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Adaptimmune Announces FDA Acceptance of Investigational New Drug (IND) Application for MAGE-A10 T in Patients With Non-Small Cell Lung Cancer

PHILADELPHIA and OXFORD, England, July 2, 2015 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a clinical stage biopharmaceutical company focused on the use of T-cell therapy to treat cancer, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's investigational new drug (IND) application for autologous genetically modified T-cells expressing enhanced T cell receptors (TCRs) specific for MAGE A10 (MAGE-A10 T) in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC), and that the IND is now active.

The acceptance of this IND allows Adaptimmune to initiate an open label Phase I/II study designed to evaluate its wholly-owned MAGE-A10 T therapeutic candidate in NSCLC. Site initiation activities are now underway, and the Company anticipates that enrollment will begin in 2015.

MAGE-A10 (melanoma antigen family A10) is a member of the MAGE-A family of cancer/testis tumor-associated antigens. It is believed to be expressed in approximately 30 percent of lung (squamous cell carcinoma), bladder and skin melanomas, and at a lower incidence in many other cancers. Adaptimmune's proprietary technology enables the Company to routinely generate TCRs which address intracellular targets, such as MAGE-A10, that are not accessible to certain other experimental modalities.

"The FDA's acceptance of this IND represents an important step in our strategy to identify and develop new T-cell-based immunotherapeutics to combat non-small cell lung cancer and other cancers, and we are excited to be working toward initiating clinical development of another of our promising TCR therapeutic candidates," said James Noble, Adaptimmune's Chief Executive Officer. "In addition, this validates the progress we are making in applying our platform to develop a broad pipeline of novel proprietary TCR therapeutics."

This will be an open label phase I/II dose escalating study of three doses of genetically engineered MAGE-A10 T-cells in HLAA*0201 and HLA-A*02:06 patients with advanced (stage IIIB or stage IV) NSCLC whose tumors express this antigen. The study will assess the safety and tolerability of MAGE-A10 T in these patients. Secondary objectives will include the assessment of efficacy of MAGE-A10 T, measurements of durability of persistence of MAGE-A10 T-cells in the blood, and evaluations of the phenotype and functionality of MAGE-A10 T-cells.

About Adaptimmune's TCR Technology

Adaptimmune's proprietary TCR technology enables the Company to genetically optimize T-

cell receptors (TCR) in an effort to equip them to recognize and bind cancer antigens that are presented in small quantities on the surface of a cancer cell, whether of intracellular or extracellular origin, thus initiating cell death. The Company's differentiated, proprietary technology allows it to reliably generate parental TCRs to naturally presented targets, affinity optimize its TCRs to bind cancer proteins from solid and hematologic cancers that are generally unavailable to naturally occurring TCRs, and to significantly reduce the risk of side effects resulting from off-target binding of healthy tissues.

About NSCLC

Lung cancer is the third most common form of cancer in the US after prostate cancer in men and breast cancer in women. However, it is by far the leading cause of cancer deaths in both men and women in the United States. Non-small cell lung cancer or NSCLC is the most common type of lung cancer, representing approximately 85 percent of lung cancers. The 1- and 5-year relative survival rates for lung cancer are 44 percent and 17 percent, respectively. More than half of lung cancer patients (57 percent) are diagnosed at a late stage of cancer development, for which the 1- and 5-year survival is only 26 percent and 4 percent, respectively.

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 A10, is scheduled to enter the clinic in 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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