

# CombiGene and Cobra Biologics sign agreement to secure GMP production of plasmids for production of CombiGene's gene therapy CG01

The agreement is part of preparations for GMP production of material for the first clinical study of CG01

#### Lund, Sweden and Keele, UK, 10 September 2020:

Cobra Biologics (Cobra), part of the Cognate BioServices family, an international CDMO manufacturer of biological materials and pharmaceuticals, and CombiGene AB (publ) (CombiGene), the leading gene therapy company in the Nordic region, today announced that they have signed agreements covering Good Manufacturing Practice (GMP) production of two essential plasmids needed for the manufacture of CGO1, a gene therapy designed for the treatment of drug resistant focal epilepsy.

The GMP production of two essential plasmids, derived from master cell banks, represents a crucial development in the production of CGo1 for the first clinical study. Increasing production of plasmids to large scale and according to GMP requires management of the scale-up process to ensure plasmids are of therapeutic-grade quality. Cobra's long-established plasmid production platform along with in-house expertise will ensure high quality plasmids are produced for CGo1.

The agreement follows the recent announcement that Cobra had successfully completed production of the GMP master cell banks to produce the plasmids used as starting material for CombinGene's gene therapy vector, CGo1.



#### Jan Nilsson, CEO, CombiGene:

"The fact that CombiGene has now signed an agreement with Cobra regarding the production of two plasmids is very positive as we thus secure access to crucial components for the production of CGo1. Cobra has

consistently delivered in terms of both time and quality and it is therefore very satisfactory that they will now be responsible for the production of this important part in the production of CG01. Through this agreement with Cobra, we are taking another step closer to clinical studies."



# Peter Coleman, Chief Executive, Cobra Biologics:

"We are excited to continue the journey with CombiGene and this agreement is the next big 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**

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 drug candidate CG01 is estimated at USD 750 –1500 million annually.

#### PRESS RELEASE

Lund, September 10th 2020



#### About CombiGene AB

#### 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 codeveloped 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, together with its parent company Cognate BioServices, 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.

Cobra is supported by leading shareholder EW Healthcare Partners, as well as Medivate Partners, Blackrock, and a Middle Eastern Sovereign Wealth Fund, who continue supporting the business and its expansion activities.

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