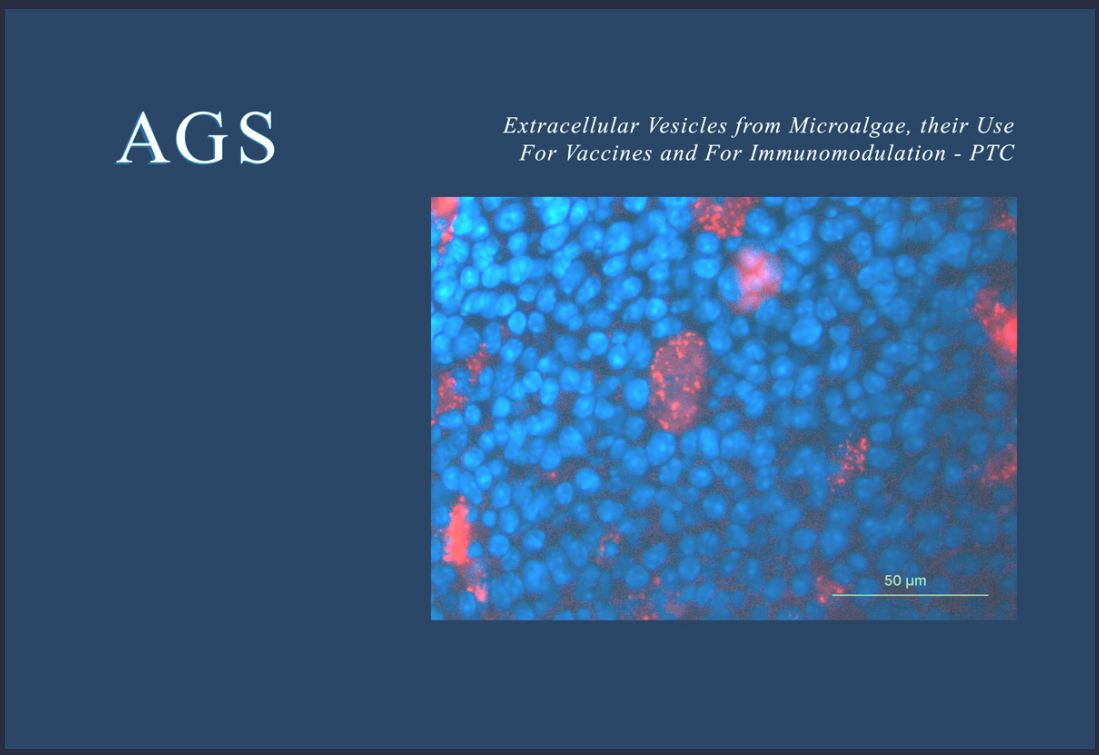
AGS Therapeutics

PRESS RELEASE

« AGS Therapeutics strengthens its Patent Portfolio on Microalgae Extracellular Vesicles (MEVs) with an International Patent Application for the use of MEVs in vaccines, including oral mucosal vaccination, and immunomodulation », Evry, FR, Oct. 1, 2024.



AGS Therapeutics strengthens its Patent Portfolio on Microalgae Extracellular Vesicles (MEVs) with an International Patent Application for the use of MEVs in vaccines, including oral mucosal vaccination, and immunomodulation.

MEVs are a universal delivery system; suitable for delivering innovative therapeutics, vaccines and gene therapies. MEVs can be loaded with a diversity of payloads or therapeutic modalities and administered through multiple routes; they overcome stringent biological barriers and reach difficult-to-access tissues, thus overcoming challenges faced by other delivery systems. MEVs deliver their payload in target tissues of interest, where the payload elicits its desired biological activity.

Evry, France, October 1, 2024 – AGS Therapeutics, a preclinical-stage biotech company pioneering microalgae extracellular vesicles (MEVs) as a new, universal delivery system, announced the recent publication of its **PCT International Application No. PCT/EP2024/057645 – Publication WO 2024/194423**, titled *Extracellular Vesicles from Microalgae, their Use For Vaccines and For Immunomodulation*, that follows the earlier published PCT application WO 2023/00894. The International Patent Application published on September 26, and earlier published applications, describe major aspects of MEVs, including their use for vaccination and immunomodulation.

