

**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): **May 19, 2021**

ADAPT IMMUNE THERAPEUTICS PLC

(Exact name of registrant as specified in its charter)

England and Wales
(State or other jurisdiction of
incorporation)

1-37368
(Commission File Number)

Not Applicable
(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:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
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 May 19, 2021, Adaptimmune Therapeutics plc issued a press release announcing that initial data from its Phase 2 SPEARHEAD-1 trial, with afamitresgene autoleucel (afami-cel, formerly ADP-A2M4), will be reported at the American Society of Clinical Oncology (ASCO) congress. Full abstracts were released online today, May 19, 2021. Data will be presented in an oral presentation by Dr. Sandra D'Angelo of the Memorial Sloan Kettering Cancer Center (Abstract #11504) on June 4, 2021.

The press release is furnished as Exhibit 99.1 and is 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	Press release dated May 19, 2021
104	Cover Page Interactive Data 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.

ADAPT IMMUNE THERAPEUTICS PLC

Date: May 19, 2021

By: /s/ Margaret Henry

Name: Margaret Henry

Title: Corporate Secretary



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 autoleucl next year -
- Responses observed across a broad range of antigen expression -
- Initial safety and durability are encouraging -

PHILADELPHIA, PA., and OXFORDSHIRE, U.K., 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 autoleucl (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)

¹ Responses were evaluated by RECIST v1.1 per Investigator assessment

- 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 ≥ 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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