



Nouscom announces initial results from Phase 1 trial for NOUS-209, an 'off-the-shelf' neoantigen cancer vaccine, in MSI-H solid tumors

Results presented at the European Society of Medical Oncology (ESMO) congress

BASEL, Switzerland – 16th September 2021 - Nouscom, a clinical stage immuno-oncology company developing off-the-shelf and personalized cancer neoantigen vaccines, today announced initial results from the Phase 1 trial of NOUS-209, the first clinical results for the company. NOUS-209, an off-the-shelf cancer vaccine based on shared neoantigens, in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab, was shown to be safe, highly immunogenic, and demonstrated promising early signs of clinical efficacy with no dose-limiting toxicities, in the treatment of Microsatellite Instable High (MSI-H) gastric, colorectal and gastro-esophageal junction solid tumors.

The results were presented in an e-poster (#1004P) at the European Society of Molecular Oncology (ESMO) congress which is taking place September 16 to 21, 2021. The primary author of the poster is Dr Michael Overman, Principal Investigator (PI) of the trial and Professor in the Department of Gastrointestinal Medicine at the University of Texas MD Anderson Cancer Center.

Dr Michael Overman, PI of the trial, said: *“There is still a significant unmet need in the treatment of MSI-H tumors, with many patients not responding to a single agent immunotherapy. The technology developed by Nouscom is innovative and looks to address this issue – the Phase 1 results are very encouraging, and this data provides exciting early validation of the multi-neoantigen approach in humans, supporting the compelling preclinical data seen previously. I look forward to reporting on the fully enrolled Phase 1 results.”*

The Phase 1 study (NCT04041310) is 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. The trial enrolled 21 patients in the US.

Furthermore, the trial was designed to define the recommended Phase 2 dose (RP2D), with dose level 2 selected as RP2D, based on safety and tolerability, and supportive data gained from infectious disease studies.

“Presenting the first clinical dataset from our lead candidate NOUS-209 for the treatment of MSI-H solid tumors at ESMO, a major oncology conference, is an important milestone for Nouscom.” **Dr Marina Udier, Chief Executive Officer of Nouscom** added. *“We are very pleased to have demonstrated NOUS-209 is safe, highly immunogenic and shows early signs of clinical efficacy. NOUS-209 leverages a core strength of the company’s platform, namely the capacity of its proprietary viral vectors to encode a large number of neoantigens.”*

MSI-H tumors are characterized by a defective DNA mismatch repair system, which generates highly immunogenic frame shift peptides (FSPs) that are not found on healthy tissue. NOUS-209 encodes 209 FSP cancer neoantigens, selected by Nouscom’s proprietary GENESIS (**GE**(netic)**NE**(oantigen)**S**(election)**I**(n)**S**(ilico)) algorithm, so that each patient’s tumor will express, on average, 50 of these neoantigens.

NOUS-209 is Nouscom's lead candidate and has been developed from its proprietary heterologous prime/boost viral vector platform, which combines viral vector vaccines based on neoantigens, with other immunomodulators to harness the full power of the immune response. The vaccine is composed of four Great Ape Adenoviral (GAd) and four Modified Vaccinia Ankara (MVA) vectors.

The poster is available to registered congress participants, speakers and viewers on the ESMO website (<https://www.esmo.org/meetings/esmo-congress-2021>).

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About NOUS-209

Nous-209 is an off-the-shelf immunotherapy for Microsatellite Instable High (MSI-H) tumors. The design of NOUS-209 is based on the neoantigens created by frameshift mutations (frameshift peptides, FSP) and are shared across multiple MSI tumors, not found in healthy tissues. NOUS-209 comprises 209 shared FSP neoantigens, selected by a proprietary algorithm on the basis that an average of 50 neoantigens on any patient's tumor will be shared with those in NOUS-209. These FSPs were cloned into proprietary Great Ape Adenoviral (GAd) and Modified Vaccinia Ankara (MVA) vectors to generate the viral-vectored vaccine.

NOUS-209 is in Phase 1 clinical trial in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab in US patients with gastric, colorectal and gastro-esophageal junction MSI tumors.

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

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