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ASIA EDITION

GMP certification for Exothera further extends its viral vector manufacturing capacity

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Exothera S.A., a CDMO specialized in the development and manufacture of viral vectors for vaccines and gene therapies, received Good Manufacturing Practices (GMP) certification from the Federal Agency for Medicines and Health Products (FAMHP) for its facilities in Jumet, Belgium. This accreditation follows a series of successful inspections ensuring that Exothera can manufacture biopharmaceutical products according to the highest quality standards. This will enable Exothera to extend its services to more customers, supporting biopharma companies from the early development of biotherapeutic candidate to full scale manufacture.

Exothera was founded in 2020 to help tackle two of the most critical challenges manufacturers face in bringing advanced therapies to market: a lack of production capacity and scarcity of bioprocessing expertise. Specific viral vector bioprocessing expertise is key to addressing the more complex manufacturing processes required for cell and gene therapy manufacture. These challenges have been keeping costs unnecessarily high and slowing the development and delivery of ground-breaking therapies from reaching those who need them most.

Initial operations began at two sites located in Nivelles and Gosselies while renovation and construction of new offices and large process development and production areas took place in two buildings on the Univercells campus in Jumet. These facilities now provide a combined area of 8,600 m² (92,570 ft²). Exothera together with Univercells' team and selected partners has built one of Europe's largest state-of-the-art facilities with a GMP qualified manufacturing area totaling 2,100 m² (22,600 ft²) in just 18 months. The facility includes 5 upstream grade C clean rooms with several bioreactor technologies for adherent and suspension cell culture. The bioreactors can go up to 2 x 2,000L for the suspension platform and 2 x 600m² (2 x 6,450 ft²) for the adherence platform giving clients great flexibility and choice.

In parallel, the company continued to expand its expert team recruiting candidates with extensive knowledge of viral vectors, like Hanna Lesch who joined as Chief Technology Officer in October 2021. Exothera currently has 140 experts who can work hand-in-hand with manufacturers to rapidly develop and bring affordable treatments for patients to market.

Exothera has already worked on more than 28 projects for clients in the EU and US and has the space available to develop a further 9,000 m^2 (96,900 ft^2) on the Jumet campus plus other greenfield options. The company is also considering options to grow internationally depending on client needs.

"This GMP accreditation for our facility extension is the cornerstone of everything we have been building since the beginning. We are extremely proud of the amazing work done by all the teams," says Exothera's CEO Thibault Jonckheere. *"It will not only allow us to welcome new customers whose products are in early development stage but will also allow all of our existing partners to meet their large scale manufacturing needs".*

The addition of more manufacturing capacity is an important step to alleviate some of the current constraints in the industry. The pressure to develop and manufacture billions of vaccines, together with an expected 30+ new drug approvals by the FDA in the next year will put immense pressure on the global manufacturing capacity*. Exothera hopes to play a significant role in addressing some of these capacity needs by offering well-equipped facilities with the right technology and team that can rise to the challenge.

Exothera has demonstrated that it can accelerate the development of its own site, completing the build in record time. Its ambition is to create a new class of CDMO that will transform the time it takes customers to deliver their therapy so that life-changing therapies can be available to all patients who need them quickly.