PSIOXUS THERAPEUTICS INITIATES COMBINATION STUDY OF MERCK'S KEYTRUDA WITH ONCOLYTIC VIRUS ENADENOTUCIREV

Study to Explore Reversal of Checkpoint Inhibitor Resistance for Certain Tumour Types

OXFORD, UK – 16 December 2015 – PsiOxus Therapeutics Ltd. (PsiOxus), the immuno-oncology company, has initiated a study to assess the safety and efficacy of a therapy combining Merck's Keytruda® (pembrolizumab) and PsiOxus' lead product, enadenotucirev, to treat patients with carcinomas. Enadenotucirev is an oncolytic virus that has been shown in phase I clinical trials to reach and selectively infect cancer cells when administered by intravenous infusion.

The SPICE study

The **S**tudy of **P**embrolizumab **I**n **C**ombination with **E**nadenotucirev (**SPICE**) study aims to assess the ability of enadenotucirev to reverse resistance to checkpoint inhibitors for certain tumour types, including metastatic colorectal cancer. The study will involve several leading clinical centres in the United States and is planned to run until 2017. Initially, the SPICE study will explore the safety of this combination therapy.

Dr John Beadle, CEO of PsiOxus, commented: "Although checkpoint inhibitors represent a tremendous breakthrough in immunotherapy, the majority of tumours are currently resistant to these agents. More than 90 percent of colorectal tumours, for example, are currently regarded as checkpoint resistant. We aim to show that a combination of enadenotucirev with pembrolizumab can reverse that resistance and significantly open up the market for checkpoint inhibitors and enadenotucirev, for the very important benefit of patients."

Combination enadenotucirev with checkpoint inhibitors

The ability to deliver enadenotucirev systemically via intravenous infusion represents a significant advantage over other oncolytic therapies, such as Imlygic® (T-vec), that require intra-tumoural delivery. Furthermore, phase I clinical trials have shown that the selective infection of tumour cells by enadenotucirev is associated with the infiltration of immune cells (T-cells) into colorectal tumours.

Interestingly, pre-clinical studies using human cells have shown that the virus can directly stimulate immune cell activity and this stimulation has recently been shown to synergise with the activity of checkpoint inhibitors. The SPICE study thus aims to explore this combination in a range of solid tumour types including colorectal cancer.

Next generation oncolytic viruses

Building on recent clinical success by checkpoint inhibitor antibodies, the field of cancer immunotherapy is now focussing on combination treatment regimens to further improve efficacy benefits to patients. However, combining such systemically dosed agents is associated with a number of challenges including enhanced side effect profiles and high costs. Dosing the therapeutics directly into the tumour rather than systemically is an emerging strategy, but many tumours will not be accessible for this type of treatment.

Looking to the future, PsiOxus will use its intravenous platform to 'arm' enadenotucirev with the genetic instructions required to force cancer cells into producing immune-therapeutic agents in situ, thus opening up an exciting form of gene therapy whereby the metastatic tumour is forced into acting as an anti-cancer "drug factory."

To date, PsiOxus has developed enadenotucirev-based viruses capable of producing a wide range of functioning therapeutic antibodies including anti-PDL1 and anti-CTLA4, in preclinical studies. However, besides antibodies of different specificities, the arming platform can also be used to deliver a broad variety of biological agents including proteins, peptides, and oligonucleotides such as shRNA. Up to three different therapeutic molecules can be incorporated in each virus product in order to produce combination therapies in a single dose form.

About PsiOxus Therapeutics, Ltd.

PsiOxus Therapeutics is an Oxford, UK-based development stage biotechnology company with a particular focus on immune therapeutics in oncology. PsiOxus has developed a patented platform for tumour-targeted delivery based on its oncolytic vaccine, enadenotucirev. Enadenotucirev's unique design allows it to be delivered systemically via intravenous administration. The anti-cancer scope of enadenotucirev can be expanded through "arming" – a process that involves addition of new genes into enadenotucirev. The "Armed EnAd" platform makes possible creation of a broad range of unique oncolytic immune therapeutics, including oncolytic vaccines that express one or more antibodies (AbEnAd), cytokines or other immunomodulatory proteins, or nucleotide based payloads such as RNAi. The Armed EnAd platform is in preclinical stage, while phase I/II clinical trials are ongoing with the parent unarmed EnAd in different tumour types.

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