

Two Complete Responses and Response Rate of 41% for People with Synovial Sarcoma Reported at ASCO in Adaptimmune's Phase 2 SPEARHEAD-1 Trial

- Data will support BLA filing for afamitresgene autoleucel next year -
- Responses observed across a broad range of antigen expression -
- Initial safety and durability are encouraging -

PHILADELPHIA and OXFORDSHIRE, United Kingdom, May 19, 2021 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in cell therapy to treat cancer, will report initial data from its Phase 2 SPEARHEAD-1 trial, with afamitresgene autoleucel (afami-cel, formerly ADP-A2M4), at the American Society of Clinical Oncology (ASCO) congress. Full abstracts were released online today. Data will be presented in an oral presentation by Dr. Sandra D'Angelo of the Memorial Sloan Kettering Cancer Center (Abstract #11504) on June 4th.

"Patients are seeing substantial benefit from afami-cel in SPEARHEAD-1 across a broad range of cell doses and levels of MAGE-A4 expression," said Adrian Rawcliffe, Adaptimmune Chief Executive Officer. "We have shown a high response rate and these responses are still evolving in many patients with increasing depths of response over time and encouraging durability. I am confident that SPEARHEAD-1 will support our BLA submission next year and offer a life-changing treatment for people with synovial sarcoma."

"Initial data from SPEARHEAD-1 indicate that afami-cel has the potential to offer people with synovial sarcoma a promising new treatment option where there is currently a great unmet medical need," said Dr. Sandra P. D'Angelo of the Memorial Sloan Kettering Cancer Center. "As clinicians, we want to be able to provide a treatment regimen that can help offer a better quality of life."

SPEARHEAD-1 data will be presented at the time of the oral presentation scheduled for June 4th during the sarcoma session taking place from 1:30 p.m. to 4:30 p.m. EDT.

Afami-cel is efficacious and well-tolerated in heavily pre-treated patients based on initial data

- At the time of data cut-off (March 29, 2021), 37 patients had received afami-cel (32 with synovial sarcoma, 5 with myxoid/ round cell liposarcoma [MRCLS])
- Of the 37 patients who had received afami-cel, 4 patients were pending first efficacy

assessment, and 33 had at least one scan as of data cut off (29 with synovial sarcoma, 4 with MRCLS)

- The overall response rate¹ was 39.3% (13/33), 41.4% (12/29) for synovial sarcoma; 25.0% (1/4) for MRCLS
- Of the 29 patients with synovial sarcoma with at least one scan, 2 had complete responses (CRs), 10 had partial responses (PRs), 13 had stable disease (SD), 4 had progressive disease (PD)
- The disease control rate for people with synovial sarcoma was 86.2% (25/29) (defined as either response or stable disease)
- Of the 4 patients with MRCLS with at least one scan, 1 patient had a partial response, 2 had stable disease, and 1 had progressive disease
- Objective responses have been reported across a wide range of cell doses and MAGE-A4 antigen expression levels
- Initial durability data is encouraging, and the median duration of response has not been reached
- To date, the safety profile of afami-cel has been favorable, with mainly low-grade cytokine release syndrome and tolerable/reversible hematologic toxicities.

Overview of 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, which will be used to support the BLA filing next year. 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.

Eligible patients were ≥ 16 and < 75 years, HLA*02 positive with MAGE-A4 expression in $\geq 30\%$ of tumor cells that were $\geq 2^+$ by immunohistochemistry. Eligible patients received afami-cel doses between $1-10 \times 10^9$ transduced T-cells after receiving lymphodepleting chemotherapy.

The primary endpoint is overall response rate per RECIST v1.1 by independent review. The primary endpoint will be evaluated using a one-sided exact-based Clopper-Pearson 97.5% confidence interval (CI). If the lower bound of the CI exceeds the response rate reported with historical second line therapy(ies), the trial will have met the pre-specified threshold for demonstrating efficacy.

An independent Data Safety Monitoring Board reviews ongoing safety and benefit:risk during the interventional phase of the trial.

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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 6, 2021 and our other SEC filings. 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 Responses were evaluated by RECIST v1.1 per Investigator assessment



Source: Adaptimmune Therapeutics plc