

June 4, 2018



# 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 (GLOBE NEWSWIRE) -- 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 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<sup>9</sup> transduced SPEAR T-cells to evaluate safety, including DLTs
- 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 (≥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/m<sup>2</sup>/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<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 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).

### **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 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.

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