

# Adaptimmune Presents Study Designs for Ongoing MAGE-A4 and NY-ESO SPEAR T-cell Clinical Trials at the Society for Immunotherapy of Cancer (SITC) Annual Meeting

PHILADELPHIA and OXFORD, U.K., Nov. 10, 2017 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, is presenting two trials in progress posters summarizing study designs for ongoing clinical trials with MAGE-A4 and NY-ESO SPEAR T-cells at the 2017 SITC annual meeting at the Gaylord National Hotel & Convention Center in National Harbor, Maryland, United States.

## Overview of Study Designs:

- MAGE-A4 SPEAR T-cells targeting multiple solid tumors<sup>1</sup>:
  - Open-label, non-randomized pilot study evaluating the safety, tolerability, and antitumor activity of MAGE-A4 SPEAR T-cells in patients with HLA-A\*02 and MAGE-A4 positive inoperable locally advanced or metastatic tumor(s)
  - This dose escalation study utilizes a modified 3+3 design:
    - *Group 1*: to enroll 3-6 patients; dose of 100 million transduced SPEAR T-cells, 21-day interval for safety review
    - *Group 2*: to enroll 3-6 patients; dose of 1 billion transduced SPEAR T-cells, 7-day interval for safety review<sup>2</sup>
    - *Group 3*: to enroll 3-6 patients; dose of 1-5 billion transduced SPEAR T-cells, 7-day interval for safety review<sup>2</sup>
    - Study allows for expansion at optimal dose range up to 20 patients across tumors
  - Patients must be: ≥ 18 yrs old; HLA-A\*02 positive; have MAGE-A4 positive inoperable locally advanced or metastatic tumor(s) at ≥1+ intensity in ≥ 10% of tumor cells MAGE-A4 expression by immunohistochemistry (IHC); have ECOG status 0 or 1; and adequate organ function
  - Lymphodepletion regimen: fludarabine (30 mg/m<sup>2</sup>/day) and cyclophosphamide (600 mg/m<sup>2</sup>/day) for 3 days
  - Efficacy 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
  - The study is open and enrolling
- NY-ESO SPEAR T-cells with or without KEYTRUDA® (pembrolizumab) in multiple myeloma:

- Open-label, randomized pilot study evaluating the safety, tolerability, and antitumor activity of NY-ESO SPEAR T-cells with or without KEYTRUDA in patients with multiple myeloma
- Eligible patients will be randomly assigned to a treatment arm: NY-ESO SPEAR T-cells alone (Arm 1) or NY-ESO-1 SPEAR T-cells in combination with KEYTRUDA (Arm 2)
- Target enrollment is 20 patients with 10 in each arm; eligible patients who do not receive the T-cell infusion may be replaced.
- Patients must be:  $\geq 18$  yrs old; HLA-A\*02:01, \*02:05, or \*02:06 positive; have histologically confirmed diagnosis of multiple myeloma with either primary refractory or relapsed/refractory disease expressing NY-ESO-1 and/or LAGE-1a; have received prior therapies including IMiD and a proteasome inhibitor as separate lines or a combined line of therapy; have ECOG status 0 or 1; and adequate organ function
- Lymphodepletion regimen: fludarabine ( $30 \text{ mg/m}^2/\text{day}$ ) and cyclophosphamide ( $600 \text{ mg/m}^2/\text{day}$ ) for 3 days, followed by granulocyte-colony stimulating factor
- For patients in Arm 2, KEYTRUDA will be administered every 3 weeks, starting at week 3 following T-cell infusion until week 108
- Target dose of  $1 - 8 \times 10^9$  transduced SPEAR T-cells
- Efficacy will be assessed by the International Myeloma Working Group (IMWG) Uniform Response Criteria. Overall response rate, time to response, duration of response, progression-free survival, and overall survival will be determined.
- The study is open and enrolling

### **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.

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<sup>1</sup> Urothelial cancer (transitional cell cancer of the bladder, ureter or renal pelvis), melanoma, squamous cell carcinoma of the head and neck, ovarian cancer, NSCLC (squamous, adenosquamous, or large cell), esophageal (squamous and adenocarcinoma) or gastric cancer

<sup>2</sup> If, in Group 1 or Group 2, 1 out of 3 patients experiences a dose limiting toxicity (DLT) requiring expansion of an additional 3 patients (n=6), the subsequent observation periods in Group 2 or Group 3 will be increased from 7 days to 14 days for the respective groups.

Source: Adaptimmune Therapeutics plc