

Exothera announces industrial scale AAV manufacturing collaboration with LogicBio Therapeutics and Polyplus

The project aims to demonstrate the scalability & reproducibility of Exothera's AAV production processes from small scale (1-2 L) up to 2,000L bioreactor scale.

- Exothera will lead the project at its facility in Jumet, Belgium.
- LogicBio will provide its mAAVRx™ plasmid technology and its AAV expertise for the scope of the project.
- Polyplus will provide access to innovative FectoVIR®-AAV transfection reagent along with process development expertise for large scale transient processing.

Jumet, Belgium – 15th June 2022 – Exothera SA today announced a collaboration with LogicBio® Therapeutics and Polyplus-transfection® SA. for the development of a highly scalable AAV manufacturing platform with a capacity from 200 L to 2,000 L.

Adeno-associated viruses (AAV) are non-enveloped, non-pathogenic viruses largely used as drug delivery vectors for biotherapeutics, like gene therapies and vaccines. Although the application of AAV is spreading rapidly, the industry is struggling to find cost-effective manufacturing strategies to reach clinical and commercial scales.

The collaboration among Exothera, LogicBio, and Polyplus aims to focus on the scale-up of a transient transfection-based AAV serotype 8 (AAV8) manufactured in suspension cell culture. The consortium selected the Allegro™ stirred tank Single-Use Bioreactor (from Pall) as a suspension culture device due to its scalability and single-use features. The project aims to assess reproducibility and comparability between the different scales of suspension bioreactors, up to 2,000 L bioreactor scale.

Exothera will provide state-of-the-art production space, process development expertise and access to the latest enabling technologies. LogicBio will support the initiative with its mAAVRx™ plasmid technology and its AAV expertise. Polyplus will provide transfection reagent expertise with FectoVIR®-AAV for a smooth scaled-up GMP-eligible process development.

Hanna Lesch, Chief Technology Officer at Exothera: *“Exothera’s team is proud to work with the experienced teams at biotech companies like LogicBio and Polyplus. The success of AAV-based therapeutics requires a change in the manufacturing paradigm and through this collaboration, we aim to enable a new approach to consistently scale AAV manufacturing.”*

Matthias Hebben, Global Vice President, Technology Development at LogicBio: *“We are excited to collaborate with Exothera, an emerging leader in the CDMO industry and with Polyplus, a long-time transfection partner, for implementing an AAV manufacturing process at 200L scale and above. We believe our proprietary mAAVRx™ plasmid technology could dramatically help to improve manufacturing yields and consequently reduce AAV manufacturing costs. We are hopeful that the work done under this collaboration will be an important step forward in making gene therapy products accessible for a greater number of patients.”*

Roel Gordijn, Chief commercial Officer at Polyplus: *“We are delighted to scale up AAV Viral vector Manufacturing processes to larger bioreactor volumes with innovators in the industry like Exothera and LogicBio. At Polyplus we aim to improve gene-therapy viral vector manufacturing economics by increasing titers in the upstream processes using novel transfection reagents like FectoVIR®-AAV. The collaboration will use a combination of state-of-the-art manufacturing technologies, innovative plasmid technologies and scalable transfection reagents which will make gene-therapy viral vector therapies affordable”.*

Exothera specializes in the industrialization of vaccine and gene therapy processes. It has recently performed successful viral vector manufacturing scale-up studies in adherent and suspension cell systems helping its clients to

reach the clinical trial scale. Additionally, the team is operating and continuously improving its own GMP manufacturing platform, exoREADY, for viral vector-based gene therapies and vaccine production.

About Exothera SA

Exothera is a viral vector CDMO (contract manufacturing and development organization) using standard and innovative bioproduction platforms to rapidly deliver affordable viral vector-based vaccines and cell and gene therapies. As a Univercells company, Exothera capitalizes on novel manufacturing technologies and best-in-class bioprocessing expertise to provide custom-made process optimization and GMP clinical and commercial production of viral vectors. Based on its extensive technology expertise, Exothera selects technologies to optimally answer customer needs for cost-effective and agile viral vector manufacturing and provides QC services and analytical development.

LinkedIn: <https://www.linkedin.com/company/exothera/> / Website: www.exothera.world

About LogicBio® Therapeutics

LogicBio® Therapeutics is a clinical-stage genetic medicine company pioneering genome editing and gene delivery platforms to address rare and serious diseases from infancy through adulthood. The company's genome editing platform, GeneRide®, is a new approach to precise gene insertion harnessing a cell's natural DNA repair process potentially leading to durable therapeutic protein expression levels. The company's gene delivery platform, sAAVy™, is an adeno-associated virus (AAV) capsid engineering platform designed to optimize gene delivery for treatments in a broad range of indications and tissues. The company's proprietary system, mAAVRx™, aims to overcome some of the current limitations of AAV manufacturing by optimizing the transfection process to improve yields and product quality. The company is based in Lexington, MA.

Website: www.logicbio.com

About Polyplus-transfection® SA

Polyplus-transfection® SA is a leading provider of upstream process solutions for advanced biologic and cell and gene therapy production from research to commercial grade. Leveraging more than 20 years of innovative nucleic acid transfection expertise, upstream solutions are tailored to meet strict scientific and regulatory standards from research to clinical development phases. Headquartered in Europe, and with locations in the United States, and Asia Polyplus supplies an extensive and growing, range of transfection reagents worldwide.

Website: www.polyplus-transfection.com.

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