

EVERZom achieves first bioproduction of clinical grade stem cell-derived exosomes in large scale bioreactors in partnership with the French Blood Establishment (EFS) with unprecedented yields

- *The disruptive, proprietary technology developed by EVERZom offers a yield 100 times higher than traditional methods.*
- *This innovation has just been tech-transferred and validated in a GMP-grade biomanufacturing environment.*
- *This first clinical batch will enable EVERZom to initiate regulatory non-clinical studies of its first drug candidate EVERGel™.*

Paris-Créteil, October 2nd, 2024. EVERZom, a biopharmaceutical company developing exosome based biodrugs, announces that it has reached a key milestone in its development with the production of a first exosome GMP batch in a 10L bioreactor with unprecedented yields. Regulatory validation of the technology was carried out in GMP clean rooms of the Cellular Therapy and Engineering Unit of the French Blood Establishment (EFS) Ile-de-France in Créteil, a unit of reference for the bioproduction and quality control of Advanced Therapy Medicinal Product (ATMPs) and complex biologics.

'We are extremely proud to have reached this key milestone in the biomanufacturing of our first batch of GMP-quality exosomes in collaboration with the EFS Créteil platform. This will enable us to accelerate the beginning of our clinical trials. Securing biomanufacturing is an essential technological building block for the progress of our lead programme EVERGel™ for the treatment of digestive fistulas in patients suffering from Crohn's disease. With this first batch, we will carry out the regulatory non-clinical studies, scheduled for early 2025, with the objective of the first-in-human early 2026,' explains **Jeanne Volatron, CEO of EVERZom**

'We are delighted to share our expertise to EVERZom for this first production of clinical-grade exosomes at yields unmatched to date. This technology will make exosomes available to patients as a therapeutic solution, enabling us to offer new disruptive biotherapies in the years to come' explains **Prof. Hélène Rouard, Head of the ATMP platform, from the EFS Créteil.**

The growing interest in extracellular vesicles in regenerative medicine

Exosomes or extracellular vesicles are biological nanoparticles around 100 nm in size, found in all body fluids (blood, saliva, urine). They play a major role in inter-cell communication by transporting genetic information via RNA. Ten times more abundant than cells in the body, exosomes are the body's natural vectors. They are not immunogenic, have a strong capacity to penetrate cells and can be kept frozen on a long time. Thanks to these characteristics, they could revolutionize cell and gene therapies by opening the way to 'off the shelf' cell-free therapies. This is why research in this field is intensifying, with around 10,000 publications a year and numerous clinical trials confirming their safety and efficacy.

Stem cell-derived exosomes, the main focus of EVERZom's research, have the capacity to regenerate tissues in a variety of pathologies such as osteoarthritis, tissue reconstruction after myocardial infarction and liver and kidney diseases.

However, the clinical use of this new therapeutic modality is limited by the absence of a GMP-compliant bioproduction protocol and the very low yields of traditional production methods. This means very long research and preclinical testing times, as well as high costs.

EVERZOM, pioneering exosome-based therapies

Since its inception in 2019, EVERZOM has focused on developing innovative technological building blocks to make this therapeutic modality a reality for patients. The start-up developed and patented a bioproduction technology that enables reproducible, transferable and scalable production and is capable of multiplying yields by 100, thanks to mechanical stimulation of the cells based on the Kolmogorov length, backed up by a robust quality control system. Today, EVERZOM is capable of producing clinical-grade exosomes and aims to develop its pipeline of proprietary therapeutic products for regenerative medicine or in co-development. The company has already forged more than twenty research partnerships worldwide, with biotechnology companies, pharmaceutical laboratories dedicated to human or animal health, and cosmetics companies.

This industrial research program has been funded by the EIC Accelerator as part of the European Union's Horizon Europe program.

About EVERZOM

EVERZOM, a biopharmaceutical company developing exosomes based biodrugs. Exosomes are a new biological tool in regenerative medicine which are now seen as a promising alternative to cell-based therapies.

A spin-off from the CNRS and the Université de Paris Cité, EVERZOM initially developed an exclusive proprietary industrial process to produce exosomes on an industrial scale at high yield. EVERZOM's ambition today is to build on this technological innovation platform to develop its therapeutic pipeline in three key therapeutic areas: digestive tissue healing, dermatology and liver regeneration. EVERZOM has won numerous awards and programmes, including i-Lab and the prestigious EIC Accelerator, for its technological innovation platform. For more information: <http://everzom.com>

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About EFS

The Établissement français du sang is France's public blood service.

We are nearly 10,000 professionals, present at every stage of the healthcare chain, helping to treat over 1 million patients every year.

We give to blood the power to heal and are a unique and essential player in the French healthcare system.

Over the years, our establishment has built up an entire ecosystem of research and innovation. This activity gives rise to innovative therapies that we are able to develop and produce for the EFS and its partners.

For over 10 years, EFS has capitalized on its expertise in cell bioproduction to offer its know-how in clinical batch biomanufacturing, developing innovative medical processes and treatments on its 4 pharmaceutical platforms (MTI) throughout France.