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# **Adaptimmune Provides Update on Clinical Study Evaluating its SPEAR® T-Cell Therapy Targeting NY-ESO-1 in Ovarian Cancer**

PHILADELPHIA and OXFORD, United Kingdom, Oct. 12, 2016 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, today announced that its amended protocol using its NY-ESO SPEAR® (Specific Peptide Enhanced Affinity Receptor) T-cell therapy in ovarian cancer patients with treatment resistant or refractory metastatic ovarian cancer is now actively recruiting.

To date, no objective clinical responses have been reported in the ovarian cancer patients who received NY-ESO SPEAR T-cell therapy in the initial iteration of this trial. Of note, these initial patients received a preconditioning regimen which consisted of cyclophosphamide alone, rather than including fludarabine. Data from Adaptimmune's studies of its NY-ESO SPEAR T-cell therapy in synovial sarcoma patients have indicated the importance of including fludarabine in the preconditioning regimen. The use of fludarabine appears to be required for expansion, response and persistence of transduced cells. As a result, this trial will enroll patients under a revised protocol including a pre-conditioning regimen that includes fludarabine in combination with cyclophosphamide.

"Based on our clinical experience to date, we have amended the protocol for this trial to include both fludarabine and cyclophosphamide in the conditioning regimen," said Dr. Rafael Amado, Adaptimmune's Chief Medical Officer. "We hope that, as previously observed in synovial sarcoma, this lymphodepleting regimen will enable anti-tumor immune responses mediated by NY-ESO SPEAR T-cell therapy in these patients with advanced chemotherapy relapsed or refractory ovarian cancer."

This is a Phase I/IIa, open-label study of autologous T-cells genetically engineered with an enhanced affinity NY-ESO-1 T-cell receptor in ovarian cancer patients with the HLA-A\*0201, HLA-A\*0205, and/or HLA-A\*0206 allele and whose tumor expresses the NY-ESO-1 tumor antigen. Though the prevalence of HLA sub-types varies from population to population, the most common in the western world is HLA-A2. Among the HLA-A2 variants, the most prevalent are HLA-A\*0201 and HLA-A\*0206.

This multi-center study is intended to enroll up to 10 additional patients under the revised protocol, and will assess the safety and tolerability of Adaptimmune's NY-ESO SPEAR T-cell therapy in patients with treatment resistant or refractory metastatic ovarian cancer expressing the NY-ESO-1 antigen. Secondary objectives will include the assessment of clinical efficacy, measurements of durability of persistence of NY-ESO SPEAR T-cells in the blood, and exploratory tumor biomarker studies, and evaluations of the phenotype and functionality of NY-ESO-1 SPEAR T-cells.

For more information on this clinical trial, visit ClinicalTrials.gov at: <https://clinicaltrials.gov/> (Identifier: NCT01567891).

### **About Ovarian Cancer**

As reported by the American Cancer Society, epithelial ovarian cancer is the leading cause of death from gynecologic cancer in the United States and the country's fifth most common cause of cancer mortality in women. It is estimated that in 2016 in the United States, 22,280 women will receive a new diagnosis of ovarian cancer, and approximately 14,240 women will die of this disease. Overall, the five-year relative survival rate is 45 percent. If the cancer is detected and treated early, at the localized stage when the cancer is only in the part of the body where it started, the five-year relative survival rate is 92 percent. However, only 15 percent are detected at the localized stage. No treatment is available for patients with refractory or resistant metastatic ovarian cancer.

### **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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