

Advanced Manufacturing Supercluster investment to accelerate life-changing cell and gene-based therapies

(August 21, Toronto, ON) -- Next Generation Manufacturing Canada (NGen) today announced its conditional support for a consortium led by iVexSol Canada to develop an advanced manufacturing process for lentiviral vectors. These gene-editing reagents are critical components in the manufacturing processes of cell and gene therapies (CGTs), which have been successfully employed to fight cancer and repair a variety of rare and inherited genetic disorders in both children and adults.

iVexSol (**intelligent Vector Solutions**) Canada is a newly formed vector manufacturing company founded on an advanced technology that transforms the way lentiviral vectors (LVVs) are produced. The project will enable the development of an advanced LVV manufacturing platform in Canada – a first of its kind – and aims to establish the country as a world leader in gene-editing tools and technology.

NGen, which runs Canada’s Advanced Manufacturing Supercluster, will provide \$1.89 million in Supercluster funding to the \$4.25 million project, an investment expected to lead to the creation of approximately 470 jobs.

Over the past 30 years, LVVs have delivered an outstanding safety and therapeutic record. But they are produced using legacy methods that are costly, inefficient and hard-to-scale. These limitations have caused global shortages of this critical reagent and slowed the progress of clinical trials leading to the development of lifesaving CGTs. iVexSol’s clinically proven, LVV manufacturing process promises to address these shortages by producing nearly 10 times the quantity of potent, high quality vectors at a fraction of the cost and duration of legacy processes.

Establishing such an advanced manufacturing platform requires a diversity of skills and resources not found in a single organization. Using the catalyst of NGen funding, iVexSol intends to form a core team of partners:

- **CCRM Enterprises Inc.**, a wholly owned subsidiary of the Centre for Commercialization of Regenerative Medicine (CCRM), to provide the supporting manufacturing infrastructure and downstream processing capabilities;
- **GE Healthcare** to provide the required knowledge and expertise of manufacturing processes, along with access and use of specialized tools and technology;
and,
- **STEMCELL Technologies** to provide advanced reagents.

This collaborative project will attract and retain highly educated talent in Canada. Access to a steady supply of high-quality LVVs will also drive growth in the Canadian CGT ecosystem of about 40 Canadian companies, while attracting others to Canada. Participation of the partners is subject to the partners entering into a final agreement and obtaining internal approval by the relevant stakeholders of the partners.



About Next Generation Manufacturing (NGen) Canada

Canada's Advanced Manufacturing Supercluster is led by Next Generation Manufacturing Canada (NGen), an industry-focused, not-for-profit corporation dedicated to positioning Canada as a world leader in advanced manufacturing capabilities. NGen connects manufacturers and technology companies to accelerate the development, adoption, and scale-up of transformative capabilities in Canadian manufacturing.

NGen aims to strengthen the competitiveness of Canada's manufacturing sector, drive more innovation and investment in advanced manufacturing technologies in Canada, generate new commercial opportunities for Canadian companies in global markets, grow more large-scale world-leading Canadian enterprises, and develop a modern and inclusive workforce with the skills to excel in advanced manufacturing. More information at www.ngen.ca.

“Advanced technologies are not just leading to the development of new life-saving therapeutics; they're opening up new ways to manufacture biomedical products. This project shows how advanced manufacturing leads to more investment and high value jobs in Canada.”

Jayson Myers, CEO, NGen Canada

About iVexSol Canada

iVexSol Canada is a newly formed vector manufacturing company founded on a proprietary, next-generation, stable lentiviral vector production process that transforms the way these essential gene-delivery vehicles are made. Its technology will greatly reduce the complexity, cost and development time of these critical reagents, thereby accelerating the development and enabling greater access to life-changing cell and gene therapies. For more information, please visit www.ivexsol.com.

“iVexSol Canada looks forward to working with NGen and its partners to make a significant contribution to next generation manufacturing, which will lower costs and increase access for patients waiting to receive these life-changing treatments.”

Dr. Rod Rietze, CEO, iVexSol Canada.

About CCRM Enterprises Inc.

