PRESS RELEASE
Lund, September 28 2020

CombiGene launches large-scale production of CG01 for upcoming safety and biodistribution studies

In early September, CombiGene signed an agreement regarding production of CG01 with the Spanish gene therapy manufacturer Viralgen. The plasmids included in the production of CG01 have been delivered by Cobra Biologics and all necessary quality analyses, developed by CGT Catapult, have been integrated into the production process, and Viralgen will now begin the first large-scale production of CG01.

There are two purposes with this first large-scale production. The first purpose is to test all parts of the production process under completely realistic conditions to identify any need for alterations. The production can thus be seen as a dress rehearsal for the upcoming cGMP production (Current Good Manufacturing Practice) when CG01 will be produced for studies in humans. The second aim is to produce material for the preclinical safety and biodistribution studies planned to be conducted in 2021.

When this first production of CG01 is completed, a comprehensive quality and documentation review will take place.

"The fact that we can now carry out large-scale production of CG01 is a significant milestone in this project," says Karin Agerman, Chief Research and Development Officer. *"Once all the quality work related to production has been completed, we are ready to begin the safety and biodistribution studies, which is the next big step in the CG01 project."*

About CG01

CG01 is a gene therapy developed to treat drug-resistant focal epilepsy. Every year, approximately 47,000 drug-resistant patients with this type of epilepsy are estimated to be added in the United States, EU5, Japan and China. CombiGene believes that it is realistic that 10-20 percent of these patients could be treated with the company's gene therapy. The global market for the drug candidate CG01 is estimated at USD 750 –1 500 million annually.

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

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About CombiGene

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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

www.viralgenvc.com

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. The company specializes in the production of rAAV viral vectors, and has built an optimized facility in San Sebastian, Spain that maximizes throughput and efficiency of the proprietary Pro10™ suspension manufacturing platform, enabling industry-leading scalability, reproducibility, and speed to market.

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

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

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