EXO Biologics Pioneers with EVENEW Clinical Trial in Broncho Pulmonary Dysplasia.

First MSC-derived Extracellular Vesicles interventional study approved by the European Medicines Agency.

Liège, Belgium 17 July 2023 – EXO Biologics SA, a Belgian biotech company committed to developing biopharmaceuticals using Extracellular Vesicles (EVs) to treat rare diseases with high unmet medical needs, received approval from the European Medicines Agency (EMA) for the EVENEW study, enabling site activation in Europe. EVENEW is an adaptive, seamless Phase 1/2 trial assessing the safety and efficacy of intratracheal administration of EXOB-001 in preventing Bronchopulmonary Dysplasia (BPD) in preterm newborns. The EVENEW Study is the first mesenchymal stromal cell (MSC)-derived extracellular vesicles trial approved by the EMA.

> *"We are proud to be at the forefront of a paradigm shift in medicine. Our MSC-derived EVs promise to transform the treatment landscape by offering patients a non-invasive and adaptable therapeutic platform," said* ***Hugues Wallemacq****, Chief Executive Officer (CEO) of EXO Biologics. "This approval strengthens our approach. Our natural MSC-derived EVs have a wide range of possible therapeutic indications. At EXO Biologics, we are initially focusing on rare diseases with unmet medical needs, such as BPD, the most* common and severe consequence of pre-term birth."

BPD, the most common and severe consequence of preterm birth

Bronchopulmonary dysplasia (BPD) is a severe lung disease that primarily affects extremely pre-mature infants (< 28 weeks gestational age) who require prolonged oxygen therapy to support their breathing. Despite improved perinatal care in developed countries, 40% of extremely pre-term babies develop BPD, the most common and severe consequence of pre-term birth and the most common morbidity of pre-maturity.[1] BPD persists throughout life. Patients show reduced lung function and respiratory symptoms during childhood and young adulthood[2]**.** In addition, BPD patients are at higher risk of many other complications related to pre-maturity[3] and a higher risk of mortality for cardiovascular causes[4] . Consequently, the healthcare system costs are much higher during and after the perinatal period for BPD patients.

First EMA-Approved Trial in Preventing BPD

Committed to developing biopharmaceuticals using EVs to treat rare diseases with unmet medical needs, EXO Biologics received approval for the EVENEW study from EMA on 11 July 2023. EVENEW is a multi-center adaptive, seamless Phase 1/2 trial assessing the safety and efficacy of intratracheal administration of EXOB-001 in preventing severe forms of 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 40 patients will be enrolled for up to three dose levels and two regimes.

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[1] Shah PS, Sankaran K, Aziz K, Allen AC, Seshia M, Ohlsson A, et al. Outcomes of preterm infants <29 weeks gestation over a 10-year period in Canada: a cause for concern? J Perinatol. (2012) (https://pubmed.ncbi.nlm.nih.gov/21593814/)

[2] Moschino, Bonadies, and Baraldi 2021

[3] Jobe and Bancalari 2001

[4] Crump et al. 2019

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).

> *"Despite the improved perinatal care, BPD is one the most severe consequences of pre-term birth,"* said **Dr Beatrice De Vos**, Chief Medical Officer of EXO Biologics. *"Inflammatory pathways are pertinent for developing BPD, with systemic inflammation occurring before any clinical symptoms become apparent. The Study is designed to assess the safety of EXOB-001 and its effect in reducing BPD severity."*
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> "The start of an industry-leading clinical trial is a significant milestone for EXO Biologics," expressed **Dr Maurizio Muraca**, Co-Director of the Institute for Paediatric Research at the University of Padova in Italy, who was at the cutting edge of discovering EVs as intracellular communicators more than 15 years ago. And continued, *"Seeing our ground-breaking discovery evolving into a potentially lifesaving therapy is a great result of the intensive cooperation with EXO Biologics. Furthermore, the therapeutic potential of EVs as loaded cargo represents an exciting avenue to explore to benefit patients worldwide".*

Enabling GMP Scalable Production in Liège, Belgium

EXO Biologics is based in Liège, on the LégiaPark site. Since its inception, EXO Biologics has experienced remarkable growth, expanding its team to over 20 FTEs.

> *"With a shared vision, we have achieved a unique scalable production platform that addresses the challenges of industrial GMP production and harnesses the revolutionary therapeutic potential of EVs,"* said **Marcin Jurga**, Chief Scientific Officer of EXO Biologics.

With the recent EMA approval of the EVENEW study, EXO Biologics is poised to embark on a fundraising initiative to fuel its growth trajectory further. Supported by Private and Public, current and new investors, EXO Biologics will be well-positioned to further develop its unique High Scale and Low-Cost Manufacturing Platform.

> *"In tandem with our unwavering dedication, we eagerly anticipate expanding our GMP Manufacturing Platform in Liège, unlocking new possibilities for enhanced research, development, production, and ultimately, the delivery of new EV therapies. This step further solidifies our commitment to driving innovation and improving patient well-being", concluded **Hugues Wallemacq**, CEO of EXO Biologics.*

About EXOB-001

EXO Biologics has developed EXOB-001, a novel EV-based drug candidate produced with the Company's scalable manufacturing platform. Extracellular Vesicles are derived from cultured human umbilical cord mesenchymal stromal cells (hMSCs). Human MSCs are characterized by their ability to secrete various growth factors and cytokines that modulate the immune system and promote tissue repair and regeneration. EVs are nanoparticles naturally released from these cells. EVs are expected to be a safer therapeutic alternative to MSCs as they eliminate the risk of emboli and immune response. Since EVs are nuclei-free, they eliminate the risk of malignant transformation and ectopic colonization.

About EXO Biologics

EXO Biologics is a Belgian biotech company committed to developing biopharmaceuticals using EVs to treat rare diseases with unmet medical needs. Partnering with leading academic researchers, EXO Biologics aims 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.
www.exobio.be

Contact

Hugues Wallemacq – CEO
+32 499251311 - info@exobio.be