

November 13, 2024



# Adaptimmune's Lete-cel Achieves Primary Endpoint in Pivotal Trial

*42% of people with advanced or metastatic synovial sarcoma or MRCLS had clinical responses with lete-cel*

*Results include six complete responses (6/64); twenty-one partial responses (21/64)*

*Data to be presented at Connective Tissue Oncology Society 2024 Annual Meeting*

*Company plans to initiate a rolling BLA submission for lete-cel for the treatment of advanced or metastatic synovial sarcoma and MRCLS by end of 2025*

*Company to host virtual KOL event Monday, November 18, 2024; 2:30 PM EST featuring Dr. Sandra D'Angelo, M.D. (Memorial Sloan Kettering Cancer Center) - register [here](#)*

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - November 13, 2024) - Adaptimmune Therapeutics plc (NASDAQ: ADAP), a company working to redefine the treatment of solid tumor cancers with cell therapy, today announced data from the primary analysis of its pivotal Phase 2 IGNYTE-ESO trial of lete-cel in people with synovial sarcoma or myxoid/round cell liposarcoma (MRCLS) who received previous anthracycline-based therapy. The primary analysis data are being presented at the Connective Tissue Oncology Society (CTOS) 2024 Annual Meeting which takes place from November 13-16, 2024 in San Diego.

Based on these positive data, Adaptimmune plans to initiate a rolling Biologics License Application (BLA) submission for lete-cel for the treatment of advanced or metastatic synovial sarcoma and MRCLS by the end of 2025. Lete-cel builds on the potential of Adaptimmune's sarcoma franchise to change the way solid tumors are treated using cell therapies, more than doubling the addressable patient population eligible for Adaptimmune cell therapies to also include NY-ESO-1 positive synovial sarcoma and MRCLS solid tumors.

**Sandra D'Angelo, MD, Sarcoma Medical Oncologist and Cell Therapist, Memorial Sloan Kettering Cancer Center:** "Individuals with both synovial sarcoma and MRCLS are commonly diagnosed under 40, facing a devastating disease with limited treatments in the prime of their lives. I've been seeing these patients throughout my career and have frequently faced the frustrating reality of having incredibly limited treatment options to offer them. I'm encouraged by these data as they could lead to a potential therapeutic option and an improved prognosis for these patients."

**Elliot Norry, MD, Adaptimmune's Chief Medical Officer:** "We are thrilled to see that 42% of patients with synovial sarcoma or MRCLS responded to treatment with lete-cel, following prior treatment with currently available therapies. Responses were durable across both indications, with an overall median duration of response greater than 18 months for people with synovial sarcoma and greater than one year for MRCLS. These data underscore lete-

cel's potential to transform the lives of people with these cancers who have a poor prognosis and few treatment options. We look forward to presenting our findings at CTOS and initiating a rolling Biologics License Application for lete-cel in 2025 for the treatment of both synovial sarcoma and MRCLS, building on the potential of our sarcoma franchise."

The primary analysis includes data from 64 people with synovial sarcoma or MRCLS who received lete-cel manufactured with the proposed commercial manufacturing process in the IGNYTE-ESO trial. In the analysis, 27/64 (42%) people with synovial sarcoma or MRCLS had RECISTv1.1 responses by independent review, with six complete responses and 21 partial responses. The response rate was 14/34 (41%) for people with synovial sarcoma and 13/30 (43%) for people with MRCLS.

The median duration of response (DoR) was 12.2 months (95% CI 6.8, 19.5). In synovial sarcoma, the median duration of response was 18.3 months (95% CI 3.3, -). In MRCLS, the median duration of response was 12.2 months (95%, CI 5.3, -). The median progression free survival (PFS) was 5.3 months (95% CI 4.0, 8.0).

Safety findings were consistent with the known profile of lete-cel from previous data. All patients experienced treatment-emergent adverse events: cytopenias, cytokine release syndrome (CRS) and rash were the most common adverse events. Overall, toxicities were manageable, and consistent with an acceptable benefit to risk profile.

