

## **Clinical Trial Program**

COV-IMMUNO- A randomized phase III trial of immunization with IMM-101 versus observation for the prevention of serious respiratory and COVID-19 related infections in cancer patients at increased risk of exposure

April 1, 2020 - January 1, 2022. **Highlights** • This trial has been developed to address a critical and urgent need to Solid Tumours, protect cancer patients undergoing BioCanRx contribution: active treatment during the \$750,000 Myeloma, COVID-19 pandemic. Lymphoma • Cancer patients are particularly vulnerable to severe COVID-19 infections because they are both The main goal of this trial is to immunocompromised and cannot investigate the effectiveness in IMM-101 adhere to strict quarantine as they at increasing an innate immune need to visit the hospital regularly for response in patients undergoing treatment. treatment and to determine whether • IMM-101 is a safe, killed, whole cell IMM101 can improve the efficacy of immunomodulator that has been COVID-19 vaccines in cancer patients shown to induce an innate immune undergoing active therapy. response in cancer patients. • This trial will evaluate the ability of IMM-101 to train the immune Canadian Cancer imm odulon system by boosting natural immunity Trials Group and improving immune response to the COVID-19 vaccine. Canadian The Ottawa

## **About the project**

As cancer patients have dysfunctional innate immune responses, they are at higher risk of severe COVID-19 infections, which at best, can result in delays in their treatment of their active cancer, and at worst, an increased incidence of mortality. It is also unclear whether the approved COVID-19 vaccines work as well in patients actively undergoing treatment.

Stimulation of the innate immune system (known as "trained immunity") is a promising approach to optimizing the innate to adaptive transition for many infections, including COVID-19. This principle has been shown in the past with recipients of the tuberculosis vaccine, known as BCG, demonstrating an increased resistance to multiple other infections due to a parallel, non-specific stimulation of their innate immunity. While BCG

vaccination is being tested in healthcare workers against COVID-19 infection in multiple clinical trials around the globe, because it is composed of a live (but modified) bacteria, its use is contraindicated in patients with a weakened immune system, such as cancer patients.

In contrast, IMM-101, the investigational drug for this trial, is a whole cell immunomodulator that is safe to use in cancer patients because the bacteria has been killed. IMM-101 (Immodulon Therapeutics) is a systemic immune modulator containing a suspension of heat-killed whole cell Mycobacterium obuense, an environmental, harmless saprophyte. Given that it is NOT a live vaccine, it is being developed as an anti-cancer therapy, based on the same rationale of trained immunity, but against cancer cells. IMM-101 has been shown to induce an innate immune response in cancer patients of equal or greater magnitude to that reported with BCG treatment.

The purpose of this trial is to examine 1) IMM-101 impacts on the overall innate immune response/"immune training" of patients with cancer undergoing active treatment 2) the immune response to the COVID-19 vaccines in cancer patients on active therapy, 3) whether IMM-101 can improve the immune response of the COVID-19 vaccines or other vaccines, especially patients on immunosuppressive therapies.



Hospital

## **Clinical Trial Sites** Hamilton/Toronto Juravinski Cancer Centre Dr. Rosalyn Juergens Sunnybrook Health Sciences Ottawa/Kingston Centre/Odette Cancer Centre The Ottawa Hospital Dr. Martin Smoragiewicz Dr. Rebecca Auer Dr. Kelvin Chan Canadian Cancer Trials Group; Dr. Nicole Mittman Queen's University Princess Margaret Cancer Montrèal Dr. Christopher O'Callaghan Centre CHUM-Centre Hospitalier de Dr. Janet Dancey Dr. Grainne O'Kane l'Université de Montrèal Vancouver Ontario Institute for Cancer Dr. Dongsheng Tu Dr. David Roberge Ms. Judy Needham BC Cancer Agency Research (OICR) McGill University Dr. Jonathan Loree Dr. John Bartlett Dr. George Zogopoulos Dr. Laszlo Radvanyi **Partners** Dalhousie University Dr. Scott Halperin **Immodulon Therapeutics -**\$400,000 (in-kind) **Canadian Clinical Trials Group** London (CCTG)/ Canadian Cancer Society -Lawson Health Research Institute Dr. Eric Winquist \$1,368,611 (cash + in-kind) Key **Ontario Institute for Cancer** Milestónes Research (OICR) - \$100,000 (inkind) **The Ottawa Hospital Academic** June 30, 2020 Medical Organization - \$96,000 Anticipated start date ATGen - \$44,550 (in-kind) The Ottawa Hospital Foundation -\$25,000 November 30, 2021 November 30, 2020 • Patient follow-up completed · Patient accrual completed



January 1, 2022
• Final report issued