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

Clinical Trial Fact Sheet

Phase I clinical trial of Anti-Minor Histocompatibility Antigen Immunotherapy Broadening the Scope of Application for Precision Therapeutics (GLIDE)

Key Information

Who may qualify?

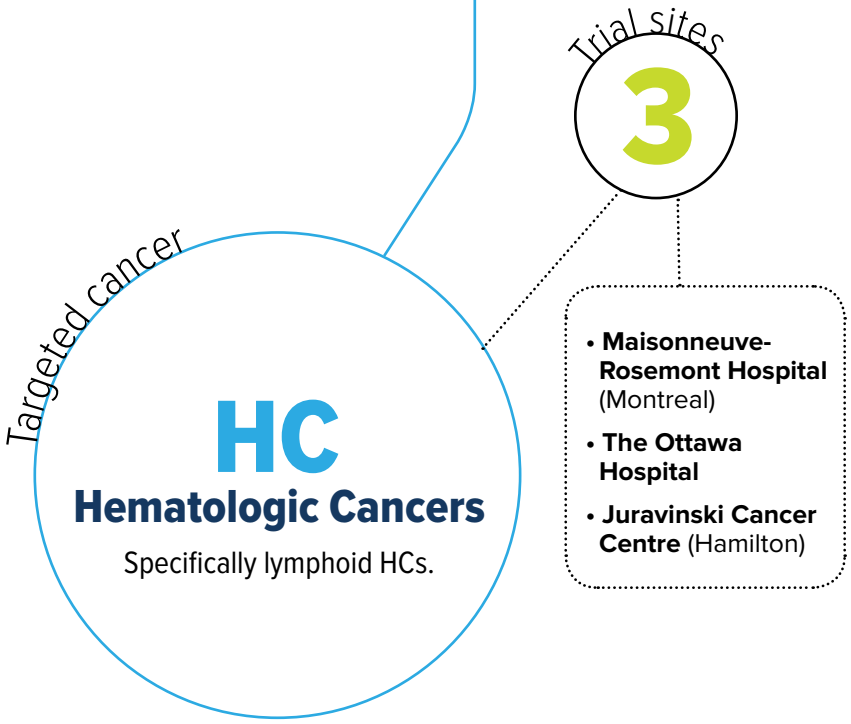
- Patients with treatment-resistant hematoligic cancers
- Patients must contain specific human leukocyte antigens (HLAs)
- Minimum six months post stem cell transplantation
- For full inclusion criteria, click on the link at the bottom of page

Recruitment status

- Suspended

Key words

- lymphoid, hematologic, blood cancer, stem cell, AHCT, GLIDE, lymph, MiHAs, transplant



About the project

Hematologic cancers (HCs) are cancers that affect the blood and lymph system, and represent about 10% of all cancers. The number of new cases of HCs in Canada is approximately 16,000 per year. HC affects both adults and children, and while around 50% of patients with HC can be cured by chemotherapy, the other 50% develop resistance to chemotherapy and ultimately succumb to their disease. This project's objective is to provide safer and more effective treatments for patients with resistant HCs.

For most HC patients, allogeneic hematopoietic cell transplantation (AHCT) is the only curative treatment. It is now known that the curative effects of AHCT result from immune system cells that recognize tumor Minor Histocompatibility Antigens (MiHAs), small cell-surface proteins that function as 'signals' for immune system cells. However, the use of adoptive immunotherapy is hampered by two factors: i) the variable anti-HC activity of AHCT, and ii) the risk of a devastating complication, graft-vs.-host disease (GVHD=donor cells attacking the patient).

Currently, the inability to selectively target malignant cells leads to the occurrence of GVHD. The team envisions that their work will transform AHCT into a consummate model of personalized cancer therapy because their strategy will tailor AHCT components as a function of the proteome of the cancer cells. They are initiating a phase I clinical trial to test this novel immunotherapeutic strategy in patients. The T cell product with anti-MiHA activity has been called "GLIDE" for Guided Lymphocyte Immunotpeptide Derived Expansion against MiHAs.

