Media Release

Leading-edge Centre for Cell and Vector Production Open for Business

New Toronto facility to deliver cell and gene therapies for patients

October 18, 2018 (Toronto, ON) – CCRM and the University Health Network (UHN) have opened a new 20,000 ft^2 (~1,900 m^2) Good Manufacturing Practices (GMP) facility located at CCRM in downtown Toronto, adjacent to some of Canada's leading hospitals and research institutes, and a short drive from Toronto Pearson International Airport. The Centre for Cell and Vector Production (CCVP), a contract manufacturing facility, will produce clinical-grade cells and viral vectors for Phase 1 and 2 clinical trials to meet the growing demand from patients seeking cell and gene therapies around the world.

"Exceptional research environments help push Canadian innovation and attract the best and brightest talent from Canada and around the world," says the Honourable Kirsty Duncan, Minister of Science and Sport. "Our investment of more than $7 million today will provide researchers with the tools they need to develop regenerative medical technologies."

"Today marks a significant milestone for CCRM," says Dr. Michael May, President and CEO of CCRM. "As a leader in developing and commercializing regenerative medicine technologies and cell and gene therapies, we are now able to manufacture cell and gene therapy products for patients for years to come. With R&D capabilities in-house and access to industry-leading know-how and technologies through our partnerships with GE Healthcare and other leading organizations, we will help the industry move closer to delivering on the promise of regenerative medicine as a possible cure for many diseases and conditions."

"CCVP will fill a much needed gap for the thriving regenerative medicine industry in Toronto," adds Dr. Brad Wouters, Executive Vice President, Science and Research at UHN. "Cell and gene therapy products hold tremendous potential for many diseases with unmet clinical need—from cancer to heart disease—and this new facility will accelerate the development of these transformative health care solutions for patients. With all of the research excellence at UHN, such as that at the McEwen Centre for Regenerative Medicine, and at other local leading institutions, Toronto is now uniquely positioned to become a global leader in this area."

CCRM and UHN partnered to design and build the CCVP. CCRM will manage the day-to-day operations of manufacturing cells and viral vectors for early phase clinical trials and already has a pipeline of industry and academic projects in place.

The facility is the first of its kind in Toronto. It cost an estimated $25 million for construction, equipment and operations. The Canada Foundation for Innovation, the

Government of Ontario, the Federal Economic Development Agency for Southern Ontario, and other partners, including private donors through the Toronto General & Western Hospital Foundation, provided financial support.

The facility is designed to meet international standards and be compliant with Health Canada, the U.S. FDA, and the European Medicines Agency good manufacturing practices for early-phase materials in the cell and gene therapy markets.

Features include skilled personnel, 10 Grade B clean rooms, cryogenic storage, a cell irradiator, an in-house quality control (QC) laboratory, a robust quality management system, and specialized cell processing hardware. Services offered include full manufacturing and release of cell and viral vector materials, QC testing, access to clean rooms, cell bank creation, assay development, technology transfer, training services, supplier management and audit support services.

On October 19 at 9 am EDT, CCRM and UHN are hosting the grand opening ceremony in the atrium of the MaRS Discovery District, where CCRM and the CCVP are based, and then guests will tour the facility.

CCRM has received ISO 9001:2015 certification for its quality management system.

Quick Facts:

- $25 million for construction, operating and equipment costs
- 20,000 ft^2 (~1,900 m^2) facility
- Designed to be Health Canada, U.S. FDA and EMA compliant
- Positive and negative pressure clean rooms, for cell and viral production
- Facilities for quality control and quality assurance activities
- Two vector production suites totalling 258 ft^2 (~24 m^2)
- Eight clean room suites: five at 236 ft^2 (~22 m^2) and three at 301 ft^2 (~28 m^2)
- ISO Class 7/Grade B clean rooms

About CCRM

CCRM, a Canadian not-for-profit organization funded by the Government of Canada, the Province of Ontario, and leading academic and industry partners, 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 aims to accelerate the translation of scientific discovery into new companies and marketable products for patients, with specialized teams, dedicated funding, and unique infrastructure. CCRM is the commercialization partner of the Ontario Institute for Regenerative Medicine and the University of Toronto's Medicine by Design. CCRM is hosted by the University of Toronto. Visit us at ccrm.ca.

About University Health Network (UHN)
University Health Network consists of Toronto General and Toronto Western Hospitals, the Princess Margaret Cancer Centre, Toronto Rehabilitation Institute, and The Michener Institute of Education at UHN. The scope of research and complexity of cases at University Health Network has made it a national and international source for discovery, education and patient care. It has the largest hospital-based research program in Canada, with major research in cardiology, transplantation, neurosciences, oncology, surgical innovation, infectious diseases, genomic medicine and rehabilitation medicine. University Health Network is a research hospital affiliated with the University of Toronto. www.uhn.ca

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For more information, please contact:

Stacey Johnson
CCRM
stacey.johnson@ccrm.ca
416-946-8869

Jessie Park
UHN
jessie.park@uhn.ca
416-340-4636