CCRM Enterprises Inc. is the for-profit venture investment arm of the Centre for Commercialization of Regenerative Medicine (CCRM). CCRM is a Canadian not-for-profit organization funded by the Government of Canada and leading academic and industry partners, supporting the development of advanced therapies, regenerative medicines and associated enabling technologies, with a specific focus on cell and gene therapy. CCRM Enterprises invests in early stage ventures and projects developing therapeutic technologies and manufacturing



capacity. Through an extensive network of investors, it catalyzes risk capital to support these early-stage ventures as they scale up along the development pathway. By tapping into CCRM's manufacturing infrastructure and expertise, CCRM Enterprises provides capital-efficient support to accelerate and de-risk these high potential early-stage ventures, further enabling the development of an advanced therapies ecosystem. Visit us at www.ccrm.ca.

“The large-scale industrial platform and the ensuing facility that will be created for LVV manufacturing is an important development for Canada, and CCRM is excited to offer its advanced manufacturing expertise and infrastructure to help realize this project. This initiative aligns perfectly with CCRM's purpose to revolutionize health care by solving the big problems in regenerative medicine, including cell and gene therapy.”

Dr. Michael May, President and CEO, CCRM

About GE Healthcare Life Sciences

GE Healthcare Life Sciences helps therapy innovators, researchers and healthcare providers accelerate how precision diagnostics and therapies are invented, made and used. Our products enable biological analysis, research, development and the manufacture of advanced therapies and vaccines. Life Sciences is part of the \$19.8 billion healthcare business of GE (NYSE: GE). With over 100 years of experience in the healthcare industry and more than 50,000 employees globally, GE Healthcare helps efficiently improve outcomes for patients, healthcare providers, researchers, and life sciences companies around the world.

Visit our website www.gehealthcare.com/about/life-sciences for more information.

“Cell and gene therapies have the potential to truly transform the way life-altering diseases are treated. The establishment of this large-scale LVV manufacturing platform is a great next step and a testament to the success of the work we've started with CCRM and is critical for the development of the next generation of regenerative medicines in Canada. GE Healthcare will share our expertise and knowledge to help this project reach its full potential.”

**Catarina Flyborg, General Manager,
Cell and Gene Therapy, GE Healthcare**

About STEMCELL Technologies Canada Inc.

STEMCELL Technologies is a Canadian biotechnology company based out of Vancouver that supports life sciences research with more than 2,500 specialized reagents, tools, and services. STEMCELL offers high-quality cell culture media, cell separation technologies, instruments, accessory products, and educational resources that are used by scientists performing stem cell, immunology, cancer, regenerative medicine, and cellular therapy research globally. More information at www.stemcell.com.

Background:

In the last two years, Canadian and U.S. regulators have approved the first CGTs for market release which, along with approved clinical trials being conducted in Canada and the U.S., are showing positive results in treating a variety of conditions including leukemia. Expectations of further breakthroughs have attracted billions of dollars of investment into advanced clinical research for CGTs for other diseases, leading to an unprecedented leap in demand for viral vectors, the molecular tools used to package and deliver genetic material into patients.

The future of CGTs are therefore heavily dependent on resolving the manufacturing challenges facing the production of viral vectors, from rising demand from clinicians to reducing costs and ensuring a high-level of quality and safety.

iVexSol believes the transformative nature of its manufacturing platform will position the consortium as a global leader in supplying this critical therapeutic agent to meet rapidly expanding global demand. Based on an expected 200 clinical trial applications each year, the U.S. Food and Drug Administration anticipates approving 10 to 20 new CGTs per year by 2025.

Supplying the global market of vectors will ultimately require significant infrastructure and a highly skilled workforce that will require continued training as the technology evolves. It will also spur innovation in medical, engineering and environmental fields, as well as other supportive industries, leaving an enduring legacy of benefits to Canadian advanced manufacturing and, equally important, those receiving life-changing treatments as a result of these advances.

Project Lead:	iVexSol Canada
Partners:	CCRM Enterprises Inc. GE Healthcare STEMCELL Technologies Canada Inc.
Estimated Project Cost:	\$4.258 million
Supercluster Funding:	\$1.891 million

For more information on NGen’s Supercluster projects please contact:
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