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Adaptimmune Announces Positive Safety Data from Pilot Studies with MAGE-A10 SPEAR T-cells and First Patient to Receive 1 billion Target Cell Dose

PHILADELPHIA and OXFORD, United Kingdom, Jan. 08, 2018 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, today announced initial safety data from its two ongoing pilot studies of SPEAR T-cells targeting MAGE-A10, one in non-small cell lung cancer (NSCLC) and a triple tumor study in bladder, melanoma, and head & neck cancers.

To date, 8 patients have each received 100 million transduced MAGE-A10 SPEAR T-cells in the first dose cohorts of both studies. No evidence of toxicity related to off-target binding or alloreactivity has been observed. There have been no reports of neurotoxicity safety events similar to CAR-T cell-related encephalopathy syndrome (CRES)[1]. In the NSCLC study, there has been one serious adverse event of cytokine release syndrome (CRS), a Grade 4 event that resolved with treatment. This event led to cohort 1 expansion from 3 to 6 patients. No dose limiting toxicities were observed in cohort 1 of the triple tumor study.

Following review by the independent safety review committee (SRC), the decision has been made to escalate to the next dose of 1 billion transduced MAGE-A10 SPEAR T-cells in the triple tumor study. This was the therapeutic threshold dose observed with SPEAR T-cells targeting NY-ESO in the synovial sarcoma pilot study. The decision to escalate in the NSCLC cohort will be reviewed by the SRC following dosing of the 6th patient.

“These safety results, with one of our wholly-owned SPEAR T-cell treatments, and the upcoming escalation to the next dose in the triple tumor study are significant as they allow us to progress treating patients in these studies at a potentially active cell dose,” said Rafael Amado, Adaptimmune’s Chief Medical Officer. “As data accumulate throughout 2018, we will continue to share meaningful safety and efficacy data from the MAGE-A10 and MAGE-A4 programs at relevant scientific venues.”

Details about Ongoing Trials with SPEAR T-cells Targeting MAGE-A10
There are two ongoing clinical trials with SPEAR T-cells targeting MAGE-A10; one in non-small cell lung cancer (NSCLC), and a triple tumor study in bladder, melanoma, and head & neck cancers. Both studies are dose escalation trials that evaluate three doses of transduced SPEAR T-cells, administered after a lymphodepleting chemotherapy regimen. The three doses being evaluated are 100 million, 1 billion and 1 to 5 billion transduced SPEAR T-cells.

NSCLC study: In this study, five patients have received SPEAR T-cells in the first group of Cohort 1 (1a without fludarabine) [2], and there was one report of Grade 4 CRS that resolved

with treatment.

Triple Tumor Study: Three patients have been dosed in the first cohort. There were no reports of CRS greater or equal to Grade 3, and all cases resolved with supportive treatment.

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 on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 2, 2017, 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.

[1] Chimeric antigen receptor T-cell therapy - assessment and management of toxicities.*Nat Rev Clin Oncol*. 2017 Sep 19.

[2] In the NSCLC study, the first cohort of patients is composed of 2 groups: Group 1a received Cytoxan only at 1800mg/m^2 for two days without fludarabine for lymphodepletion. All other patients in MAGE-A10 and MAGE-A4 studies are to receive or have received Cytoxan (600mg/m^2/day) and fludarabine (30mg/m^2/day) for 3 days, which was the regimen used in Cohort 4 of the synovial sarcoma pilot study with SPEAR T-cells targeting NY-ESO.

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