



Nouscom Announces Clinical Trial Collaboration and Supply Agreement with MSD to Evaluate NOUS-209 in combination with KEYTRUDA® (pembrolizumab) in a Phase 2 Randomized Trials in dMMR/MSI-High Metastatic Colorectal Cancer

BASEL, Switzerland – 5th January 2023 - Nouscom, a clinical stage immuno-oncology company developing off-the-shelf and personalized immunotherapies, today announced that it has entered into a clinical trial collaboration and supply agreement with MSD (Merck & Co., Inc., Rahway, NJ, USA), to evaluate Nouscom's wholly-owned lead candidate, NOUS-209, in combination with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) versus KEYTRUDA alone in randomized Phase 2 trials in patients with Mismatch Repair/Microsatellite Instable High (dMMR/MSI-H) Metastatic Colorectal Cancer (CRC).

NOUS-209 is an off-the-shelf immunotherapy targeting 209 specific, shared neoantigens found in dMMR/MSI-H unresectable or metastatic gastric, colorectal and gastro-esophageal junction tumors.

The Phase 2 study includes two cohorts in dMMR/MSI-H unresectable and metastatic CRC assessing the efficacy and safety of NOUS-209 in combination with pembrolizumab at multiple active sites across Europe and the US (NCT04041310).

1. A randomized cohort enrolling patients who are eligible for first line treatment, randomized 2:1 to NOUS-209 plus pembrolizumab versus pembrolizumab alone;
2. A single arm cohort enrolling patients who have stopped responding to previous anti-PD1 treatment.

Dr Marina Udier, Chief Executive Officer of Nouscom, added: *“We are thrilled to collaborate with MSD, a global leader in immuno-oncology, and to work with their highly experienced and talented clinical development team, allowing us to accelerate the ongoing US and EU Phase 2 trial with NOUS-209. Based on our published and presented Phase 1 clinical data^{1,2} we see great potential of this combination approach in addressing the unmet medical need in these patients. We look forward to presenting preliminary data in 2023.”*

Under the terms of the agreement, MSD will supply KEYTRUDA. Nouscom retains all worldwide commercial rights to NOUS-209.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

References

1. **ASCO Presentation:** 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), Professor Marwan G. Fakhri, M.D.
2. A.M. D'Alise et al. **Adenoviral Based-Vaccine Promotes Neoantigen Specific CD8+ T Cell Stemness And Tumor Rejection**, *Science Translational Medicine*; 14, 657, 2022

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About NOUS-209

NOUS-209 is an off-the-shelf cancer immunotherapy for Microsatellite Instable High (MSI-H) tumors. MSI-H tumors are characterized by a defective DNA mismatch repair system, which generates highly immunogenic neoantigens called frame shift peptides (FSP) that are not present in healthy tissue.

NOUS-209 encodes for 209 shared FSP neoantigens, selected by Nouscom's proprietary GENESIS (**GE**(netic)**NE**(oantigen)**S**(election)**I**(n)**S**(ilico)) algorithm. In published prospective validation studies, approximately 50 of the 209 neoantigens are expressed in any one patient's tumor. These FSPs are cloned into Nouscom's heterologous prime / boost viral vector platform of a Great Ape Adenoviral (GAd) and Modified Vaccinia Ankara (MVA) and potentially generate FSP neoantigen specific CD8+ T cells, which have been shown to successfully infiltrate tumor microenvironments to exert anti-tumor activity.

NOUS-209 is being investigated in multi-center EU and US Phase 2 randomized clinical trials in patients with dMMR/MSI-H unresectable and metastatic colorectal cancer (CRC) (NCT04041310) in combination with checkpoint inhibitors (CPI) versus CPI alone and in patients who have stopped responding to previous anti-PD1 and other approved CPI therapies.

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 to safely and potentially harness the power of the immune system

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

- NOUS-209, an off-the-shelf cancer immunotherapy for the treatment of MSI-H solid tumors in combination with pembrolizumab
- NOUS-209, an off-the-shelf monotherapy in Lynch Syndrome Carriers with potential to 'intercept cancer' before it advances
- 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 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](#)



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