Celyad
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Press Release
Regulated Information
25 August 2016
07:00 am CEST

Celyad Reports First Half 2016 Financial Results and Operational Progress

Management to Host Conference Call at 2pm CEST/8am EDT Today

Mont-Saint-Guibert, Belgium - Celyad (Euronext Brussels and Paris, and NASDAQ: CYAD), a leader in the discovery and development of cell therapies, today announced its consolidated financial results for the six-month period ending 30 June 2016 prepared in accordance with IFRS as endorsed by the European Union. The full interim financial report (regulated information) is available on our website in the Investors section. The Half Year 2016 consolidated financial statements were subject to a limited review by the company's statutory auditors.

Operational highlights

Immuno-Oncology Platform

- **Clinical Trials**
  The NKR-2 autologous program (Phase I single administration, dose escalation trial investigating the safety and feasibility of NKR-2 in AML and MM patients):
  - Successful completion of the second and third dose level cohorts.
  - The last patient in the fourth, and final, dose level cohort has been infused and will be evaluated upon completion of the 21-day safety follow-up period.
  - No dose limiting toxicities have been reported to date.
  - Results from the trial are expected to be available in the fourth quarter of 2016.
  - Initiation of multiple-dose trials in AML, MM and solid tumors (bladder, triple-negative breast, colorectal, ovarian and pancreatic cancers) to commence upon successful completion and analysis of the fourth dose level cohort. Interim data from the multiple dose trials is expected in the second half of 2017.

- **Scientific Partnerships and Collaborations**
  - Following the end of the first half, on July 11, we announced an exclusive licensing agreement with ONO Pharmaceutical for the development and commercialization of our allogeneic NKR-2 T-cell therapy in Japan, Korea and Taiwan. Total deal value of up to 31.325 JPY B (€282 million or $311.5 million) plus double digit royalties on net sales in ONO territories.
  - Academic research collaboration with Institut Curie's Immunity and Cancer Unit to benefit from their translational, pre-clinical and clinical expertise in cancer biology and immunology.
  - Creation of a Scientific Advisory Board, comprised of ten of the leading international immuno-oncology experts.

- **Management Team and Leadership**

- Dr. David Gilham, one of Scientific Advisory Board members, joined Celyad full-time as Vice President of Research and Development.

- **Intellectual Property**
  Our allogeneic platform
  - Issuance of US Patent 9,273,283 that provides broad protection for our proprietary method of producing allogeneic human T-cells that are engineered to be T-Cell Receptor (TCR)-deficient and express a Chimeric Antigen Receptor (CAR).
  - In combination with US Patent 9,181,527, issued in November 2015 and covering all TCR-deficient T-cells, regardless of production method, we possess a robust IP portfolio in the field of TCR-deficient T-cells for the treatment of cancer and other diseases.
  - We plan to enter allogeneic NKR-2, which incorporates TCR Inhibitory Molecules (TIMs), into the clinic in 2H17.

Cardiovascular Platform

- **Clinical Trials**
  - At the end of June, we announced the top-line results of the Phase III CHART-1 trial, evaluating C-CURE® for the treatment of ischemic heart failure. The primary endpoint of the trial was not met.
  - We are analyzing the data and evaluating potential options for the C-CURE® program. We are encouraged by initial indications from investigators that a significant subgroup of patients, within well-defined baseline end-diastolic volume parameters, receive a clinically meaningful benefit from C-CURE® therapy.
  - CHART-1 results will be outlined in a Late Breaking Session at the European Society of Cardiology Congress on Sunday, August 28, 2016.

- **Partnerships and Collaborations**
  - We will seek guidance from the European Medicines Agency (EMA) regarding future steps and will pursue a partner to continue the development and commercialization of C-CURE®.

Corporate and financial Highlights

- During the first half of the year, we enhanced our executive management team with the hire of several experienced professionals: David Gilham – VP Research & Development; Jean-Pierre Latere – VP Business Operations & Commercialization; Richard Mountfield – VP Global Clinical Operations & Regulatory Affairs; and Graham Morrell – VP Investor Relations & Communication.

- Celyad ended the first half of 2016 with EUR 86 million in cash and short-term deposits. This amount in treasury should enable to fund the Group operating expenses and capital

expenditure requirements, based on the current scope of our activities, until the end of 2018.

