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U.S. Food and Drug Administration Grants Breakthrough Therapy Designation for Adaptimmune's Affinity Enhanced T-cell Therapy Targeting NY-ESO in Synovial Sarcoma

PHILADELPHIA and OXFORD, United Kingdom, Feb. 09, 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) has granted Breakthrough Therapy designation for the company's affinity enhanced T-cell therapy targeting NY-ESO in synovial sarcoma for HLA-A*201, HLA-A*205 or HLA-A*206 allele-positive patients with inoperable or metastatic synovial sarcoma who have received prior chemotherapy and whose tumor expresses the NY-ESO-1 tumor antigen.

"We are committed to investigating the potential of our NY-ESO-1-T cell therapy across a variety of cancers. We are pleased that the FDA has granted Breakthrough Therapy designation for our T-cell therapy in synovial sarcoma, recognizing both the unmet need for patients suffering from this disease as well as the promise of these early data," said Dr. Rafael Amado, Adaptimmune's Chief Medical Officer. "We look forward to working closely with the FDA to expedite the clinical development of this therapeutic candidate."

The Breakthrough Therapy designation was based on the results of a phase I/II trial in patients with unresectable, metastatic or recurrent synovial sarcoma who have received prior chemotherapy. Patients were treated with lymphodepleting chemotherapy followed by immunotherapy with T-cells engineered to recognize an HLA-A2 restricted NY-ESO-1 peptide.

Data from this study were most recently presented at the 2015 Annual Meeting of the Society of Immunotherapy for Cancer (SITC) in November 2015. In the primary efficacy analysis, 60 percent of the 10 patients receiving the target dose of cells responded, and there was a 50 percent overall response rate in the 12 patients receiving any dose of cells. 90 percent (9/10) of those patients who received the target dose and 75 percent (9/12) of all patients were alive and on long term follow-up. The most common adverse events included nausea, anemia, pyrexia, lymphopenia and neutropenia. Cytokine release syndrome (CRS) was seen in four of twelve subjects, with grade 3 CRS observed in two subjects; no grade 4 CRS events were observed.

Adaptimmune recently announced that it will aim to initiate pivotal studies with its affinity enhanced T-cell therapy targeting NY-ESO in synovial sarcoma around year end 2016, and that it will also explore development in myxoid round cell liposarcoma. Studies with this therapy are also under way in myeloma, melanoma, ovarian cancer and non-small cell lung cancer.

About Breakthrough Therapy Designation
The breakthrough therapy designation was enacted as part of the Food and Drug Administration Safety and Innovation Act of 2012 and is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. According to the FDA, breakthrough therapy designation conveys all of the fast track program features, more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers, and eligibility for rolling review and priority review of the company's Biologic License Application when submitted.

About Soft Tissue Sarcoma
Soft tissue sarcomas can develop from soft tissues like 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 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. The American Cancer Society estimates 11,930 new soft tissue sarcoma diagnoses (6,610 cases in males and 5,320 cases in females) in the United States in 2015, representing approximately 2 percent of all cancers, and approximately 4,870 Americans (2,600 males and 2,270 females) are expected to die of soft tissue sarcomas.

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 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. 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 on October 13, 2015. 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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