PsiOxus to Present Positive Biomarker Data at ESMO 2021 Demonstrating the Potential of Their Novel Tumor-Selective T-SIGn® vector, NG-350A, to Re-Engineer Advanced Cancers

- Key data from the first-in-human FORTITUDE trial shows that a single cycle of intravenous (IV) NG-350A drives dose-dependent increases in specific inflammatory biomarkers, consistent with the mechanism of the encoded anti-CD40 agonist.
- IV dosing of NG-350A led to elevations in IL-12, IFNγ and IL-17 that were higher and sustained for longer than those reported for systemic CD40 agonists.
- NG-350A monotherapy was well-tolerated and dose exploration will continue in combination with a PD-1 inhibitor.

OXFORD, UK, 15 September 2021: PsiOxus Therapeutics, Ltd. (PsiOxus), a tumor re-engineering company, today announced that they will present key safety and translational data from their first-in-human phase 1 FORTITUDE clinical study at the European Society for Medical Oncology (ESMO) Congress 2021 this week. Data from the completed monotherapy dose-escalation part of the FORTITUDE study, initiated in 2019 to assess the safety and tolerability of the NG-350A T-SIGn® vector, will be presented on 16th September 2021, with the poster available in full at www.psioxus.com shortly afterwards.

NG-350A is a T-SIGn® vector designed to re-engineer cancers by selectively expressing a CD40 agonist monoclonal antibody, a potent activator of immuno-inflammatory responses, within the tumour microenvironment. PsiOxus is developing this agent as one of several products within its T-SIGn® portfolio of vectors that combine systemic delivery with localized production of powerful transgene payloads to allow the selective re-engineering of both primary and metastatic tumors.

The data to be presented at the ESMO Congress show that IV delivery of NG-350A results in sustained elevations of inflammatory cytokines in the phase 1 FORTITUDE trial. In particular, marked and persistent dose-dependent increases in both IL-12 and IFNγ were observed after a single 1-week course of NG-350A, indicative of robust activation of antigen presenting cells via CD40 agonism generated within the tumor. Expansion of new T cell clones, a high proportion of which were new clones, was also observed following a single cycle of NG-350A. Safety data from the 25 patients treated with NG-350A as part of the now completed monotherapy dose-escalation part of

FORTITUDE demonstrated that NG-350A was well-tolerated, with few of the adverse events associated with systemic delivery of anti-CD40 agonists observed.

Together, these data suggest NG-350A contributes to the re-programming of the tumour microenvironment while avoiding the toxicity associated with systemic non-localized dosing of anti-CD40 antibodies.

“The headline data shared at the ESMO Congress confirms previous findings that our T-SIGn vector replicates selectively in primary tumor cells and metastases and persists for several months after intravenous delivery. Even more importantly, the biomarker data indicates that ongoing vector replication in tumors effectively translates into sustained production of the transgene payload, in this case a CD40 agonistic antibody. This translational data is a first in class demonstration of a downstream effect of tumor re-engineering, using T-SIGn vectors to turn the patient’s tumor cells into small drug factories,” said Tom Lille, M.D., Ph.D., Chief Medical Officer, PsiOxus.

Based on these highly promising data, NG-350A will be assessed in combination with an anti–PD-1 checkpoint inhibitor in Part B of FORTITUDE.

About PsiOxus

PsiOxus is a clinical stage oncology company pioneering systemic immune oncology products that drive sustained reprogramming of the tumor microenvironment to overcome the central challenge of resistance to therapy. Our flexible and validated T-SIGn® vector platform can deliver multiple transgene payloads that re-engineer both primary and metastatic tumors. We have a rapidly expanding pipeline of novel monotherapy and combination products to dramatically improve outcomes for patients with cancer. For more information, please visit https://psioxus.com/.

About T-SIGn®

Tumor-Specific Immuno-Gene Therapy (T-SIGn) is a broad platform for tumor re-engineering by delivering combinations of transgenes encoding immunotherapeutic proteins in a single agent. Transgenes are selected based on their functional abilities to reprogram the tumor microenvironment and thus promote anti-tumor responses. T-SIGn utilizes a systemically deliverable viral vector with clinically demonstrated selectivity for, and activity in, tumor cells. In addition to NG-350A, NG-641 (a bi-specific antibody approach targeting the tumor stroma) is also in ongoing clinical trials and further candidates are in late-stage preclinical development. This portfolio of multi-targeted vector candidates are being developed by PsiOxus alone or in collaboration with partners.

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