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

Enabling Studies Program

Enabling Cell Manufacturing and Regulatory Compliance for CLIC-02: A Phase I Clinical Trial of a Novel Made-In-Canada CD22-Specific CAR-T Cell Product

Project duration: 2025-3-9 to 2027-3-31

Targeted cancer type:

Leukemia and Lymphoma

This project supports the manufacturing, regulatory, and safety testing activities essential to advancing their ongoing CD22 CAR-T Phase I clinical trial for leukemia and lymphoma patients.

1 Point of Care Site

BC Cancer's Conconi Family Immunotherapy Lab

Project value:

$3,706,410

BioCanRx Contribution:
$730,000

2 Partners

BC CANCER FOUNDATION

CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

Key Investigators:

Project Lead:
Dr. Kevin Hay

Dr. Brad Nelson

BC CANCER RESEARCH
Provincial Health Services Authority

Biotherapeutic:
Adoptive cell therapy

About the project:

Patients with aggressive B-cell leukemias and lymphomas that are resistant to standard therapies have a dismal outcome, with survival measured in months. Chimeric antigen receptor (CAR) T cell therapy targeting CD19, a marker on these cancers, has proven highly effective for treating such patients and has recently become standard of care. Unfortunately, however, 50-60% of patients show resistance to CD19 CAR-T cell therapy. To help such patients, the team leveraged BioCanRx support to develop a new CAR-T cell product targeting a different B-cell marker called CD22. They recently opened a phase I clinical trial to evaluate this new CD22 CAR-T cell product in leukemia and lymphoma patients at seven clinical sites across Canada.

BioCanRx will now support costs assosicated with: (1) manufacturing CD22 CAR-T cells for 24 adult and pediatric leukemia and lymphoma patients; (2) performing essential regulatory procedures to meet Health Canada requirements; and (3) developing essential assays to measure CAR-T cell safety and potency. This trial offers an urgently needed new treatment option for Canadian patients while substantially increasing the size and global impact of our CAR-T cell consortium.

Partners:

BC Cancer Foundation **CIHR**

Total Pledged Partner Contribution: $2,976,410

Total Pledged Matched Contributions: $749,308

Total Leveraged Partner Contributions: $2,227,102

Key Deliverables

1. Manufacturing CLIC-2201 CAR-T cells for the CLIC-02 clinical trial
2. Development and implementation of an Aseptic Process Simulation (APS) protocol
3. Development and qualification of optimized Quality Control assays

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

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