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# Adaptimmune Provides Update on Study of NY-ESO SPEAR® T-cell Therapy in Synovial Sarcoma at the European Society for Medical Oncology (ESMO) 2016 Congress

PHILADELPHIA and OXFORD, United Kingdom, Oct. 09, 2016 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, today announced a poster presentation of updated data on its lead clinical program, an NY-ESO SPEAR® (Specific Peptide Enhanced Affinity Receptor) T-cell receptor therapy, in patients with synovial sarcoma at the European Society for Medical Oncology (ESMO) 2016 Congress.

“These data help clarify the design of our upcoming pivotal studies in sarcoma,” said Dr. Rafael Amado, Adaptimmune’s Chief Medical Officer. “We have seen durable tumor responses to our SPEAR T-cells and the preliminary benefit:risk profile appears favorable. Further, although the data are preliminary, we do see activity against tumors with lower levels of NY-ESO expression, which we hope will further expand the utility of this therapy, and we have evidence that fludarabine is required in the pre-conditioning regimen. With these data in hand, we will initiate Cohort 4 with our modified fludarabine pre-conditioning regimen, and continue toward our goal of bringing this novel TCR-based immunotherapy to sarcoma patients.”

In a poster presentation entitled, "Open Label Non-Randomized Multi-Cohort Pilot Study of Genetically Engineered NY-ESO-1 Specific NY-ESO SPEAR T-cells in HLA-A\*02+ Patients with Synovial Sarcoma," Crystal Mackall, M.D., Professor of Pediatrics and Medicine; Associate Director of the Stanford Cancer Institute, provided an update on the following synovial sarcoma cohorts:

- Cohort 1: Subjects with high ( $\geq 50$  percent 2+/3+ by IHC) NY-ESO-1 antigen expression and lymphodepletion with cyclophosphamide and fludarabine
- Cohort 2: Subjects with low ( $> 1$  percent to  $< 50$  percent 2+/3+ by IHC) NY-ESO-1 antigen expression and lymphodepletion with cyclophosphamide and fludarabine
- Cohort 3: Subjects with high ( $\geq 50$  percent 2+/3+ by IHC) NY-ESO-1 antigen expression and lymphodepletion with cyclophosphamide alone (no fludarabine)
- Cohort 4: Subjects with high ( $\geq 50$  percent 2+/3+ by IHC) NY-ESO-1 antigen expression and lymphodepletion with a modified (lower) dose than Cohort 1 of cyclophosphamide and fludarabine

## Cohort 1

Adaptimmune has previously announced that in the first cohort of synovial sarcoma patients, NY-ESO SPEAR T-cells demonstrated a robust clinical response, including a 50 percent

(6/12) response rate, and a 60 percent response rate (6/10) in those who received the target dose of at least  $1 \times 10^9$  transduced cells. The median duration of response is reported to be approximately 31 weeks (August 31 data cutoff). Ongoing NY-ESO SPEAR T-cell persistence has been observed for up to 36 months.

## **Cohort 2**

Four subjects of a targeted 10 are currently enrolled in the second cohort; three patients have been treated with NY-ESO SPEAR T-cells. As of August 31, 2016 best responses seen in these three patients were: one partial response (PR), one stable disease (SD), and one progressive disease (PD).

## **Cohorts 3 and 4**

Five patients are currently enrolled in the third cohort; no objective responses have been observed to date. As pre-specified in the protocol, enrollment in cohort 3 has ceased, and company has initiated enrollment in Cohort 4.

## **Tolerability**

NY-ESO SPEAR T-cells continue to demonstrate a generally acceptable benefit: risk profile in all treated patients to date. The most common (>30%) related adverse events include pyrexia, lymphopenia, decreased white blood cell (WBC), nausea, anemia, neutropenia, fatigue, decreased platelet count (PLT), sinus tachycardia, and rash. Most common toxicities related to therapy can be monitored and managed with medical intervention and supportive care. While there are differences in the patient populations, incidence of cytokine release syndrome (CRS) with NY-ESO-1c259 SPEAR T appears to be of lower frequency and severity than reported with CD19 CAR-T therapy. As previously reported at the 2016 Annual American Society of Clinical Oncology (ASCO) Meeting, there was one fatal SAE of bone marrow failure in Cohort 2 of our synovial sarcoma trial. Internal investigations have not identified a mechanism by which NY-ESO SPEAR T-cells may have caused bone marrow failure.

Adaptimmune's SPEAR T-cell candidates are novel cancer immunotherapies that have been engineered to target and destroy cancer cells by strengthening a patient's natural T-cell response. T-cells are a type of white blood cell that play a central role in a person's immune response. Adaptimmune's goal is to harness the power of the T-cell and, through its multiple therapeutic candidate, significantly impact cancer treatment and clinical outcomes of patients with solid and hematologic cancers.

## **About Adaptimmune**

Adaptimmune is a clinical stage biopharmaceutical company focused on novel cancer immunotherapy products based on its SPEAR® (Specific Peptide Enhanced Affinity Receptor) T-cell platform. Established in 2008, the company aims to utilize the body's own machinery - the T-cell - to target and destroy cancer cells by using engineered, increased affinity TCRs as a means of strengthening natural patient T-cell responses. Adaptimmune's lead program is a SPEAR T-cell therapy targeting the NY-ESO cancer antigen. Its NY-ESO SPEAR T-cell therapy has demonstrated signs of efficacy and tolerability in Phase 1/2 trials in solid tumors and in hematologic cancer types, including synovial sarcoma and multiple myeloma. Adaptimmune has a strategic collaboration and licensing agreement with GlaxoSmithKline for the development and commercialization of the NY-ESO TCR program. In addition, Adaptimmune has a number of proprietary programs. These include SPEAR T-

cell therapies targeting the MAGE-A10 and AFP cancer antigens, which both have open INDs, and a further SPEAR T-cell therapy targeting the MAGE-A4 cancer antigen that is in pre-clinical phase with IND acceptance targeted for 2017. The company has identified over 30 intracellular target peptides preferentially expressed in cancer cells and is currently progressing 12 through unpartnered research programs. Adaptimmune has over 250 employees and is located in Oxfordshire, U.K. and Philadelphia, USA. For more information: <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 August 8, 2016, 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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