Dr. Christian Homsy, CEO of Celyad, said: "*The first half of 2016 was an important period for Celyad. We continued to deliver on our development objectives for NKR-2 and reached important clinical milestones with the successful completion of our Phase I trial first three cohorts. With the last patient of the trial being treated, we now look forward to reporting the outcome and starting the next phase of our clinical development plan, the start of our multiple dosing umbrella trials testing NKR-2 in five solid and two blood malignancies. The signature of key international academic and industrial partnerships and the strong reinforcement of our intellectual property portfolio have confirmed the potential and attractiveness of our platform.*

Celyad has also announced the results of the CHART-1 Phase III trial evaluating C-Cure® cell therapy. Though the primary endpoint was unfortunately not met, a clinically and statistically significant outcome, consistent across all parameters tested, was observed for a substantial, clearly definable, group of heart failure patients. Those results and the feedback from our cardiology program advisors encourage us to seek guidance from the regulatory authorities in Europe and the USA on the path forward for this promising technology. Consistent with our strategic repositioning in immune-oncology, we are actively looking for a partner to further develop C-Cure and fund the CHART-2 trial in the USA.

Looking forward, Celyad is focusing its efforts and accelerating the development of its immuno-oncology platform, with the objective to become a global leader in engineered cell-based immunotherapies for cancer treatment. The funds raised last year as well as the payment resulting from our license agreement with ONO provide a solid financial foundation for us to continue to advance our vision of developing pioneering breakthrough therapies for life-threatening diseases."

Patrick Jeanmart, Chief Financial Officer of Celyad, said: "*We terminated the first semester of 2016 with a solid cash position. The EUR 86 million in hands does not include yet the EUR 11 million payment of ONO Pharmaceuticals, resulting from the license deal announced earlier in July. This cash position offers us a lot of perspectives in our future Immuno-oncology development activities.*"

Selected First Half 2015 Financial Results

In million euros	H1 2016	H1 2015
Research & Development expenses	14.8	11.5
General & Administration expenses	4.7	3.6
Operating loss	17.2	15.1
Loss of the period	16.9	15.3

Loss per share (in €)	1.8	2.1
Change in net cash and cash equivalent	**46.5**	**88.5**
Cash and short term investment	**86.0**	**107.5**

Management to Host Conference Call at 2pm (CEST)/8am (EDT) today

Conference Call Details

A conference call will be held on Thursday 25 2016 at 2:00pm (CEST) / 8:00am (EDT) to review the financial results. Christian Homsy, Chief Executive Officer, and Patrick Jeanmart, Chief Financial Officer, will deliver a brief presentation followed by a Q&A session.

Participants are asked to call the assigned numbers approximately five minutes before the conference call begins.

The call can be accessed by dialling the numbers below and using the passcode: 70807261.

International:	+44 (0) 1452 584233
Belgium:	024003425
France:	0800947325
UK:	08002795994
US:	1 866 629 0057

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About Celyad

Celyad is a clinical-stage biopharmaceutical company focused on the development of specialized cell-based therapies. The Company utilizes its expertise in cell engineering to target severe diseases with significant unmet need, including cancer. Celyad's Natural Killer Receptor (NKR) based T-Cell platform has the potential to treat a broad range of solid and liquid tumors. Its lead oncology candidate, NKR-2, is currently being evaluated in a Phase I clinical trial. In addition, Celyad has completed a Phase III trial in the EU for its C-Cure® cardiovascular disease candidate in ischemic heart failure.

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 NASDAQ Global Market, all under the ticker symbol CYAD.

Forward looking statements

In addition to historical facts or statements of current condition, this press release contains forward-looking statements, including statements about the potential safety and feasibility of NKR-2 T-cell therapy and C-Cure and the clinical potential of the Company's technology platform generally and the timing of future clinical trials, which reflect our current expectations and projections about future events, and involve certain known and unknown risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements.

In particular, it should be noted that the safety data described in the release are preliminary in nature and the Phase I trial is not completed. There is limited data concerning safety and feasibility of NKR-2. These data may not continue for these subjects or be

repeated or observed in ongoing or future studies involving our NKR-2 therapy, C-Cure or other product candidates. It is possible that safety issues or adverse events may arise in the future.

These forward-looking statements are further qualified by important factors, which could cause actual results to differ materially from those in the forward-looking statements, including risks associated with conducting clinical trials; the risk that safety, bioactivity, feasibility and/or efficacy demonstrated in earlier clinical or pre-clinical studies may not be replicated in subsequent studies; risk associated with the timely submission and approval of anticipated regulatory filings; the successful initiation and completion of clinical trials, including Phase III clinical trials for C-Cure® and Phase I clinical trial for NKR-2; risks associated with the satisfaction of regulatory and other requirements; risks associated with the actions of regulatory bodies and other governmental authorities; risks associated with obtaining, maintaining and protecting intellectual property, our ability to enforce our patents against infringers and defend our patent portfolio against challenges from third parties; risks associated with competition from others developing products for similar uses; risks associated with our ability to manage operating expenses;, and risks associated with our ability to obtain additional funding to support our business activities and establish and maintain strategic business alliances and business initiatives. A further list and description of these risks, uncertainties and other risks can be found in the Company's Securities and Exchange Commission filings and reports, including in the Company's prospectus filed with the SEC on June 19, 2015 and future filings and reports by the Company. 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. The Company 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.