# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 8-K

**Current Report**
**Pursuant to Section 13 or 15(d) of**
**the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **October 31, 2023**

# ADAPTIMMUNE THERAPEUTICS PLC

(Exact name of registrant as specified in its charter)

| **England and Wales** | **1-37368** | **Not Applicable** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**60 Jubilee Avenue, Milton Park**
**Abingdon, Oxfordshire OX14 4RX**
**United Kingdom**
(Address of principal executive offices, including zip code)

**(44) 1235 430000**
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Trading Symbol** | **Name of each exchange on which registered** |
|---|---|---|
| American Depositary Shares, each representing 6 Ordinary Shares, par value £0.001 per share | ADAP | The Nasdaq Global Select Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.☐

**Item 7.01 Regulation FD Disclosure.**

On October 31, 2023, Adaptimmune Therapeutics Plc ("Adaptimmune") issued a press release reporting the outcome of a protocol-defined interim analysis of data from the pivotal IGNYTE-ESO trial with lete-cel for synovial sarcoma or myxoid/round cell liposarcoma (MRCLS). Lete-cel is in the process of transitioning back to Adaptimmune from GSK. Additionally, Dr. Melissa Burgess of University of Pittsburgh Medical Center will present a poster summarizing results of Substudy 1 of the IGNYTE-ESO clinical trial exploring the feasibility, efficacy, and safety of lete-cel in the first line setting for treatment-naïve patients with metastatic or unresectable synovial sarcoma or MRCLS on Thursday, November 2, 2023 at the Connective Tissue Oncology Society (CTOS) annual meeting in Dublin, Ireland.

The press release is furnished as Exhibit 99.1 and incorporated by reference herein.

The information in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**tem 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description of Exhibit |
|---|---|
| 99.1 | Press release dated October 31, 2023 |
| 104 | Cover Page Interactive Date File (embedded within the Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ADAPTIMMUNE THERAPEUTICS PLC

Date: October 31, 2023

By: /s/ Margaret Henry
Name: Margaret Henry
Title: Corporate Secretary

**Exhibit 99.1**

# Adaptimmune Reports Positive Data with Lete-cel[1] from an Interim Analysis of the Pivotal IGNYTE-ESO Trial for People with Synovial Sarcoma or MRCLS

40% (18/45) of people with synovial sarcoma or MRCLS and who have received ≥ 2 prior lines of therapy had clinical responses with lete-cel, by independent review[2]; primary efficacy endpoint requires 16/60 patients have responses

Median duration of response was ~11 months, data are immature and still evolving

80% (4/5) response rate by investigator assessment with lete-cel in a small substudy of treatment-naïve synovial sarcoma patients with all responses ongoing at the time of this analysis (CTOS 2023)[3]

PHILADELPHIA, PA. and OXFORD, UK, October 31, 2023 – Adaptimmune Therapeutics plc (Nasdaq: ADAP), a leader in cell therapy to treat cancer, is reporting the outcome of a protocol-defined interim analysis of data from the pivotal IGNYTE-ESO trial with lete-cel for people with synovial sarcoma or myxoid/round cell liposarcoma (MRCLS) who received ≥ 2 prior lines of therapy.

Additionally, Dr. Melissa Burgess of University of Pittsburgh Medical Center will present a poster summarizing results of Substudy 1[4] of the IGNYTE-ESO clinical trial exploring the feasibility, efficacy, and safety of lete-cel in the first-line setting for treatment-naïve patients with metastatic or unresectable synovial sarcoma or MRCLS on Thursday November 2nd at the Connective Tissue Oncology Society (CTOS) annual meeting taking place in Dublin, Ireland.

**Elliot Norry, MD, Adaptimmune's Chief Medical Officer:** "The remarkable responses we are seeing in the interim analysis from IGNYTE-ESO provide us with a compelling opportunity to continue the clinical development of lete-cel for both synovial sarcoma and MRCLS. We'll be able to leverage our learnings and capabilities from afami-cel as we consider next steps to further develop lete-cel."

## Interim analysis data from the IGNYTE-ESO pivotal trial with lete-cel

Lete-cel, an engineered T-cell therapy targeted against NY-ESO-1, is being investigated for the treatment of synovial sarcoma or MRCLS in the pivotal IGNYTE-ESO (NCT03967223) trial in patients who received ≥ 2 prior lines of therapy.

The interim analysis for efficacy includes data from 45 people with synovial sarcoma or MRCLS who have received lete-cel in the IGNYTE-ESO trial and who had at least 6 months follow up. At the time of this analysis, 18/45 (40%) (99.6% CI: 20.3%, 62.3%) people with synovial sarcoma or MRCLS had RECISTv1.1 responses by independent review with two complete responses and 16 partial

---

1 Adaptimmune and GSK have agreed terms for transfer of the lete-cel program back to Adaptimmune (announced April 2023) and the transition is still in progress.

2 Substudy 2 in patients who have received ≥ 2 prior lines of treatment; responses for primary efficacy endpoint by independent review

3 Substudy 1 in the first-line treatment setting

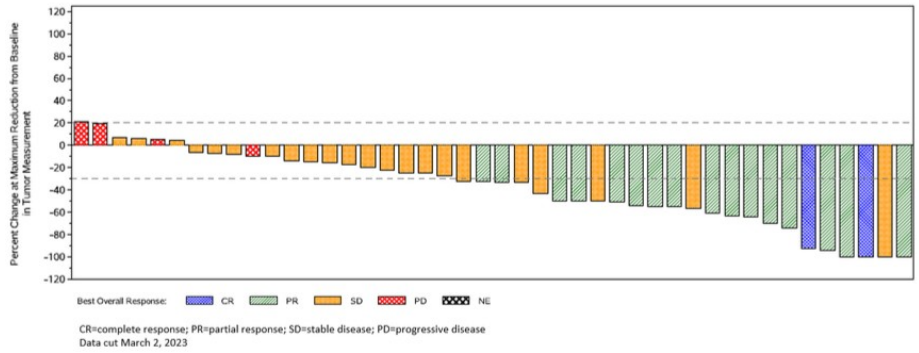
4 Substudy 1 in the first-line treatment setting

responses. The response rate was 9/23 (39%) for people with synovial sarcoma and 9/22 (41%) for people with MRCLS by independent review.

