



## **PsiOxus Therapeutics Announces First-in-Human Dosing of their Second Gene Therapy Cancer Treatment**

March 13, 2019 – OXFORD, UK - PsiOxus Therapeutics, Ltd. (PsiOxus), the gene therapy for cancer company, today announced that it has started dosing NG-350A, an antibody based cancer gene therapy, to cancer patients. The Phase 1 FORTITUDE study is being conducted at multiple cancer centers in the United States and will assess the safety, tolerability and preliminary anti-tumor activity of NG-350A in subjects with solid tumors.

“Our approach is to systemically deliver a gene therapy vector to turn tumor cells into drug factories,” stated Dr Brian Champion, the Chief Scientific Officer of PsiOxus. “The patient’s own tumor cells are used to produce the therapeutic antibody directly in the tumor micro-environment to treat their cancer.” The monoclonal antibody delivered by NG-350A is a CD40 agonist, a potentially powerful activator of a patient’s immuno-inflammatory response. When delivered systemically, CD40 agonists have produced adverse events that may limit their use. NG-350A directs the production of the antibody locally within the tumor and PsiOxus is developing this agent to improve the potential for a tolerable and effective treatment. John Beadle, M.D., Chief Executive Officer of PsiOxus stated “PsiOxus is delighted to have our second cancer gene therapy in clinical development. We look forward to generating clinical data on this exciting new product to treat and benefit cancer patients.”

FORTITUDE is an open-label, dose expansion, multicenter, Phase 1 study expected to enroll up to 125 patients across multiple clinical study sites in the United States. Phase 1a of the study will assess the safety, tolerability and dose of NG-350A and will enroll patients at study sites in the United States, led by Dr Aung Naing of the MD Anderson Cancer Center. Phase 1b of the study will evaluate NG-350A in expansion cohorts in subjects with specific metastatic or advanced tumors. The ClinicalTrials.gov identifier for the NG-350A study is: NCT03852511. A link to the ClinicalTrials.gov listing for the study can be found [here](#).

PsiOxus’ proprietary T-SIGn platform uses the enadenotucirev oncolytic virus as a vector to deliver combinations of therapeutic transgenes to carcinomas to fight cancer. All T-SIGn products are administered intravenously and are designed to selectively infect and replicate only in tumor cells. NG-348, the first T-SIGn virus to enter clinical trials, is licensed to Bristol-Myers Squibb.

### **About PsiOxus Therapeutics**

PsiOxus aims to be the world’s leading cancer gene therapy company, delivering medicines of value to patients with cancer. Our work is product and platform based with a focus on discovering and developing gene-based immuno-oncology therapies for the treatment of solid tumors. The T-SIGn gene therapy platform is based on the company’s oncolytic virus, enadenotucirev, which has properties that allow systemic IV delivery and payload capacity to deliver genes as a viral vector. While delivered systemically, PsiOxus’ T-SIGn gene therapy products act locally within the tumor micro-environment, replicating only in tumor cells. T-SIGn gene therapy products are “armed” through the addition of genes that cause the tumor to express combinations of biologics including

antibodies, cytokines, immunomodulatory proteins, or nucleotides (RNA). In effect, the T-SIGn viruses turn the tumor cells into “drug factories” to express combination gene therapy. The result is a revolutionary way to deliver biological anticancer therapeutics that act locally within the tumor microenvironment for the treatment of cancer.

PsiOxus’ first gene therapy program, NG-348, is partnered with Bristol-Myers Squibb and is in clinical development. In addition to NG-350A, PsiOxus has multiple additional gene therapy programs in research and pre-clinical development. Clinical trials are also ongoing with the unarmed enadenotucirev oncolytic virus in solid tumors and in combination trials with a checkpoint inhibitor and with a chemotherapeutic. [www.psioxus.com](http://www.psioxus.com)

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