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Adaptimmune Completes Submission of Rolling Biologics License Application (BLA) to U.S. FDA for Afami-cel for the Treatment of Advanced Synovial Sarcoma

First BLA for an engineered T-cell therapy for solid tumors submitted to U.S. Food and Drug Administration

Afami-cel data demonstrate better outcomes for people with synovial sarcoma compared to historical control data; pivotal trial has met primary endpoint for efficacy

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - December 6, 2023) - Adaptimmune Therapeutics plc (NASDAQ: ADAP), a leader in cell therapy to treat cancer, today announced the completion of the submission of its rolling Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for afami-cel, an investigational engineered T-cell therapy for advanced synovial sarcoma. Afami-cel is eligible for a Priority Review, which would shorten the FDA's review of the application to 8 months versus a standard review timeline of 12 months.

This submission is supported by positive data from Cohort 1 of the pivotal trial SPEARHEAD-1, which met its primary endpoint for efficacy. Data from the trial were recently presented at the [Connective Tissue Oncology Society \(CTOS\) 2023](#) Annual Meeting.

Adrian Rawcliffe, Adaptimmune's Chief Executive Officer: "With this submission, we have completed a critical step toward making cell therapy a mainstream treatment option for people with solid tumors. I would like to thank the trial participants and clinical trial investigators, the synovial sarcoma community, and our afami-cel team for their diligent efforts in completing the BLA submission. We look forward to continued collaboration with the FDA as they review the first ever application for marketing approval for an engineered T-cell therapy for solid tumors. We continue to prepare for the commercial launch of afami-cel and the evolution of our sarcoma cell therapy franchise, which now includes lete-cel."

Brandi Felser, Chief Executive Officer of the Sarcoma Foundation of America: "I celebrate the promise that breakthrough therapies like afami-cel offer to sarcoma patients. Such advancements offer hope and transformative possibilities for the sarcoma patient community, addressing critical unmet needs and offering increased and improved treatments for people diagnosed with sarcoma. I am hopeful for and excited about a new treatment choice for people diagnosed with synovial sarcoma."

The FDA granted Orphan Drug Designation (ODD) for afami-cel for the treatment of soft tissue sarcomas and Regenerative Medicine Advanced Therapy (RMAT) designation for the treatment of synovial sarcoma.

About Afami-cel

Afami-cel is an engineered T-cell receptor (TCR) T-cell therapy, targeted to the MAGE A4 cancer target, and designed as a single-dose treatment for advanced synovial sarcoma. The last FDA approved therapy for treatment in this setting was for Votrient in 2012. The BLA submission for afami-cel was supported by clinical data from the SPEARHEAD-1 pivotal trial, which has met its primary endpoint for efficacy. ~39% of patients who received afami-cel had clinical responses with a median duration of response of ~12 months ([CTOS 2022](#)). Median overall survival (mOS) was ~17 months in SPEARHEAD-1 compared to historical mOS of <12 months for people with synovial sarcoma who received two or more prior lines of therapy^[1]. Seventy percent of people with advanced synovial sarcoma who respond to afami-cel are alive two years post-treatment.

About synovial sarcoma

There are more than 50 different types of soft tissue sarcomas which are categorized by tumors that appear in fat, muscle, nerves, fibrous tissues, blood vessels, or deep skin tissues.¹ Synovial sarcoma accounts for approximately 5% to 10% of all soft tissue sarcomas (there are approximately 13,400 new soft tissue cases in the U.S. each year).² One third of patients with synovial sarcoma will be diagnosed under the age of 30.² The five-year survival rate for people with metastatic disease is just 20% and most people undergoing standard of care treatment for advanced disease experience recurrence and go through multiple lines of therapy, often exhausting all options.³

¹. <https://www.cancer.org/cancer/types/soft-tissue-sarcoma/about/soft-tissue-sarcoma.html> ². [Synovial Sarcoma - NCI \(cancer.gov\)](#) ³. Aytikin MN, et al. *J Orthop Surg (Hong Kong)*. 2020;28(2)

About Adaptimmune

Adaptimmune is a clinical-stage biopharmaceutical company focused on designing, developing, and delivering cell therapies to transform the lives of people with cancer. The Company's unique engineered T-cell receptor (TCR) platform enables the engineering of T-cells to target and destroy cancers across multiple solid tumor types.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). These forward-looking statements involve certain risks and uncertainties. Such risks and uncertainties could cause our actual results to differ materially from those indicated by such forward-looking statements, and include, without limitation: the success, cost and timing of our product development activities and clinical trials and our ability to successfully advance our TCR therapeutic candidates through the regulatory and commercialization processes. For a further description of the risks and uncertainties that could cause our actual results to differ materially from those expressed in these forward-looking statements, as well as risks relating to our business in general, we refer you to our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2022, our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other filings with the Securities and Exchange Commission. The forward-looking statements contained in this press release speak only as of the date the statements were made and we do not undertake any obligation to update

such forward-looking statements to reflect subsequent events or circumstances.

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