

April 7, 2016



Adaptimmune Announces FDA Acceptance of IND Application for Affinity Enhanced T-Cell Therapy Targeting AFP in Liver Cancer

PHILADELPHIA and OXFORD, United Kingdom, April 07, 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 accepted the company's investigational new drug (IND) application for autologous genetically modified T-cells expressing affinity enhanced T-cell receptors (TCRs) specific for alpha fetoprotein (AFP) in patients with locally advanced or metastatic hepatocellular carcinoma, the sixth most common cancer worldwide. The IND is now active.

This will be Adaptimmune's second wholly-owned therapeutic candidate to enter clinical trials. The company initiated a study in December 2015 to evaluate its unpartnered T-cell therapy targeting the MAGE-A10 cancer antigen in patients with non-small cell lung cancer.

The acceptance of this IND allows Adaptimmune to initiate an open label Phase I study designed to evaluate the safety and anti-tumor activity of its AFP therapeutic candidate in hepatocellular carcinoma (HCC). Site selection activities are under way, and the company anticipates that enrollment will commence in the second half of 2016.

"Hepatocellular carcinoma is one of the most common and deadly types of cancer in the world and it represents a significant unmet medical need, as there is a dearth of effective therapies for advanced disease," said Rafael Amado, Adaptimmune's Chief Medical Officer. "We are pleased to initiate clinical evaluation of our AFP T-cell therapeutic candidate in this patient population."

AFP is believed to be highly expressed in approximately 30 percent of hepatocellular carcinomas. Expression has been shown to be absent or very low in most adult non-reproductive tissues and will be evaluated prior to enrollment. Adaptimmune's proprietary technology enables the company to routinely generate TCRs which address intracellular targets, such as AFP, that are not accessible to other therapies.

This will be a Phase I open label clinical trial evaluating the safety and anti-tumor activity of autologous T-cells expressing enhanced TCRs specific for AFP in HLA-A2 positive subjects with advanced HCC. The study will enroll up to 30 subjects with measurable, histologically confirmed HCC, not amenable to resection or loco-regional therapy, and progressive disease following (or intolerant of or refuses) sorafenib treatment. The primary objective of the study is to evaluate the safety and tolerability of this therapy in subjects with AFP-positive HCC. Additional objectives include anti-tumor activity, persistence of genetically modified cells in the body, and evaluation of the phenotype and functionality of genetically modified cells isolated from peripheral blood or tumor post infusion.

About Adaptimmune's TCR Technology

Adaptimmune's proprietary T-cell receptor (TCR) technology enables the company to genetically optimize TCRs 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 Hepatocellular (Liver) Cancer

A cancer that starts in the liver is called primary liver cancer. Hepatocellular cancer is the most common form of liver cancer in adults. More than 700,000 people are diagnosed with this cancer each year throughout the world. Liver cancer is also a leading cause of cancer deaths worldwide, accounting for more than 600,000 deaths each year. In the United States, it is estimated that about 39,000 new cases will be diagnosed in 2016, and about 27,000 people will die from it. Liver cancer death rates have generally been increasing since 1980; from 2003 to 2012, rates increased by 2.7 percent per year. It is often hard to detect liver cancer early because signs and symptoms often do not appear until the disease is in its later stages.

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.

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Source: Adaptimmune Therapeutics plc