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Adaptimmune Announces Partial Clinical Hold of Planned Pivotal Study of NY-ESO SPEAR® T-cell Therapy in Myxoid Round Cell Liposarcoma

PHILADELPHIA and OXFORD, United Kingdom, Aug. 03, 2016 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy for treatment of cancer, today announced that it has received notice from the U.S. Food and Drug administration that a partial clinical hold has been placed on its planned pivotal study of NY-ESO SPEAR® T-cell therapy in myxoid round cell liposarcoma (MRCLS). This trial is not yet active at any investigational sites, and has not recruited any patients. This notification of partial clinical hold does not apply to any other Adaptimmune study.

The FDA notification is not based on safety concerns. In its correspondence, the FDA requested additional CMC information and answers to certain trial design questions prior to the trial start. Adaptimmune intends to provide a full response to the FDA shortly.

“Adaptimmune is running a number of different studies with its NY-ESO program and continues to enroll patients in synovial sarcoma, ovarian, and lung cancer trials in the U.S.,” said James Noble, Adaptimmune CEO. “We have been in dialogue with the FDA since achieving breakthrough status earlier this year and this partial clinical hold requires a number of questions to be answered before we can start a new MRCLS trial intended to be used for registration purposes. We will be providing a full response to the FDA shortly and will update the markets when we have further news to report.”

The company will discuss this notice of partial clinical hold during its conference call to discuss the second quarter ended June 30, 2016, scheduled for 8:00 a.m. Eastern Time (1:00 p.m. BST) on Monday August 8, 2016.

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 May 12, 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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