

Vinnova supports the formation of a Nordic CCRM hub

May 24, 2023 (Gothenburg, Sweden) – 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 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.

"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.

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.

"I am delighted that Vinnova is committed to supporting this consortium to develop a CCRM hub for Sweden and its neighbors," says Michael May, President and CEO of CCRM, Toronto. "CCRM believes global collaboration is needed to maximize the health and economic benefits of ATMPs, and we have sought to partner with like-minded organizations with substantial activities and investments in regenerative medicine and cell and gene therapy. I am confident a CCRM Nordic will expedite the development of durable treatments for some of the world's most debilitating and devastating diseases."

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.

"At AstraZeneca, we recognize the potential of cell and gene therapies to slow, stop and even cure diseases where significant unmet need still exists," explains Regina Fritsche Danielson, SVP and Head of Research and Early Development, Cardiovascular Renal and Metabolism, BioPharmaceuticals R&D, AstraZeneca, and CCRM Nordic board member. "The facility being established by CCRM Nordic in Gothenburg will create a center of scientific excellence that we hope enhances collaboration,

knowledge and skill sharing, and drives innovation in this rapidly advancing field. It will help ensure that the right infrastructure is in place to deliver the next wave of innovative therapies for patients."

"Cell and gene therapies have the potential to transform global health care and cure once incurable diseases. Establishing a CCRM facility in Sweden will help create the infrastructure that is needed in the Nordic region to ensure these therapies are developed using GMP standards," says Emmanuel Abate, President, Genomic Medicine, Cytiva.

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 has 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 CCRM 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 network 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. Visit us at ccrmnordic.se.

About CCRM:

CCRM is a global, public-private partnership headquartered in Canada, established with seed funding provided by the Government of Canada, the Province of Ontario, and leading academic and industry partners. CCRM supports the development of regenerative medicines and associated enabling technologies, with a specific focus on cell and gene therapy. A network of researchers, leading companies, investors and entrepreneurs, CCRM accelerates the translation of scientific discovery into new companies and marketable products for patients, with specialized teams, dedicated funding, and unique infrastructure. In 2022, CCRM established OmniaBio Inc., a pre-clinical to commercial-stage CDMO for manufacturing gene-modified cells and viral vectors for cell and gene therapies. CCRM is hosted by the University of Toronto. Visit us at ccrm.ca.

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