

**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 6, 2019**

**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))

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.

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

**Item 8.01 Other Events.**

On May 6, 2019, Adaptimmune Therapeutics plc (the “Company” or “Adaptimmune”) issued a press release announcing significant clinical progress and responses with ADP-A2M4 in synovial sarcoma and antitumor activity in other solid tumors, and that the Company will initiate the SPEARHEAD-1 trial in patients with synovial sarcoma and myxoid/round cell liposarcoma (MRCLS) later this year. The Company also announced that it is expanding its clinical trial program by initiating a radiation sub-study, as well as opening a next-generation ADP-A2M4CD8 study (SURPASS trial), for which the IND has been filed. The Company also announced that the first patient with HCC was treated in Cohort 2 (1 billion SPEAR T-cells) of the ADP-A2AFP study and showed good tolerability to treatment and a transient decrease in serum AFP as well as tumor shrinkage at first scan.

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

The information in Item 8.01 of this Form 8-K, including the attached 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 incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by the Company by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	<a href="#">Press release dated May 6, 2019.</a>

**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: May 6, 2019

By: /s/ Margaret Henry

Name: Margaret Henry

Title: Corporate Secretary



### Significant Clinical Progress as Adaptimmune Announces Responses with ADP-A2M4 in Synovial Sarcoma and Antitumor Activity in Other Solid Tumors

- Partial responses in 4 out of 5 synovial sarcoma patients treated with ~10 billion cells, with tumor shrinkage in nearly all assessed synovial sarcoma patients in the ADP-A2M4 pilot study -
  - Initiating SPEARHEAD-1 trial in synovial sarcoma and myxoid/round cell liposarcoma with ADP-A2M4 -
    - Aim to launch first TCR T-cell therapy in 2022 -
    - Evidence of antitumor activity in other solid tumors with ADP-A2M4 and ADP-A2M10 -
      - IND filed for ADP-A2M4CD8 next generation SPEAR T-cells -
- First hepatocellular carcinoma (HCC) patient treated with ADP-A2AFP at 1 billion cell dose shows transient serum AFP decrease and tumor shrinkage at first scan -
  - Strong momentum with stem cell derived T-cells in allogeneic (“off-the-shelf”) program -
    - Conference call to be held today at 8:00 a.m. EDT (1 p.m. BST) -

PHILADELPHIA, Pa. and OXFORD, U.K., May 06, 2019 - Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, today announced significant clinical progress with partial responses in 4 out of 5 synovial sarcoma patients treated with ~10 billion cells in the ADP-A2M4 pilot study, and tumor shrinkage seen in nearly all assessed synovial sarcoma patients. Based on these data, the Company will initiate the SPEARHEAD-1 trial in patients with synovial sarcoma and myxoid/round cell liposarcoma (MRCLS) later this year.

Beyond sarcoma, there is evidence of antitumor activity with ADP-A2M4 and ADP-A2M10 in other solid tumors. Based on these data and translational findings, the Company is expanding its clinical trial program by initiating a radiation sub-study, as well as opening a next-generation ADP-A2M4CD8 study (SURPASS trial), for which the IND has been filed. Finally, the first patient with HCC was treated in Cohort 2 (1 billion SPEAR T-cells) of the ADP-A2AFP study and showed good tolerability to treatment and a transient decrease in serum AFP as well as tumor shrinkage at first scan.

“Today is a watershed moment for the Company. We now have confirmed responses in an unmet medical indication, synovial sarcoma, with our wholly owned ADP-A2M4 SPEAR T-cells. As we prepare to start the SPEARHEAD-1 study, we are one step closer to realizing our ambition to be the first T-cell company with an approved therapy in solid tumors in 2022,” said James Noble, Adaptimmune’s Chief Executive Officer. “There is also early evidence of activity in other solid tumors with all three products and I am delighted to announce that we have filed an IND for a more potent, next-generation program with MAGE-A4 as the target. Working with world-class clinical trial centers and having a robust manufacturing and supply capability, we look forward to making further progress across the entire portfolio in the coming months.”

#### **ADP-A2M4 responses and data in synovial sarcoma patients**

- 10 patients treated
  - 8 patients assessed, with 6 showing tumor shrinkage
  - 3 confirmed partial responses, 1 unconfirmed partial response
  - 3 stable diseases (SD) and 1 progressive disease (PD)
- ADP-A2M4 SPEAR T-cells appear to show a favorable benefit:risk profile in patients with synovial sarcoma
- Good tolerability overall. Most adverse events are consistent with those typically experienced by cancer patients undergoing cytotoxic chemotherapy or other cancer immunotherapies

