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FOR IMMEDIATE RELEASE

AGS Therapeutics Expands Leadership Team, Appointing Dr. Kristin Luther to Drive CMC and Analytics

Dr. Kristin Luther, a Seasoned Industry Professional based in Boston, to Play a Key Role in driving AGS Therapeutics' efforts to ensure readiness of AGS's innovative technology for clinical trials.

PARIS, FRANCE, December 18, 2024 – AGS Therapeutics, a preclinical-stage biotech company pioneering Microalgae Extracellular Vesicles (MEV) as a novel, universal delivery system, announced today the appointment of Dr. Kristin Luther as an Operating Partner for Chemistry, Manufacturing, and Controls (CMC) and Analytics.

MEV manufacturing is inherently sustainable, leveraging light, fresh water, and minerals to create a process that is environmentally, and literally, green. The approach eliminates the need for toxic organic solvents or mammalian-derived materials, ensuring a simple, safe, and cost-effective process. Strikingly, MEVs are a common, general-purpose envelope that can be used with diverse payloads, formulations, and routes of administration (RoA). Thus, MEVs can be produced in bulk, quality-controlled, released, and stored for off-the-shelf use, with loading achievable at later stages.



Dr. Kristin Luther brings a wealth of first-hand experience, extensive expertise, and a proven track record in the field of extracellular vesicles. With over eight years of focused experience in biopharmaceutical CMC development, she offers in-depth knowledge of downstream processes, analytics, regulatory filings, and tech transfer to CDMOs for extracellular vesicle-based therapeutics. Dr. Luther has held key roles at leading companies, including Vesigen Therapeutics (USA), Nanoview Biosciences (USA), and Capricor Therapeutics (USA). Her contributions have played a critical role in the successful filing of Investigational New Drug (IND) applications with the FDA for extracellular vesicle-based product candidates.

“We are so excited to welcome Dr. Kristin Luther to our leadership team”, said Manuel Vega, CEO of AGS Therapeutics. “Her extensive expertise in the field, combined with her technical

and regulatory skills, will be instrumental in ensuring the highest quality of our future clinical-grade MEVs. Kristin is one of the very, very few global experts with hands-on experience in developing CMC plans and working with the FDA for extracellular vesicle-based therapeutics. Her insights will be pivotal as we prepare for AGS's first two IND filings with the FDA, planned for the next two years".

Dr. Luther expressed, "AGS's approach of using extracellular vesicles from microalgae is truly exciting, because it offers several advantages compared with other sources of EVs. In addition to being more economically and ecologically practical, the vesicles can cross biological barriers that mammalian EVs cannot, making them attractive candidates for non-invasive delivery to therapeutically relevant cell types of the eye, spleen, intestine, and brain. Notably, the lack of requirement for a fusogenic surface protein for functional delivery of cargo to recipient cells sets them apart. Combined with AGS's strong IP portfolio, these features make MEVs a recipe for success as delivery modalities for biological therapeutic entities."

Dr. Luther holds a PhD in Pharmacology from Loyola University Chicago. Her award-winning thesis and postdoctoral research at Cedars-Sinai focused on the beneficial effects and mechanisms of adult stem cell EVs on cardiac conditions. Subsequently, she worked at Capricor Therapeutics, where she developed scalable downstream processes and bioassays for their cardiosphere-derived cell EVs. She then moved to Nanoview Biosciences, gaining first-hand experience with single-particle analysis methodologies in leading academic and industry laboratories. Building on these experiences, she joined Vesigen Therapeutics as their fifth employee. Over the next four years, she built the downstream processing and analytical capabilities and supported the preclinical development of Vesigen's programs. Dr. Luther is also actively engaged with a group of scientists in the EV therapeutics industry, called Partnership for Therapeutic EVs (PTEV), to establish a consensus on best practices for demonstrating safety and efficacy for regulatory bodies such as the FDA and EMA. Additionally, PTEV offers guidance to product development teams to both streamline efforts and ensure that essential steps are not overlooked.

About AGS

AGS Therapeutics, based in Paris and 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 therapeutics, 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's 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's MEVs are easy to manufacture in large quantities with processes that are sustainable, straightforward (simple), scalable, resource-effective, and cost-effective. 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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