Duration of Response (DoR) is still being followed in 9/18 (50%) of responders at the time of the data cut-off. The median duration of response was 10.6 months (95% CI: 3.3, NE). The DoR ranges from 1.18+ to 16.6+ months and 12 out of 18 patients were censored for this analysis.

At the time of this data cut, 18/45 of people with synovial sarcoma or MRCLS had RECISTv1.1 responses with lete-cel, by independent review. The pre-defined success criteria for this planned interim analysis required at least 14 responders out of 45 patients and the primary endpoint for efficacy will require 16 responders out of 60 patients by independent review.

**Responses by independent review from interim analysis of IGNYTE-ESO**




By investigator review, 15/45 (33%) of people with synovial sarcoma or MRCLS had RECISTv1.1 responses. The response rate was 7/23 (30%) for people with synovial sarcoma and 8/22 (36%) for people with MRCLS by investigator review.

The safety population included 73 people who had received lete-cel at the time of this interim analysis. Safety findings were consistent with the known profile of lete-cel from previous data. 65 (89%) patients had cytokine release syndrome (CRS), with the majority of CRS cases at grades 1 and 2, and 9 (12%) at grade 3 and no cases reported at Grade 4 or 5. 64 (88%) patients had hematopoietic cytopenias and the majority (86%) of events were Grade 3 or higher. Less than 5% of patients experienced immune effector cell-associated neurotoxicity (ICANS) and all events were grade 1. Overall, the safety profile of lete-cel was acceptable, including CRS and reversible hematologic toxicities.

The primary analysis will be conducted in the first half of 2024 when the 60$^{th}$ treated patient has 12 months of follow-up.

## Data from Substudy 1 of the IGNYTE-ESO trial (CTOS 2023)

Substudy 1 was designed to explore the feasibility, efficacy, and safety of lete-cel in the first-line setting for treatment-naïve patients with metastatic or unresectable synovial sarcoma or MRCLS.

Of the five evaluable patients in the substudy, one exhibited a complete response, with an additional three partial responses, yielding an overall response rate of 80% (4/5) by investigator assessment. All five patients experienced cytokine release syndrome, all cases resolved; four were treated with tocilizumab. Overall, the substudy reveals encouraging efficacy in this small population of treatment-naïve patients in the advanced/metastatic setting with 80% ORR, with all responses ongoing at the time of this analysis.

## Overview of IGNYTE-ESO trial design

IGNYTE-ESO is a Phase 2, open-label trial for people with 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 highly expressed in synovial sarcoma and MRCLS in the context of HLA-A*02.

Key eligibility criteria include ECOG performance status of 0 or 1; HLA*02 positive with confirmed NY-ESO expression in ≥ 30% of tumor cells ≥ 2+ by immunohistochemistry; aged ≥ 10 years; and patients must have measurable disease according to RECIST v1.1 at the time of treatment. The IGNYTE-ESO master protocol include two substudies – Substudy 1 was designed to investigate lete-cel in previously untreated advanced (metastatic or unresectable) synovial sarcoma or MRCLS; and Substudy 2 lete-cel in advanced (metastatic or unresectable) synovial sarcoma or MRCLS post-anthracycline chemotherapy. Eligible patients received lete-cel doses between 1-15 × 10^9 transduced T-cells after receiving lymphodepleting chemotherapy.

Approximately 10 people were planned to be treated in Substudy 1, 5 patients were treated and enrollment was stopped. Approximately 60 people were planned to be treated in Substudy 2 and enrollment is complete.

## About lete-cel [5]

Lete-cel is an engineered TCR T-cell therapy against the solid tumor antigen NY-ESO-1.

## 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 accessed Oct. 24, 2023 2. Synovial Sarcoma - NCI (cancer.gov) accessed Oct. 24, 2023 3. Aytekin MN, et al. *J Orthop Surg (Hong Kong)*. 2020;28(2)

---

5 Adaptimmune and GSK have agreed terms for transfer of the lete-cel program back to Adaptimmune (announced April 2023) and the transition is still in progress.

## About Myxoid/round cell liposarcoma (MRCLS)

Myxoid/round cell liposarcoma (MRCLS) is a type of soft tissue sarcoma that is predominantly found in the limbs. MRCLS accounts for approximately 5% to 10% of all soft tissue sarcomas.[1] One-third of MRCLS cases will become metastatic with tumors spreading to unusual bone and soft tissue locations. MRCLS commonly presents at an age ranging from 35-55 years and has a poor prognosis because it recurs locally and tends to metastasize quickly and widely. The 5-year survival rate for metastatic MRCLS is only 5%.[2]

1. https://www.cancer.gov/pediatric-adult-rare-tumor/rare-tumors/rare-soft-tissue-tumors/myxoid-round-cell-liposarcoma accessed Oct. 24, 2023 2. https: www.orpha.net accessed Oct. 24, 2023

## 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.

## Adaptimmune Contacts

**Investor Relations**
Juli P. Miller, Ph.D. - VP, Corporate Affairs and Investor Relations
M : +1 215 460 8920
Juli.Miller@adaptimmune.com

**Media Relations**
Dana Lynch, Senior Director of Corporate Communications
M: +1 267 990 1217
Dana.Lynch@adaptimmune.com