

Catalyst Program

Development of a bioreactor system to automate T-cell

manufacturing

Highlights

Oct. 1, 2015 to Dec. 31, 2016

- Accelerates development of Canadian-based technology that would create a desktop GMP laboratory-in-a-box and greatly increase the number of clinical sites capable of performing T-cell therapy for cancer treatment
- The proposed bioreactor would dramatically reduce the cost of preparing T cells for cancer therapies
- Successful development of this technology could move beyond T-cell manufacturing and have significant global impact

new cases of these cancers in 2015

> Ovarian Melanoma ancers Leukemia

deaths from these cancers in 2015

\$92,500 from BioCanRx

\$105,000

McMaster University

\$15,000

Boris Family Fund

cure: blood cancer

About the project

Early results from clinical trials of engineered T-cell therapies have resulted in potent anti-tumour responses. Industry's enthusiasm for this approach is high, resulting in investment across the U.S. and Europe that exceeded USD \$1 billion in an 18-month period around 2014. Current estimates indicate that these engineered T-cell therapies could generate annual revenues of USD \$10 billion, if approved to treat multiple forms of cancer. However, the cost of manufacturing clinical-grade, engineered T cells remains a major hurdle that must be overcome. Currently, it is estimated that a single course of therapy can cost as much as \$500,000. It is well recognized that automation will be required to reduce the cost of goods and enable cell production that will meet the market demands. However, most industry capital is being directed at clinical development, resulting in a gap in manufacturing innovations. This project addresses that gap.

T cells

for Adoptive T-cell

Therapy and CAR T-Cell Therapy

A central component of any automated manufacturing process is the bioreactor used to propagate the cells. Dr. Bramson's team has designed hollow-fibre membrane bioreactors that could offer substantial advantages over the existing technology and prove to be of significant value to all BioCanRx investigators interested in cell therapies. Given the potential significance of T-cell therapies, the development of automated scalable processes for manufacturing the cells is important in allowing more clinical sites to offer these cell therapies.

Looking beyond this immediate project, successful innovations in automated manufacturing solutions for this industry will have tremendous impact globally that will extend beyond T-cell therapies.

Dr. Jonathan Dr. Raja University

Catalyst Project investigators Centre de Recherche Hôpita Maissoneuve-Rosemont Scientific investigators Dr. Denis-Claude Roy Dr. Jean-Sebastien Delisl McMaster University Scientific investigators **BioCanRx partner** Dr. Jonathan Bramson **BioCanRx** Dr. Raja Ghosh \$92,500 Boris Family Fund, Faculty of Health Sciences, **Cure: Blood Cancer McMaster University** approved on \$15.000 To fund any part of the project June 10, 2015 \$105,000 for research materials and technical expertise Oct. 1, 2015 to March 31, 2016 • Fabricate hollow-fibre membrane bioreactors (HFMB) prototypes • Integrate HFMB prototypes with fluid and instrumentation components Oct. 1, 2015 • Assess mass transport of key oxygen and nutrients Project starts for HFMB prototypes Develop T-cell culture process for HFMB prototypes. April 1, 2016 to Sept. 30, 2016 •Complete assessment of mass transport of key oxygen and nutrients for HFMB prototypes • Complete development of T-cell culture process for HFMB The power to kill cancer lies within us. prototypes • Fabricate HFMB variants Let's tell our bodies how. • Integrate HFMB variants with fluid and instrument components • Assess mass transport for HFMB variants • Develop T-cell culture process for HFMB variants Oct. 1, 2016 to Dec. 31, 2016 • Complete integration of HFMB variants with fluid and instrument components • Complete assessment of mass transport for HFMB variants • Complete development of T-cell culture process for HFMB

Biothérapies pour le traitement du cancei