

# **Third Dosing Cohort to be initiated in MAGE-A4 SPEAR T-cell Basket Study After Favorable Review of Safety from One Billion Cell Dose Cohort**

PHILADELPHIA and OXFORD, United Kingdom, Aug. 15, 2018 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, today announced a favorable review of safety data from the second dose cohort of patients who received one billion transduced SPEAR T-cells targeting MAGE-A4 in the ongoing basket study in nine solid tumor indications. Based on these data, the Safety Review Committee (SRC) has endorsed dose escalation to the third dose cohort of 1.2 to 6 billion cells.

To date, three patients have received 100 million transduced MAGE-A4 SPEAR T-cells in the first dose cohort, and three patients received one billion cells in the second cohort. 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.

“In Cohorts 1 and 2, we have observed cell expansion consistent with the doses administered. We are initiating dosing with 1.2 to 6 billion cells in the MAGE-A10 and MAGE-A4 studies. We have a number of patients whose cell products have been manufactured and these cells can be used when patients are ready for therapy. We remain on track to deliver initial data on response assessments from these cohorts during the second half of 2018,” said Rafael Amado, Adaptimmune’s President of Research & Development.

## **Overview of Study Design MAGE-A4 Pilot Study**

- This is a first-in-human, open-label study utilizing a modified 3+3 design in up to 36 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
- This active trial is being evaluated 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)
- Patients are screened under a separate protocol (Screening Protocol: NCT02636855) to identify those who have the relevant HLA-A\*02 alleles and MAGE-A4 tumor expression
- There was a 21-day stagger between patients in Cohort 1, with this stagger dropping to 7 days in Cohorts 2, and 3. There is no pre-determined stagger 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 30 patients
- The lymphodepletion regimen are:
  - Cohorts 1 and 2 - fludarabine (flu) (30mg/m<sup>2</sup>/day) and cyclophosphamide (cy) (600 mg/m<sup>2</sup>/day) for 3 days
  - Cohorts 3 and expansion phase - flu (30mg/m<sup>2</sup>/day) for 4 days and cy (600 mg/m<sup>2</sup>/day) for 3 days
- Efficacy is 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

### **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 be 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 1.2-6 billion SPEAR T-cells 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. 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 August 2, 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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