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Yposkesi

The annual listing of 10 companies that are at the forefront of providing Virology solutions and transforming businesses

Yposkesi

Pushing the Boundaries of Gene Therapy


Alain Lamproye

Over half a year into the pandemic crisis, the pharma industry is still working overtime to develop an effective vaccine to counter the COVID-19 virus. Meanwhile, work continues apace to bring the next generation of advanced therapeutic medicinal products (ATMPs) through clinical evaluation and on to patients. On this front, Yposkesi, a leading contract development manufacturing organisation (CDMO), is aptly positioned through one of the largest adeno-associated virus (AAV) vector and lentiviral vector production capacities in Europe, which are widely leveraged for the development of gene therapies for orphan genetic diseases.

"Our proven expertise in developing gene- and cell-therapies is playing a critical role in the current ATMP development scene," says Alain Lamproye, Executive Chairman of Yposkesi.

Yposkesi is backed by over 30 years of gene-therapy expertise from Genethon, a pioneer in the development of gene therapy products. Therefore, Yposkesi's access to some of the best research experts and technological resources places it at a level above other CMOs and CDMOs in the U.S. and Europe. The company facilitates continuous innovation and improvement in gene therapy, ensuring that its clients receive a level of quality and performance that exceeds their expectations.

Lamproye notes that today, gene therapy products demand a high dose of viral vectors for therapeutic indications. But for most CMOs, the technology isn't advanced enough to reliably deliver on this. When time is of the essence, this manufacturing bottleneck can throw a wrench in the clients' development processes and timelines. Yposkesi utilises cutting-edge technology to produce the viral vectors capable of delivering the high performance required by pharma companies. The company supports efficient process development and production scale-up, thanks to its cGMP compliant facility and skilled workforce.

In fact, Yposkesi's cGMP grade facility is one of the largest in Europe, and has made the company a leading player for adeno-associated virus (AAV) and lentiviral vector production in the continental gene therapy scene. The company utilises a unique suspension process for lentivirus production, which is being used for the therapeutic treatment of indications like immunodeficiencies and cancer in patients.

A case in point is the selection of Yposkesi to produce large-scale and commercial AAV micro-dystrophin material for the treatment of muscular dystrophy. The co-development program, led by Genethon and Sarepta Therapeutics, has already shown significant efficacy during the pre-clinical testing. In the next stage of development, to produce clinical and large-scale commercial batches, Yposkesi will play a critical role, using its proprietary suspension process using distinct producer clones and a specific transfection agent. The company, through its extensive manufacturing facility, will streamline the entire production process, thus enabling the clients to reach their milestones on time.

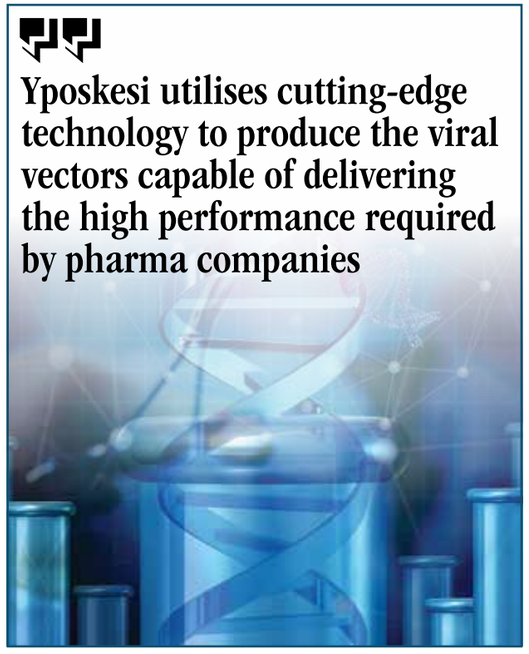
And most notably, not just for this program, but the proprietary suspension process of Yposkesi is enabling gene therapy clients across entire Europe and US to push their boundaries in gene therapy development. Especially, Yposkesi's lentivirus process is currently being used for engineering the chimeric antigen receptor-modified T (CAR-T) cells, which are used in immunotherapy as well as the treatment of cancer. "Lentivirus and AAV represent up to 70 percent of the total clinical pipeline, and will continue to do so for the next 10years," mentions Lamproye.

Extending a Helping Hand for Clients

During the production of lentivirus and AAV vectors for its clients, Yposkesi provides full professional support from the early stages of process development to the delivery of the final product, including a full suite of services for the rapid, successful development of advanced therapy medicinal products (ATMPs). Yposkesi is fully equipped to handle process development—from small scale process evaluation to full-scale feasibility batches of ATMPs in the pilot lab. The process development team of the company performs process and optimisation studies at a scale of up to 10 litres in bioreactors. For industrial development, Yposkesi transfers final processes to its cGMP grade facility, where scale-up experiments can be performed up to 200 litres in a single-use bioreactor or 24-cell factory for adherent cells. More than forty GMP batches of AAV and an equivalent amount of LV have been produced to date. In every step of the way, from innovation and development to production, Yposkesi ensures that the processes are subject to the highest quality standards.

The full range of post-production services, ranging from analytical development to quality assurance (QA) and regulatory support offered by the company, eliminates the need for clients to deal with multiple subcontractors. Yposkesi's project management team coordinates all the activities on-site and facilitates on-time delivery as per manufacturing contracts. The team also ensures that the projects are well within budget. Thus, the clients have one single point of contact throughout the production process.

> **Yposkesi utilises cutting-edge technology to produce the viral vectors capable of delivering the high performance required by pharma companies**



Today, such client-friendly collaborations, powered by its cutting-edge cGMP grade facility and highly-skilled workforce, have firmly cemented Yposkesi's footing in the European CDMO landscape. The company is continuously innovating and reinventing its techniques to improve process robustness and scalability according to the evolving needs of the customers. Yposkesi is preparing to double its global footprint to 100,000 square meters with another large-scale facility for commercial production with EMA and FDA compliance. "Our investments in innovation and bioprocessing are aimed at augmenting the capabilities and speed-to-market of gene therapy developers and delivering high-quality projects at cost-effective rates," concludes Lamproye.