

Clinical Trials Program

Human Immune

Testing Suites

Hamilton, ON

Victoria. BC

The Ottawa Hospital

Affiliated with a uOttawa

Dr. Natasha

Kekre

Canadian-Led Immunotherapies in Cancer: CLIC-1901 for the Treatment of Patients with Relapsed/Refractory CD19 Positive Hematologic Malignancies

May 15, 2019 to March 31, 2021 **Highlights** \$2,229,077 • This trial uses Chimeric Antigen Receptor modified T cells as a new tool for \$400,000 treating patients who have From BioCanRx had poor responses to other treatments. **Blood** • CAR T cells are made by isolating a sample of a patient's Tlymphocytes from their blood, The Ottawa genetically modifying and Hospital activating the cells in the lab, and then re-administering them to the same patient, allowing for a patient's Leukemia and Lymphoma immune cells to be targeted **Autologous** against their tumour. CLIC-1901 cells + • CAR T is very personalized, so significant infrastructure Lentivirus and expertise are required to produce and deliver this treatment safely and successfully. This is the first clinical trial **Biotherapeutics** of Canadian-made CAR T Manufacturing Centre cells. Ottawa, ON Molecular and Cellular Immunology Core

About the project

Patients with some forms of blood cancer that do not respond to standard therapies have a particularly poor chance of survival. Chimeric Antigen Receptor modified T cells (CAR Ts) are a powerful new tool for treating these patients. CAR T cells are made by isolating a sample of a patient's T lymphocytes (a type of white blood cell) from their blood, genetically modifying and activating the cells in the lab, and then re-administering them to the same patient, allowing for a patient's immune cells to be targeted against their tumour.

The evidence to date for the use of CAR T cells in certain leukemias and lymphomas has been phenomenal in some cases, with durable responses, suggesting that these patients who respond are cured of their underlying malignancy. Because CAR T therapy is very personalized (it requires genetically engineering the patient's own cells, these is considerable infrastructure and expertise required to manufacture and deliver this treatment safely and successfully.

BioCanRx was integral to providing the funding needed to develop the processes and manufacture the materials needed for CAR T-cell production, and to write the clinical trial application for this to be an approved procedure under Health Canada for a clinical trial. Our team is now ready to provide this therapy and seeks funding from BioCanRx to support the roll-out of this clinical trial, which would fund manufacturing and clinical care costs of patients in the first clinical trial of Canadian-made CAR T cells.

Clinical trial sites and investigators

Clincal Trial Sites:

- •The Ottawa Hospital
- ·Vancouver General Hospital

Ottawa Hospital Research Institute, The Ottawa Hospital

Clinical Investigator

- Dr. Natasha Kekre Scientific Investigators
- Dr. John Bell
- Dr. Dean Furgusson

Vancouver

BC Cancer Agency, University of British Columbia

Clinical Investigator

- Dr. Kevin Hay Scientific Investigators
- Dr. Brad Nelson
- Dr. Rob Holt

Hamilton

McMaster University
Scientific Investigator

Dr. Johnathan Bramson

BioCanRx \$400,000 approved on

Partner contributions

BC Cancer Foundation \$1,000,000

OICR \$569,937 The Ottawa Hospital Foundation \$259,140

June 5, 2019

DELIVERABLE #2

Determine if the safety of CLIC-1901 cells administered to adult participants with ALL or NHL is similar to a priori expectations of anti-CD19 CAR T cells in these diseases.

DELIVERABLE #3

Determine if the efficacy of CLIC-1901 cells manufactured in a manner compatible with a distributed point of care model is similar to published reports of anti-CD19 CAR T cells.

DELIVERABLE #4

Determine if there are specific CLIC-1901 cell factors that influence safety and/or efficacy outcomes.

DELIVERABLE #1

Determine the feasibility of administering CLIC-1901 cells (ie. Canadian made anti-CD19 CAR T cells) manufactured in a manner compatible with a distributed point of care model.

The power to kill cancer lies within us. Let's tell our bodies how.



