

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.

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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

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Partners



ThermoFisher
SCIENTIFIC

Key Investigators:

Project Lead:

Dr. Megan Leving

Dr. Brad Nelson

Dr. Lori West

Dr. Kevin Hay

Dr. Manoj Lalu

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.