# **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: June 4, 2018 (Date of earliest event reported: June 2, 2018)

# ADAPTIMMUNE THERAPEUTICS PLC

(Exact name of registrant as specified in its charter)

Not Applicable (IRS Employer Identification No.)

**England and Wales** (State or other jurisdiction of incorporation)

1-37368 (Commission File Number)

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) П
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- П Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- п 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.

#### Item 8.01 **Other Events**

On June 2, 2018, Adaptimmune Therapeutics plc (the "Company" or "Adaptimmune") issued a press release announcing an oral presentation on initial data from the ongoing pilot study of NY-ESO SPEAR T-cells in myxoid/round cell liposarcoma (MRCLS). The data were presented at the 2018 American Society of Clinical Oncology (ASCO) annual meeting in Chicago, Illinois. During an oral presentation on June 2, 2018, entitled, "Pilot Study of NY-ESO-1c259T Cells in Advanced Myxoid/Round Cell Liposarcoma," Dr. Sandra P. D'Angelo of the Memorial Sloan Kettering Cancer Center presented an update from this ongoing study.

On June 4, 2018, Company issued a press release announcing a presentation on safety data from its two ongoing pilot studies with SPEAR T-cells targeting MAGE-A10 in non-small cell lung cancer (NSCLC) and the triple tumor study in bladder, melanoma, and head & neck cancers. The data were presented during a poster session at the 2018 ASCO annual meeting.

On June 4, 2018, the Company also issued a press release announcing that the independent safety review committee has recommended dose escalation in the Company's MAGE-A4 basket study, based on an acceptable safety profile in three patients dosed with 100 million cells. The Company will start treating patients with the target dose of one billion transduced MAGE-A4 SPEAR T-cells in its ongoing basket study.

In addition, after confirming expression levels for MAGE-A4 from synovial sarcoma and myxoid/round cell liposarcoma (MRCLS) tumor samples, Adaptimmune has amended the study to add these two indications to the ongoing basket study, which already includes bladder, melanoma, head & neck, esophageal, gastric, ovarian, and nonsmall cell lung (NSCLC) cancers. Screening of patients with synovial sarcoma and MRCLS is ongoing.

In the same press releases, the Company also provided call in details and the webcast link for a live teleconference that it will host on June 4, 2018 at 8:00 AM EDT (1:00 PM BST) to discuss the updated data. Call in details and the webcast link are also available in the Investors section of Adaptimmune's website (https://www.adaptimmune.com). The press releases are attached as Exhibits 99.1, 99.2 and 99.3 and are incorporated by reference herein.

The information contained in Item 8.01 of this Form 8-K, including Exhibits 99.1, 99.2 and 99.3 furnished herewith, 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.

Exhibit No.	Description of Exhibit
99.1	Press release dated June 2, 2018.
99.2	Press release regarding MAGE-A10 pilot studies dated June 4, 2018.
99.3	Press release regarding MAGE-A4 basket study dated June 4, 2018.
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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

By: <u>/s/ Margaret Henry</u>

Name:	Margaret Henry
Title:	Corporate Secretary

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Date: June 4, 2018



### Updated Myxoid/Round Cell Liposarcoma Data with NY-ESO, Presented at ASCO Annual Meeting, Further Supports Promising Benefit:Risk Profile

PHILADELPHIA, Pa. and OXFORD, U.K., June 02, 2018 — Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, presented initial data from the ongoing pilot study of NY-ESO SPEAR T-cells in myxoid/round cell liposarcoma (MRCLS). With eight patients treated, the best overall responses include three confirmed partial responses, one unconfirmed partial response, three stable disease, and one recently treated patient awaiting assessment. These data were presented during an oral presentation by Dr. Sandra P. D'Angelo of the Memorial Sloan Kettering Cancer Center at the American Society of Clinical Oncology (ASCO) annual meeting.

GlaxoSmithKline plc (LSE:GSK) (NYSE:GSK) exercised its option to exclusively license the right to research, develop, and commercialize the NY-ESO SPEAR T-cell therapy program in September 2017. Transition of this program to GSK is ongoing.

"We continue to see responses in patients with advanced MRCLS who have failed previous standard chemotherapy," said Rafael Amado, Adaptimmune's Chief Medical Officer. "We observe significant proliferation of our SPEAR T-cells in peripheral blood, and infiltration into metastases that were previously devoid of inflammatory cells. These findings bode well for a broad therapeutic potential of SPEAR T-cells across multiple solid tumors."

#### Data Update from the Ongoing NY-ESO MRCLS Study

During an oral presentation on June 2<sup>nd</sup> entitled, "Pilot Study of NY-ESO-1<sup>e259</sup>T Cells in Advanced Myxoid/Round Cell Liposarcoma," Dr. D'Angelo presented an update from this ongoing study (data cut-off May 23 2018).

