

# Celyad Reports Full Year 2019 Financial Results and Provides Business Update

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- *First patient successfully dosed in expansion cohort of autologous CYAD-01 THINK trial for patients with relapsed/refractory (r/r) acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS)*
- *CYCLE-1 trial of autologous CYAD-02 for the treatment of r/r AML and MDS ongoing*
- *Expansion cohort of alloSHRINK trial evaluating allogeneic CYAD-101 for metastatic colorectal cancer (mCRC) on target to begin in second half 2020*
- *Submission of IND for short hairpin RNA (shRNA)-based allogeneic CYAD-211 candidate for multiple myeloma (MM) expected in mid-2020*
- *Treasury position of €39.3 million (\$44.0 million) as of December 31, 2019*

**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 its consolidated financial results for fiscal year 2019 ended December 31, 2019 and provided a business update.

*"This is an exciting time for us as we advance Celyad as an innovative leader in the industry which is focused on developing CAR-T therapies for cancer patients. The progress we made throughout 2019 positions Celyad with a balanced pipeline of clinical and preclinical CAR-T candidates as we enter the new decade with several milestones on the horizon,"* commented Filippo Petti, Chief Executive Officer of Celyad. *"We now have two autologous clinical CAR-T candidates in development for the treatment of r/r AML and MDS and a portfolio of promising allogeneic CAR-T candidates, led by CYAD-101, for the treatment of mCRC. We look forward to providing key updates on our clinical progress throughout 2020. Over the past year, we also progressed our shRNA platform for next-generation CAR-T candidates, including our preclinical allogeneic BCMA-targeted candidate, CYAD-211. I am extremely proud of our team's achievements over the past twelve months and look forward to a productive 2020."*

## **Recent Business Highlights and Pipeline Updates**

### **CYAD-01 – Autologous NKG2D CAR-T for r/r AML and MDS**

The Company's lead NKG2D CAR-T clinical candidate CYAD-01 continues to advance in Phase 1 trials for the treatment of patients with r/r AML or MDS. In December 2019, the Company presented the latest data from the CYAD-01 Phase 1 THINK and DEPLETHINK clinical trials at the American Society of Hematology annual meeting. In February 2020, the Company began recruitment in the expansion cohort of the THINK trial evaluating CYAD-01 as a monotherapy. Both the expansion cohort of the THINK trial and the dose-escalation DEPLETHINK trial are now assessing CYAD-01 produced with the Company's proprietary OptimAb manufacturing process.



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### *CYAD-02 – Autologous NKG2D CAR-T for r/r AML and MDS*

In January 2020, the Company announced the first patient has been dosed in the Phase 1 dose-escalation CYCLE-1 trial evaluating the next-generation NKG2D-based CAR-T candidate for the treatment of r/r AML and MDS. The CYCLE-1 trial will evaluate the safety and clinical activity of a single infusion of CYAD-02 produced with the OptimAb manufacturing process following preconditioning chemotherapy with cyclophosphamide and fludarabine. The trial will evaluate three dose levels of CYAD-02 up to one billion cells per infusion.

### *CYAD-101 – Allogeneic TIM-based, NKG2D CAR-T for mCRC*

The Company's allogeneic NKG2D CAR-T clinical candidate CYAD-101, which incorporates the non-gene edited T-cell receptor Inhibitory Molecule (TIM) technology, continues to advance in the dose-escalation alloSHRINK trial assessing the safety and clinical activity of CYAD-101 administered concurrently with FOLFOX chemotherapy in patients with r/r mCRC. In November 2019, preliminary data from the ongoing alloSHRINK trial were presented at the Society for Immunotherapy of Cancer annual meeting and showed no clinical evidence of Graft-versus-Host Disease post-infusion of CYAD-101. In addition, encouraging anti-tumor activity with two out of 12 patients experiencing a partial response and five patients experiencing stable disease with a minimum of three months of duration. Based on the preliminary data from the Phase 1 alloSHRINK trial, the Company plans to expand the trial to confirm initial safety and clinical activity of CYAD-101 with chemotherapy in refractory mCRC patients.

### *CYAD-211 – Allogeneic shRNA-based, BCMA CAR-T for r/r MM*

The Company continues to pursue the development of the proprietary non-gene edited allogeneic shRNA SMARTvector platform through the CYAD-200 series of product candidates. The Company's lead preclinical CAR-T candidate from the series, CYAD-211, targets B-cell maturation antigen (BCMA) for the treatment of relapsed / refractory multiple myeloma (r/r MM). The Company continues to progress towards submitting an Investigational New Drug (IND) application for CYAD-211.

## **Update on COVID-19 Pandemic**

In light of the outbreak of the novel coronavirus, COVID-19, the Company has implemented strong measures to help prevent the spread of the virus and protect our employees. In addition, we have put into practice our business continuity plan to minimize the impact on our operations. While the Company is not currently experiencing any major disruptions in its business related to COVID-19, given the recent developments associated with the virus both in Belgium and in the United States and due to recently adopted government policies, the Company does anticipate enrollment delays within our r/r AML and MDS program. The Company is continuing to monitor the impact of COVID-19 on both our clinical and non-clinical planned milestones below and will adjust accordingly as the pandemic continues to rapidly evolve.

