PRESS RELEASE
Lund, November 25 2020

CombiGene, together with gene therapy manufacturer Viralgen, has successfully completed the first large-scale production of CG01

CombiGene, together with the Spanish gene therapy manufacturer Viralgen, has successfully completed the first large-scale production of the gene therapeutic drug candidate CG01, which is developed for the treatment of drug-resistant focal epilepsy. CombiGene will now, together with Viralgen, carry out extensive quality analyses of the produced material to meet all aspects of the requirements that the pharmaceutical authorities will impose on future production of materials intended for clinical studies. This work is expected to be completed sometime around the turn of the year of 2020/2021.

Final preclinical studies in 2021
When the comprehensive quality analyses are completed, the produced material will be used to conduct the CG01 project's final preclinical studies, including the important biodistribution and safety studies. These studies will be conducted by CombiGene's American CRO partner NBR.

Clinical studies 2022
Once the final preclinical studies have been conducted and analysed with documented positive results, CombiGene will be ready to apply for approval to start the first study in humans, a so-called clinical study. CombiGene is currently working with interested clinics and doctors to design the first clinical study. CombiGene also plans to present its plan for the study to the Swedish regulatory agency Läkemedelsverket and British MHRA (Medicines & Healthcare Products Regulatory Agency) in the final quarter of 2020.

The CG01 project has high commercial potential
Unlike many gene therapies, which are developed for the treatment of rare diseases, CG01 caters to a large population of patients. Epilepsy is a major global problem. Every year, approximately 47,000 drug-resistant patients with focal epilepsy are estimated to be added in the US, EU4 + UK, Japan and China. CombiGene believes that it is realistic that 10-20% of these patients could be treated with the drug candidate CG01.

Assuming, for example, that the therapy cost per patient is somewhere between $134,000 and $200,000 (which compared to approved gene therapy drugs is low), it provides sales between $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

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

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 have 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 a superior technology platform, Viralgen 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´s new commercial facility will be in production by the end of 2021 in San Sebastian (Spain).

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