Press release
June 23, 2021

CG01-GMP plasmids released
Ready to start GMP production of CG01

Lund, Sweden and Keele, United Kingdom, 23 June 2021

Cobra Biologics (Cobra), the gene therapy division of Cognate BioServices, a Charles River Laboratories International, Inc. company and CombiGene AB (publ) (CombiGene), the leading gene therapy company in the Nordic region, today announce that they have successfully completed the production and quality assurance of the plasmids to be used in the GMP production of CG01, for CombiGene's gene therapy for the treatment of drug-resistant focal epilepsy.

The now released GMP plasmids were produced by Cobra in January/February this year. The material has since been quality assured through a variety of analyses. These analyses are now complete, and the plasmids have been released at Cobra and are ready to be used as starting material for the GMP batch that will be used in the first clinical study scheduled to begin in 2022. The analyzed plasmids are now part of a stability study, which is required for the company's upcoming Clinical Trial Application, CTA. The plasmid production itself was very successful and generated so much material that, according to current estimates, it will be enough for more productions of CG01 than originally planned.

“The release of the plasmids produced by Cobra means that we will be able to start GMP production of CG01 later this year. In doing so, we are taking another important step towards the first in human study that we plan to start in 2022”, says Jan Nilsson, CEO of CombiGene.

Mike Austin, Corporate Vice President, Global Operations Cell and Gene Therapy CDMO, Charles River, comments: “We are pleased to continue the journey with CombiGene and the release of the GMP plasmids represents a crucial step in the production of CG01. We have a well-established plasmid production platform and in-house expertise in quality control that will ensure the delivery of GMP quality plasmid.”

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 programme under grant agreement No 823282

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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 Cobra Biologics

www.cobrabio.com
Cobra Biologics, the gene therapy division of Cognate BioServices, a Charles River company, is a leading international contract development and manufacturing organisation (CDMO) providing the highest quality development and manufacturing services for the cell and gene therapy fields, ranging from early stage development and pre-clinical services to clinical and commercial supply. Cobra and Cognate service an international customer base from its manufacturing and development facilities in the UK, Sweden, and the US.

Each of the Company's GMP approved facilities are tailored to serving our customers around the world. We offer a broad range of integrated and stand-alone contract development and manufacturing services for the clinical trial and the commercial markets.

As a trusted provider and a key partner in the drug development and commercialisation process, we take pride in our manufacturing excellence and comprehensive range of services to the pharmaceutical and biotech industries.

For more information:

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