

CombiGene signs production agreement with Spanish gene therapy manufacturer Viralgen

After having carried out a successful pilot production of CGO1 in July at the Spanish gene therapy manufacturer Viralgen, CombiGene AB (publ) and Viralgen have today signed an agreement for the production of CGO1. CombiGene's reason for choosing Viralgen as a partner is that the company can offer a suspension-based production method based on AskBio's Pro10™ platform. The suspension technology makes it possible to produce large scales and drive the development of CGO1 faster and at a lower cost than would otherwise be the case. CGO1 is being developed for the treatment of patients with drug-resistant focal epilepsy.

Like many other early stage gene therapy companies, CombiGene has until today used an adherent production method. This method has served the company well during the early development phases, which only require smaller volumes of the drug candidate. However, scaling up an adherent production method is both costly and time-consuming and cannot be done on a large enough scale to efficiently supply programs like CombiGene's. By working with Viralgen and their platform suspension method, CombiGene can use a single process to produce materials for the CGO1 project's final preclinical studies, future clinical studies and future commercial supply.



"I am very pleased that CombiGene and Viralgen have now signed an agreement for the production of CGO1. The fact that CombiGene will use a suspension method for the production of CGO1 means that we will be able to keep a faster pace in the further development of the project. At the same time, CombiGene

has now a production method that is suitable also for scaling up for future commercial production for the treatment of patients with drug-resistant focal epilepsy", says Jan Nilsson, CEO of CombiGene.



"We are very excited about this collaboration. Our production platform will bring great value to CombiGene's development in epilepsy by allowing fast, large-scale development from preclinical, clinical and all the way into commercial" Javier Garcia, Viralgen's CEO, quoted.

For CombiGene's other suppliers, CGT Catapult and Cobra Biologics, CombiGene's new agreement with Viralgen means the following:

- The cooperation with CGT Catapult on the development of an adherent production method continues with respect to the development of analytical methods that will ensure the quality of production. This work is expected to provide final analytical methods during the month of September this year.
- The collaboration with Cobra Biologics regarding the production of plasmids will continue as before.

"I would like to also take this opportunity to thank our partner CGT Catapult for the development of the important analytical methods that will be used as quality control in the production of CGO1. It is also safe to have a solid and professional partner in Cobra who will continue to be our supplier of plasmids", says Jan Nilsson, CEO of CombiGene.

This information is information that CombiGene is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at september 3 2020, at 10.00.

PRESS RELEASE

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About CombiGene AB

www.combigene.com

CombiGene's vision is to offer patients affected by severe life-changing diseases opportunities for a better life through innovative gene therapies.

CombiGene's business concept is to develop effective gene therapies for serious diseases that today lack adequate treatment methods. Research assets are taken in from a network of external researchers and developed further up to clinical concept verification. Drug candidates for common diseases will be co-developed and commercialized through strategic partnerships, while CombiGene may drive the development and commercialization in-house for medicines aimed at limited patient populations.

The company is public and listed on the Nasdaq First North Growth Market and the company's Certified Advisor is FNCA Sweden AB, +46 (0)852 80 03 99, info@fnca.se.

About Viralgen

Viralgen is a CDMO born as a joint venture between AskBio and Columbus Venture Partners, combining decades of technology and drug development experience in multiple platforms to support best-in-class service offerings to the gene therapy market.

Viralgen was created in 2017 to respond to the unmet need for manufacturing of gene therapies, with the goal to help broaden access to these life-saving therapeutics and to contribute to the advancement of health and human welfare around the world. We specialize in the production of rAAV viral vectors, and have built an optimized facility in San Sebastian, Spain that maximizes throughput and efficiency of our proprietary Pro10™ suspension manufacturing platform, enabling industry-leading scalability, reproducibility, and speed to market.

Through our superior technology platform, we deliver industry-leading titers and cGMP-certified quality for all AAV serotypes to our client partners, optimize the cost-of-goods, and accelerate clinical development and commercialization of life-saving genetic medicines.

Viralgen new commercial facility will be in production by the end of 2021 in San Sebastian (Spain).

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