



Commercializing Living Therapies

MicrofluidX and CCRM partner on end-to-end bioprocessing of CAR-T cell therapies

Stevenage, UK, and Toronto, Canada, January 11, 2023— <u>MicrofluidX</u> (MFX), a UK-based provider of nextgeneration bioreactors for cell research and manufacturing, today announced a partnership with <u>CCRM</u>, a leader in developing and commercializing regenerative medicine-based technologies and cell and gene therapies, to advance manufacturing of lentivirus (LV) CAR-T cells with their next generation platform, the Cyto Engine[™].

The project will address the urgent need for higher transduction efficiency, higher homogeneity of the transduced cell population, shorter bioprocessing times, and closed system automation. Early trials (data available <u>here</u>) suggest that primary T-cells can be transduced in the MFX bioreactors with 5x higher efficiency (or 10x lower virus consumption) and 2x more homogeneity than conventional approaches.

"Engineered lentivirus is still the most popular vector for CAR-T gene editing, but current methods consume large amounts of virus, and cells come out with a wide range of vector copy number. This leads to people using non-viral methods, which come with their own challenges. We are very excited about this collaboration because we will be able to show that it doesn't have to be this way. Virally edited cells in our platform are highly viable, highly transduced, and highly homogeneous, for a fraction of the amount of virus used previously," said Antoine Espinet, CEO of MicrofluidX.

"CCRM's skilled process development team has been working to solve challenges in cell and viral vector manufacturing, including closing and automating processes, and we frequently collaborate with cutting-edge technology providers around the globe," explains Michael May, President and CEO of CCRM. "This project with MicrofluidX is an opportunity to develop a more efficient and lower-cost process that can assist therapy developers. When the industry is able to bring down manufacturing costs, patients will benefit."

Currently viruses are engineered and used as vectors to bring genetic material into T-cells, augmenting the cells with specific therapeutic properties such as tumour detection. However, the production of these viruses is complex and, as a result, a few microliters of virus can cost several thousands of dollars. Moreover, traditional bioreactors don't allow for fine control over virus particle interaction with cells, resulting in a proportion of cells remaining uninfected and a proportion of cells being infected multiple times.

Since only infected cells have therapeutic use, a long expansion phase is required to achieve doseable quantities of cells. Additionally, there are strict release criteria around the percentage of cells that have repeat infections (vector copy number), resulting in lower yields of the end product. Therefore, there is an unmet need in the cell and gene therapy industry for a controlled transduction platform that can lower virus consumption and reach near to one infection per cell. There is also a broader need for closed, automated platforms that can process CAR-T cells end-to-end, through cell selection, activation, transduction, expansion, concentration and formulation. MicrofluidX believes the Cyto Engine™ platform will fulfil these needs, reducing the cost and time of cell therapy manufacture and cutting the delivery times of lifesaving treatments to patients.

With this project, MFX and CCRM will assess the capabilities of the MFX platform with CCRM's process, staff and facility. Feedback will be used to further improve the platform and CCRM will be able to frame the experiments to suit its needs.



MicrofluidX Ltd Stevenage Bioscience Catalyst Gunnels Wood Road Stevenage SG1 2FX www.microfluidx.co.uk

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"If the outcome is as expected, <u>OmniaBio</u>, a subsidiary of CCRM, may be interested in bringing the Cyto Engine™ platform in-house for its pre-clinical to commercial-stage manufacturing needs, offering our customers more options to choose from," says Dr. May.

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About MicrofluidX

MicrofluidX is an advanced therapy manufacturing platform company based in the Stevenage Bioscience Catalyst, UK. It is developing the Cyto Engine[™], a proprietary next generation, scalable bioprocessing platform for cell and gene therapy manufacture. Its mission is to make precision medicines accessible to patients around the world by disrupting the current advanced therapy development process, providing scalable, fully automated platforms that can be used in research and taken through to large-scale GMP manufacture. For more information visit <u>www.microfluidx.co.uk</u>

About CCRM

CCRM is a global, public-private partnership headquartered in Canada. It receives funding from 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 <u>OmniaBio</u> <u>Inc.</u>, a pre-clinical to commercial-stage CDMO for manufacturing gene-modified cells and viral vectors for cell and gene therapies. CCRM is the commercialization partner of the University of Toronto's Medicine by Design. CCRM is hosted by the University of Toronto. Visit us at <u>ccrm.ca</u>.

Contact

MicrofluidX James Kusena james@microfluidx.co.uk +44 7730 494532

CCRM Stacey Johnson stacey.johnson@ccrm.ca 1-647-309-1830



MicrofluidX Ltd Stevenage Bioscience Catalyst Gunnels Wood Road Stevenage SG1 2FX www.microfluidx.co.uk