Nouscom announces first patient dosed in a Phase 1b Trial with NOUS-PEV, a novel personalized cancer immunotherapy, in advanced melanoma or lung cancer

BASEL, Switzerland – August 24th, 2021: Nouscom, a clinical stage immuno-oncology company developing off-the-shelf and personalized cancer neoantigen vaccines, today announced that the first patient has been dosed in a Phase 1b clinical trial evaluating NOUS-PEV. In this first-in-human trial NOUS-PEV, a personalized neoantigen cancer vaccine, is being administered in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab to patients with either locally advanced 1L melanoma or 1L non-small cell lung cancer (NSCLC) expressing more than 50% PD-L1.

NOUS-PEV-01(NCT04990479) is a multicenter Phase 1b open-label study, assessing the safety, feasibility and preliminary efficacy as per RECIST 1.1 criteria of the NOUS-PEV vaccine, in combination with pembrolizumab. The study will evaluate vaccine-induced immune responses, as well as preliminary signs of anti-tumor activity in treated patients. The PEV vaccines will be prepared on an individual basis, following a tumor biopsy performed at the time of screening to identify patient-specific tumor mutations. The trial will enroll patients from Spain, Belgium and the UK.

The principal investigator (PI) of the trial is Stefan Symeonides M.D., a Medical Oncologist and Clinical Scientist in the Department of Oncology at The University of Edinburgh.

Stefan Symeonides, M.D. and PI of the trial, said: "*There is still a significant unmet medical need for new therapeutics to overcome tumor resistance to anti-PD1 immunotherapies. Vaccination, and especially personalized vaccination, has huge potential and Nouscom's innovative technology has unique features that are promising for a best-in-class platform. It is excellent news that the first patient has now been dosed with NOUS-PEV. We expect this trial to deliver important initial clinical data for the development of NOUS-PEV and I really look forward to seeing preliminary results in 2022."*

NOUS-PEV is a personalized cancer vaccine based on patient-specific neoantigens sourced from individual patient tumor mutanomes[1]. The identified neoantigens are encoded in Nouscom's heterologous prime boost platform comprising a proprietary non-human adenoviral vector (GAd) and Modified Vaccinia Ankara vector (MVA). Each of the two viral vector systems encodes multiple personalized neoantigens selected by a proprietary algorithm (VENUS[2]), which prioritizes up to 60 mutations that represent the most immunogenic neoantigens. Including a large number of neoantigens in NOUS-PEV aims to ensure broad and deep immune responses, potentially overcoming issues of tumor heterogeneity and escape through immunoediting.

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[1] The mutanome is the entirety of somatic cancer mutations in an individual tumor

[2] **V**accine **E**ncoded **N**eoAg **U**nrestricted **S**election (VENUS). The innovative science behind VENUS has recently been published online in the peer-reviewed journal *Vaccines*. The full publication can be accessed here: https://doi.org/10.3390/vaccines9080880

Patricia Delaite, M.D., Chief Medical Officer of Nouscom, said**:** "*NOUS-PEV leverages our heterologous prime boost platform to enable the fastest in class 'needle-to-needle' turn-around timelines, while subsequently inducing a broad and potent anti-tumor T cell response. Having now successfully designed, manufactured and dosed an individualized cancer vaccine, we look forward to progressing the Phase 1b clinical study and gathering important patient data in the coming months."*

Dr. Marina Udier, Chief Executive Officer of Nouscom, added: "*The initiation of this study represents a significant milestone for Nouscom, as it marks the second clinical program to emerge from our proprietary platform based on uniquely engineered viral vectors that are optimized for the efficient expression of tumor neoantigens. We look forward to presenting the preliminary data in 2022.*"

Ends

About NOUS-PEV

NOUS-PEV is a personalized cancer immunotherapy designed for each patient based on selection and prioritization of mutations unique to that patient's tumor. The strategy is based on Nouscom's heterologous prime boost platform already clinically validated by its lead off-the-shelf clinical development program NOUS-209. The platform is composed of a proprietary non-human adenoviral vector (GAd) and Modified Vaccinia Ankara vector (MVA). Each of the two viral vector systems encodes multiple personalized neoantigens selected with a proprietary algorithm (VENUS), which prioritizes up to 60 mutations that represent the most immunogenic neoantigens.

NOUS-PEV is being evaluated in a Phase 1b clinical trial in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab in patients with either locally advanced 1L melanoma or 1L non-small cell lung cancer (NSCLC) expressing more than 50% PD-L1. The trial (NCT04990479) commenced in 2021 and is currently enrolling patients across multiple clinical sites in Europe.

About Nouscom

Nouscom is a clinical stage immuno-oncology company developing off-the-shelf and personalized cancer neoantigen vaccines. Nouscom's proprietary technology platform harnesses the full power of the immune response by combining viral vectored vaccines based on neoantigens with other immunomodulators.

Nouscom is currently advancing the clinical development of its programs:

- NOUS-209 (lead), an off-the-shelf cancer immunotherapy for the treatment of MSI solid tumors, and
- NOUS-PEV, a personalized cancer immunotherapy for the treatment of advanced melanoma or lung cancer

Nouscom is led by an experienced management team with deep roots in the pharma and biotech industry and are veterans in the field of viral vectored vaccines. Nouscom is headquartered in Basel, Switzerland with operations in Rome, Italy, and is backed by international life sciences investors.

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

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