

## Celyad Announces FDA Acceptance of IND Application for CYAD-101, a First-in-Class Non-Genetically Edited Allogeneic CAR-T Candidate

- FDA acceptance of IND for world's first non-genetically edited allogeneic CAR-T clinical program
- First of a family of non-genetically edited allogeneic CAR-T, targeting colorectal cancer to build on the experience from the SHRINK autologous CAR T program

**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 the U.S. Food and Drug Administration (FDA) has accepted the company's Investigational New Drug (IND) application for CYAD-101, the first non-genetically edited allogeneic clinical program. The FDA has indicated that the Allo-SHRINK trial, evaluating the safety and clinical activity of CYAD-101 in patients with unresectable colorectal cancer in combination with standard chemotherapy, is allowed to proceed.

**Dr. Christian Homsy, CEO of Celyad:** *"We are pleased to have achieved this important milestone. Celyad is the first company clinically evaluating a non-genetically edited CAR-T candidate, which, we believe, offers significant advantages over gene edited approaches. Our non-genetically edited program consists of a family of technologies aimed at reducing or eliminating T cell receptor (TCR) signaling without requiring genetic manipulation. CYAD-101 is part of a robust clinical development plan, establishing the foundations of next generation CAR-T products."*

CYAD-101, Celyad's first allogeneic CAR-T cell product, encodes both the company's autologous CYAD-01 CAR-T and a novel peptide, TIM (TCR Inhibiting Molecule), an inhibitor of TCR signaling. TCR signaling is responsible for the Graft versus Host Disease (GvHD), and tampering or eliminating its signaling could therefore reduce or eliminate GvHD. In CYAD-101, the TIM peptide is encoded alongside the CAR construct allowing allogeneic T cell production through a single transduction step. CYAD-101 benefits from using a manufacturing process that is highly similar to Celyad's well established process for its clinical autologous CAR-T cell products.

While autologous CAR-T therapies now have well established efficacy in B cell malignancies, the approach can be more challenging for some patients, especially those where the quality of the apheresis is poor. Allogeneic CAR-T cell therapy may provide an alternative approach



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for this patient population, utilizing cells manufactured from a healthy donor which could allow greater reproducibility and reduced manufacturing costs.

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### 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.

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### Forward-looking statements

This release may contain forward-looking statements, including statements regarding the safety and efficacy of CYAD-01 and the new mAb manufacturing method used to manufacture this drug product candidate; statements concerning the ongoing and planned clinical development of CYAD-01. 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 interim data summarized above are preliminary in nature. There is limited data concerning safety and clinical activity following treatment with the CYAD-01 drug product candidate. These results may not be repeated or observed in ongoing or future studies involving the CYAD-01 drug product candidate. 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 new mAb manufacturing process and with respect to



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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 in the United States and Europe and subsequent commercial success of CYAD-01, 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 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 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.