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Adaptimmune Announces U.S. FDA Acceptance of Biologics License Application for Afami-cel for the Treatment of Advanced Synovial Sarcoma with Priority Review

- *If approved, afami-cel will be the first engineered T-cell therapy for solid tumors and the first effective treatment option for synovial sarcoma in more than a decade*

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - January 31, 2024) - Adaptimmune Therapeutics plc (NASDAQ: ADAP), a company redefining the treatment of solid tumor cancers with cell therapy, today announced that the U.S. Food and Drug Administration (FDA) has accepted for priority review its Biologics License Application (BLA) for afami-cel, an investigational engineered T-cell therapy for advanced synovial sarcoma. The application has a Prescription Drug User Fee Act (PDUFA) target action date of August 4, 2024.

Adrian Rawcliffe, Adaptimmune's Chief Executive Officer: "The FDA's acceptance of the BLA submission brings us one step closer to redefining treatment for people with synovial sarcoma. Our franchise has great potential and, if approved, we have the capabilities and the capital to launch afami-cel - the first engineered T-cell therapy on the market for a solid tumor cancer."

Dennis Williams, PharmD, Senior VP of Late-Stage Development: "Historic outcomes are poor for advanced synovial sarcoma, with low objective response rates for second-line therapies and overall survival of less than 12 months for people who have received two or more prior lines of therapy. In clinical trials, afami-cel has demonstrated an impressive response rate of ~39% among heavily pre-treated patients with advanced synovial sarcoma and about a 17-month median survival. This regulatory milestone is a testament to our teams' relentless work to deliver a novel treatment option to more people diagnosed with synovial sarcoma."

This acceptance 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 presented at the [Connective Tissue Oncology Society \(CTOS\) 2023 Annual Meeting](#).

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 categorised 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 Aytekin MN, et al. *J Orthop Surg (Hong Kong)*. 2020;28(2).

About Adaptimmune

Adaptimmune is a cell therapy company out to redefine cancer treatment. With personalized medicines that radically improve the patient's experience with the therapy as much as the therapy itself, Adaptimmune is tackling difficult-to-treat solid tumor cancers so that patients and families may experience more unforgettable and important personal moments. 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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