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**Upcoming Milestones**

- Report additional data from the dose-escalation segment of the CYAD-101 alloSHRINK Phase 1 trial during the second quarter of 2020
- Submit IND application for an shRNA-based allogeneic BCMA CAR-T candidate, CYAD-211, for the treatment of patients with r/r MM by mid-2020
- Report preliminary data from expansion cohort of the Phase 1 THINK and dose-escalation Phase 1 DEPLETHINK trials evaluating CYAD-01 produced with OptimAb manufacturing process during second half of 2020, due to enrollment delays caused by the COVID-19 pandemic
- Begin expansion segment of the CYAD-101 alloSHRINK Phase 1 trial during the second half of 2020
- Report preliminary data from the dose-escalation Phase 1 CYCLE-1 trial for CYAD-02 by year-end 2020

**2019 Financial Results**

As of December 31, 2019, Celyad had a treasury position of approximately €39.3 million (\$44.0 million). The Company expects that the existing treasury position will be sufficient, based on the current scope of activities, to fund operating expenses and capital expenditure requirements through the first half of 2021.

Key financial figures for full-year 2019, compared with full-year 2018, are summarized below:

<b>Selected key financial figures (€ millions)</b>	<b>Full-Year 2019</b>	<b>Full-Year 2018</b>
<b>Revenue</b>	-	3.1
<b>Research and Development expenses</b>	(25.2)	(23.6)
<b>General and Administrative expenses</b>	(9.1)	(10.4)
<b>Other income/(expenses)</b>	5.4	(7.3)
<b>Operating loss</b>	(28.9)	(38.2)
<b>Loss for the year</b>	(28.6)	(37.4)
<b>Net cash used in operations</b>	(28.2)	(27.2)
<b>Treasury position<sup>(1)</sup></b>	<b>39.3</b>	<b>49.7</b>

(1) Treasury position<sup>(1)</sup> is an alternative performance measure determined by adding Short-term investments and Cash and cash equivalents from the statement of financial position prepared in accordance with IFRS.

The Company's license and collaboration agreements generated no revenue for the year ended December 31, 2019, compared to €3.1 million for the year ended December 31, 2018.

Research and development expenses were €25.2 million for the year ended December 31, 2019, compared to €23.6 million for the year ended December 31, 2018. The €1.6 million increase was primarily driven by spending related to the Company's preclinical product candidates and its investments in process development, scale-up and automation of its manufacturing processes.

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General and administrative expenses were €9.1 million for the year ended December 31, 2019, compared to €10.4 million for the year ended December 31, 2018. The difference of €1.3 million was primarily due to the decrease of non-cash expense associated with the vesting of warrants and lower consulting fees for the period.

The Company's other income/other expenses mainly include:

- Non-cash expenses relating to liability reassessment, required by International Financial Reporting Standards (IFRS), associated with the advancement in the Company's NKG2D CAR-T candidates. Overall, the Company posted €0.3 million in net profit for the year ended December 31, 2019, compared to a net loss of €6.6 million for the year ended December 31, 2018;
- Government grant income of €3.3 million for the year ended December 31, 2019, primarily due to new grants from the Walloon Region received in the fourth quarter of 2019, compared to grant income of €0.8 million for the year ended December 31, 2018;
- R&D tax credit, recognized as income, of €1.6 million for the year ended December 31, 2019, compared to income of €0.3 million for the year ended December 31, 2018.

Net loss was €28.6 million, or €(2.29) per share, for the year ended December 31, 2019, compared to a net loss of €37.4 million, or €(3.36) per share, for the same period in 2018. The decrease in net loss between periods was primarily due to the increase in net other income.

Net cash used in operations, which excludes non-cash effects, for the year ended December 31, 2019 amounted to €28.2 million, compared to €27.2 million for the same period in 2018. The difference was driven primarily by an increase in spend associated with Research and Development described above.

**Annual Report 2019**

The Annual Report for the year ended December 31, 2019 will be published tomorrow, March 25, 2020, and will be available on the Company's website, [www.celyad.com](http://www.celyad.com). The Company's statutory auditor, BDO Réviseurs d'Entreprises SCRL (BDO), has confirmed that the completed audit has not revealed any material misstatement in the consolidated financial statements. BDO also confirmed that the accounting data reported in the press release are consistent, in all material respects, with the consolidated financial statements from which it has been derived.

