

# Adaptimmune Announces Favorable Review of Safety from One Billion Cell Dose Cohort in MAGE-A10 SPEAR T-cell Study and Initiation of Third Dosing Cohorts

PHILADELPHIA and OXFORD, United Kingdom, July 18, 2018 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, today announced favorable review of safety data from the second dose cohort of patients who received one billion transduced SPEAR T-cells targeting MAGE-A10 in the non-small cell lung cancer (NSCLC) study. Based on these data, the Safety Review Committee (SRC) has endorsed dose escalation to the third dose cohorts in both MAGE-A10 pilot studies (i.e., the NSCLC and the triple tumor studies).

To date, eight patients have received 100 million transduced MAGE-A10 SPEAR T-cells in the first dose cohorts of both studies, and three patients have received one billion cells in the second cohort of the NSCLC study. No evidence of toxicity related to off-target binding or alloreactivity has been reported. Most adverse events were consistent with those typically experienced by cancer patients undergoing cytotoxic chemotherapy or other cancer immunotherapies.

"We are pleased that the SRC has recommended proceeding with dose escalation to the final dose group, as our MAGE-A10 SPEAR T-cells appear to be well-tolerated without evidence of off-target or non-specific reactivity," said Rafael Amado, Adaptimmune's Chief Medical Officer. "These studies will continue dosing up to 6 billion cells in conjunction with a higher intensity preconditioning regimen, which, based on our data from the NY-ESO trials, may result in greater therapeutic potential. This final dose escalation represents excellent progress toward our goal of delivering response data by the end of 2018. As we get more data throughout 2018, we will share meaningful safety and response data from this and our other wholly owned programs."

## **Overview of Study Design MAGE-A10 Pilot Studies**

- These are first-in-human, open-label studies utilizing a modified 3+3 design in up to 28 patients with escalating doses of 100 million (Cohort 1), 1 billion (Cohort 2), and 1.2-6 billion (Cohort 3) transduced SPEAR T-cells to evaluate safety, including dose limiting toxicities (DLTs) followed by a possible expansion phase with doses of up to 10 billion SPEAR T-cells
- One study is in NSCLC and the other study is in bladder, melanoma, and head & neck cancers (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
- There was a 21-day stagger between patients in Cohort 1, with this stagger dropping to 7 days in Cohorts 2, 3, and also in the potential expansion phase
- Cohorts 1-3 were intended to enroll 3 patients each with an expansion to 6 patients if DLTs were observed
- The expansion phase can enroll up to 10 patients
- The lymphodepletion regimen for:
  - Cohort 1 (NSCLC only) cyclophosphamide (cy) (1800 mg/m²/day) for 2 days;
  - Cohorts 1 (triple tumor) and 2 (both studies) fludarabine (flu) (30mg/m²/day) and cy (600 mg/m²/day) for 3 days
  - Cohorts 3 and expansion phase flu (30mg/m²/day) for 4 days and cy (600 mg/m²/day) for 3 days
- For NSCLC efficacy is assessed by overall 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
- For Triple Tumor 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

## **Adaptimmune's Pipeline**

Adaptimmune's proprietary technology enables the Company to consistently generate affinity enhanced T-cell receptors (TCRs) that address intracellular targets on solid tumors that may not accessible to certain other immunotherapy treatment modalities. Adaptimmune has three wholly owned SPEAR T-cells in active clinical trials, with additional first and next generation SPEAR T-cells being evaluated by means of Adaptimmune's proprietary preclinical testing platform in advance of proceeding to the clinic.

Adaptimmune's wholly owned SPEAR T-cells targeting MAGE-A10, MAGE-A4, and AFP are being evaluated in four active clinical trials across ten solid tumor indications:

- MAGE-A10: Two active trials, one in NSCLC, and a triple tumor study in urothelial (bladder), melanoma, and head & neck cancers
- MAGE-A4: One active trial across nine solid tumor indications including urothelial, melanoma, head and neck, ovarian, NSCLC, esophageal, and gastric cancers; as well as synovial sarcoma and myxoid/round cell liposarcoma (MRCLS)
- AFP: One active study in hepatocellular (liver) cancer

Patients are receiving doses of 1 billion SPEAR T-cells and above across all the MAGE-A4 and MAGE-A10 trials as there has been no evidence of off-target toxicity, to date, which has supported dose escalation

#### **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 <a href="http://www.adaptimmune.com">http://www.adaptimmune.com</a>

## **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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