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

Clinical Trials Program

Interrogation of Biomarkers in Patient Samples from a Phase Ib Trial of the Immune Checkpoint Inhibitor, Avelumab, in Combination with SMAC Mimetic Debio1143

April 23rd, 2018 to March 31st, 2022

Highlights

- The immunological impact of Debio1143 and Avelumab combination therapy has never been studied
- This combinatory clinical approach will introduce a new cancer treatment option for patients
- The results from this study will provide a deeper understanding of tumour biology, and result in identification of biomarkers for a more logical and scientific patient selection for Phase II and III trials

Patients: **61**

Trial sites: **13**

Project value: **$19,867,177**
$779,777 from BioCanRx

Biotherapeutics: **2**

Eligible cancer: **Solid malignancies**

Understanding the immune mechanisms at play prior to and after exposure to the SMAC Mimetic Debio1143 with the anti-PD-L1 antibody Avelumab combination therapy to identify sensitive populations and biomarkers of efficacy that will drive further development.

Debio 1143 (SMAC Mimetic) and Avelumab (checkpoint inhibitor antibody)

Core Facilities: **3**

- **Immunogenomics Core Facility**
- **Molecular and Cellular Immunology Core (MCIC)**
- **Human Immune Testing Suite (HITS)**

Partners: **4**

Pfizer
DebiopharmGroup™ WE DEVELOP FOR PATIENTS
EMD SERONO
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About the project

Recently, immunotherapy with immune checkpoint inhibitors (ICI) has profoundly impacted the management of many different cancers. While there is substantial clinical data to support ICI's efficacy in extending survival, this efficacy is variable across and within tumour types. Combination immunotherapy is an accepted future direction for improving outcomes but without appropriate predictive biomarkers, testing combinations of agents remains empiric with little chance of success. Furthermore, given the very high cost of approved ICIs, tailoring them to patients who will benefit is of utmost importance; especially in the context of a Canadian public health care system. Therefore, research characterizing the molecular and immunological profiles of tumors to identify the relevant indicators of efficacy will be clinically, scientifically, and economically beneficial.

To execute the above strategy, the investigators have initiated a Canada-wide collaboration of scientists and clinicians, who each contribute expertise to the focus areas of immunology, genetics and programmed cell death. Collaborators include network investigators in three BioCanRx core facilities dedicated to genomic sequencing and immune cell characterization. Within these three fields of interest, we intend to characterize tumours, interrogate efficacy biomarkers and evaluate changes in biology upon exposure to drug in tumour samples from an ongoing Phase I clinical trial of SMAC mimetic Debio1143 with ICI Avelumab in patients with solid tumors and non-small cell lung cancer (NSCLC). Our assembled team of internationally renowned researchers have the experience and drive to guarantee this project's success.

Certainly, support from BioCanRx for this project will lead to improved cancer outcomes for Canadians.

Key investigators

Project lead:
Dr. Glenwood **Goss**

Co-Principal Investigators:
Dr. Harmanjatinder **Sekhon**
Dr. Bryan **Lo**
Dr. Jonathan **Bramson**
Dr. Brad **Nelson**
Dr. Rob **Holt**

BC CANCER
McMaster University
The Ottawa Hospital
Affiliated with uOttawa

Clinical trial sites and investigators

Vancouver/Victoria
BC Cancer Agency
Dr. Robert Holt
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Debio 1143-NSCLC-105
Delivered
June 16th, 2017

Partner contributions

Debiopharm International SA
$17,737,400

Pfizer, EMD Serono, Merck KGaA
$1,350,000

Aim 1
- Immune profiling

Aim 2
- Assessment and evolution of neoantigen burden

Aim 3
- Validation of identified biomarkers from human trial companion studies in murine models of cancer (including PDX tumours in humanized mice)

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

BioCanRx
Biotherapeutics for Cancer Treatment
Biothérapies pour le traitement du cancer