BioCanRx
Canada's Immunotherapy Network
Le réseau canadien d'immunothérapie

Clinical Trial Program

The Selected Tumor-infiltrating Lymphocyte Against Refractory Melanoma-01 Trial (STAR-M01)

October 1, 2020 - March 31, 2024.

Highlights

- For the majority of cancer patients, their endogenous anti-tumor T-cell response cannot be sufficiently reinvigorated with just immune checkpoint blocking (ICB) antibodies. As a promising alternative, BioCanRx is emphasizing the development of T cell-based immunotherapies.
- Cell sorting is based on the expression by T cells of a cell surface marker called PD-1, which acts as a "tag" for tumour-reactivity. The researchers have optimized a cell sorting technique and the cell culture conditions to expand sorted T cells into large numbers that can be used for infusion into patients.
- This is likely the first project in Canada that has optimized cell sorting for clinical research, a technology that can be repurposed to enhance T cell products developed by other researchers.

targeted cancers

Metastatic Melanoma

The main goal of this project is to test the feasibility, the safety, and the potential efficacy of this T cell immunotherapy in 24 patients with metastatic melanoma resistant to standard treatment.

Project value

$2.98 M

BioCanRx contribution: **$675,000**

Patients enrolled

24

Partners

9

CHUM

CRCHUM CENTRE DE RECHERCHE

HÉMA-QUÉBEC

Center for Commercialisation of Cancer IMMUNOTHERAPY

INSTITUT DU CANCER DE MONTRÉAL

Canada Research Chair in Patient and Public Partnership

Centre of Excellence on Partnership with Patients and the Public

HMR Centre d'excellence en thérapie cellulaire Hôpital Maisonneuve-Rosemont
Centre affilié à l'Université de Montréal

Technology used

1

Cell Sorting

About the project

The infusion of ex-vivo expanded tumour-infiltrating T lymphocytes (TILs) is a promising approach for the treatment of solid tumour cancers because it addresses the problem of tumour heterogeneity by targeting multiple tumor antigens. An important challenge remains: since bystander (non tumour-reactive) T cells are attracted intratumorally by inflammation, only a small proportion of TILs are tumour-reactive, and standard bulk ex vivo expansion often favors the overgrowth of bystander T cells.

In Cycle 1, Dr. Turcotte and team were funded through the Catalyst Study Program to enhance TIL efficacy by selecting tumor-infiltrating T cells expressing PD-1, that act as a "tag" for tumor-reactive T cells. To do this, the team optimized the use of a clinical-compliant flow cytometry cell sorter to select reactive TILs from tumors prior to ex vivo expansion.

The STAR-M01 is a prospective, open-label, two-cohort, non-randomized, single center phase 1b study in stage IIIC unresectable or stage IV metastatic melanoma patients refractory to PD-1 immune checkpoint blockade. The primary objective of this trial is to test the feasibility, the safety, and the potential efficacy of this T cell immunotherapy after lymphodepletion and with intravenous IL-2, in 24 melanoma patients.

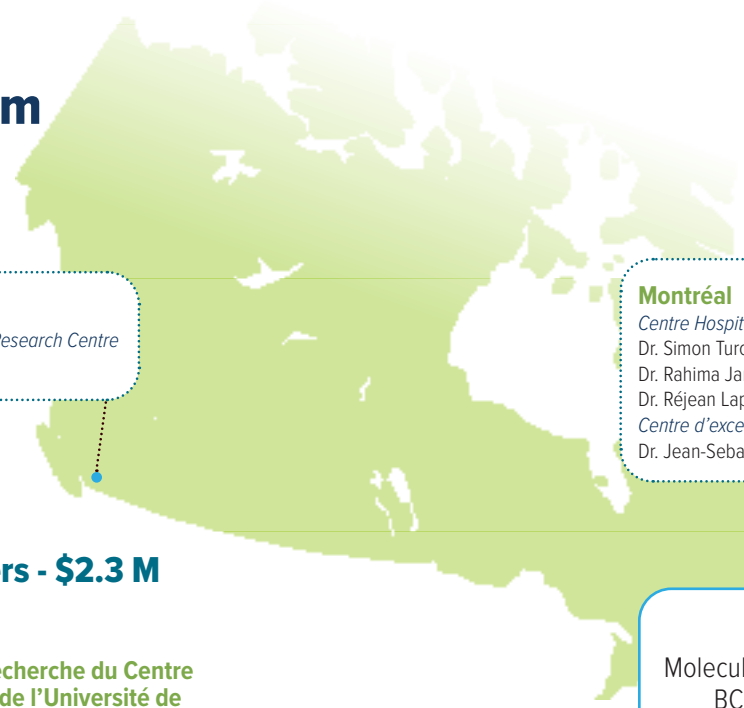
Additionally, enrolled patients will have the option to participate in a patient-led support group to help them understand and communicate with others about what to expect from anti-tumour T-cell transfusion immunotherapy.

Key investigators

Dr. Simon **Turcotte**

CHUM

Project Team Members



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Partners - $2.3 M

Centre de Recherche du Centre Hospitalier de l'Université de Montréal / Centre Hospitalier de l'Université de Montréal

Institut du cancer de Montréal

Héma-Québec

Canada Research Chair in Patient and Public Partnership

Centre d'Excellence en Thérapie Cellulaire

Centre of Excellence on Partnership with Patients and the Public

C3i (Centre for Commercialization of Cancer Immunotherapy)

Facility Utilization:
Molecular & Cellular Immunology Core (MCIC)
BC Cancer Deeley Research Centre

Key Milestones

- Extensive trial-related biobank for characterization of source tumour, peripheral blood and TIL products
- Trial activation by Q1 of 2021
- Interim safety analysis
- End of accrual within 2.5 years
- Development of a patient-led T cell immunotherapy support group
- Report on safety and feasibility of PD-1+-selected TILs with preliminary results on efficacy and correlative data

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

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