapies, today provided an update on key clinical and operational developments for the first quarter ended March 31, 2018.

### FIRST QUARTER 2018 AND RECENT HIGHLIGHTS

- Robust clinical development plan is foundation for new trials focusing on AML and CRC
- Steady progress related to ongoing THINK, SHRINK and LINK trials
- Good safety profile of CYAD-01 confirmed
- Lead publication *Haematologica* publishes THINK Study Case Report

**Dr. Christian Homsy, CEO of Celyad commented** : “We had a productive first quarter, further defining our strategy that will guide CYAD-01 in becoming the foundation for cancer therapies. Not only have we progressed in the THINK trial, we have also treated our first patients in the SHRINK and LINK trial. The absence of any observed critical on target/off tumor toxicity in our trials is an important signal validating our technology. The next months will be exciting for our company and we look forward communicating results on our clinical trials in scientific congresses.”

### FIRST QUARTER 2017 OPERATIONAL AND FINANCIAL REVIEW

In February 2018, Celyad provided a detailed clinical update summarizing the promising results achieved in 2017: the THINK trial resulted in signs of clinical activity ranging from Stable Disease (SD) to Complete Response (CR), despite the absence of preconditioning therapy and the lower doses used at that stage of the trial. The company also announced that it will further evaluate CYAD-01 in a series of additional Phase 1 clinical trials in patients with AML and CRC.

Also in February 2018, Celyad organized a Key Opinion Leader meeting on CAR-T therapy in New York, USA. The meeting featured a presentation by Marco Davila, MD, PhD (Moffitt Cancer Center). The numerous attendants received information on the unmet medical need in blood cancers as well as details on Celyad’s clinical strategy.

- 1 **T**H erapeutic **I** mmunotherapy with CAR-T **NK** G2D
- 2 **S** tandard **C** H emotherapy **R** egimen and **I** mmunotherapy with **NK** G2D
- 3 **L** oco-regional **I** mmunotherapy with **NK** G2D

On the operation side, during this first quarter, Celyad progressed well in the THINK trial as well as the in LINK trial:

- The company dosed the three CRC patients in the third dose cohort in the solid arm of the THINK trial, and the two last AML patients in the second dose. Celyad plans to initiate the third dose in the AML arm in May 2018, and complete the recruitment of three additional CRC patients at the higher dose by mid-2018. In 2018, all patients were dosed with the our new production process adopted in December 2017.
- The company also treated its first CRC patient in the LINK trial. This patient received three planned injections at the first Dose level ( $3 \times 10^8$ ). LINK adopts a loco-regional approach in treating CRC by administering CYAD-01 through multiple hepatic transarterial injections.

The company ended the quarter with €25.1 million in cash, cash equivalents and short-term investments. Use of cash over the first quarter of 2018 amounted to €8.8 million, in line with expectations. The company confirms that existing cash and cash equivalents and short term investments are sufficient to fund operating expenses and capital expenditure requirements, based on the current scope of activities, until the end of Q1 2019.

#### **EVENTS SUBSEQUENT TO QUARTER-END:**

In April 2018, Celyad's world's first reported complete response by a CAR-T cell therapy in a patient with refractory and relapsed AML was published as a case report in the leading scientific publication *Haematologica*. The publication detailed the first objective response related to this patient that is still in remission, more than 9 months after study enrollment.

In May 2018, Celyad achieved an important milestone in its CYAD-01 clinical strategy by dosing the first metastatic CRC patients in the LINK and SHRINK trials. No drug related toxicity was observed in the first patients of both SHRINK and LINK trials.

Generally, Celyad's progress is the result of the company's clinical development plan aiming at defining the best of three approaches for CYAD-01 in patients with AML and CRC:

- 1) CYAD-01 as a stand-alone investigational therapy, currently being evaluated in the THINK trial with relapsed refractory AML and CRC patients. Promising results have already been reported including a complete response and stable diseases.

Based on data as of April 5, 2018, the date of Celyad's most recent interim safety report for the THINK trial, Celyad had collected safety data from 20 patients treated with CYAD-01 in the THINK trial. Of the 20 patients included in the interim safety report of the THINK trial (11 solid and nine hematologic cancer patients), Celyad reported the following serious adverse events:

- Grade 4 serious adverse events occurred in two patients: one patient in the hematologic cohort experienced respiratory failure and other Grade 4

adverse events after administration of dose level one of CYAD-01. The other patient, who was in the solid tumor cohort, experienced cytokine release syndrome and other Grade 4 adverse events after administration of dose level three of CYAD-01, which was adjudicated as a dose limiting toxicity (DLT).

- Those two patients each experienced a Grade 5 event that was deemed unrelated to administration of CYAD-01.

2) CYAD-01 administered concurrently with standard of care treatments. The SHRINK trial was recently initiated with the dosage of one CRC patient in April 2018. No Grade 4 or higher adverse event has been reported so far. This trial evaluates the concurrent administration of CYAD-01 with the standard chemotherapy FOLFOX. We expect that another similar trial aimed at AML patients, EPITHINK trial, will be initiated soon.

3) CYAD-01 administered after preconditioning of the patients using lymphodepletion. We expect trials in AML (DEPLETHINK AML) and CRC (DEPLETHINK CRC) patients to be initiated in the coming weeks.

\*\*\*END\*\*\*

### 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 Natural Killer Receptor based T-Cell (NKR-T) platform has the potential to treat a broad range of solid and hematologic tumors. Its lead oncology candidate, CYAD-01 (CAR-T NKG2D), has been evaluated in a single dose escalation Phase 1 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). Celyad was founded in 2007 and is based in Mont-Saint-Guibert, Belgium, and Boston, Massachusetts. 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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*This press release contains inside information within the meaning of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation).*

#### **Forward-looking statements**

This release may contain forward-looking statements, including statements regarding the proposed timing and size of the offering; our ongoing and planned clinical development of CYAD-01; our manufacturing processes; and our estimated cash, cash equivalents and short-term investments at March 31, 2018. 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. 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 respect to manufacturing drug product with the desired number of T cells under our clinical trial protocols, and our ability to improve and automate these manufacturing procedures in the future; our reliance on the success of our drug product candidates; 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 and ability to obtain such financing when needed; the potential benefits of strategic collaboration agreements and our ability to 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; and 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.