PRESS RELEASE
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CombiGene has completed a successful pilot production of CG01 using Viralgen's suspension manufacturing platform

CombiGene AB (publ) has recently completed a successful pilot production of CG01 together with Viralgen. The data supports a commercially viable manufacturing strategy using the Pro10 platform. Viralgen's proprietary suspension recombinant AAV (rAAV) production platform is based on a technology developed by AskBio that has recently been made available via Viralgen and their cGMP facility. The process based on the Pro10TM cell line enables a very cost-effective way to scale up production volumes from small volumes intended for research and development to full-scale commercial volumes of GMP quality. CG01 is developed for the treatment of patients with drug-resistant focal epilepsy.

Large-scale production of gene therapeutic drugs was for a long time a challenge for the entire industry. Existing production methods, relying on adherent production, have been excellent for producing small volumes of gene therapeutic drugs, but have inherent and significant difficulties in scaling up production volume. For CombiGene´s drug candidate CG01, this posed particular difficulties as it is developed for a significant patient population compared to many other gene therapies. The company estimates that nearly 10,000 patients annually will be candidates for treatment with CG01.

The Spanish company Viralgen, whose production platform for AAV is based on AskBio's Pro10TM production method, established a manufacturing facility in San Sebastian which received cGMP certification for manufacturing of AAV in 2019. The manufacturing process is based on a suspension platform that proved to be a technology that is very well suited for scaling up from small research volumes to large commercial volumes with GMP quality. The outcome of the pilot study that CombiGene has now conducted together with Viralgen is very positive. The data supports a commercially viable manufacturing strategy using the Pro10 platform.

CombiGene will now evaluate all aspects of the pilot study before the company makes a final decision on if the production method should be switched already now to suspension production.

Karin Agerman, Chief Research and Development Officer, CombiGene: *"The data is very exciting and opens up the possibility for a scalable manufacturing strategy all the way through to a commercial production already at this early stage in development."*

"We are very excited about this collaboration with CombiGene and we are committed to their success. Our production platform brings great value to our customers by allowing fast, large-scale development from preclinical, clinical to commercial gene therapy products. CombiGene's work in epilepsy brings great hope for patients suffering from this disease" Javier Garcia, Viralgen´s CEO, quoted.

CombiGene's lead project CG01 has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 823282

www.combigene.com
CombiGene AB (publ) Medicon Village, SE-223 81 Lund, Sweden
info@combigene.com

About CombiGene AB

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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).

For further information:

CombiGene AB (publ)
Bert Junno, Chairman of the board
Phone: +46 (0)707 77 22 09
bert.junno@combigene.com

Jan Nilsson, CEO
Phone: +46 (0)704 66 31 63
jan.nilsson@combigene.com

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