# 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): **August 1, 2024**

## 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 August 1, 2024, Adaptimmune Therapeutics plc. (the "***Company***") issued a press release announcing that the U.S. Food and Drug Administration (the "***FDA***") approved TECELRA® (afamitresgene autoleucel), the first engineered cell therapy for a solid tumor cancer approved in the U.S. TECELRA® was approved for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The furnished under 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 liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "***Securities Act***") or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

**Item 8.01 Other Events.**

As noted in Item 7.01 above, on August 1, 2024, the Company announced that the FDA approved TECELRA® (afamitresgene autoleucel), the first engineered cell therapy for a solid tumor cancer approved in the U.S., for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.

**Forward Looking Statements**

This Current Report on Form 8-K may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements address our expected future business, financial performance, financial condition, as well as the results of operations and often contain words such as "anticipate" "believe," "expect," "may," "plan," "potential," "will," and similar expressions. Such statements are based only upon current expectations of Adaptimmune. Reliance should not be placed on forward-looking statements because they 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 ("***SEC***") for the year ended December 31, 2023, our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other filings with the SEC. 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.

**Item 9.01 Financial Statements and Exhibits.**

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

(d) Exhibits.

| **Exhibit No.** | **Description of Exhibit** |
|---|---|
| 99.1 | Press Release, dated August 1, 2024. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

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**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: August 2, 2024

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

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**Exhibit 99.1**

**Adaptimmune Receives U.S. FDA Accelerated Approval of TECELRA® (afamitresgene autoleucel), the First Approved Engineered Cell Therapy for a Solid Tumor**

*Approved for advanced MAGE-A4+synovial sarcoma in adults with certain HLA types who have received prior chemotherapy*

*TECELRA is the first new treatment option for people with synovial sarcoma in more than a decade*

*Adaptimmune to hold webcast at https://www.gowebcasting.com/13428*
*on August 2, at 8:00 a.m. EDT*

**Philadelphia, Pennsylvania and Oxford, United Kingdom –** (BusinessWire). – August 1, 2024 - Adaptimmune Therapeutics plc (NASDAQ: ADAP), a company working to redefine the treatment of solid tumor cancers with cell therapy, today announced U.S. Food and Drug Administration (FDA) accelerated approval of TECELRA® (afamitresgene autoleucel) for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. TECELRA is the first engineered cell therapy for a solid tumor cancer approved in the U.S., and the first new therapy option in more than a decade for synovial sarcoma, a rare, soft tissue cancer that most commonly impacts young adults.

**Adrian Rawcliffe, Adaptimmune's Chief Executive Officer:**

"The approval of TECELRA is a momentous step in Adaptimmune's journey to redefine the way cancer is treated and the culmination of a decade of groundbreaking R&D. I want to thank the patients, caregivers, investigators, and clinical teams as well as everyone at Adaptimmune and our partners who made possible this watershed moment for cell therapy and for people with synovial sarcoma. We are committed to advancing our robust clinical pipeline to serve more patients in need and plan to progress lete-cel, the next late-stage investigational treatment in our sarcoma franchise, with a rolling BLA submission to the FDA next year."

The approval of TECELRA was based on results of the SPEARHEAD-1 (Cohort 1) trial, which included 44 patients. The major efficacy outcome was overall response rate (ORR) determined by independent review and supported by duration of response. TECELRA treatment resulted in an ORR of 43% with a complete response rate of 4.5%. The median duration of response was 6 months (95% CI: 4.6, not reached). Among patients who were responsive to the treatment, 39% had a duration of response of 12 months or longer.*

Data from the pivotal SPEARHEAD-1 trial were previously published in The Lancet earlier this year.

With this approval, Adaptimmune is positioned to make a significant impact on the synovial sarcoma community HCPs can begin testing patients, Adaptimmune systems are ready to take TECELRA orders, and an integrated support program, AdaptimmuneAssist, is available to enable a seamless and personalized experience through the treatment journey. Adaptimmune plans to have at least six to ten authorized treatment centers (ATCs) up and running this year and to onboard approximately 30 treatment centers within the first two years. These ATCs are recognized leaders in sarcoma research and treatment.

**Per Kaplan-Meier method*

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**Brandi Felser, Chief Executive Officer, Sarcoma Foundation of America:**

"For decades, therapeutic options for people diagnosed with synovial sarcoma have been limited. With a current five-year survival rate as low as 36%, and for those with metastatic disease at diagnosis, as low as 20%, it is long past time that synovial sarcoma patients have expanded treatment options. Since one third of patients are diagnosed under age 30, improved outcomes can have a tremendous impact. Today, there is a renewed sense of hope for this patient community."