#### · Responses:

- Best overall responses include 3 confirmed partial responses, 1 unconfirmed partial response, 3 patients with stable disease, and 1 recently treated patient
  awaiting assessment
- · There is an overall trend in tumor burden decrease among the majority of patients
- The tumor burden decrease across target lesions ranged from 16.9% to 50%
- · Three patients have now progressed
- Safety: Thus far, data indicate that NY-ESO SPEAR T-cells remain generally well tolerated in this patient population:
- There was one event of cytokine release syndrome (CRS) $\geq$  Grade 3, which was characterized by fever, hypotension, rash, headache, and supraventricular tachycardia. The patient was treated with tociluzumab. The CRS resolved six days post-infusion.
  - There were four SAEs reported by three patients:
    - · Grade 3 CRS (noted above), which resolved
      - Two Grade 2 events of CRS, both of which resolved
    - · Grade 2 pleural effusion, which improved with treatment and the patient was subsequently discharged from hospital
  - Most adverse events were consistent with those typically experienced by cancer patients undergoing cytotoxic chemotherapy or cancer immunotherapies
- SPEAR T-cell persistence: Although data are preliminary, there appears to be a correlative trend between SPEAR T-cell persistence and response.

#### **Overview of Study Design**

- Open-label, non-randomized pilot study evaluating the safety, tolerability, and antitumor activity of NY-ESO SPEAR T-cells in patients with MRCLS
  Initially, 10 patients are planned to be enrolled, with potential to enroll an additional 5 patients. Patients who do not receive the minimum cell dose or who do not receive the T-cell infusion may be replaced
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- Patients must be: ≥ 18 years old; HLA-A\*02:01, \*02:05, or \*02:06 positive; have advanced (metastatic or inoperable) MRCLS expressing NY-ESO-1 at 2+/3+ intensity in ≥30% of tumor cells by immunohistochemistry (IHC); measurable disease; prior systemic anthracycline therapy; have ECOG status 0 or 1; and adequate organ function
- · Lymphodepletion regimen: fludarabine (30mg/m²/day) and cyclophosphamide (600 mg/m²/day) for 3 days; same as Cohort 4 in Synovial Sarcoma study
- Target dose of  $1 8 \times 10^9$  transduced SPEAR T-cells
- Efficacy assessed by overall response rate, time to response, duration of response, progression-free survival, and overall survival at weeks 4, 8, and 12, month 6, and then every 3 months until confirmation of disease progression
- This study is open and actively enrolling

# More about Soft Tissue Sarcomas

MRCLS and synovial sarcoma are both considered soft tissue sarcomas. MRCLS is a type of liposarcoma, characterized by the proliferation of adipocyte (fat cell) precursors called lipoblasts that have stopped differentiating. This malignancy arises from a translocation between chromosomes 12 and 16 resulting in a fusion protein that blocks adipocyte differentiation and promotes malignant transformation. Synovial sarcoma is characterized by a different chromosomal translocation involving the X chromosome and chromosome 18 and, unlike the known immature fat cell cellular origin of MRCLS, the cell of origin for synovial sarcoma remains unknown.

It is estimated that there are approximately 2000 patients in the United States and Europe with MRCLS each year. MRCLS has a peak incidence of occurrence in patients who are 30 to 50 years of age and it typically follows a more aggressive course than other liposarcomas. MRCLS also exhibits a unique presentation pattern arising first in the proximal areas of the extremities and typically spreading to the bones (particularly the spine), serosal surfaces, retroperitoneum, abdomen, pelvis, as well as to other soft tissues. This metastatic pattern is different from the characteristic pulmonary spread exhibited by synovial sarcoma.

# **Conference Call Information**

The Company will host a live teleconference and webcast to answer questions about the updated safety data on June 4, 2018 at 8:00 a.m. EDT (1:00 p.m. BST). The live webcast of the conference call will be available via the events page of Adaptimmune's corporate website at https://bit.ly/2shwniM. An archive will be available after the call at the same address. To participate in the live conference call, if preferred, please dial please dial +1-(833) 652-5917 (U.S.) or +1-(430) 775-1624 (International). After placing the call, please ask to be joined into the Adaptimmune conference call and provide the confirmation code (9199456).

# About Adaptimmune

Adaptimmune is a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapy products. The Company's unique SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform enables the engineering of T-cells to target and destroy cancer, including solid tumors. Adaptimmune is currently conducting clinical trials with SPEAR T-cells targeting MAGE-A4, -A10, and AFP across several solid tumor indications. GlaxoSmithKline plc (LSE:GSK) (NYSE:GSK) exercised its option to exclusively license the right to research, develop, and commercialize Adaptimmune's NY-ESO SPEAR T-cell therapy program in September 2017. Transition of this program to GSK is ongoing. The Company is located in Philadelphia, USA and Oxfordshire, U.K. 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

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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 filed on form 10-Q with the Securities and Exchange Commission (SEC) on May 9, 2018 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.

