Nouscom Announces First Patient Dosed in Phase 2 Randomized Trial with NOUS-209, an 'off-the shelf' Neoantigen Cancer Immunotherapy in dMMR/MSI-High Metastatic Colorectal Cancer

BASEL, Switzerland – 15th November 2022 - Nouscom, a clinical stage immuno-oncology company developing off-the-shelf and personalized immunotherapies, today announced the first patient has been dosed in a randomized Phase 2 clinical trial evaluating NOUS-209 in combination with anti-PD1 checkpoint inhibitor (CPI) pembrolizumab versus pembrolizumab alone. NOUS-209 is an off-the-shelf immunotherapy targeting 209 specific neoantigens for the treatment of Mismatch Repair/Microsatellite Instable High (dMMR/MSI-H) unresectable or metastatic gastric, colorectal and gastro-esophageal junction tumors.

Nouscom is assessing the efficacy and safety of NOUS-209 in combination with pembrolizumab at multiple sites across Europe and the US (NCT04041310). The Phase 2 study will include two cohorts in dMMR/MSI-H unresectable and metastatic colorectal cancer (CRC):

1. A randomized cohort enrolling patients who are eligible for first line treatment of NOUS-209 plus pembrolizumab versus pembrolizumab alone;
2. A single arm cohort enrolling patients who have stopped responding to previous anti-PD1 and other approved therapies

Dr Michael J. Overman, Principal Investigator of the trial and Professor in the Department of GastroIntestinal Medical Oncology at the University of Texas MD Anderson Cancer Center, said: "*The continued clinical development of NOUS-209 is critical as there remains a significant unmet need in the treatment of CRC, including overcoming tumor resistance to anti-PD1 immunotherapies. Data from the Phase 1 study presented at ASCO 2022[1] and published in Science Translational Medicine[2] demonstrated how NOUS-209 induces neoantigen specific CD8+ T cells which infiltrate metastatic tumors and exert anti-tumor efficacy, providing hope for better treatment options for this patient population with difficult to treat cancers."*

Dr Marina Udier, Chief Executive Officer of Nouscom, added: "*The initiation of the Phase 2 study is another significant milestone this year for our company. Building on our published safety, immunogenicity and mechanism of action clinical data, the trial, together with the Phase 1 'cancer interception' monotherapy study in Lynch Syndrome carriers, will allow us to demonstrate the efficacy of NOUS-209 and illustrate the power of our platform. We look forward to presenting interim results at key conferences during 2023."*

References

1. **ASCO Presentation**: First clinical and immunogenicity results including all subjects enrolled in a phase I study of NOUS-209, an off-the-shelf immunotherapy, with pembrolizumab, for the treatment of tumors with a deficiency in mismatch repair/microsatellite instability (dMMR), Professor Marwan G. Fakih, M.D.
2. A.M. D'Alise et al. ***Adenoviral Based-Vaccine Promotes Neoantigen Specific CD8+ T Cell Stemness And Tumor Rejection,*** *Science Translational Medicine; 14, 657, 2022*

Ends

About NOUS-209

NOUS-209 is an off-the-shelf cancer immunotherapy for Microsatellite Instable High (MSI-H) tumors. MSI-H tumors are characterized by a defective DNA mismatch repair system, which generates highly immunogenic neoantigens called frame shift peptides (FSP) that are not present in healthy tissue.

NOUS-209 encodes for 209 shared FSP neoantigens, selected by Nouscom's proprietary GENESIS (**GE**(netic)**NE**(oantigen)**S**(election)**I**(n)**S**(ilico)) algorithm. In published prospective validation studies, approximately 50 of the 209 neoantigens are expressed in any one patient's tumor. These FSPs are cloned into Nouscom's heterologous prime / boost viral vector platform of a Great Ape Adenoviral (GAd) and Modified Vaccinia Ankara (MVA) and potently generate FSP neoantigen specific CD8+ T cells, which have been shown to successfully infiltrate tumor microenvironments to exert anti-tumor activity.

NOUS-209 is being investigated in multi-center EU and US Phase 2 randomized clinical trials in patients with dMMR/MSI-H unresectable and metastatic colorectal cancer (CRC) (NCT04041310) in combination with checkpoint inhibitors (CPI) versus CPI alone and in patients who have stopped responding to previous anti-PD1 and other approved CPI therapies.

About Nouscom

Nouscom is a clinical stage immuno-oncology company developing next-generation, off-the-shelf and personalized cancer immunotherapies. Nouscom's proprietary viral vector platform has the capacity to encode for large payloads of neoantigens or other immunomodulators and to safely and potently harness the power of the immune system

Nouscom is currently advancing the clinical development of its wholly owned programs:

- NOUS-209, an off-the-shelf cancer immunotherapy for the treatment of MSI-H solid tumors in combination with pembrolizumab
- NOUS-209, an off-the-shelf monotherapy in Lynch Syndrome Carriers with potential to 'intercept cancer' before it advances
- NOUS-PEV, a personalized cancer immunotherapy for the treatment of advanced melanoma or lung cancer

Nouscom has also exclusively out-licensed VAC-85135, an off-the-shelf immunotherapy developed under a multi-project agreement, which is currently under evaluation in a Phase 1 trial for the treatment of Myeloproliferative Neoplasms sponsored by Janssen Research & Development and Bristol-Myers Squibb.

Nouscom, which was founded in 2015 and is headquartered in Basel, Switzerland, is backed by international life sciences investors and led by an experienced management team with deep roots in the pharma and biotech industry.

For more information on Nouscom, please visit the company's website at www.nouscom.com or follow us on LinkedIn

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