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# **U.S. Food and Drug Administration Grants Orphan Drug Designation to Adaptimmune's T-cell Therapy Targeting NY-ESO for Treatment of Soft Tissue Sarcoma**

PHILADELPHIA and OXFORD, United Kingdom, March 30, 2016 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in the use of TCR engineered T-cell therapy to treat cancer, today announced that the U.S. Food and Drug Administration (FDA)'s Office of Orphan Products Development has granted orphan drug designation for the company's affinity enhanced T-cell therapy targeting NY-ESO for the treatment of soft tissue sarcoma, a solid tumor cancer.

Adaptimmune is developing its NY-ESO therapy in certain soft tissue sarcomas: the company expects to initiate pivotal studies in synovial sarcoma around year end 2016, and will explore development in myxoid round cell liposarcoma.

"Soft tissue sarcomas are among the most aggressive forms of cancers, often affecting a young patient population and, for patients with metastatic and recurrent disease, therapeutic options are limited," said Dr. Rafael Amado, Adaptimmune's Chief Medical Officer. "We are pleased that the FDA recognizes the significance of the unmet medical need in these rare cancers, and we look forward to working with them further to expeditiously advance our T-cell therapy targeting NY-ESO through clinical development in this disease."

There are approximately 50 different types of soft tissue sarcomas. The American Cancer Society estimates that, in 2016, about 12,310 new soft tissue sarcomas will be diagnosed (6,980 cases in males and 5,330 cases in females) in the United States, and approximately 4,990 Americans (2,680 males and 2,310 females) are expected to die of soft tissue sarcomas.

Adaptimmune's affinity enhanced T-cell therapeutic 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 candidates, significantly impact cancer treatment and clinical outcomes of patients with solid and hematologic cancers.

## **About Orphan Drug Designation**

The status of orphan drug designation is granted by the FDA's Office of Orphan Products Development for drugs that are intended for the safe and effective treatment of rare conditions that affect fewer than 200,000 people in the United States. Orphan drug designation qualifies a company for several benefits under the Orphan Drug Act of 1983 that

apply across all stages of drug development. The benefits include seven years of market exclusivity following marketing approval, eligibility for orphan drug grants, and waiver of the Prescription Drug User Fee for the marketing application.

### **About Soft Tissue Sarcoma**

Soft tissue sarcomas can develop from soft tissues including fat, muscle, nerves, fibrous tissues, blood vessels, or deep skin tissues. There are approximately 50 types of soft tissue sarcomas, including synovial sarcoma, a cancer of the connective tissue around the joints. Soft tissue sarcomas can develop at almost any anatomic site, such as the extremities, trunk or thorax, abdomen and retroperitoneum, pelvis and the head and neck region. The more common soft tissue sarcomas originate from muscle, nerve tissue, fat, or deep skin tissue. For a number of sarcomas, such as synovial sarcoma, the tissue origin is not well characterized. Surgical resection is the standard therapy for localized disease and radiation therapy (preoperative or postoperative) is added in selected cases.

### **About Adaptimmune**

Adaptimmune is a clinical stage biopharmaceutical company focused on novel cancer immunotherapy products based on its T-cell receptor (TCR) 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 an affinity enhanced T-cell therapy targeting the NY-ESO cancer antigen. Its NY-ESO TCR affinity enhanced T-cell therapy has demonstrated signs of efficacy and tolerability in Phase I/II 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. 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 200 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 Annual Report on Form 20-F filed with the Securities and Exchange Commission (SEC) on October 13, 2015 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.

Will Roberts  
Vice President, Investor Relations  
T: (215) 825-9306  
E: will.roberts@adaptimmune.com

Margaret Henry  
Head of PR  
T: +44 (0)1235 430036  
Mob: +44 (0)7710 304249  
E: margaret.henry@adaptimmune.com



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