#### Adaptimmune Contacts:

# Media Relations:

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### Adaptimmune Presents Detailed Safety Update from Ongoing MAGE-A10 Pilot Studies at ASCO

- Acceptable safety profile with no evidence of off-target toxicity in 100 million cell safety cohorts -

#### - Dosing continues with the one billion "target" cell dose -

PHILADELPHIA, Pa. and OXFORD, U.K., June 04, 2018 — Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, presented a safety update from its two ongoing pilot studies with SPEAR T-cells targeting MAGE-A10 in non-small cell lung cancer (NSCLC) and the triple tumor study in bladder, melanoma, and head & neck cancers at the American Society of Clinical Oncology (ASCO) annual meeting.

"Based on these safety data, we are enrolling patients and dosing at the target dose of one billion transduced cells in both MAGE-A10 studies, and we anticipate response data later this year," said Rafael Amado, Adaptimmune's Chief Medical Officer. "Given our preclinical validation and safety testing data, as well as available clinical results, we anticipate that MAGE-A10 SPEAR T-cells will continue to have an acceptable safety profile as we dose patients in higher cell dose cohorts."

#### Safety Update

A safety update from the two ongoing MAGE-A10 pilot studies was presented during a poster session (data cut-off 04 May 2018):

- Eight patients in the 100 million cell safety cohorts received MAGE-A10 SPEAR T-cells in the two ongoing pilot studies: 3 in Cohort 1 of the triple tumor study, and 5 in Cohort 1a of the NSCLC study
- Out of the eight patients treated in the safety cohorts, seven received 100 million transduced SPEAR T-cells, and one patient in the triple tumor study received 90 million cells
- · There were no deaths attributable to SPEAR T-cell therapy
- To date, there has been no evidence of off-target toxicity
- There were two events of cytokine release syndrome (CRS), both in the NSCLC study: one Grade 4 and one Grade 1; both events resolved
- The Grade 4 event of CRS was considered a dose limiting toxicity (DLT), at the time, and cohort 1a of the NSCLC study was expanded from 3 to 6 patients
- Overall, most adverse events were consistent with those typically experienced by cancer patients undergoing cytotoxic chemotherapy or other cancer immunotherapies
- While no anti-tumor effects were observed at the 100 million cell dose level, transduced SPEAR T-cells cells were detectable in peripheral blood
- Although cells were readily detectable, observed SPEAR T-cell peak expansion was approximately tenfold lower than what was seen at doses of at least one billion cells in other studies, such as those with NY-ESO SPEAR T-cells

After review of these initial safety data by the safety review committee (SRC), the decision was made to escalate to the next dose of one billion transduced MAGE-A10 SPEAR T-cells in the triple tumor and the NSCLC study. One billion cells was the therapeutic threshold dose observed with SPEAR T-cells targeting NY-ESO in the synovial sarcoma pilot study.

Response data from these ongoing studies is anticipated throughout the remainder of 2018.

#### **Overview of Study Designs**

- Open-label studies of MAGE-A10 SPEAR T-cells in patients with NSCLC; bladder, melanoma, or head & neck cancers (known as 'the triple tumor study)
- Patients are screened under a separate protocol (Screening Protocol: NCT02636855) to identify those who have the relevant HLA-A\*02 alleles and MAGE-A10 tumor expression
- Both trials are first-in-human studies utilizing a modified 3+3 design with escalating doses of 0.1, 1.0 and 1-6 x 10 transduced SPEAR T-cells to evaluate safety, including DLTs

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- · After completing Group 3 (1-6 x 10<sup>9</sup> transduced cells), doses up to 10 billion (1.0 x 10<sup>10</sup>) transduced cells will be included
- The DLT observation period was the first 30 days following SPEAR T-cell infusion for each patient in the initial safety cohorts (100 million cells) and is 7 days in subsequent ( $\geq 1$  billion cells) cohorts
- · NSCLC Study:
  - Patients must be at least 18 years of age and have Stage IIIb or IV NSCLC, have failed at least one platinum-containing regimen (may have received CPIs), have measurable disease, ECOG 0-1, adequate organ function, and be without brain metastases, history of severe autoimmune disease or current uncontrolled illness
  - The lymphodepletion regimen for patients receiving:
    - 100 million transduced cells was cyclophosphamide alone (1800 mg/m²/day) for 2 days
      - One billion (1.0 x 10<sup>9</sup>) transduced cells is cyclophosphamide 600mg/m<sup>2</sup>/day and fludarabine 30 mg/m<sup>2</sup>/day on Days -7, -6 and -5
    - One to six billion (1-6 x 10<sup>9</sup>) or up to ten billion (1.0 x 10<sup>10</sup>) transduced cells is cyclophosphamide 600mg/m<sup>2</sup>/day on Days -7, -6, -5 and fludarabine 30 mg/m<sup>2</sup>/day on Days -7, -6, -5, and -4
  - Efficacy is assessed by response rate, duration of response, progression-free survival, and overall survival at weeks 4, 8, and 12, month 6, and then every 3 months (for 2 years) and then every 6 months until confirmation of disease progression

