

# **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 SARS-\$750,000 Myeloma, COV2 pandemic. argeted cancer Lymphoma • Cancer patients are particularly vulnerable to severe COVID-19 infections because they are both The main goal of this study is to immunocompromised and cannot investigate the effectiveness of IMM-101 adhere to strict quarantine as they at preventing "flu-like illnesses" that are need to visit the hospital regularly consistent with symptomatic COVID-19 for treatment. infections, or confirmed COVID-19 • IMM-101 is a safe, killed, whole cell infections, AND that result in a change or immunomodulator that has been delay in cancer treatment administration, shown to induce an innate immune hospitalization, or death. response in cancer patients. TOHAMO The Ottawa Hospit • Innate immune activation, through a process called trained immunity, is Canadian Cancer imm odulon

### About the project

a promising approach to protecting

high-risk individuals from severe

COVID-19 infections.

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. While numerous efforts are currently underway globally to design and test a safe and effective COVID-19 vaccine that provides long-term and repeated protection, the timeline for its wide-spread availability is approximately 12-18 months.

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 workeres 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.

While this trial is not testing immunotherapy for the treatment of cancer, it has the potential to not only lessen respiratory symptoms for cancer patient such as those that present because of COVID-19, enabling patients to be physically able to receive active cancer therapy, but also reduce the incidence of mortality due to respiratory illnesses such as COVID-19.



Trials Group

## **Clinical Trial Sites**

#### Vancouver

BC Cancer Agency Dr. Jonathan Loree

#### Hamilton/Toronto

Juravinski Cancer Centre

- Dr. Rosalyn Juergens
- Sunnybrook Health Sciences Centre/Odette Cancer Centre
- Dr. Martin Smoragiewicz
- Dr. Kelvin Chan
- Dr. Nicole Mittman
- Princess Margaret Cancer Centre
- Dr. Grainne O'Kane
- Ontario Institute for Cancer Research (OICR)
- Dr. John Bartlett
- Dr. Laszlo Radvanyi

#### Ottawa/Kingston

The Ottawa Hospital

- Dr. Rebecca Auer
- Canadian Cancer Trials Group; Queen's University
- Dr. Christopher O'Callaghan
- Dr. Janet Dancey
- Dr. Dongsheng Tu
- Ms. Judy Needham

#### Montrèal

CHUM-Centre Hospitalier de l'Université de Montrèal

Dr. David Roberge

McGill University

Dr. George Zogopoulos

#### **Partners**

**Immodulon Therapeutics -**\$400,000 (in-kind)

**Canadian Cancer Trials Group** (CCTG)/ Canadian Cancer Society -\$1,368,611 (cash + in-kind)

**Ontario Institute for Cancer** Research (OICR) - \$100,000 (inkind)

**The Ottawa Hospital Academic** Medical Organization - \$96,000

ATGen - \$44,550 (in-kind)

The Ottawa Hospital Foundation -\$25,000

**Canadian Centre for Applied Research in Cancer Control** (ARCC) - \$50,000

Dalhousie University Dr. Scott Halperin

#### London

Lawson Health Research Institute

Dr. Eric Winquist

#### June 30, 2020

Anticipated start date

#### November 30, 2020

· Patient accrual completed

Key

Milestones

### November 30, 2021

• Patient follow-up completed

**January 1, 2022** 

Final report issued

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

