



Nouscom Announces Full Phase 1 Data of NOUS-209, an ‘off-the-shelf’ Neoantigen Cancer Immunotherapy for the Treatment of dMMR/MSI-H Solid Tumors, at ASCO 2022

NOUS-209 in combination with pembrolizumab is safe, highly immunogenic, and associated with promising early and long-term clinical efficacy in 20 MSI-H GI patients

BASEL, Switzerland – 6th June 2022 - Nouscom, a clinical stage immuno-oncology company developing off-the-shelf and personalized viral vectored immunotherapies, today announced first data from the completed Phase 1 trial evaluating NOUS-209 in combination with anti-PD-1 checkpoint inhibitor (pembrolizumab). The data, presented yesterday in a poster discussion session at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, demonstrated NOUS-209 to be safe, highly immunogenic and with promising signs of clinical efficacy.

NOUS-209, Nouscom’s lead product, is an off-the-shelf cancer vaccine targeting 209 shared neoantigens. It has been investigated in a Phase 1 clinical trial, administered in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab, for the treatment of deficiency in Mismatch Repair/Microsatellite Instable High (dMMR/MSI-H) unresectable or metastatic gastric, colorectal and gastro-esophageal junction tumors.

The key findings from the study are as follows:

- NOUS-209 continues to be safe and well tolerated
- NOUS-209 immunogenicity was demonstrated by ex-vivo IFN- γ ELISpot assay in 83% of evaluable patients; vaccine induced immune responses were potent and broad
- Early signs of clinical efficacy with 10 durable confirmed partial responses (PR), 4 durable stable disease (SD) and 6 progressive disease (PD)

Previously presented interim clinical and translational data of the combination indicated that neoantigen-specific CD8+ T cells expand and diversify only upon treatment with NOUS-209, and successfully infiltrate the tumor microenvironment to exert anti-tumor activity (presented at the American Association for Cancer Research (AACR)¹ in April 2022).

Professor Marwan G. Fakih, M.D., Medical Oncology Specialist at City of Hope's Duarte California, and Study investigator said: *“With clinical and translational data now available from all patients enrolled in this trial, it is encouraging to see NOUS-209 continuing to be safe, highly immunogenic and have signs of clinical efficacy. Durability of response in all PR and SD patients is particularly encouraging and provides hope for this patient group where there is still a significant unmet need. I look forward to seeing further clinical development of this compound in MSI-H patients.”*

Dr. Marina Udier, Chief Executive Officer of Nouscom, said: *“These new data with all patients enrolled continues to reinforce our compelling and differentiating data for NOUS-209. This is a significant step for the company, validating the potency of our platform in inducing neoantigen specific CD8+ T cells, which are also able to successfully infiltrate tumors of metastatic cancer patients, exerting anti-tumor efficacy. We are actively working on the next*

stages of NOUS-209's clinical development plan and look forward to announcing the start of the Phase 2 study in the second half of 2022."

Poster Presentation Details:

- **Title:** *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)*
The abstract is available [here](#)

Ends

References

1. **AACR Presentation:** 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), Professor Marwan G. Fakh, M.D.

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, to generate the viral-vectored vaccine, combined with other immunomodulators to harness the full power of the immune response by generating neoantigen specific CD8+ T cells, which successfully infiltrate tumor to exert anti-tumor activity.

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 platform harnesses the full power of the immune response by designing viral vectored vaccines based on multiple neoantigens and 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 has also exclusively out-licensed VAC85135, an off-the-shelf cancer vaccine which has received US FDA IND clearance, developed under a partnered multi-project agreement.

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 or follow us on LinkedIn at www.linkedin.com/company/nouscom-ag/

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