



## **Nouscom receives approval to begin Phase 1b trials of NOUS-PEV, a novel personalized cancer immunotherapy**

**BASEL, Switzerland – 11<sup>th</sup> March 2021:** Nouscom, a clinical stage immuno-oncology biotech developing next generation viral-vector based immunotherapies, today announces it has received approval from the Spanish National Agency of Medicines and Medical Devices (*Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)*) to start a Phase 1b trial of its personalized cancer immunotherapy, NOUS-PEV. NOUS-PEV will be investigated in the study as a potential treatment for patients with either locally advanced 1L melanoma or 1L non-small cell lung cancer (NSCLC).

NOUS-PEV is a personalized vaccine 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 underpinning its lead off-the-shelf clinical program NOUS-209, composed of a proprietary non-human adenoviral vector (GAd) and Modified Vaccinia Virus (MVA). Each of the two viral vector systems encodes multiple personalized neoantigens selected with a proprietary algorithm (VENUS<sup>1</sup>), which prioritizes up to 60 mutations that represent the most immunogenic neoantigens.

Results from preclinical proof-of-concept studies (published in *Nature Communications*<sup>2</sup>) demonstrated that a single administration of the GAd vaccine incorporating many neoantigens can eradicate large tumors when combined with checkpoint inhibition such as anti-PD1 or anti-PD-L1 treatment and triples the efficacy of such checkpoint inhibitors. The preclinical results also demonstrated strong and broad CD8+ and CD4+ neoantigen-specific T cell responses following vaccination, which are known to be indicative of a clinical anti-tumor effect.

The new Phase 1b trial will evaluate the safety, feasibility, and preliminary efficacy per RESIST 1.1 criteria of NOUS-PEV in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab in 28 patients with either locally advanced 1L melanoma or 1L NSCLC expressing more than 50% PD-L1. This multicenter trial will be conducted in Spain and other European countries.

**Patricia Delaite, M.D., Chief Medical Officer of Nouscom,** said: *“We have generated exciting pre-clinical data, which demonstrated the ability of NOUS-PEV to present multiple cancer neoantigens to the immune system and promote potent and broad immune responses. The enhanced anti-tumor effects seen by combining NOUS-PEV with checkpoint inhibitors suggests these two approaches are highly synergistic and could potentially overcome tumor resistance to anti-PD1 immunotherapies to address a high unmet medical need. We look forward to starting this trial in the coming weeks and to generating results that we hope will confirm these exciting results in patients.”*

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<sup>1</sup> Vaccine Encoded NeoAg Unrestricted Selection (VENUS)

<sup>2</sup> A.M. D'Alise et al. *Adenoviral vaccine targeting multiple neoantigens as strategy to eradicate large tumors combined with checkpoint blockade*, Nature Communications 2019

**Dr. Marina Udier, Chief Executive Officer of Nouscom**, said: *“The regulatory approval of this highly sophisticated study to assess our personalized vaccine NOUS-PEV is another critical milestone for the company. Similar to our lead program, NOUS-209, NOUS-PEV leverages the strength and capacity of our platform based on viral vectors, encoding a large number of neoantigens, with proven robust performance in animal models, which we believe has the potential to translate into real clinical benefits for patients.”*

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## **About Nouscom**

Nouscom is a privately held oncology company developing next-generation immunotherapies. Nouscom’s proprietary technology platform harnesses the full power of the immune response by combining viral vectored vaccines based on 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 solid tumors, and
- NOUS-PEV, a personalized vaccine in advanced melanoma and lung cancer

Nouscom is led by an experienced management team with deep roots in the pharma and biotech industry (Merck, Novartis, Lilly, Johnson and Johnson, Incyte and Okairos (acquired by GSK)), 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: 5AM, Abingworth, LSP (Life Sciences Partners) and Versant Ventures.

For more information on Nouscom, please visit the company’s website at [www.nouscom.com](http://www.nouscom.com)

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