#### • Triple Tumor Study:

- Patients must be at least 18 years of age and have inoperable or metastatic (advanced) urothelial "bladder" cancer, melanoma, or squamous cell head and neck tumors; and, have received standard of care therapies and have progressive disease
- The lymphodepletion regimen for patients receiving:
  - 100 million transduced cells was cyclophosphamide 600mg/m<sup>2</sup>/day and fludarabine 30 mg/m<sup>2</sup>/day on Days -7, -6 and -5
  - One billion (1.0 x 10°) transduced cells is cyclophosphamide 600mg/n<sup>2</sup>/day and fludarabine 30 mg/m<sup>2</sup>/day on Days -7, -6 and -5
  - One to six billion (1-6 x 10<sup>9</sup>) or up to ten billion (1.0 x 10<sup>10</sup>) transduced cells is cyclophosphamide 600mg/m<sup>2</sup>/day on Days -7, -6, -5 and fludarabine 30 mg/m<sup>2</sup>/day on Days -7, -6, -5, and -4
- Efficacy is assessed by overall response rate, best overall response, time to response, duration of response, duration of stable disease, progression-free survival, and overall survival at weeks 6, 12, 18, and 24 weeks, and then every 3 months until confirmation of disease progression

#### **Conference Call Information**

The Company will host a live teleconference to answer questions about the updated safety data today, June 4, 2018, at 8:00 a.m. EDT (1:00 p.m. BST). The live webcast of the conference call will be available via the events page of Adaptimmune's corporate website at https://bit.ly/2shwniM. An archive will be available after the call at the same address. To participate in the live conference call, if preferred, please dial please dial +1-(833) 652-5917 (U.S.) or +1-(430) 775-1624 (International). After placing the call, please ask to be joined into the Adaptimmune conference call and provide the confirmation code (9199456).

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### Adaptimmune Announces First Patient to Receive One Billion Target Cell Dose after Positive Safety Data from Pilot Study with MAGE-A4 SPEAR T-cells

#### - No evidence of off-target toxicity at 100 million cells for second wholly owned asset -

#### - Synovial sarcoma and MRCLS added to the seven solid tumors already in the MAGE-A4 basket study -

PHILADELPHIA, Pa. and OXFORD, U.K., June 04, 2018 — Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, today announced that the independent safety review committee has recommended dose escalation in the MAGE-A4 basket study, based on an acceptable safety profile in three patients dosed with 100 million cells. The company will start treating patients with the target dose of one billion transduced MAGE-A4 SPEAR T-cells in the ongoing basket study.

In addition, after confirming expression levels for MAGE-A4 from synovial sarcoma and myxoid/round cell liposarcoma (MRCLS) tumor samples, Adaptimmune has amended the study to add these two indications to the ongoing basket study, which already includes bladder, melanoma, head & neck, esophageal, gastric, ovarian, and non-small cell lung (NSCLC) cancers. Screening of patients with synovial sarcoma and MRCLS is ongoing.

"Today's announcement that we are dosing patients with one billion cells, which we believe is a potentially therapeutic dose based on data from NY-ESO, means that we are on target to get response data in our MAGE-A4 study, to which we have added two solid tumor indications, in 2018," said James Noble, Adaptimmune's Chief Executive Officer. "This follows the earlier announcement that pilot studies in our other program, MAGE-A10, have also moved to the one billion cells dose."

Target validation, investigating antigen expression in tumor samples, has been a key focus for Adaptimmune to understand the breadth of patients that have the potential to benefit from SPEAR T-cell treatment. Data from monitoring target antigen expression levels across literature, databases, and tumor samples indicate that MAGE-A4 is expressed in both synovial sarcoma and MRCLS. Evaluation of expression of target antigens, including MAGE-A4, in other cancers will continue.

The MAGE-A4 basket study is a Phase 1, open-label, pilot study to evaluate the safety and efficacy of Adaptimmune's SPEAR T-cells targeting MAGE-A4 in cancers in which MAGE-A4 is expressed.

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