**Sandra D'Angelo, MD, Sarcoma Medical Oncologist and Cell Therapist, Memorial Sloan Kettering Cancer Center; SPEARHEAD Trial Principal Investigator:**

"TECELRA (afami-cel), which uses each patient's own immune cells to recognize and attack their cancer cells in a one-time infusion treatment, is significantly different than the current standards of care for advanced synovial sarcoma. This approval represents a much-needed new option for people diagnosed with this sarcoma and an important milestone for the use of cell therapies in solid tumor cancers."

TECELRA is contraindicated in adults who are heterozygous or homozygous for HLA-A*02:05P.

TECELRA can cause serious side effects, including cytokine release syndrome (CRS), immune effector cell–associated neurotoxicity syndrome (ICANS), prolonged severe cytopenia, infections, secondary malignancies, and hypersensitivity reactions. Most common adverse reactions (incidence ≥20%) were CRS, nausea, vomiting, fatigue, infections, pyrexia, constipation, dyspnea, abdominal pain, non-cardiac chest pain, decreased appetite, tachycardia, back pain, hypotension, diarrhea, edema, low white blood cells, low red blood cells and low platelets. **Please see Important Safety Information, including Boxed Warning below.**

Biomarker tests for human leukocyte antigens (HLA) type and melanoma-associated antigen A4 (MAGE-A4) tumor expression are required prior to treatment with TECELRA. Adaptimmune has partnered with Agilent Technologies for the development, manufacturing, and supply of a companion diagnostic for the MAGE-A4 biomarker, MAGE-A4 IHC 1F9 pharmDx, which also received approval today from the U.S. FDA and is now available. Additionally, the company partnered with Thermo Fisher Scientific to expand the labeling of Thermo Fisher's companion diagnostic product SeCore™ CDx HLA-A Locus Sequencing System to include TECELRA and to aid in the identification of HLA-A*02:01, A*02:02, A*02:03, and A*02:06-positive patients with synovial sarcoma.

For more information about TECELRA visit www.adaptimmune.com.

**Conference Call Details**

The Company will host a live webcast to provide additional details tomorrow, August 2, 8:00 a.m. EDT. A live webcast of the conference call and replay can be accessed here: https://www.gowebcasting.com/13428. Call in information is as follows: **1-844-763-8274 (TOLL FREE US or Canada) or +1-647-484-8814 (International)** and additional

options available HERE.

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**About Synovial Sarcoma**

There are more than 50 different 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 approximately 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.[1,3]

**About TECELRA**

TECELRA® (afamitresgene autoleucel) is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.

This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATION: DO NOT use TECELRA in adults who are heterozygous or homozygous for HLA-A*02:05P.**

**BOXED WARNING: Cytokine release syndrome (CRS), which may be severe or life-threatening, occurred in patients receiving TECELRA. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care. Ensure that healthcare providers administering TECELRA have immediate access to medications and resuscitative equipment to manage CRS.**

**CRS**

- CRS occurred in 75% of patients (2% Grade ≥3) with a median onset of 2 days (range: 1 to 5 days) and median resolution of 3 days (range: 1 to 14 days). CRS (including Grade 1) was managed with tocilizumab in 55% of patients who experienced CRS.
- In patients who experienced CRS, the most common symptoms included fever, tachycardia, hypotension, nausea/vomiting, and headache.


1. "What is a Soft Tissue Sarcoma?" American Cancer Society. https://www.cancer.org/cancer/types/soft-tissue-sarcoma/about/soft-tissue-sarcoma.html. Accessed June 24, 2024.
2. "Soft Tissue Sarcoma." Cleveland Clinic. https://my.clevelandclinic.org/health/diseases/21732-soft-tissue-sarcoma. Accessed June 24, 2024.
3. Jami SA, Mobarak SA, Jiandang S, et al. Clinical and strategic outcomes of metastatic synovial sarcoma on limb. *Int J Health Sci(Qassim).* 2020;14:38–43.


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**Immune Effector Cell–associated Neurotoxicity Syndrome (ICANS)**

- ICANS has been observed following administration of TECELRA. One patient (2%) had Grade 1 ICANS with a median onset of 2 days and resolution of 1 day.
- ICANS symptoms can include mental status changes, disorientation to time and place, drowsiness, inattention, altered level of consciousness, seizures, cerebral edema, impairment of cognitive skills, progressive aphasia, and motor weakness.
- Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy machinery or potentially dangerous machinery for 4 weeks following infusion due to the potential for neurologic events, including dizziness and presyncope.