Thanks to their rare and natural capacity to overcome certain stringent biological barriers, MEVs can be used to deliver payloads to tissues and organs that have been so far either difficult or impossible to access by current alternative systems like LNPs, viral gene therapy vectors, or mammalian EVs.

Key Findings on MEV Technology in Vaccination and Immunomodulation

1. Oral Vaccine Delivery and Immune Response: “MEVs have demonstrated that upon oral administration they can pass the gastric barrier and, once in the intestine, they are internalized by the intestinal epithelial cells, as well as by resident macrophages and dendritic cells in the GALT (Gut Associated Lymphoid Tissue)”, said Lila Drittanti, AGS’ Chief Operating Officer. Upon involvement of GALT cells, antigen-loaded MEVs elicit an immune response against the antigenic payload. The humoral response includes class switching from IgG to IgA, indicating the generation of antigen payload-specific mucosal immunity. Meanwhile, no neutralizing response to MEVs is observed when administered orally, which allows for repeat dosing. Similar characteristics of class switching from IgG to IgA are also observed with non-adjuvanted intramuscular administration (IM) of antigen-loaded MEVs.

2. Immunomodulation via MEVs: "AGS has demonstrated that ligand-loaded MEVs can be used to deliver specific ligands to endosomal TLRs (like TLR3 and TLR9 among others) in intestinal epithelial cells, and in lung cells, and, in doing so, to modulate the downstream signalling pathways of such TLRs", said Lila Drittanti. MEVs have the rare capacity to find their way to deliver their payloads in compartments accessible to buried endosomal receptors. In vivo, orally administered TLR9-ligand-loaded MEVs can be used to reverse a disease phenotype in disease-induced animal models, by modulating the profile of inflammatory/anti-inflammatory cytokines and other factors controlled by the endosomal TLR9.

"The published patent application highlights the use of MEVs for the oral and IM administration of vaccines triggering a mucosal immune response, as well as MEVs' ability to reach compartments where TLR 3, 7, 8, and 9 reside and modulate their activity", said Marie-Helene Leopold, AGS' Chief Corporate Development Officer. "This patent is foundational for our Vaccines and Immuno-Modulation Verticals, two verticals addressing multi-billion markets."

"The potential impact on public health issues, as well as the market potential, of MEVs as a delivery system that is suitable for oral and for mucosal vaccination is literally gigantic. Besides that, the ability to deliver TLR-ligands in situ by oral administration wide opens the door to therapeutic strategies aiming at the modulation of the innate immunity, and of inflammatory disorders, among others, including infectious diseases, multifactorial diseases, and cancer", said Manuel Vega, AGS' CEO.

AGS' portfolio of Intellectual Property is managed by Stephanie Seidman, at Womble Bond Dickinson, San Diego (www.womblebonddickinson.com/us/people/stephanie-seidman).

About AGS

AGS Therapeutics, based at Genopole (www.genopole.fr), Evry, France, is a biotech company pioneering the use of microalgae extracellular vesicles (MEVs) as a universal delivery system for innovative biologics, vaccines and gene therapies. AGS has shown MEVs to be a safe, targeted and highly versatile delivery system for mRNA, siRNA, DNA oligos, plasmids, proteins, and peptides relevant to a broad range of human diseases. AGS-M, the company's CDMO subsidiary, produces the MEVs needed to support R&D from AGS and from companies partnering with AGS. AGS' MEVs are derived from Chlorella, a two-billion-year-old single-cell algae, labelled by the FDA as GRAS for consumption as a food supplement. AGS' MEVs are easy to manufacture in large quantities with processes that are both eco-friendly and easily scalable. Through strategic partnerships and a commitment to scientific excellence, the company aims to challenge the delivery landscape and improve the lives of patients across the globe. For more information visit www.ags-tx.com and www.ags-m.com.

Forward looking statement

This announcement may include predictions, estimates or other information that might be considered forward-looking. While these forward-looking statements represent our current judgement on what the future holds, they are subject to risks and uncertainties that could cause actual results to differ materially. You are cautioned not to place undue reliance on these forward-looking statements, which reflect our opinions only as of the date of this communication.

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