ExoXpert, a CDMO launched by EXO Biologics to service increasing worldwide demand for exosomes

Liege, Belgium, January 31, 2024 – EXO Biologics SA, a Belgian biotech company committed to developing biopharmaceuticals using exosomes to treat rare diseases with high unmet medical needs, today announces the worldwide launch of ExoXpert™, a contract development and manufacturing organization (CDMO) specializing in exosomes. ExoXpert offers a MSC-based exosome manufacturing platform used in European clinical trials. ExoXpert is a wholly owned subsidiary of EXO Biologics™.

During the development of its lead exosome candidate, EXOB-001, Exo Biologics developed ExoPulse™, an industrial exosome manufacturing platform designed for GMP production of exosomes. In July 2023 the European Medicines Agency (EMA) authorized the EVENEW study, a Phase 1/2 European clinical trial using EXOB-001. This is EXO Biologics' lead MSC-based exosome candidate for prevention of Bronchopulmonary Dysplasia (BPD) in preterm newborns.

ExoXpert will operate the ExoPulse platform to serve demand from exosome developers for R&D-grade exosome vials as well as GMP manufacturing capabilities.

"The potential of exosomes continues to be demonstrated across the cell and gene therapy sector. As a result, exosome-based clinical trials have the potential to significantly increase in number, if industrial supply of exosomes can be met. Currently there is a lack of exosome production, manufacturing specialists and facilities to supply exosomes for both R&D and clinical trials," **said Romain de Rauville, Chief Business Officer, EXO Biologics.** *"ExoXpert has been launched using our expertise in the development of exosome-based therapeutics to offer GMP-compliant specialist exosome manufacturing capabilities to the market. This will make a significant contribution to the industry's efforts to develop exosome-based products."*

ExoXpert has an exosome manufacturing plant with Grade A/B and C clean rooms, highly specialist staff and management. ExoXpert will utilize the ExoPulse manufacturing platform, developed by EXO Biologics. ExoPulse comprises upstream, downstream, analytical and quality-controlled processes at an industrial scale. This will provide affordable manufacturing solutions to exosome developers. ExoXpert is based in the Legiapark biotech campus in Liege, Belgium. The facility is close to European and US connections via Brussels airport.

"Challenges around producing and characterizing exosomes remain a significant barrier to the development of exosome-based therapeutics and their delivery to patients. In addition, navigating the regulatory pathways to their production is a major hinderance across the

market," **said Hugues Wallemacq, CEO, EXO Biologics.** *"EXO Biologics has now developed a regulatory-compliant GMP manufacturing platform and facility that provides a solution to biotech companies developing exosome-based therapeutics. ExoXpert is already supporting the development of products for two biotech companies and is at the center of ExoFasttrack, a major Biowin project, to create an industrial exosome ecosystem. EXO Biologics has launched ExoXpert to be a major division of the Company with the aim of contributing to the global development of exosomes."*

About EXOB-001

EXO Biologics™ has developed EXOB-001, a novel exosome-based drug candidate produced with ExoPulse™. Exosomes, also known as extracellular vesicles (or EVs), are derived from cultured human umbilical cord mesenchymal stromal cells (hMSCs). Human MSCs are characterized by their ability to secrete growth factors and cytokines that modulate the immune system and promote tissue repair and regeneration. Exosomes are nanoparticles naturally released from these cells. Exosomes are expected to be a safer therapeutic alternative to MSCs as they eliminate the risk of emboli and an immune response. Since exosomes are nuclei-free, they eliminate the risk of malignant transformation and ectopic colonization. EXO Biologics has been granted Rare Pediatric Disease Designation and Orphan Drug Designation by the FDA and ODD by EMA for EXOB-001 for the prevention of Bronchopulmonary Dysplasia (BPD) in preterm newborns.

About EVENEW

EVENEWis a multi-center adaptive, seamless Phase 1/2 trial conducted by EXO Biologics. The trial is assessing the safety and efficacy of intratracheal administration of EXOB-001 in preventing severe forms of Bronchopulmonary Dysplasia (BPD) in preterm newborns. Phase 1 is a single-arm, dose-escalating study to assess the safety of the intratracheal administration of EXOB-001, enriched with a historical nested case-control group to compare clinical outcomes for further evaluation. In this dose escalation part of the trial, a maximum of forty patients will be enrolled for up to three dose levels and two regimes. The second phase, triggered by a positive interim analysis, is a double-blind, randomized, placebo-controlled dose-finding study with efficacy evaluation of EXOB-001 on reducing BPD severity grade. Patients will be monitored up to the corrected age of two years (in hospital and outpatient).

About EXO Biologics

EXO Biologics is a clinical-stage Belgian biotechnology company specializing in the development of biopharmaceuticals using exosomes to treat rare diseases with unmet medical needs. Partnering with leading academic researchers, EXO Biologics is ideally placed to set the stage for future nanomedicines. The Company's development strategy

focuses on novel drug candidates for therapeutic applications in respiratory diseases, inflammatory bowel diseases, neurology, and oncology. EXO Biologics' lead candidate EXOB-001 is studied in a Phase 1/2 clinical trial targeting Bronchopulmonary Dysplasia (BPD) in preterm newborns.