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# Adaptimmune Expands Trial of T-cell Therapy for Synovial Sarcoma and Achieves Clinical Milestones

## First Patient Dosed in Expanded Phase I/II Study

PHILADELPHIA, and OXFORD, UK, Sept. 1, 2015 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), ("Adaptimmune" or the "Company"), a clinical stage biopharmaceutical company focused on the use of T-cell therapy to treat cancer, today announced that the first patient has been dosed in its expanded Phase I/II trial of its affinity enhanced T-cell receptor (TCR) therapeutic targeting the NY-ESO-1 cancer antigen in synovial sarcoma patients.

Based on encouraging results in the first cohort of 10 patients, presented at the American Association for Cancer Research (AACR) annual meeting in April 2015, the trial is being expanded to encompass an additional 20 patients in two further cohorts.

The expansion of Adaptimmune's trial also triggers two milestone payments from GlaxoSmithKline (GSK). Adaptimmune is collaborating with GSK for the development of its NY-ESO TCR program through a strategic cancer immunotherapy partnership announced in June 2014. Under the terms of the agreement, GSK has an exclusive option to license Adaptimmune's NY-ESO TCR therapeutic and upon exercise would assume full responsibility for further development and commercialization of the therapeutic.

"We are encouraged by the promising data from the first cohort of patients and pleased to have commenced enrollment into the next two cohorts of this study," commented Dr. Rafael Amado, Adaptimmune's Chief Medical Officer. "Metastatic synovial sarcoma is largely incurable, with as few as 20 percent of patients surviving for more than two years after diagnosis. In the first cohort of this trial, we saw evidence of antitumor activity resulting from treatment with our NY-ESO TCR therapeutic in a solid tumor setting. These early data provide confidence to expand the trial in these patients who currently lack proven, effective treatment options."

Synovial sarcoma is a cancer of the connective tissue and a type of solid tumor primarily affecting adolescents and young adults. Most metastatic soft tissue sarcomas are currently incurable - 75 to 80 percent of patients do not survive past two to three years - and there are limited treatment options for unresectable and recurrent synovial sarcoma, which is nearly always fatal.

Adaptimmune's clinical study includes synovial sarcoma patients who have received standard first line therapy containing ifosfamide and/or doxorubicin and who are intolerant or no longer responding to the regimen, and whose tumor expresses a tumor antigen known as NY-ESO-1. The NY-ESO-1 antigen is believed to be present in 60 to 70 percent of synovial

sarcoma patients.

The primary objectives of the study are to determine the safety of adoptively transferred autologous T cells expressing an affinity enhanced T cell receptor that recognizes the NY-ESO-1 antigen in HLA-A\*0201, HLA-A\*0205, and/or HLA-A\*0206 positive patients with unresectable, metastatic or recurrent synovial sarcoma. Secondary objectives include the determination of efficacy through response rate and duration of response.

All eligible patients will be treated with lymphodepletive chemotherapy followed by administration of Adaptimmune's NY-ESO TCR therapeutic. In the first cohort, patients whose tumor expressed NY-ESO-1 at high levels received a single course of cyclophosphamide and fludarabine for lymphodepletion prior to administration of Adaptimmune's NY-ESO TCR therapeutic. Cohort 2 will enroll patients whose tumor expresses lower levels of the NY-ESO-1 antigen and who will receive the same treatment as patients in the first cohort. Cohort 3 will enroll patients whose tumor expresses high levels of the NY-ESO-1 antigen and will study the removal of fludarabine as part of the lymphodepletion regimen. Both cohorts are expected to open concurrently.

For more information on the trial, visit ClinicalTrials.gov at: <https://clinicaltrials.gov/> (Identifier: NCT01343043).

Adaptimmune is currently running trials in multiple cancers across the U.S. targeting the NY-ESO-1 cancer antigen in both solid and hematologic cancers. As of May 30, 2015, 85 patients had been treated with Adaptimmune's NY-ESO TCR therapeutic: 47 under Adaptimmune's IND, and 38 under a National Cancer Institute IND. Data from the Company's Phase I/II study in synovial sarcoma were presented at AACR. As of April 20, 2015, 11 patients in the first cohort had received Adaptimmune's NY-ESO TCR therapeutic. Of the first 10 patients, six responded, with one complete response. Data from Adaptimmune's Phase I/II study in 20 patients with advanced multiple myeloma were published in Nature Medicine online on July 20, 2015 and in the print publication on August 6, 2015.

### **About synovial sarcoma**

Soft tissue sarcomas can develop from soft tissues including fat, muscle, nerves, fibrous tissues, blood vessels, or deep skin tissues, and synovial sarcoma, a cancer of the connective tissue around the joints, accounts for approximately 6 to 10 percent of all soft tissue sarcomas. Approximately one third of synovial sarcomas occur in childhood and the peak incidence is in the third decade of life, with 70 percent of sarcomas occurring in patients younger than 40 years old. The majority of patients who develop metastatic soft tissue sarcomas are currently incurable, with 75 to 80 percent of patients not surviving past two to three years. First line therapy typically involves radiotherapy and chemotherapy, as well as surgical resection where possible.

### **About Adaptimmune**

Adaptimmune is a clinical stage biopharmaceutical company focused on novel cancer immunotherapy products based on its T-cell receptor 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 T-cell receptors (TCRs) as a means of

strengthening natural patient T-cell responses.

Adaptimmune's lead program is an affinity enhanced TCR therapeutic targeting the NY-ESO cancer antigen. Its NY-ESO TCR therapeutic candidate has demonstrated signs of efficacy and tolerability in Phase 1/2 trials in solid tumors and in hematologic cancer types. In June 2014, Adaptimmune announced that it had entered into a strategic collaboration and licensing agreement with GlaxoSmithKline (GSK) for the development and commercialization of the NY-ESO TCR program in partnership with GSK. In addition, Adaptimmune has a number of proprietary programs and its next TCR therapeutic candidate, directed at MAGE A-10, is scheduled to enter the clinic in late 2015. The company has identified over 30 intracellular target peptides preferentially expressed in cancer cells and is currently progressing eight of these through unpartnered research programs. Adaptimmune has over 100 employees and is located in Oxfordshire, UK and Philadelphia, USA. For more information: <http://www.adaptimmune.com>

### **Forward-Looking Statements**

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "believe," "may", "will," "estimate," "continue," "anticipate," "intend," "expect" and other words of similar meaning. 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; our ability to submit an IND and successfully advance our technology platform to improve the safety and effectiveness of our existing TCR therapeutic candidates; the rate and degree of market acceptance of T-cell therapy generally and of our TCR therapeutic candidates; government regulation and approval, including, but not limited to, the expected regulatory approval timelines for TCR therapeutic candidates; and our ability to protect our proprietary technology and enforce our intellectual property rights; amongst others. 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 final Prospectus filed with the Securities and Exchange Commission on May 7, 2015. We urge you to consider these factors carefully in evaluating the forward-looking statements herein and are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by this cautionary statement. 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. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

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