Press release
July 26, 2021

CombiGene initiates GMP production of CG01 for the first-in-human study

CombiGene, in collaboration with its manufacturing partner, the leading AAV gene therapy contract manufacturer Viralgen, has today started GMP production of the drug candidate CG01, a gene therapy developed for the treatment of drug-resistant focal epilepsy.

GMP production of CG01 begins as planned after the recent release of the GMP plasmids that make up the starting material for the production of CG01 by CombiGene's plasmid producer Cobra Biologics.

The CG01 material is now produced on a large scale for use in the first clinical study with CG01. The produced material will be analyzed from all relevant aspects and data from the analyses will form a central part of the upcoming Clinical Trial Application (CTA). The material will then be used in CG01's first clinical study, which is scheduled for the second half of 2022.

"The fact that CombiGene is now starting GMP production of CG01 in collaboration with Viralgen means that this important project now achieves another value-creating milestone and takes a big step closer to the first-in-human study," says Jan Nilsson, CEO of CombiGene.

"We are excited to continue to build our relationship with CombiGene and support their progress towards clinical studies with this important next step in their first clinical program", said Javier Garcia, CEO of Viralgen.

About CG01

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.

Horizon 2020

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

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

About CombiGene AB

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

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. 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 more information:

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

Bert Junno, Chairman of the Board
Tel: +46(0) 70 7 77 22 09
bert.junno@combigene.com

Please read INGENEIOUS, a newsletter from CombiGene which contains general news and information that is judged not to have a significant effect on the share price. INGENEIOUS and press releases are available at www. combigene.com