



Nouscom – IND for NOUS-209, an ‘off-the-shelf’ Neoantigen Cancer Vaccine, Cleared by FDA to Commence Clinical Development in MSI Solid Tumors

BASEL, Switzerland – 3rd June 2019: Nouscom, an immuno-oncology company developing off-the-shelf and personalized cancer neoantigen vaccines, announced today that its Investigational New Drug (IND) application for the first clinical trial of its lead candidate NOUS-209 has been cleared by the US Food and Drug Administration (FDA).

The Company will proceed with its plans to conduct a phase 1 clinical trial of NOUS-209, a therapeutic vaccine for gastric, colorectal, and gastro-esophageal junction Microsatellite Instable (MSI) cancers (tumors characterized by a defective DNA mismatch repair system) in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab. The trial will be enrolling up to 30 patients across several US clinical centers and is expected to begin during the third quarter of 2019. Initial clinical data are expected in early 2020.

The primary objective of the study is to demonstrate safety and tolerability of the combination regimen. Additionally, the study will evaluate vaccine-induced immune responses, as well as preliminary signs of anti-tumor activity in enrolled patients. Based on preclinical data, NOUS-209 is expected to induce potent and broad CD8+ and CD4+ responses in humans.

*“The clearance of our IND application to evaluate NOUS-209 in combination with pembrolizumab is a significant milestone,” said **Dr. Marina Udier, CEO a.i. of Nouscom AG.** “NOUS-209 leverages a core strength of Nouscom’s platform, namely the capacity of its proprietary viral vectors, Great Ape Adenovirus and Modified Vaccinia Ankara, to encode a large number of neoantigens. As such, NOUS-209, comprising a collection of 209 Frame Shift Peptides (FSPs) selected with a proprietary algorithm, is designed to have a broad coverage in the targeted patient populations, without the need to preselect patients for treatment. Hence NOUS-209 has the potential to be the first universal cancer neoantigen off-the-shelf vaccine in MSI solid tumors. We look forward to trial initiation and study results.”*

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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 genetic vaccines based on neoantigens with other immunomodulators.

Nouscom is currently advancing the development of its lead program, NOUS-209, an off-the-shelf cancer vaccine based on shared frame-shift neoantigens, into clinical studies. The Company will also continue to develop its' product candidate, NOUS-PEV, a personalized cancer neoantigen-vaccine, which is expected to enter clinical studies in 2020.

Nouscom is led by an experienced management team that has worked together for many years in previous successful enterprises, including Merck, Novartis, and Okairos (acquired by GSK), and are veterans in the field of viral vectored genetic 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

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