Celyad Oncology Announces FDA Clearance of IND Application for CYAD-211, First shRNA-based, Non-Gene Edited Allogeneic CAR T Therapy

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- Phase 1 clinical trial evaluating the off-the-shelf anti-BCMA CAR T candidate CYAD-211 for the treatment of relapsed/refractory multiple myeloma (r/r MM) expected to begin by year-end 2020
- CYAD-211 represents the company’s first allogeneic CAR T clinical candidate using shRNA technology

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 company’s Investigational New Drug (IND) application for CYAD-211, the company’s first-in-class short hairpin RNA (shRNA)-based allogeneic CAR T candidate and second non-gene edited off-the-shelf program, is in effect with the U.S. Food and Drug Administration (FDA). The company’s lead allogeneic candidate from its next-generation CYAD-200 series, CYAD-211 targets B-cell maturation antigen (BCMA) for the treatment of relapsed / refractory multiple myeloma (r/r MM), CYAD-211 is engineered to co-express a BCMA-targeting chimeric antigen receptor and a single shRNA, which interferes with the expression of the CD3ζ component of the T-cell receptor (TCR) complex.

“The FDA’s permission to begin the Phase 1 clinical trial of our lead shRNA-based allogeneic candidate CYAD-211 is a watershed moment for our organization,” commented Filippo Petti, Chief Executive Officer of Celyad Oncology. “Today’s announcement demonstrates our ability to advance in parallel multiple off-the-shelf product candidates based on differentiated non-gene edited allogeneic technologies into the clinic. In addition, our team has delivered on incredible timelines for the CYAD-211 program, moving the project from concept to an effective IND in under two years. We are excited to have the CYAD-211 IND in effect to initiate the Phase 1 trial by year-end 2020 for this first-in-class CAR T candidate for patients with multiple myeloma and look forward to accelerating the development of additional shRNA-based allogeneic candidates from our CYAD-200 series towards clinical trials.”

Celyad Oncology’s shRNA-based Platform for Allogeneic CAR T

Celyad Oncology is advancing a pipeline of proprietary, non-gene edited allogeneic CAR T candidates from its CYAD-200 series, which is underpinned by its shRNA technology platform. The shRNA platform coupled with the company’s all-in-one vector approach provides flexibility, versatility, and efficiency to the design of novel, off-the-shelf CAR T candidates through a single step engineering process. Next-generation candidates exploring the breadth and depth of the Celyad Oncology shRNA platform are currently under preclinical development. Combining shRNA knockdown with additional functional components in a single CAR T construct may also offer therapeutic opportunity to the non-gene edited allogeneic CYAD-200 series of product candidates. In 2018, Celyad Oncology signed an exclusive agreement with Horizon Discovery Group for the use of its SMARTVector shRNA technology for the development of allogeneic CAR T therapies.

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 may include statements regarding: the safety and clinical activity of Celyad Oncology’s pipelines and financial condition, results of operation and business outlook. 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 risk and uncertainty includes the expected date of the Phase 1 trial initiation by year-end 2020, our development of additional shRNA-based allogeneic candidates from our CYAD-200 series towards clinical trial, and the duration and severity of the COVID-19 pandemic and government measures implemented in response thereto. A further list and description of these risks, uncertainties and other risks can be found in Celyad Oncology’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 March 25, 2020 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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