



Toronto centre solving cell manufacturing challenges to benefit patients and global industry

CCRM and Cytiva, formerly part of GE Healthcare Life Sciences, renew collaboration agreement for

Centre for Advanced Therapeutic Cell Technologies

June 2, 2020 (Toronto, ON, Marlborough, MA) – With Health Canada and the Food and Drug Administration beginning to approve and reimburse cell and gene therapies in significant numbers, the demand for cell and viral vector manufacturing will continue to grow. Consequently, the industrialization challenges associated with the variability of cell and gene therapies, and with manufacturing them on a commercial scale, must be overcome. CCRM and Cytiva, formerly part of GE Healthcare Life Sciences, have renewed their Collaboration Agreement for continued operation of the Centre for Advanced Therapeutic Cell Technologies (CATCT), which was created to accelerate the development and adoption of cell manufacturing technologies for novel regenerative medicine-based therapies.

"Together, CCRM and Cytiva have established a commercialization hub where great minds, state-of-theart equipment and a spirit of innovation meet," says Michael May, President and CEO of CCRM. "Continuing to partner in the operation of CATCT will enable us to move the cell and gene therapy industry closer to fulfilling its promise of creating cures, and enabling treatments to get to patients."

"By creating an innovative platform and approach to tackle the issues facing commercialization of living therapies, we are supporting the viability of the regenerative medicine industry," says Catarina Flyborg, Vice President, Cell & Gene Therapy, Cytiva. "In CATCT, we are creating the technologies, processes and equipment that will enable our customers, and the broader industry, to achieve its goals and help patients."

Established in 2016, CATCT is a partnership between CCRM and Cytiva, with initial funding from the Federal Economic Development Agency for Southern Ontario (FedDev Ontario). Its staff of 40 works in a 10,000 ft² (~930 m²) process development facility, located in the MaRS Discovery District, next to Toronto's world-leading hospitals and the University of Toronto.

The global regenerative medicine market was valued at US\$23.8 billion (2018), and it is anticipated to grow to US\$151 billion by 2026 with an annual growth rate of 26.1 per cent. Operating CATCT allows CCRM and Cytiva to address the manufacturing bottlenecks that would otherwise have the potential to impede the industry's growth.

CATCT's key areas of expertise are:

- Immuno-oncology: CAR-T, NK, cell selection, transduction, expansion, downstream processing and cryopreservation; autologous process closure, automation and workflow design;
- Viral vectors: Upstream production, downstream purification, formulation and workflow design;
- Media development: Screening and de novo development of custom cell and gene therapy media;
- Scale-up: Pluripotent stem cells, viral and allogenic scale-up and workflow design; and,

• Analytics: Assay development, automation and qualification; flow cytometry, infectious titre, cell enumeration and functional assays.

The work conducted in CATCT can be categorized as follows: the first is fee-for-service development projects that advance customers' therapeutic technologies towards industrialization; second, the team's New Product Introductions (NPIs) efforts provide core biological expertise in Cytiva's product development process; finally, internal technology development builds additional capabilities and innovative solutions for cell and gene therapies.

A recent success stemming from the work being done in CATCT is the involvement of CCRM and Cytiva in a consortium led by iVexSol Canada, with conditional funding from Next Generation Manufacturing Canada (NGen), to build an advanced manufacturing platform for lentiviral vectors. As core partners in this consortium, which was <u>announced in August 2019</u>, CCRM will provide supporting manufacturing infrastructure and downstream processing capabilities, and Cytiva will share expertise of manufacturing processes, and access to and use of specialized tools and technology.

The new collaboration agreement between CCRM and Cytiva has a three-year term and it became effective on October 15, 2019. The funding will be a combination of in-kind contributions, milestone payments, reinvested fee-for-service revenue and any successful grant opportunities. FedDev's funding of CATCT was for a three-year term and ended in December 2018.

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, strategic investors and entrepreneurs, CCRM accelerates the translation of scientific discovery into new companies and marketable products for patients, with specialized teams, funding, and 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 Cytiva

Cytiva is a 3.3 billion USD global life sciences leader with nearly 7,000 associates operating in 40 countries dedicated to advancing and accelerating therapeutics. As a trusted partner to customers that range in scale and scope, Cytiva brings speed, efficiency and capacity to research and manufacturing workflows, enabling the development, manufacture and delivery of transformative medicines to patients. Visit www.cytiva.com for more.

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