**Monitoring for CRS and ICANS During and Following TECELRA Infusion**

- Ensure that healthcare providers administering TECELRA have immediate access to medications and resuscitative equipment to manage CRS and ICANS. Ensure patients are euvolemic prior to initiating TECELRA.
- During and following TECELRA administration, closely monitor patients for signs and symptoms of CRS and ICANS. Following treatment with TECELRA, monitor patients for at least 7 days at the healthcare facility. Continue to monitor patients for at least 4 weeks following treatment with TECELRA. Counsel patients to seek medical attention should signs or symptoms of CRS or ICANS occur.
- At the first sign of CRS or ICANS, immediately evaluate patients for hospitalization and administer supportive care based on severity and consider further management per clinical practice guidelines.

**Prolonged Severe Cytopenia**

- Anemia, neutropenia, and/or thrombocytopenia can occur for several weeks following lymphodepleting chemotherapy and TECELRA infusion. Patients with Grade ≥3 cytopenia not resolved by week 4 included anemia (9%), neutropenia (11%), and thrombocytopenia (5%). The median time to resolution was 7.3 weeks (range: 6.1 to 8.4 weeks) for anemia, 9.3 weeks (range: 6.4 to 12.3 weeks) for neutropenia, and 6.3 weeks (range: 6.1 to 6.4 weeks) for thrombocytopenia.
- Monitor blood counts after TECELRA infusion. Manage cytopenia with growth factor and blood product transfusion according to clinical practice guidelines.

**Infections**

- Infections may occur following lymphodepleting chemotherapy and TECELRA infusion and occurred in 32% of patients (14% Grade 3).
- Do not administer TECELRA to patients with active infections and/or inflammatory disorders.

- Monitor patients for signs and symptoms of infection before and after TECELRA infusion and treat patients appropriately.
- Febrile neutropenia was observed in patients after TECELRA infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care, as medically indicated.
- Viral reactivation has occurred in patients following TECELRA. Perform screening for Epstein-Barr virus, cytomegalovirus, hepatitis B virus, hepatitis C virus, and human immunodeficiency virus (HIV) or any other infectious agents if clinically indicated. Consider antiviral therapy to prevent viral reactivation per local guidelines.

**Secondary Malignancies**

- Patients treated with TECELRA may develop secondary malignancies or recurrence of their cancer. Monitor for secondary malignancies.

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**Hypersensitivity Reactions**

- Serious hypersensitivity reactions, including anaphylaxis, may occur due to dimethyl sulfoxide (DMSO) in TECELRA. Observe patients for hypersensitivity reactions during infusion.

**Potential for HIV Nucleic Acid Test False-Positive Results**

- The lentiviral vector used to make TECELRA has limited, short spans of genetic material that are identical to HIV. Therefore, some commercial HIV nucleic acid tests may yield false-positive results in patients who have received TECELRA.

**Adverse Reactions**

- Most common adverse reactions (incidence ≥20%) are CRS, nausea, vomiting, fatigue, infections, pyrexia, constipation, dyspnea, abdominal pain, non-cardiac chest pain, decreased appetite, tachycardia, back pain, hypotension, diarrhea, and edema.
- Most common Grade 3 or 4 laboratory abnormalities (incidence ≥20%) were lymphocyte count decreased, neutrophil count decreased, white cell blood count decreased, red blood cell decreased, and platelet count decreased.
- Most common serious adverse reactions (≥5%) were CRS and pleural effusion.

**Please see full Prescribing Information, including Boxed Warning and Medication Guide.**

**About AdaptimmuneAssist**

An integrated support program, AdaptimmuneAssist is now available to provide access support for patients, their caregivers, and healthcare providers throughout the TECELRA treatment journey. AdaptimmuneAssist includes connection with a Treatment Navigator, travel and financial support programs for eligible patients, and access to the AdaptimmuneAssist Order Portal (for healthcare providers only). For more information, physicians and patients may call 1-855-246-9232 or visit www.adaptimmuneassist.com.

**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 improve the patient's cancer treatment experience.

**Forward-Looking Statements**

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). Forward-looking statements address our expected future business, financial performance, financial condition, as well as the results of operations and often contain words such as "anticipate" "believe," "expect," "may," "plan," "potential," "will," and similar expressions, and are based on Adaptimmune's current beliefs and expectations. Such statements are based only upon current expectations of Adaptimmune. Reliance should not be placed on forward-looking statements because they 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.

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

**Adaptimmune Contact**

**Investor Relations**
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

**Media Relations**

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