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Adaptimmune Reports Better Outcomes for People with Synovial Sarcoma who Received Afami-cel Compared to Historical Control

~39% of patients who received afami-cel in the pivotal SPEARHEAD-1 trial 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]

70% of people with advanced synovial sarcoma who respond to afami-cel are alive two years post-treatment

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - October 31, 2023) - Adaptimmune Therapeutics plc (Nasdaq: ADAP), a leader in cell therapy to treat cancer, to present outcome data from Cohort 1 of its pivotal SPEARHEAD-1 trial at the Connective Tissue Oncology Society (CTOS) annual meeting in Dublin, Ireland. These data will be shared in an oral presentation by SPEARHEAD-1 investigator, Brian A. Van Tine, MD, PhD, Washington University School of Medicine in St. Louis, on Friday, November 3rd, during Session 5: Immunology & Immunotherapy from 9-10 a.m. GMT / 5-6 a.m. EDT (Paper 30).

Dr. Brian A. Van Tine, Professor of Medicine and Pediatrics at Washington University School of Medicine in St. Louis: "The additional data shown at CTOS 2023 demonstrate an increased prolonged efficacy for people with synovial sarcoma who received afami-cel compared to a year ago. This is a transformational therapy for synovial sarcoma, and I know there is a groundswell of support to make this product widely available. The international effort to recruit eligible patients demonstrates the commitment of sarcoma centers to rapidly find rare tumor patients."

Dennis Williams, Pharm. D., Senior Vice President of Late-Stage Development at Adaptimmune: "These results demonstrate the efficacy that a single treatment of afami-cel provides for patients living with advanced synovial sarcoma. Adaptimmune is focused on making afami-cel commercially available and we are grateful to the investigators and patients who participated in the SPEARHEAD-1 trial."

Positive outcome data from the pivotal SPEARHEAD-1 trial with afami-cel (Cohort 1 data at CTOS 2023)

People with synovial sarcoma in the pivotal SPEARHEAD-1 trial had advanced metastatic disease and were heavily pre-treated having received a median of 3 prior lines of systemic

therapy (range: 1-12).

There was an overall response rate of ~39% with afami-cel and responses were durable with a median duration of ~12 months ([CTOS 2022](#)).

Historical outcomes are poor for advanced synovial sarcoma with a mOS of <12 months for people who have received two or more prior lines of therapy.² The time to next treatment has a strong correlation with overall survival in metastatic sarcoma and the historical median time to next treatment is approximately 6, 3, or 2 months after two, three, or four lines of prior systemic therapy, respectively.^[2]

In the SPEARHEAD-1 trial, outcomes compare favorably to historical control data after a single dose of afami-cel. Patients had encouraging treatment-free intervals and the median time to next treatment was ~7 months overall and ~17 months among patients with a RECISTv1.1 response.

The median OS was ~17 months overall and patients who respond to afami-cel have an estimated 70% chance of being alive two years post-treatment. Additional analyses demonstrate higher afami-cel cellular persistence was associated with longer overall survival.

Toxicities include cytokine release syndrome and reversible hematologic toxicities, in line with previous findings indicating an acceptable safety profile.

Afami-cel is on track to be Adaptimmune's first commercial product

Adaptimmune has completed submission of the preclinical (Part 1) and clinical modules (Part 2) of the Biologics License Application (BLA) for afami-cel for the treatment of synovial sarcoma, which is targeted for completion in Q4 2023. This BLA is supported by data from Cohort 1 of the pivotal SPEARHEAD-1 trial, which has met its primary endpoint for efficacy. For afami-cel, the FDA has granted Orphan Drug Designation (ODD) for the treatment of soft tissue sarcomas and Regenerative Medicine Advanced Therapy (RMAT) designation for the treatment of synovial sarcoma.

Overview of SPEARHEAD-1 trial design

SPEARHEAD-1 is a Phase 2, open-label trial for people with advanced synovial sarcoma or myxoid/round cell liposarcoma (MRCLS) to evaluate the efficacy, safety, and tolerability of afami-cel. Afami-cel's engineered TCR T-cells target MAGE-A4+ tumors. MAGE-A4 is highly expressed in synovial sarcoma in the context of HLA-A*02.

Approximately 90 patients were planned to be treated: 45 in Cohort 1 and 45 in Cohort 2. Enrollment in both cohorts is complete. The primary efficacy analysis is for Cohort 1 only. Cohort 2 will strengthen the efficacy and safety database and will aid in descriptive subgroup analyses. Cohort 2 has an overall response rate nearly identical to Cohort 1 (data will be reported when follow-up is mature). Cohort 3 is now open to provide access to afami-cel ahead of planned commercialization.

Key eligibility criteria include ECOG performance status of 0 or 1; HLA*02 positive with MAGE-A4 expression in ≥ 30% of tumor cells ≥ 2+ by immunohistochemistry; aged ≥ 16 and

≤ 75 years; and patients must have received either an anthracycline- or ifosfamide-containing regimen. Eligible patients received a single dose of afami-cel between 1-10 × 10⁹ transduced T-cells after receiving lymphodepleting chemotherapy.

About Afami-cel

Afami-cel is an engineered T-cell receptor (TCR) designed to kill cancer cells in solid tumors expressing a protein called MAGE-A4. Adaptimmune has initiated a rolling BLA submission for afami-cel for the treatment of synovial sarcoma with the third and final module expected to be submitted by end of 2023.

About synovial sarcoma

There are approximately 50 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. Aytakin 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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[1] Carroll C, et al. Future Oncology; NOTE: patients in SPEARHEAD-1 were heavily pre-treated having received a median of 3 prior lines of systemic therapy (range: 1-12) (CTOS 2023)

[2] Savina M, et al. BMC Med. 2017;15(78)



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