# 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): November 9, 2020

# **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
American Density of the second and the Conditioner		registered
American Depositary Shares, each representing 6 Ordinary	ADAP	The Nasdaq Global Select Market
Shares, par value £0.001 per share		

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  $\Box$ 

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 November 9, 2020, Adaptimmune Therapeutics plc issued a press release announcing a presentation of data from its Phase 1 SURPASS trial using its ADP-A2M4CD8 SPEAR T-cells in a poster at the Society for the Immunotherapy of Cancer conference held in virtual format.

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)	EXIIIOIIIS.

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Exhibit No.	Description of Exhibit		
<u>99.1</u>	Press release dated November 9, 2020		
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.

Date: November 9, 2020

ADAPTIMMUNE THERAPEUTICS PLC

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



#### Two Confirmed Responses and Five out of Six Patients with Initial Tumor Reductions from Early Dose Cohorts of SURPASS Trial, Presented at SITC

- Data support continued development of ADP-A2M4CD8 -

- On track to start Phase 2 trial in gastroesophageal cancers in the first half of 2021 -

PHILADELPHIA, Pa. and OXFORDSHIRE, UK., November 09, 2020 — Adaptimmune Therapeutics plc (Nasdaq: ADAP), a leader in cell therapy to treat cancer, presented data from the dose escalation cohorts of its Phase 1 SURPASS trial using ADP-A2M4CD8 in a poster at the Society for the Immunotherapy of Cancer ("SITC") Conference.

In these cohorts of heavily pre-treated patients with advanced cancers (n=6), three were treated with target doses of 1 billion SPEAR T-cells, and three with target doses of 5 billion. Most adverse events were consistent with those typically experienced by cancer patients undergoing cytotoxic chemotherapy or cancer immunotherapy.

"We have seen responses in two out of six patients treated in the safety cohorts of the SURPASS trial as well as antitumor activity in five of them. The responses and antitumor activity we have seen with our next-generation ADP-A2M4CD8 SPEAR T-cells, across a range of solid tumors, support our belief that this is a highly active product," said Ad Rawcliffe, Adaptimmune's Chief Executive Officer. "Based on these data, we will initiate the Phase 2 trial in gastroesophageal cancers in the first half of 2021 and look forward to identifying additional indications to take into late-stage development."

There were two confirmed partial responses (PRs): one in a patient with esophagogastric junction (EGJ) cancer, previously reported, and one in a patient with head and neck cancer, reported as unconfirmed in May. The four other patients had best overall responses of stable disease (SD). Overall, five out of six patients treated had initial tumor shrinkage.

*In vitro* translational data using the manufactured products from patients in the SURPASS trial indicate that co-expression of the CD8 $\alpha$  co-receptor on CD4 ADP-A2M4 SPEAR T-cells enables them to kill MAGE-A4 expressing target cells with equal potency as CD8<sup>+</sup> SPEAR T-cells targeting MAGE-A4. These data, combined with the responses and antitumor activity observed at low doses, indicate that ADP-A2M4D8 may be a more potent product than the first-generation ADP-A2M4 SPEAR T-cells.

Best Overall Response (BOR) and maximum changes from baseline in target lesions in Cohorts 1 and 2

Indication	Dose x 109	BOR	Tumor reduction
Head and neck	4.6	PR	-63.16%
EGJ	1.2	PR	-51.52%
EGJ	1.0	SD	-34.07%
Ovarian	1.1	SD	-16.13%
Esophageal	6.0	SD	-13.37%
MRCLS	5.7	SD	+1.35%

As of data cut-off: October 1, 2020

At SITC, Adaptimmune also presented a poster entitled "Inhibition of AKT signaling during expansion of TCR-engineered T-cells from patient leukocyte material generates SPEAR T-cells with enhanced functional potential in vitro." These preclinical data indicate that AKT inhibition during the manufacture of SPEAR T-cells results in a more consistent expansion and phenotype of the final product. This process is currently being used for manufacture of ADP-A2M4CD8 for the SURPASS trial.

The Company also presented two posters summarizing data for the two completed Phase 1 trials with ADP-A2M10 (a previously terminated program).

