



PRESS RELEASE

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Vinnova supports the formation of a Nordic CCRM hub CombiGene to play an integral part in the development of a national infrastructure for ATMPs

Vinnova, Sweden’s Innovation Agency, has granted funding to establish a national cluster for commercialization of advanced therapies. The Centre for Commercialization of Regenerative Medicine (CCRM) Nordic will be located at GoCo Health Innovation City in Mölndal. CCRM Nordic is backed by an industry consortium including CombiGene that will contribute to establishing the center as an organization with specialized infrastructure and expertise focused on Advanced Therapy Medicinal Product (ATMP) development, based on the successful CCRM model founded in Toronto, Canada. The project is being coordinated by the recently formed not-for-profit CCRM Nordic AB (svb) and gathers engaged stakeholders to move the initiative forward.

“At CombiGene, we are delighted to be part of the consortium to work on a CCRM hub for Sweden and neighboring countries. ATMP products are complex both to develop and manufacture, and the field will benefit enormously from the collaboration opportunities the Nordic CCRM hub will offer. It makes the entire CombiGene team really proud to be part of this very important initiative alongside prominent colleagues such as AstraZeneca, Cytiva, Getinge, GoCo Health Innovation City, Takara Bio Europe, Tataa Biocenter and Verigraft,” says Jan Nilsson, CEO at CombiGene, and newly elected Chairman of the Board of CCRM Nordic AB.

ATMP is the European Medicines Agency (EMA) classification of cell and gene therapy drugs, and tissue engineered drugs. These products must be produced to Good Manufacturing Practice (GMP) standards and complete clinical trials before applying for market approval and becoming available to patients. Organizations like Canada’s CCRM ensure ATMPs are manufactured and controlled according to the required quality standards, strengthening the chances these novel therapeutics will make it to patients.

“A lot is happening within the ATMP field both nationally and internationally and I’m therefore very excited about the opportunity to manage the CCRM Nordic initiative from the establishment phase and onwards,” says Fredrik Wessberg, CCRM Nordic CEO. “It is inspiring to see such great interest from developers and industry who are part of this consortium.” Mr. Wessberg has a background in stem cell science, GMP production and scientific services in the pharma industry.

CCRM Nordic will be established as a new entity with national infrastructure for development, manufacturing and commercialization of ATMPs, and will be accessible by stakeholders from academia, industry and the health-care sector. The initiative has strong support from industry with major Swedish ATMP organizations such as AstraZeneca, CombiGene, Cytiva, Getinge, Takara Bio Europe, TATAA Biocenter and Verigraft as well as local innovation actors such as GoCo Health Innovation City and GU Ventures. As host, GoCo will construct a purpose-built facility that is expected to be operational in 2026 and will provide temporary offices and labs until then.

The CCRM Nordic hub answers to the assignment from the Swedish government to establish a hub for commercialization of ATMPs and will complement and collaborate with previous public-private partnerships such as Testa Center and the innovation hub located at NorthX Biologics. The assignment springs from the Vinnova financed vision-driven Innovation Milieu 2030, focused on making “Sweden a world leader in development and implementation of advanced therapies by 2030” and is intended to accelerate the focus on increased capacity for industrial development and manufacture of ATMPs in Sweden. The initiative has also been supported by the strategic innovation program for health and life



science Swelife and Västra Götalandsregionen. The project grant will be coordinated by Jim Lund who have been deeply involved in the preparatory work for CCRM Nordic. Over the long term, CCRM Nordic will lay the foundation for a prosperous Nordic ATMP industry that will transform the excellent research within the area into products that could change the lives of patients worldwide.

About CCRM Nordic

CCRM Nordic is a not-for-profit infrastructure for commercialization of advanced therapies based on the Canadian model and formed as a public private partnership backed by an industry consortium and the Swedish Innovation agency Vinnova. CCRM Nordic will accelerate commercialization of ATMPs and related technologies by providing specialized expertise and infrastructure. Our ambition is to collaborate with our Nordic neighbors as well as being part of the CCRM Global international networks of hubs. CCRM Global is an alliance of international hubs operating to coordinate and optimize opportunities in the field of cell and gene therapies and regenerative medicine-based technologies. The CCRM Nordic Board of Director members are starting with chair: Jan Nilsson, CombiGene; Lennart Johansson, Investor/Patricia Industries; Catarina Flyborg, Cytiva; Regina Fritsche Danielson, AZ; Carl-Peter Mattsson, GU Ventures, Michael May, CCRM. Visit us at ccrmnordic.se.

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.

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