

SK pharmteco's subsidiary Yposkesi launches AAVelocity[™], a plug-and-play Adeno-Associated Virus (AAV) platform

Designed to shorten turnaround on manufacturing AAVs, this new platform offers Cell and Gene Therapy developers more flexibility in producing viral vectors for clinical and commercial use

Evry-Courcouronnes (near Paris), France, November 7, 2023 – Yposkesi, SK pharmteco's European clinical and commercial viral vector manufacturing subsidiary for Cell and Gene Therapies (C>), today launches AAVelocityTM, a plug-and-play Adeno-Associated Virus (AAV) platform. AAVelocity is designed to bring cost and time-efficiencies to drug developers in the production of AAV gene delivery systems used to transport a gene therapy into tissue to prevent, treat or cure inherited disorders and rare diseases.

The AAVelocity plug-and-play platform can provide a 12-month turnaround on drug developer projects, lowering industry average standard bioprocessing timeframes by at least six months and helping clients save on associated costs.

Also new is AAVelocity's inherent flexibility. This enables bioproduction teams to easily adapt to client requirements, such as achieving different purity levels within strict time constraints. It includes delivering AAVs containing the optimized amount of genetic material. AAVelocity's agility also avoids intermediary steps or the addition of others, while ensuring total integrity and purity of the genetic material.

The improved efficacy of AAVelocity will bring greater benefits to drug developers and their pipelines, according to SK pharmteco. Using single-use bioreactors, the AAV platform is scalable to meet any client need: $10L > 50L > 200L > 2 \times 200L > 1000L$.

"SK pharmteco, through Yposkesi, is pleased to launch a second platform for viral vector manufacturing with enhanced plug-and-play capabilities. Leveraging Yposkesi's many years of expertise, SK pharmteco is able to offer a genuine cost and time-effective solution for AAV manufacturing to stay in step with the increasing development and approvals of C> treatments we are witnessing today, which are set to evolve in the near future," said Alain Lamproye, Yposkesi division head. "AAVelocity will bring tangible benefits to the C> market: high yields, scalability, robustness, consistency and flexibility like no other. Clients can also benefit considerably from Yposkesi's strong track record in AAV manufacturing and its experience of participating in filing six IND¹/IMPD of AAV-based products since 2017."

The strengthening of AAV manufacturing at its subsidiary aligns with SK pharmteco's positioning to meet the growing demand.

¹ Investigational New Drug/Investigational Medicinal Product Dossier

According to the Nice Insight report 'Cell and Gene Therapy: 2023 Market Analysis, CDMO Pricing and Benchmarking': "AAV-based therapies are set for greater approval number and approval of treatments for more prevalent diseases," making it the most represented viral vector within those therapies starting in 2025. By 2028: "Sales of AAV-associated cell and gene therapies are projected to be 72% higher than LV-based therapies."

AAVelocity key features:

- High yields: 3x10¹⁰ VG/mL up to 2x10¹¹ VG/mL
- Scalable from 250ml for R&D, up to 1,000L for cGMP batches
- Robustness: No loss of titer when scaling-up
- Enriched: >80% full particles

<u>Further capabilities</u>, including plasmid manufacturing, process development, GMP vector manufacturing suites, integrated testing & analytics, regulatory services and an <u>adherent AAV</u> <u>manufacturing platform</u>, are available at the Center for Breakthrough Medicines (CBM), SK pharmteco's US clinical and commercial viral vector manufacturing subsidiary for C>.

About Yposkesi

Yposkesi is SK pharmteco's European clinical and commercial viral vector manufacturing subsidiary for Cell and Gene Therapies (C>). Located in the south of Paris, France, Yposkesi is one of Europe's largest CDMOs for viral vector manufacturing in Cell and Gene Therapies.

Now unified with the Center for Breakthrough Medicines (CBM) in the Philadelphia region, USA, Yposkesi and CBM offer a full range of services throughout the entire advanced therapy process, from research and development to manufacturing and commercialization. With locations in Europe and the US, together they operate multiple manufacturing suites for bulk drug substances and fill and finish to support the growing demand for late-phase projects.

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