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# Results of Adaptimmune's SPEARHEAD-1 Trial with Afami-cel in Advanced Sarcomas Published in the Lancet

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - March 27, 2024) - Adaptimmune Therapeutics plc (NASDAQ: ADAP), a company redefining the treatment of solid tumor cancers with cell therapy, today announced that *The Lancet* published the company's pivotal Phase 2 data with afami-cel. [The article](#), titled "SPEARHEAD-1: a single-arm phase 2 trial of afamitresgene autoleucel (afami-cel) in advanced synovial sarcoma and myxoid/round cell liposarcoma," details clinical and translational results from afami-cel's SPEARHEAD-1 trial (NCT04044768).

**Dennis Williams, PharmD., Senior Vice President, Late-Stage Development, Adaptimmune:** "It is exciting to see the Lancet share the afami-cel SPEARHEAD-1 trial results in advanced sarcomas with the broader clinical and research communities. The study further demonstrates the ability of engineered T-cell therapies to effectively target solid tumors and we are eager to introduce the first engineered T-cell therapy, afami-cel, to more patients later this year."

**Dr. Sandra D'Angelo, M.D., Sarcoma Medical Oncology, Memorial Sloan Kettering Cancer Center, lead author of the publication:** "The reported findings are clinically impactful, considering the current standard of care and limited therapies available in advanced sarcomas. Treatment with afami-cel resulted in 39% overall response rate in synovial sarcoma with durable responses. These results suggest that a one-time treatment with afami-cel has the potential to extend life while allowing responders to go off chemotherapy. The publication of this data further validates the potential of afami-cel to offer a new tool to address the unmet needs of people diagnosed with these often-devastating diseases."

**About Afami-cel (afamitresgene autoleucel):** On January 31, 2024, Adaptimmune 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.

In the SPEARHEAD-1 trial, 44 patients with advanced synovial sarcoma were treated with a single dose of afami-cel after undergoing lymphodepleting chemotherapy with cyclophosphamide and fludarabine. Safety findings were overall consistent with those previously observed in advanced cancer patients undergoing lymphodepleting chemotherapy and cell therapy. Haematologic toxicities were the most common adverse events. Low grade cytokine release syndrome occurred in most patients and was managed with standard treatments.

**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.<sup>1</sup> 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).<sup>2</sup> One third of patients with synovial sarcoma will be diagnosed under the age of 30.<sup>2</sup> 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.<sup>3</sup>

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

### **About Adaptimmune**

Adaptimmune is a cell therapy company working to redefine how cancer is treated. 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 31 December, 2023, 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.

*Dr. Sandra D'Angelo has financial interests related to Adaptimmune.*

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