



Nouscom's Personalized Neoantigen Cancer Immunotherapy NOUS-PEV Demonstrates Promising Safety, Immunogenicity and Anti-tumor Activity in Solid Tumors

Initial data from Phase 1b trial evaluating NOUS-PEV in combination with pembrolizumab to be presented at SITC 2022

BASEL, Switzerland – 7th November 2022 - Nouscom, a clinical stage immuno-oncology company developing off-the-shelf and personalized immunotherapies, today announced interim data from the Phase 1b trial evaluating NOUS-PEV which demonstrated it to be safe, well tolerated, immunogenic and with signs of anti-tumor activity. These data will be presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting, November 8-12, 2022.

NOUS-PEV is a personalized cancer immunotherapy being evaluated in a multicenter Phase 1b open-label, dose confirmation and cohort expansion study (NCT04990479). NOUS-PEV is individually designed and manufactured to contain patient-specific neoantigens identified and selected from a patient's own tumor biopsy. The Phase 1b trial is assessing the safety, feasibility and preliminary efficacy as per RECIST 1.1 criteria 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 key findings to be presented at SITC are as follows:

- **Manufacturing Feasibility:** >90% of vaccines successfully manufactured, released and delivered to patients on time
- **Safety:** Well tolerated with a favorable safety profile
- **Immunogenicity:** Potent neoantigen specific immune responses were detected in all evaluable subjects with clinical responses
- **Biomarkers/Immune correlates of clinical efficacy:** Deepening of clinical responses coincided with the increase of NOUS-PEV-induced T cells in blood; Increased T cell infiltration in the tumors; NOUS-PEV-induced neoantigen specific T cells identified in tumor biopsies in subjects with clinical responses.
- **Clinical Efficacy:** Clinical responses correlated with biomarker analyses/predictions

Dr Oliver Bechter, MD, Principal Investigator (PI) of the trial and Professor in the Department of General Medical Oncology at the Leuven Cancer Institute (Belgium), said "I am very excited to see this initial data from patients who have received NOUS-PEV. The data demonstrated NOUS-PEV to be well tolerated and to have a good safety profile, comparable to pembrolizumab monotherapy. Nouscom has already demonstrated that its platform promotes the expansion and diversification of neoantigen-specific memory CD8+ T cells that enhance anti-tumor immunity, and the early translational data from the first three melanoma patients receiving NOUS-PEV further supports this. The higher number of relevant neoantigens that can be delivered via this platform compared to other approaches will increase the likelihood of eliciting a response. This can be crucial for patients who do not respond to anti-PD1 therapy. I look forward to seeing further data to build on this immune mechanism of action with potential to provide new effective treatment options for cancer patients."

Dr Sven Gogov, MD, Chief Medical Officer of Nouscom, added: "We are delighted with the initial data from this Phase 1b trial evaluating NOUS-PEV in solid tumors. We have developed a robust and efficient nine-week needle-to-needle GMP manufacturing process that can be scaled



up as we progress in clinical development. These data further validate our proprietary platform and mechanism of action in the clinic, demonstrating that viral vector encoding cancer neoantigens drive potent and quality immune responses in metastatic cancer patients, which correlate with significant clinical responses. We look forward to presenting further data during 2023.”

Poster Presentation Details:

- Title: *NOUS-PEV, a Novel Personalized Viral-based Prime/Boost Cancer Immunotherapy Targeting Patient-Specific Neoantigens: Interim Results from the First Subjects in the Phase 1b Study (#706)*
- Date: 11th November 2022
- Time: 11:40-13:10 and 19:30-21:00 EST
- Location: Hall C
- Presenter: Dr Oliver Bechter, MD, Principal Investigator (PI) of the trial and Professor in the Department of General Medical Oncology at the Leuven Cancer Institute (Belgium)

The abstracts will be publicly available at 8am EST on 7th November 2022, and available in the Journal for Immunotherapy of Cancer (JITC) supplement.

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 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 viral vector (MVA). Each of the two viral vectors have the capacity to encode up to 60 personalized neoantigens selected and prioritized using the VENUS (Vaccine-Encoded Neontigens Unrestricted Selection) ¹ proprietary algorithm.

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.

1. Leoni *et al.* VENUS, a Novel Selection Approach to Improve the Accuracy of Neoantigens’ Prediction. *Vaccines* 9, 2021

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 safely and potently harness the power of the immune system.

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

- NOUS-209 (lead), an off-the-shelf cancer immunotherapy for the treatment of MSI-H solid tumors in combination with pembrolizumab, and
- NOUS-209, an off-the-shelf monotherapy in Lynch Syndrome Carriers with potential to ‘intercept cancer’



- 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 partnered 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](#)

Contacts

Nouscom

Rick Davis, COO

E: info@nouscom.com

T: +41 61 201 1835

MEDiSTRAVA Consulting

Sylvie Berrebi, Eleanor Perkin

E: nouscom@medistrava.com

T: +44 (0)203 928 6900