Celyad Oncology Announces FDA Lifts Clinical Hold of CYAD-101-002 Phase 1b Trial

Mont-Saint-Guibert, Belgium - Celyad Oncology SA (Euronext & Nasdaq: CYAD), a clinical-stage biotechnology company focused on the discovery and development of chimeric antigen receptor T cell (CAR T) therapies for cancer, today announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the CYAD-101-002 (KEYNOTE-B79) Phase 1b trial after the Company made changes to the eligibility criteria for the trial.

“We are pleased that the FDA lifted the clinical hold on this trial. We remain confident in the potential development of not only the candidate itself, but the continued development with our proprietary TIM technology. CYAD-101 is currently our only clinical candidate co-expressing NKG2D and TIM, and we hope to continue to showcase our expertise with our non-gene edited technologies and explore additional opportunities to utilize NKG2D in allogeneic CAR T,” said Dr. Charles Morris, Chief Medical Officer of Celyad Oncology.

As previously disclosed, on February 28, 2022, the Company announced that it was voluntarily pausing the CYAD-101-002 trial to investigate reports of two fatalities in the study. The trial was subsequently put on clinical hold in March 2022 by the FDA.

The CYAD-101-002 Phase 1b trial evaluates the TCR Inhibitory Molecule (TIM)-based allogeneic NKG2D CAR T cell investigational therapy CYAD-101 with MSD’s anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with refractory metastatic colorectal cancer (mCRC) with microsatellite stable (MSS) / mismatch-repair proficient disease.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About Celyad Oncology
Celyad Oncology is a clinical-stage biotechnology company focused on the discovery and development of chimeric antigen receptor T cell (CAR T) therapies for cancer. The Company is developing a pipeline of allogeneic (off-the-shelf) and autologous (personalized) CAR T cell therapy candidates for the treatment of both hematological malignancies and solid tumors. Celyad Oncology was founded in 2007 and is based in Mont-Saint-Guibert, Belgium and New York, NY. The Company has received funding from the Walloon Region (Belgium) to support the advancement of its CAR T cell therapy programs. For more information, please visit www.celyad.com.

Forward-Looking Statement
This release may contain forward-looking statements, within the meaning of applicable securities laws, including the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding: the continued development of the KEYNOTE-B79 trial and Celyad Oncology’s ability to engage in future opportunities using non-gene edited technologies. Forward-looking statements may involve known and unknown risks and uncertainties which might cause actual results, financial condition, performance or achievements of Celyad Oncology to differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties can be found in Celyad Oncology’s U.S. Securities and Exchange Commission (SEC) filings and reports, including in the latest Annual Report on Form 20-F filed with the SEC and subsequent filings and reports by Celyad Oncology. These forward-looking statements speak only as of the date of publication of this document and Celyad Oncology’s actual results may differ materially from those expressed or implied by these forward-looking statements. Celyad Oncology 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.

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