

# CTA Submission for TITAN-01 (Thymic Treg Immune Therapy Against GVHD)

Duration: 11/1/2024 to 4/30/2026

## Targeted Cancer:

### Blood cancers

The research team is developing regulatory T cells (Tregs) as a cell therapy to prevent or treat graft-versus-host disease in blood cancer patients undergoing bone marrow transplants. By sourcing Tregs from surgical material that is typically discarded, they reduce the costs and challenges associated with collecting Tregs directly from donors.

2

BioCanRx Funded  
Core Facilities

**BC Cancer's Molecular  
and Cellular  
Immunology Core**

**Alberta Cell Therapy  
Manufacturing\***

\*previously BioCanRx funded

## Project value:

**\$1,898,364**

BioCanRx Contribution:

**\$750,000**

Biotherapeutic:  
**Adoptive Cell Therapy**

5

Partners

## Key Investigators:

### Project Lead:

**Dr. Megan  
Levings**

**Dr. Brad  
Nelson**

**Dr. Kevin  
Hay**

**Dr. Lori West**

**Dr. Manoj  
Lalu**



**ThermoFisher  
SCIENTIFIC**

## About the project:

For many people with blood cancers, like leukemia, the only option for cure is a bone marrow transplant (BMT). BMTs work because the transplanted donor immune cells kill the patient's leukemia cells. However, donor immune cells may also attack healthy tissues, which can lead to a life-threatening complication called graft-versus-host disease (GVHD, where the graft is the donated cells, and the host is the recipient). The research team is developing ways to use regulatory T cells (Tregs), immune cells that naturally suppress or reign-in immune activity, as a cell therapy to prevent or treat GVHD without weakening the BMT anti-cancer activity. Early clinical studies of Treg therapy are promising, but it is difficult and expensive to obtain Tregs from the BMT donor. The team developed an approach to obtain Tregs from an alternate source: the thymus gland which is routinely discarded in children undergoing heart surgery. They developed new methods to isolate, expand (grow), freeze, and store, large numbers of Tregs

from thymuses. The next step toward their use in the clinic is to show that we can consistently manufacture Tregs to the required standards of purity and effectiveness. To do this, the team will finalize production methods and documentation, and make sure we can accurately measure their quality and function. Upon reaching these milestones, the team will apply for Health Canada approval to test Treg therapy in people with blood cancer who are undergoing a BMT.



## Partners:

BC Children's Hospital  
Foundation  
Canadian Immuno-Engineering  
and Biomanufacturing Hub

STEMCELL Technologies  
Thermo Fisher Scientific/Life  
Technologies  
UBC Faculty of Medicine

**Total Partner Contribution: \$1,148,365**

**Matched Partner Funds: \$1,065,040**

**Leveraged Partner Funds: \$83,325**

## Key Deliverables

1. Pre-CTA meeting with Health Canada
2. Finalize QA and QC release assays
3. Three validation tTreg batches with quality data using CTO-compliant starting material & GMP conditions
4. A complete pre-clinical data set for the CTA
5. Submitted CTA package to Health Canada

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