



## PRESS RELEASE

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# High activity level in the pain program COZY in preparation of the final preclinical toxicology program

**Since the beginning of 2023, CombiGene and the Danish company Zyneyro have jointly developed the pain program COZY. The goal is to develop an effective treatment for severe chronic pain, a common and often difficult to treat condition. The program consists of two projects – a peptide treatment (COZY01) and a gene therapy treatment (COZY02), both of which are based on a new mechanism of action for pain-relieving treatment.**

Both the peptide and the gene therapy are being developed for treatment of severe chronic pain conditions, the gene therapy is reserved for patients where the possibility of spontaneous reduction of chronic pain is judged to be limited (or unlikely). The peptide-based therapy is expected to be ready for human studies within a few years, while the gene therapy will need a few more years to reach the same point in its development.

### **Selection of partner for COZY01's pivotal preclinical toxicology program**

Since the collaboration with Zyneyro began at the beginning of the year, the level of activity has been high. After the companies' first joint steering group meeting, work has intensified regarding preparations for the pivotal preclinical toxicology program in the peptide project COZY01. The preparations include, among other things, the ongoing selection of the company that will produce the material for the pivotal preclinical toxicology program and the company that will conduct the toxicology program. Choosing the right partners is an extensive task that has long-term and important consequences.

### **Early interest from NIH**

An independent evaluation of the potential of COZY01 as a future pain treatment is ongoing at the National Institutes of Health (NIH) in the US, in a government-funded program (Preclinical Screening Platform for Pain, PSPP) aimed at finding non-opioid-based pain relief options that are not addictive or result in tolerance development. COZY01 has undergone the first level of three and has been selected to move on to the next level where the substance will be tested in different pain models as well as for any disturbances in behavior and motor activity. During the first quarter of the year, CombiGene and Zyneyro worked on preparatory activities for the next level.

“The fact that COZY01 has already been recognized by the NIH is of course extremely encouraging and points to the great need for new forms of pain relief. COZY01 has passed the first of three levels in the PSPP program and has moved on to the next level where the substance will be tested in different pain models and possible neurological side effects. It is also very gratifying to note that CombiGene and Zyneyro have quickly established a very good collaboration and that the pace of the project is now high and focused on the upcoming pivotal preclinical toxicology program,” says CombiGene's CEO Jan Nilsson.

### **About the pain program COZY**

Chronic pain can be devastating for those affected. The disease also leads to enormous costs for society. Between six and eight percent of the adult population is estimated to suffer from severe chronic pain, and the societal costs of chronic pain are estimated at USD 635 billion annually in the US alone.<sup>1</sup>

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<sup>1</sup> Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.

Appendix C. The Economic Cost of Pain in the US. Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Washington (DC): National Academies Press (US); 2011



Conventional treatment consists mainly of anti-inflammatory drugs, antidepressants, anticonvulsant drugs and opioids (a group of substances with a morphine-like mechanism of action).

The problem with these treatments is that they are not specifically developed to treat chronic pain. The pain relief that is achieved therefore often has a number of debilitating side effects such as substance abuse problems, depression, anxiety, fatigue, reduced physical and mental ability.

The COZY program is being developed to address these enormous challenges by offering effective pain relief without the problems that today's drugs can bring.

### **About Zyneyro ApS**

Zyneyro was founded by a group of researchers from the Department of Neuroscience at the University of Copenhagen and a group of entrepreneurs who together have extensive experience in all aspects of early drug development and entrepreneurship. The company's researchers have worked for more than 15 years to understand the ability of the brain and nervous system to adapt to the influence of the surrounding environment. Zyneyro's goal is to translate this knowledge of modulation of neuronal interaction into developing a number of drug candidates. The drug candidates included in the collaboration with CombiGene relate to the treatment of pain. Zyneyro also intends to develop other drug candidates for indications other than pain.

### **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 preclinical/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 has an exclusive collaboration and license agreement with Spark Therapeutics for the CG01 project and a collaboration agreement with the Danish company Zyneyro within the pain program COZY.

The company is public and listed on the Nasdaq First North Growth Market and the company's Certified Advisor is FNCA Sweden AB, [info@fnca.se](mailto:info@fnca.se).

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