



## **Nouscom Announces New Translational Phase 1 Data of NOUS-209, an 'off-the-shelf' Neoantigen Cancer Vaccine for the Treatment of MSI-H Solid Tumors, at AACR 2022**

**BASEL, Switzerland – 11<sup>th</sup> April 2022** - Nouscom, a clinical stage immuno-oncology company developing off-the-shelf and personalized viral vectored immunotherapies, today announced encouraging new translational data obtained from the ongoing Phase 1 trial evaluating NOUS-209. The data were presented yesterday in a Late Breaking session at the 2022 American Association for Cancer Research (AACR) Annual Meeting.

NOUS-209, Nouscom's lead product, is an off-the-shelf cancer vaccine targeting 209 shared neoantigens. It is being investigated in a Phase 1 clinical trial, administered in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab, for the treatment of Microsatellite Instable High (MSI-H) gastric, colorectal and gastro-esophageal junction solid tumors.

Previously presented interim clinical data of the combination (presented at the Society for Immunotherapy of Cancer's (SITC) Annual Meeting in November 2021) highlighted promising early signs of clinical efficacy in 12 MSI-H patients.

The new translational data presented at AACR 2022 further supported these findings and demonstrated NOUS-209 is safe, highly immunogenic with promising signs of clinical efficacy. Key findings were as follows:

- Vaccine immunogenicity was demonstrated by ex-vivo IFN- $\gamma$  ELISpot assay in 67% of patients in dose level 1 (n=3), and 100% (n=7) of patients in dose level 2.
- In 3 patients with long term PRs whose pre/post treatment tumor biopsies were available, the intratumoral TCR repertoire was expanded and diversified post treatment with NOUS-209. Increased T effector memory post treatment was observed.
- In one of these three patients, vaccine-induced neoantigen specific TCR was tracked from periphery in the tumor biopsy post NOUS-209 treatment.
- Results indicate that neoantigen specific CD8+ T cells, induced by NOUS-209, expand and diversify only upon treatment with NOUS-209, and successfully infiltrate the tumor microenvironment to exert anti-tumor activity.

**Marwan G. Fakh, M.D., Medical Oncology Specialist at City of Hope's Duarte California, and Study investigator** said: *“While we have seen progress in the treatment options for MSI-High solid tumors in recent years, there remains a significant unmet need. It is therefore extremely encouraging to see these new translational Phase 1 data illustrating how NOUS-209 induces robust T cell expansion and TCR diversification in patients demonstrating durable clinical responses. I very much look forward to the full analysis of the Phase 1 results and further clinical development.”*

**Dr. Elisa Scarselli, Chief Scientific Officer and Co-Founder of Nouscom,** said: *“The data, obtained from 12 metastatic MSI-H patients, highlights a common signature observed post vaccination in patients with durable clinical response. The signature is characterized by the TCR repertoire expansion and diversification in tumor infiltrating lymphocytes stimulated by*

*vaccination with NOUS-209, together with a parallel increase of T cells with effector memory phenotype. Moreover, we were able to track vaccine induced T cells among those expanded post-treatment in the tumor of one of these patients.*

*“We look forward to building upon our compelling proof-of-concept data by leveraging important learnings from the ongoing trial to support the development of NOUS-209 as potentially the first neoantigen off-the shelf cancer vaccine targeting MSI-H tumors.”*

#### **Poster Presentation Details:**

- **Title:** *Characterization of immune correlates of clinical activity for NOUS-209, an Off-the-Shelf immunotherapy, with Pembrolizumab for treatment of tumors characterized by Microsatellite Instability (MSI).*  
The abstract is available [here](#)

**Ends**

#### **About NOUS-209**

NOUS-209 is an off-the-shelf immunotherapy for Microsatellite Instable High (MSI-H) tumors. MSI-H tumors are characterized by a defective DNA mismatch repair system, which generates highly immunogenic frame shift peptides (frameshift mutations, FSPs) that are not found on healthy tissue.

NOUS-209 is designed to comprise 209 shared FSP neoantigens, selected by Nouscom's proprietary GENESIS (**GE**(netic)**NE**(oantigen)**S**(election)**I**(n)**S**(ilico)) algorithm, on the basis that an average of 50 neoantigens on any patient's tumor will be shared with those in NOUS-209. Nouscom's heterologous prime/boost platform clones these FSPs into Great Ape Adenoviral (GAd) and Modified Vaccinia Ankara (MVA) vectors, combined with other immunomodulators to harness the full power of the immune response, to generate the viral-vectored vaccine.

NOUS-209 is in Phase 1 clinical trial (NCT04041310), a multicenter, open label, multiple cohorts, first-in-human clinical study of NOUS-209 in combination with pembrolizumab, designed to evaluate safety, tolerability and immunogenicity and to detect preliminary evidence of anti-tumor activity.

#### **About Nouscom**

Nouscom is a clinical stage immuno-oncology company developing next-generation, off-the-shelf and personalized cancer vaccines. Nouscom's proprietary technology platform harnesses the full power of the immune response by combining viral vectored vaccines based on multiple 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-H solid tumors, and
- NOUS-PEV, a personalized vaccine 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, which was founded in 2015 and is headquartered in Basel, Switzerland with operations in Rome, Italy, is backed by international life sciences investors.

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

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