#### **CTOS presentation details:**

- **Title:** Planned Analysis of the Pivotal IGNYTE-ESO Trial of Lete-Cel in Patients with Synovial Sarcoma or Myxoid/Round Cell Liposarcoma (Paper 84)
- **Session 12: Immunology:** Podium presentation
- **Presenter:** Sandra D'Angelo, MD, Sarcoma Medical Oncologist and Cell Therapist, Memorial Sloan Kettering Cancer Center
- **Date/Time:** Saturday, November 16, 10:30 AM - 12:00 PM PT / 1:30 - 3:00 PM ET

#### **Adaptimmune virtual KOL event November 18<sup>th</sup>**

Adaptimmune will host a virtual event to discuss and review the IGNYTE-ESO dataset and the impact of engineered cell therapies on the treatment landscape in sarcoma. The event will feature Sandra D'Angelo, M.D., Sarcoma Medical Oncology, Memorial Sloan Kettering Cancer Center, an investigative clinician in both the SPEARHEAD and IGNYTE-ESO clinical trials, and author and presenter of the IGNYTE-ESO data update at CTOS. A live question and answer session will follow the formal presentation. The virtual event will take place on Monday, November 18, 2024 from 2:30 PM ET to 3:30 PM ET. To register, [click here](#).

#### **About the IGNYTE-ESO trial**

IGNYTE-ESO is a pivotal, Phase 2, open-label trial for people with previously treated, advanced synovial sarcoma or MRCLS to evaluate the efficacy, safety, and tolerability of lete-cel. Lete-cel's engineered TCR T-cells target NY-ESO-1+ tumors. NY-ESO-1 is a solid tumor antigen highly expressed in synovial sarcoma and MRCLS.

#### **About lete-cel**

Lete-cel is an investigational, engineered TCR T-cell therapy targeting the solid tumor antigen NY-ESO-1. Lete-cel is being investigated for the treatment of synovial sarcoma and myxoid/round cell liposarcoma (MRCLS) in the pivotal IGNYTE-ESO (NCT03967223) trial in

patients who received prior anthracycline treatment.

### **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.<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>2,3</sup> One third of patients with synovial sarcoma will be diagnosed under the age of 30.<sup>3</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>4</sup>

### **About Myxoid/round cell liposarcoma (MRCLS)**

MRCLS is one of several types of liposarcoma, a rare cancer that grows in the cells that store fat in the body. MRCLS usually grows in the arms and legs. Each year in the United States, about 2,000 people are diagnosed with liposarcoma. MRCLS is one of the most common types of liposarcoma and makes up about 30% of all liposarcoma cases. It is more common in people aged 20 to 40 years old.<sup>5</sup> One-third of MRCLS cases will become metastatic with tumors spreading to unusual bone and soft tissue locations.<sup>6</sup>

### **About Adaptimmune**

Adaptimmune is a fully integrated cell therapy company working to redefine how cancer is treated. With its unique engineered T cell receptor (TCR) platform, the Company is developing personalized medicines designed to target and destroy difficult-to-treat solid tumor cancers and to radically improve the patient's cancer treatment experience. For more information, visit <https://www.adaptimmune.com/> or follow us on [LinkedIn](#).

### **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. D'Angelo provides consulting and advisory services to Adaptimmune.**

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<sup>1</sup> "What is a Soft Tissue Sarcoma?" American Cancer Society.

<https://www.cancer.org/cancer/types/soft-tissue-sarcoma/about/soft-tissue-sarcoma.html>.

Accessed October 24, 2024.

<sup>2</sup> "Soft Tissue Sarcoma." Cleveland Clinic.

<https://my.clevelandclinic.org/health/diseases/21732-soft-tissue-sarcoma>. Accessed October

24, 2024.

<sup>3</sup> Synovial Sarcoma." National Cancer Institute. <https://www.cancer.gov/pediatric-adult-rare-tumor/rare-tumors/rare-soft-tissue-tumors/synovial-sarcoma>.

Accessed October 24, 2024.

<sup>4</sup> Aytekin MN, Öztürk R, Amer K, et al. Epidemiology, incidence, and survival of synovial sarcoma subtypes: SEER database analysis. J Orthop Surg (Hong Kong). 2020;28(2):1-12.

<sup>5</sup> "Myxoid/round cell liposarcoma" National Cancer Institute. <https://www.cancer.gov/pediatric-adult-rare-tumor/rare-tumors/rare-soft-tissue-tumors/myxoid-round-cell-liposarcoma>.

Accessed October 24, 2024

<sup>6</sup> <https://www.orpha.net> accessed Oct. 24, 2024



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