

# Celyad announces first quarter 2015 business update

Key clinical milestones achieved; Strong financial base and tight cash management

**Mont-Saint-Guibert, Belgium** - Celyad (formerly known as Cardio3 BioSciences, *Euronext Brussels and Paris: CYAD*), a leader in the discovery and development of engineered cell therapies, today provided an update on key clinical and operational initiatives for the three-month period ended 31<sup>st</sup> March 2015.

## HIGHLIGHTS OF THE 1ST QUARTER

- Entered the immuno-oncology space with the acquisition of the OnCyte CAR T-cell portfolio from Celdara Medical, LLC, consistent with its previously announced diversification strategy.
- Appointed Dr. Vincent Brichard, former global head of immuno-oncology at GSK Vaccines, as Vice President Immuno-Oncology to lead the clinical development of Celyad's oncology assets.
- Raised approximately €32 million through a private placement of ordinary shares to institutional investors in the U.S. and Europe.
- Received product-specific pediatric waiver for C-Cure® from European Medicines Agency (EMA).
- Completed patient enrollment in our CHART-1 Phase III clinical trial for C-Cure® conducted in Europe and Israel.
- Received recommendation from the Data Safety Monitoring Board, or DSMB, to continue the Phase III trial for C-Cure® based on its review of unblinded safety and efficacy data from treated and control patients included in CHART-1. The DSMB determined that the data did not support discontinuation of the trial on the basis of futility. Furthermore, the DSMB recommended the continuation of the trial with no changes to the protocol.
- Cash of €49.2 million at end of the first quarter 2015.

**Dr. Christian Homsy, CEO of Celyad, said**: *"I am pleased to report that Celyad has successfully built upon the momentum of last year to enable a transformational start to 2015. We have taken significant steps in our strategy to broaden and strengthen our position as a leading international engineered cell therapy company. We have delivered key milestones in both our cardiovascular disease program - with the completion of enrollment of CHART-1 - and in oncology, with the initiation of the clinical development of NKG2D, our leading CAR T-cell therapy. As a result of these achievements, we are well positioned to continue advancing our* 



*lead product candidates C-Cure® and NKG2D CAR T-cell, in cardiovascular diseases and immuno-oncology, respectively.* 

"We believe the capital raised in March provides us with a strong financial base from which to continue driving our pipeline development strategy."

## **OPERATIONAL AND FINANCIAL REVIEW**

In early January, Celyad announced the acquisition of OnCyte, the oncology division of privately-held U.S. biotechnology company Celdara Medical, LLC, and its portfolio of immunooncology product candidates. The acquisition marks Celyad's entry into the field of immunooncology, representing a significant step towards the Company's strategic objective of becoming leader in engineered cell therapy. The Chimeric Antigen Receptor (CAR) technology developed by OnCyte uses human Natural Killer cell (NK cell) receptors that have the potential to target blood cancers and solid tumors via a human natural receptor that targets ligands present on numerous tumor types. The research underlying this technology was originally conducted by Dartmouth College Professor Charles Sentman, and has been published in numerous peer-reviewed publications.

Also in January, following the acquisition of OnCyte, Celyad appointed Dr. Vincent Brichard as Vice President Immuno-oncology. Dr. Brichard is a physician by training, with a specialty in oncology and immunology. After an academic career, Vincent joined GlaxoSmithKline Biologicals in 2002, where he held numerous positions in the Cancer Vaccines business unit, with roles of increasing seniority. Until the end of 2014, Vincent served as Senior Vice President in the Immunotherapeutics business unit and member of the Board of Directors of GSK Vaccines.

In March, the Company raised approximately  $\leq 32$  million through a private placement of ordinary shares to investors in the United States and Europe at a price of  $\leq 44.50$  per share. The net proceeds of the private placement, approximately  $\leq 29.8$  million, will be used by the Company to further develop its newly acquired CAR-T cell technology platform, to further advance in the development of C-Cure® for the treatment of ischemic heart failure, and for general corporate purposes.

Subsequently, the Company received a Pediatric Investigation Plan (PIP) waiver from the European Medicines Agency (EMA) for C-Cure® across all subsets of the pediatric population for the treatment of ischemic heart disease.

Then Celyad completed patient enrollment in CHART-1.

Finally, Celyad announced that the Data Safety Monitoring Board, or DSMB, an independent committee comprised of international experts, reviewed unblinded safety and efficacy data from CHART-1 patients in the two arms of the trial (treated and control) and determined that



the data did not support discontinuation of the trial on the basis of futility. Furthermore, the DSMB recommended the continuation of the trial with no changes to the protocol.

The Company ended the quarter with €49.2 million in cash on hand. Management confirms its expectation that the amount is sufficient to fund the CHART-1 C-Cure® clinical program until the availability of the read-out of the primary endpoint, anticipated mid-2016, the initiation of its second Phase III clinical trial of C-Cure® in the United States and Europe, following the FDA's lift of the existing clinical hold and the Phase I clinical trial of the NKG2D CAR T-cell therapy product candidate.

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

In April, Celyad received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for a patent application covering T-cell receptor (TCR)-deficient T-cells which are engineered to express a CAR. This patent application was the first allowed application in a series of filed patent applications augmenting the Company's protection for its allogeneic T-cell technology. The claims of the patent application were subsequently amended with a request that the USPTO continue examination. The Company has applied for additional patents related to this technology, which are in various phases of USPTO review.

Later in April, Celyad announced the enrollment of the first patient in its Phase I clinical trial evaluating the Company's lead CAR T-cell therapy, NKG2D CAR T-cell, in blood cancer patients with acute myeloid leukemia (AML) or multiple myeloma (MM). One week later, the Company announced the infusion of this first patient in this trial with no short term adverse events observed.

#### \*\*\*END\*\*\*

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# **About Celyad**

Founded in 2007, and based in Belgium, Celyad is a leader in engineered cell therapy with clinical programs initially targeting indications in cardiovascular disease and oncology. Celyad is developing its lead cardiovascular disease product candidate, C-Cure®, for the treatment of ischemic heart failure, and has completed enrolment of a Phase III trial in Europe and Israel. In addition, the Company is developing a novel portfolio of CAR T-cell therapies that utilize human Natural Killer cell receptors for the treatment of numerous blood and solid cancers. Its lead oncology product candidate, NKG2D CAR T-cell, entered a Phase I clinical trial in April 2015.

Celyad's shares are listed on Euronext Brussels and Euronext Paris under the ticker symbol CYAD.

To learn more about Celyad, please visit www.celyad.com.

# **Forward looking statements**

In addition to historical facts or statements of current condition, this press release contains forward-looking statements, 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. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. 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 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 NKG2D CAR T-cell additional clinical results validating the use of adult autologous stem cells to treat ischemic heart failure and CAR T-cell autologous therapy to treat cancer; satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; obtaining, maintaining and protecting intellectual property, our ability to enforce our patents against infringers and defend our patent portfolio against challenges from third parties, competition from others developing products for similar uses, our ability to manage operating expenses, and our ability to obtain additional funding to support our business activities and establish and maintain strategic business alliances and business initiatives. Any forward-looking statements represent our views only as of today and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

C3BS-CQR-1, C-Cure, NKG2D CAR T-cell, C-Cath<sub>ez</sub>, OnCyte, Celyad, Cardio3 BioSciences and the Cardio3 BioSciences, Celyad, C-Cath<sub>ez</sub>, CHART-1, CHART-2 and OnCyte logos are signs internationally protected under applicable Intellectual Property Laws. Mayo Clinic holds equity in Celyad as a result of intellectual property licensed to the company.