The team has identified 98 MiHAs that have preferential expression on hematopoietic cells, thus minimizing the GVHD risk. Also, they were able to develop an ex vivo immunization strategy that allows T cell generation with anti-MiHA specificity. They will initiate a clinical trial using this novel strategy to treat patients with lymphoid HCs and also expand the HLA typing repertoire in order to increase patient reach to approximately 95% of the patient population (from the current 45% reach). MiHA-targeted immunotherapy would allow for safe, targeted and more effective treatment of patients with otherwise fatal HCs.

For specific information to share with your doctor and care team click here

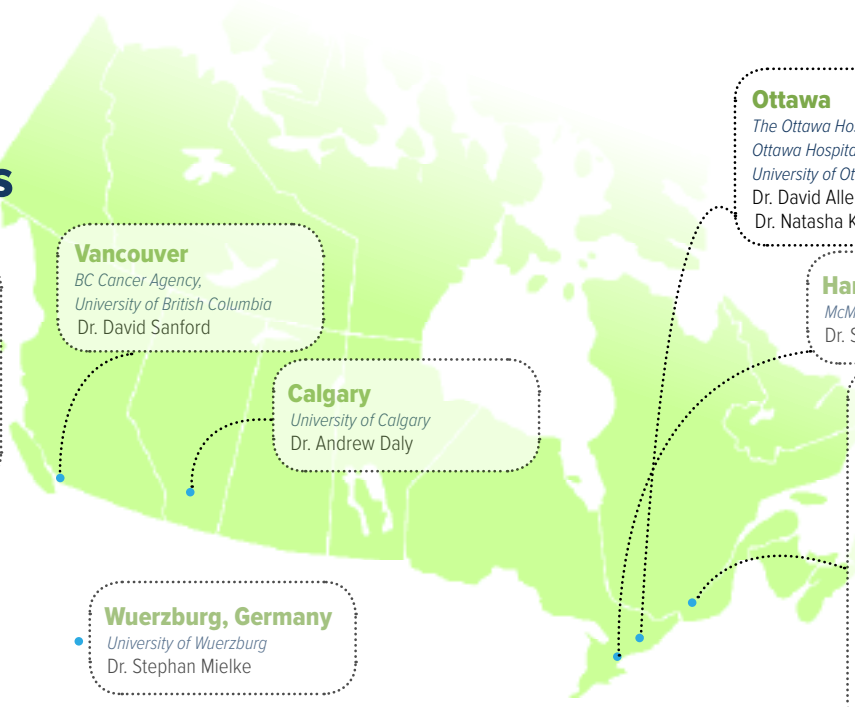
(URL--> https://bit.ly/2OP7t4q | Clinical Trial #: NCT03091933)

Clinical trial sites and investigators

Planned Clincal Trial Sites:

Phase I:

- Montreal
- Ottawa
- Calgary
- Vancouver



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Partner contributions

CIUSSS EMTL - HMR	AmorChem SpecifiT	CETC-Managment	C3i	CellCan
$500,000 in kind	$900,000 cash	$400,000 in kind	$40,000 in kind	$5,000 in kind

Year 1

- Modification to current clinical protocol to include more HLA subtypes and include new hematopoietic diesease indications
- Amendments submission to Health Canada and REB
- Improvements and Optimization of current MiHA manufacturing process
- Development of companion diagnostics
- Aquisition of new MiHA peptides
- Perform MiHA infusion in 2 patients

Year 2

- Perform MiHa infusion in 4 more patients,
- Data aquisition
- Development of Ligand binding affinity analysis algorithm to improve prediction of binding
- Use newly developed companion diagnostics on all patients

Year 3

- Perform MiHa infusion in 4 more patients
- Data acquisition
- Complete reports on clinical study
- Design of next clinical assay
- Improvement and performance of companion assays