

**PRESS RELEASE – ADAPTIMMUNE LTD**

**Adaptimmune announces Opening of Phase I/II Clinical Trial for Metastatic Melanoma at Washington University, St. Louis**

*Trial could generate future alternative treatment for metastatic melanoma*

(Oxford, UK) 13 June, 2011. Adaptimmune announced today that it has opened a Phase I/II, two cohort, open label clinical trial in metastatic melanoma at Washington University, St. Louis, Missouri.

Adaptimmune is focused on the use of T-cell therapy to treat cancer, with the body's own machinery - the T lymphocyte-- a cell that is being used to target and destroy cancerous cells. This trial is designed to investigate the safety, bioactivity and anti-tumor effect of patients' own T cells that have been genetically modified to express a high affinity T cell receptor (TCR) specific for a type of tumor antigen (protein) known as a cancer testis antigen (CT antigen).

TCRs that have been developed using Adaptimmune's unique TCR enhancement technology will be deployed to target two CT antigens called Mage-A3/6 and NYESO-1. T cell manufacturing will be performed at the Clinical Cell and Vaccine Production Facility at the Perelman School of Medicine at the University of Pennsylvania directed by Dr. Bruce Levine.

The clinical trial design includes patients who have unresectable stage III/IV melanoma. Up to 12 patients will be enrolled in the trial over a period of two years, with six patients participating in each of the NYESO-1 and MAGE-A3/6 cohorts in accordance with a genetic randomization scheme based on a patient's HLA-A type and tumor antigen status.

Dr. Carl H. June at the Abramson Cancer Center of the University of Pennsylvania and Dr. Gerald Linette of the Division Washington University's Division of Medical Oncology and Siteman Cancer Center, developed the study which was presented to the National Institutes of Health Recombinant DNA Advisory Committee last year. Dr. June is the regulatory sponsor (FDA representative) for the study and Dr. Linette is the lead clinical investigator. Adaptimmune is the financial sponsor and owns the core T cell receptor technology.

"There's a strong rationale for using immunotherapy for treating melanoma because its molecular signposts can be seen by the immune system and immunotherapeutic approaches have been effective in prior trials," says Dr. June. "With this trial, we aimed to enhance response rates using gene-based personalized cell therapy that incorporates recent advances in vector design, TCR engineering, and the T cell manufacturing process."

"TCR engineering is an important advance for cancer therapy," says Dr. Linette. "This approach of infusing autologous TCR engineered T cells creates a uniform and high frequency response to tumor antigen known to be present in the patient's cancer, and therefore it may overcome limitations previously observed with cancer vaccines."

FINAL - press release for melanoma trial opening

Patients enrolled on the study will have their T cells collected by leukapheresis, a procedure for collection of white blood cells. Once the manufacture of the genetically modified T cell product is complete, the patient will undergo cytoreductive chemotherapy to “make space” for the T cell infusion, followed a few days later with the infusion. The active phase of the study lasts three months, with up to one year of monitoring of patients responding to the treatment.

“The potential of adoptive T cell therapy to effect impressive antitumor responses in melanoma patients is generally established,” says James Noble, Adaptimmune’s CEO. “The challenge now is how to achieve reproducible responses among patients using a commercially viable manufacturing process, and I believe our high affinity TCR technology and manufacturing process address this challenge.”

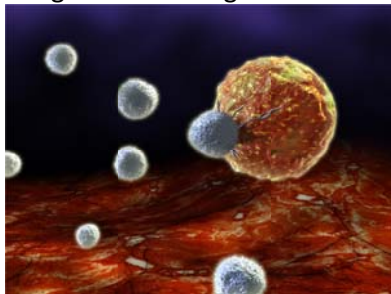
Additional study details and contact information for patients interested in finding out more about participation can be found at [clinicaltrials.gov](http://clinicaltrials.gov) under trial identifier number NCT01350401.

**Ends**

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Image : T cell killing a tumor cell



### **Notes for editors**

Dr. Carl June has no financial interest or other relationship with Adaptimmune LTD, apart from their scientific collaboration in developing the engineered killer T cell, conducting laboratory experiments and planning human clinical trials.

### **About Adaptimmune**

Adaptimmune Limited is focused on the use of T cell therapy to treat HIV and cancer. It aims to utilize the body’s own machinery – the T lymphocyte cell – to target and destroy cancerous or infected cells.

Established in July 2008, Adaptimmune was set up to develop Immunocore Ltd's (formerly Avidex/MediGene Ltd's) unique T cell receptor engineering technology for adoptive T cell therapy. Specifically, Adaptimmune makes use of the body's ability to recognize infected or cancerous cells by enhancing the power of the T cell receptor (TCR) on killer T cells. Cancerous or virally infected cells will typically present small parts or peptides of larger viral proteins or abnormal cancer proteins on their surface, offering a "molecular fingerprint" called an epitope for killer T-cells from the immune system to identify. In a healthy individual, this triggers an immune response, eliminating the affected cell. However, viruses such as HIV mutate rapidly, swiftly disguising their fingerprints to allow them to hide from killer T-cells whilst cancer proteins are usually derived from self-proteins against which natural TCRs do not respond. Adaptimmune's technology uniquely enhances the natural TCR affinity to either viral or cancer protein epitopes on an individual patient's cells overcoming these obstacles for therapeutic benefit.

Adaptimmune has undertaken significant preclinical development with a number of pipeline TCRs to demonstrate their potency and specificity in vitro. The TCRs in the current melanoma study are specific to the cancer testis antigen targets NY-ESO-1<sub>157-165</sub> (HLA A2; SLLMWITQC) and MAGE A3<sub>168-176</sub> (HLA A1; EVDPIGHLY) and were engineered using Adaptimmune's proprietary TCR engineering platform. It is poised to gather clinical safety and efficacy data on these and other TCRs with regulatory approvals for human trials in HIV and multiple cancers now in place.

<http://www.adaptimmune.com>