**Conference Call and Webcast Details**

A conference call will be held on Wednesday, 25 March at 1:00 p.m. CET / 8:00 a.m. ET to review the financial and operating results for full year 2019. Please dial-in five to ten minutes prior to the call start time using the number and conference ID below:

Conference ID:	1392585
International:	+44 (0) 2071 928501
Belgium	+32 (0) 24 01 70 35
France	+33 (0)1 76 72 89 28

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Netherlands + 31 (0) 20 71 88 527  
 United States: +1 917 720 0181

**Financial Calendar**

Annual shareholders meeting May 5, 2020  
 First quarter 2020 business update May 7, 2020  
 Half-year results 2019 August 6, 2020  
 Third quarter 2020 business update November 10, 2020

**Consolidated Statement of the Comprehensive Loss**

(€'000)	For the year ended 31 December,	
	2019	2018
<b>Revenue</b>	<b>6</b>	<b>3,115</b>
Cost of sales	-	-
<b>Gross profit</b>	<b>6</b>	<b>3,115</b>
Research and Development expenses	(25,196)	(23,577)
General & Administrative expenses	(9,070)	(10,387)
Other income	5,572	1,078
Other expenses	(191)	(8,399)
<b>Operating Loss</b>	<b>(28,879)</b>	<b>(38,170)</b>
Financial income	582	804
Financial expenses	(343)	(62)
<b>Loss before taxes</b>	<b>(28,640)</b>	<b>(37,427)</b>
Income taxes	8	0
<b>Loss for the period <sup>[1]</sup></b>	<b>(28,632)</b>	<b>(37,427)</b>
Basic and diluted loss per share (in €)	(2.29)	(3.36)

<sup>[1]</sup> For 2019 and 2018, the Company does not have any non-controlling interests and the losses for the year are fully attributable to owners of the parent.

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**Consolidated Statement of Financial Position**

(€'000)	December 31, 2019	December 31, 2018
<b>NON-CURRENT ASSETS</b>	<b>47,000</b>	<b>42,607</b>
Intangible assets	36,199	36,164
Property, Plant and Equipment	5,061	3,014
Non-current Trade and Other receivables	2,432	1,743
Non-current Grant receivables	3,051	1,472
Other non-current assets	257	215
<b>CURRENT ASSETS</b>	<b>42,836</b>	<b>51,692</b>
Trade and Other Receivables	558	367
Current Grant receivables	1,686	-
Other current assets	1,253	1,585
Short-term investments	0	9,197
Cash and cash equivalents	39,338	40,542
<b>TOTAL ASSETS</b>	<b>89,836</b>	<b>94,299</b>
<b>EQUITY</b>	<b>45,619</b>	<b>55,589</b>
Share Capital	48,513	41,553
Share premium	43,349	206,149
Other reserves	28,181	25,667
Accumulated deficit	(74,424)	(217,778)
<b>NON-CURRENT LIABILITIES</b>	<b>32,295</b>	<b>29,063</b>
Bank loans	37	229
Lease liabilities	2,967	652
Recoverable Cash advances (RCAs)	4,139	2,864
Contingent consideration payable and other financial liabilities	24,754	25,187
Post-employment benefits	398	131
<b>CURRENT LIABILITIES</b>	<b>11,922</b>	<b>9,647</b>
Bank loans	192	281
Lease liabilities	1,167	484
Recoverable Cash advances (RCAs)	346	276
Trade payables	6,969	5,916
Other current liabilities	3,248	2,690
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>89,836</b>	<b>94,299</b>

**Regulated Information**
**Consolidated Net Cash Burn Rate<sup>[2]</sup>**

(€'000)	For the year ended 31 December,	
	2019	2018
Net cash used in operations	(28,202)	(27,249)
Net cash (used in)/from investing activities	8,987	607
Net cash (used in)/from financing activities	18,276	43,928
Effects of exchange rate changes	(264)	3
<b>Change in Cash and cash equivalents</b>	<b>(1,204)</b>	<b>17,289</b>
Change in Short-term investments	(9,197)	(1,456)
<b>Net cash burned over the period</b>	<b>(10,401)</b>	<b>15,834</b>

<sup>[2]</sup> 'Net cash burn rate' is an alternative performance measure determined by the year-on-year net variance in the Group's treasury position as above-defined.

**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. Celyad has received funding from the Walloon Region (Belgium) to support the advancement of its CAR-T cell therapy programs.

**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-101, CYAD-02 and CYAD-211; statements regarding the ongoing and planned clinical development of CYAD-01, CYAD-101 CYAD-02 and CYAD-211, including the timing of trials, enrolment, data readouts and presentations; the clinical and commercial potential of CYAD-01, CYAD-101 CYAD-02 and CYAD-211; the success of the OptimAb manufacturing system; the ongoing and planned clinical and commercial potential and development of Celyad's shRNA technology; Celyad's financial condition, results of operation and business outlook. 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



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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, CYAD-101, CYAD-02 and CYAD-211 product candidates. These results may not be repeated or observed in ongoing or future studies involving the CYAD-01, CYAD-101, CYAD-02 and CYAD-211 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 OptimAb 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-101, CYAD-02 and CYAD-211 in the United States and Europe and subsequent commercial success of CYAD-01, CYAD-101, CYAD-02 and CYAD-211, 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 product candidates and statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance and the impact of the novel coronavirus, COVID-19, including potential effects on our business, clinical trials, supply chain and manufacturing capabilities. 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.