#### 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 SEC on November 5, 2020, 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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## SITC Abstract

Title: Initial safety, efficacy, and product attributes from the SURPASS trial with ADP-A2M4CD8, a SPEAR T-cell therapy incorporating an affinity optimized TCR targeting MAGE-A4 and a CD8 $\alpha$  co-receptor

Authors: David S. Hong<sup>1</sup>, Jeffrey Clarke<sup>2</sup>, Tanner Johanns<sup>3</sup>, Partow Kebriaei<sup>1</sup>, John V. Heymach<sup>1</sup>, Ahmed Galal<sup>2</sup>, Samuel D. Saibil<sup>4</sup>, Adrian Sacher<sup>4</sup>, Francine E. Brophy<sup>5</sup>, Gareth Betts<sup>6</sup>, Natalie Bath<sup>6</sup>, Will Spinner<sup>6</sup>, Alex Tipping<sup>6</sup>, Jessica Tucci<sup>5</sup>, Raymond Luke<sup>5</sup>, Trupti Trivedi<sup>5</sup>, Quan Lin<sup>5</sup>, Jean-Marc Navenot<sup>5</sup>, Paula M. Fracasso<sup>5</sup>, Karen Miller<sup>6</sup>, Elliot Norry<sup>5</sup>, Mark Dudley<sup>5</sup>, Marcus O. Butler<sup>4</sup>

# Affiliations (Institution, City, State, Country):

<sup>1</sup>The University of Texas MD Anderson Cancer Center, Houston, TX, United States of America,<sup>2</sup>Duke Cancer Center, Durham, NC, United States of America,<sup>3</sup>Washington University School of Medicine, St. Louis, MO, United States of America,<sup>4</sup>Princess Margaret Cancer Centre, Toronto, Ontario, Canada, <sup>5</sup>Adaptimmune, Philadelphia, PA, United States of America, <sup>6</sup>Adaptimmune, Abingdon, United Kingdom

#### Abstract Body:

**Background:** The ongoing SURPASS trial (NCT04044859) evaluates safety and efficacy of next-generation ADP-A2M4CD8 SPEAR T-cells co-expressing the CD8 $\alpha$  co-receptor with the engineered MAGE-A4<sup>c1032</sup> T-cell receptor (TCR).

**Methods:** First-in-human trial in HLA-A\*02 positive patients (pts) with advanced cancers expressing MAGE-A4 antigen by immunohistochemistry. Eligible pts undergo apheresis, T-cells are isolated, transduced with a Lentiviral vector containing the MAGE-A4<sup>c1032</sup> TCR and CD8 $\alpha$  co-receptor, and expanded. Expansion, transduction level, cellular composition and function of the manufactured product (MP) are assessed *in vitro*. Prior to infusion, pts receive lymphodepletion with fludarabine 30 mg/m<sup>2</sup>/day for 4 days and cyclophosphamide 600 mg/m<sup>2</sup>/day for 3 days.

**Results:** As of 16 July 2020, 5 pts (1 with MRCLS, 2 with esophagogastric junction [EGJ] cancers, 1 with ovarian cancer, and 1 with head and neck cancer) were treated with ADP-A2M4 CD8 (range ~1 to 5.7 billion transduced cells). No DLTs or SAEs have been reported. To date, 1 pt with EGJ cancer had a partial response (PR per RECIST) and has had progression-free survival >6 months. One pt with head and neck cancer also had a PR. All other pts have had best overall response of stable disease.

MP expanded by an average of 15.3-fold during manufacturing (range 5.9 to 25.6-fold). On average, 43% of T-cells in the MP expressed the TCR (range 23 to 63%). The fraction of CD4<sup>+</sup> cells in the final MP varied (range 45 to 84%). Co-expression of the MAGE-A4 TCR and CD8 $\alpha$  in CD4<sup>+</sup> T-cells in the patient MP enabled CD4<sup>+</sup> T-cells to kill tumor target cells directly *in vitro*. MAGE-A4 expression in tumor biopsies varied (H-score range 55 to 300). Transduced T-cells were detected in peripheral blood of all pts. IFN-gamma increased transiently in the serum of 1 pt who responded.

**Conclusions**: ADP-A2M4CD8 SPEAR T-cells have shown an acceptable safety profile and pts with EGJ cancer and head and neck cancer have demonstrated evidence of antitumor activity. Translational data and early clinical results indicate that co-expression of the CD8 $\alpha$  co-receptor on CD4<sup>+</sup> SPEAR T-cells may increase the potency of the product by conferring additional killing activity to the helper T-cell subset. This dose escalation trial is ongoing and updated clinical and translational data will be presented.