

November 18, 2022



# Data from Cohort 1 of SPEARHEAD-1 Trial at CTOS Continue to Support BLA Submission for Afami-cel in Synovial Sarcoma - Response Rate and Durability Remain Consistent

- Data indicate continued clinical responses with an acceptable safety profile in heavily pre-treated patients with late-stage synovial sarcoma after a single dose of afami-cel -
- Overall response rate in synovial sarcoma of 39% by independent review -consistent with previous data -
- Median duration of response of 50 weeks, consistent with previous data -
- Afami-cel drives tumor infiltration of activated and proliferative cytotoxic ("killer") T-cells into tumors - which likely contributes to antitumor response -
- Adaptimmune is on track to initiate a rolling BLA submission for afami-cel for the treatment of synovial sarcoma in Q4 2022 with a target for completion in mid-year 2023 -

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - November 18, 2022) - Adaptimmune Therapeutics plc (NASDAQ: ADAP), a leader in cell therapy to treat cancer, is presenting clinical and translational data from the final analyses of the pivotal SPEARHEAD-1 trial (Cohort 1) with afamitresgene autoleucel (afami-cel) in patients with advanced synovial sarcoma or myxoid/round cell liposarcoma (MRCLS) at the Connective Tissue Oncology Society (CTOS) annual meeting taking place this week in Vancouver, BC. The 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 18th, during Session 9: Immunology & Immunotherapy at 4:39 p.m. UTC/ 7:30 p.m. EST (Paper 61).

"With these results, we continue our excitement and optimism about the clear potential of afami-cel to address synovial sarcoma- a difficult-to-treat cancer with high unmet need," said Elliot Norry, Chief Medical Officer, Adaptimmune. "These data reaffirm our commitment to this therapy, and we are very pleased to be able to include these data in our upcoming BLA submission."

## Data reinforce clinical efficacy and acceptable safety profile of Adaptimmune's novel T-cell therapy, afami-cel (August 29, 2022 data cut)

- Data continue to support BLA submission for afami-cel in heavily pre-treated patients with synovial sarcoma with an overall response rate of 38.6% by independent review

(N=44)

- Responses are durable with a median duration of 50 weeks (range: 11.7-122 weeks)
- Toxicities include cytokine release syndrome and reversible hematologic toxicities, in line with previous findings indicating an acceptable safety profile
- Responses were observed across all evaluated subpopulations with higher response rates observed in female patients and those who had higher MAGE-A4 expression, had lower disease burden at baseline, or did not require bridging therapy. Data are consistent with those [presented earlier this year as ASCO](#)
- Translational data indicate that afami-cel drives tumor infiltration of activated and proliferative cytotoxic ("killer") T-cells, shifting the balance from immune-suppressive to a pro-immune in the tumor microenvironment which likely contributes to antitumor response

"We are on the cusp of an exciting and important time for people impacted by synovial sarcoma, a cancer that for much too long has not seen innovative treatment options," said Dr. Brian A. Van Tine, Professor of Medicine and Pediatrics at Washington University School of Medicine in St. Louis. "The SPEARHEAD-1 Trial results provide us a reason to be very optimistic about the game-changing potential to treat more people with this difficult cancer in the very near future."

[As previously announced](#), Cohort 1 of the SPEARHEAD-1 trial has completed treatment and met the primary endpoint for efficacy. Data from Cohort 1 will be used to support Adaptimmune's BLA submission. Cohort 2 of the SPEARHEAD-1 trial is ongoing with treatment 60% complete and an overall response rate nearly identical to Cohort 1. On September 28<sup>th</sup>, Adaptimmune received the Vision of Hope Award from the Sarcoma Foundation of America at its Annual Stand Up to Sarcoma Gala.

### **SPEARHEAD-1 trial design**

SPEARHEAD-1 is a Phase 2, open-label trial for people with advanced synovial sarcoma or MRCLS to evaluate the efficacy, safety, and tolerability of afami-cel. Afami-cel SPEAR T-cells target MAGE-A4+ tumors. MAGE-A4 is highly expressed in synovial sarcoma and MRCLS in the context of HLA-A\*02. Compelling clinical responses in patients with synovial sarcoma were previously reported with afami-cel in a Phase 1 trial (CTOS 2020). Approximately 90 patients are planned to be treated: 45 in Cohort 1 and 45 in Cohort 2. Enrollment in Cohort 1 is complete, and Cohort 2 is currently recruiting. The primary efficacy analysis will be for Cohort 1 only and will be used to support a BLA filing, which is expected to be initiated in Q4 2022.

No formal hypothesis testing is planned for Cohort 2. Cohort 2 will strengthen the efficacy and safety database and will aid in descriptive sub-group analyses. Key eligibility criteria: ECOG performance status of 0 or 1; HLA\*02 positive with MAGE-A4 expression in  $\geq 30\%$  of tumor cells  $\geq 2+$  by immunohistochemistry; aged  $\geq 16$  and  $\leq 75$  years; and patients must have received either an anthracycline- or ifosfamide-containing regimen. Eligible patients received afami-cel doses between  $1-10 \times 10^9$  transduced T-cells after receiving lymphodepleting chemotherapy.

### **About Adaptimmune**

Adaptimmune is a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapy products for people with cancer. The Company's unique

SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform enables the engineering of T-cells to target and destroy cancer across multiple solid tumors.

### **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, 2021, 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.

### **Adaptimmune Contact**

#### **Investor**

Juli P. Miller, Ph.D. - VP, Corporate Affairs and Investor Relations

T: +1 215 825 9310

M: +1 215 460 8920

[Juli.Miller@adaptimmune.com](mailto:Juli.Miller@adaptimmune.com)

#### **Media Relations**

Dana Lynch, Senior Director of Corporate Communications

M: +1 267 990 1217

[Dana.Lynch@adaptimmune.com](mailto:Dana.Lynch@adaptimmune.com)



To view the source version of this press release, please visit

<https://www.newsfilecorp.com/release/144701>

SOURCE Adaptimmune Therapeutics PLC