- SPEARHEAD-1 protocol summary
  - Single-arm, Phase 2 study in more than 20 centers (North America & Europe) to include 60 patients with:
    - Advanced (metastatic or inoperable) synovial sarcoma or MRCLS patients who have received prior chemotherapy
    - HLA-A\*02 & MAGE-A4 antigen positive
    - MAGE-A4 expression 30% (2<sup>+</sup>, 3<sup>+</sup>)
  - Primary endpoint will be overall response rate by RECIST v1.1 by independent review
    - Interim futility: 3 or more responses in the first 15 patients for study continuation
  - Safety endpoints with Independent Data Safety Monitoring Board
  - Exploratory endpoints with translational data and patient-reported outcomes
  - Treatment
    - Lymphodepletion: Flu: (30 mg/m<sup>2</sup>/ day) x 4 days; Cy (1800 mg/ m<sup>2</sup>/ day) x 2 days
    - Dose: up to 10 billion transduced SPEAR T-cells

#### **Antitumor activity in other indications with ADP-A2M4 and ADP-A2M10**

- Tumor shrinkage seen in lung patients (ADP-A2M10), and melanoma and ovarian patients (ADP-A2M4)
  - 7 patients treated with ADP-A2M4 in indications other than sarcoma in Cohorts 3 and Expansion phase
    - 3 SDs, 3 PDs, and 1 patient expired due to disease progression before the first scan
  - 7 patients treated with ADP-A2M10 in Cohort 3 and Expansion phase in the NSCLC and triple tumor studies
    - 4 SDs, with one patient receiving a second infusion at Week 16, and 3 PDs to date
- Adaptimmune continues to examine patient data to gain a clearer understanding of the best path forward to enhance RECIST responses
- Adaptimmune is planning to start two new studies to transform currently observed activity in epithelial tumors into durable responses
  - 1) Radiation sub-study at MD Anderson Cancer Center (MDACC) to initiate 2H 2019
    - Sub-study of the ADP-A2M4 clinical trial with up to 10 patients to be treated
    - Primary endpoint is safety and secondary endpoint is RECIST v1.1 responses
    - Radiation is 7Gy (low dose) per lesion or isocenter to be administered before lymphodepletion
  - 2) SURPASS trial (ADP-A2M4CD8) - the first next-generation approach in the clinic in multiple solid tumors to initiate later this year
    - IND filed April 2019
    - Preclinical proof-of-concept data for this next-generation SPEAR T-cell therapy were presented at AACR 2019 (<https://bit.ly/2FGIRHN>)
    - These data indicate that addition of the CD8 $\alpha$  homodimer to the ADP-A2M4 cells effectively enables CD4+ “helper” T-cells to adopt a CD8+ “killer” like phenotype in vitro
    - This is intended to speed up initial antitumor activity and broaden the antitumor response in patients
    - Protocol summary:
      - Up to 30 subjects (HLA-A\*02 with MAGE-A4<sup>+</sup>)
      - Primary endpoint: safety and tolerability
      - Secondary endpoint: antitumor activity
      - Lymphodepletion: Flu (30 mg/m<sup>2</sup>/day)  $\times$  4 days; Cy (1800 mg/m<sup>2</sup>/day)  $\times$  2 days
      - Shorter stagger between patients — anticipate faster dose escalation
      - Starting doses of ~1 billion cells (Cohort 1) and escalation through:
        - Cohort 2 (1.2 to 3.0 billion cells)
        - Cohort 3 (3.0 to 6.0 billion cells)
        - Expansion phase with up to 10 billion cells
      - Data expected in 2020

- ADP-A2M10 studies are continuing and research plans will be reassessed as more data is accumulated across the two studies

#### **ADP-A2AFP**

- Data from first HCC patient treated in Cohort 2
  - Continuing favorable safety data as was seen in Cohort 1 presented at AACR 2019 (<https://bit.ly/2FR8Lse>)
  - Shows transient serum AFP decrease and tumor shrinkage at first scan
- Data update will be provided in 1H 2020

#### **Off-the-shelf program (allogeneic platform)**

- Substantial progress with update provided in an oral presentation at the American Society of Gene & Cell Therapy Annual Meeting 2019 by Dr. Jo Brewer, VP Allogeneic Research (<https://bit.ly/2UWmqma>)

#### **Conference Call and Webcast Link for Clinical and Business Update Slide Presentation today (May 6<sup>th</sup>)**

The Company will host a live teleconference and slide presentation at 8:00 a.m. EDT (1:00 p.m. BST) today (Monday May 6, 2019). The live webcast of the conference call and slides will be available at <https://edge.media-server.com/m6/p/pfkkjdm4>. An archive will be available after the call at the same address. To participate in the live webinar, if preferred, please dial (833) 652-5917 (U.S. and Canada) or +1 (430) 775-1624 (International).

#### **About Adaptimmune**

Adaptimmune is a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapy products for cancer patients. 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. For more information, please visit <http://www.adaptimmune.com>.

#### **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 (SEC) on February 27, 2019, 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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