



Essai Clinique

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Titre	A Phase I/II Trial Investigating Safety and Efficacy of Autologous TAC T Cells Targeting CD19 in Relapsed or Refractory Large B-Cell Lymphoma
Protocole ID	TAC01-CD19-01
ClinicalTrials.gov ID	NCT03880279
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase I-II
Stade	Maladie réfractaire
Type étude	Traitement
Médicament	Technologie TAC - TAC01-CD19
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL  PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
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Statut	Actif en recrutement
But étude	Phase I/II study to evaluate TAC01-CD19 in subjects with relapsed or refractory B-cell lymphomas. TAC technology is a novel way to genetically modify T cells and to redirect these T cells to target cancer antigens by co-opting the natural T cell receptor. The dose finding portion of this study will evaluate the safety and tolerability of increasing dose levels of TAC01-CD19 to identify a Maximal Tolerated Dose (MTD) or Recommended Phase II Dose (RP2D). The dose expansion portion of the study will further evaluate the safety, efficacy and pharmacokinetics of TAC01-CD19 at the RP2D.
Critères d'éligibilité	• Histologically confirmed CD19+ Large B-Cell Lymphoma including Diffuse Large B-cell Lymphoma (DLBCL) not otherwise specified (including de novo and transformed lymphoma), Primary Mediastinal Large B-cell Lymphoma, High-Grade B-cell Lymphoma with MYC and BCL2 and/or BCL6 rearrangement per WHO 2016 classification. • Relapsed or refractory disease after greater than 2 lines of therapy including anthracycline and anti-CD20 therapy and either having failed autologous stem cell transplant (ASCT) or being ineligible for ASCT. • ECOG 0-1. • Adequate organ function.
Critères d'exclusion	• Prior treatment with any of the following: allogeneic bone marrow transplantation, gene therapy, adoptive cell transfer of any kind, including CAR T cells. • Active central nervous system (CNS) lymphoma involvement. • History or presence of clinically relevant CNS pathology. • Active inflammatory neurological disorders, autoimmune disease, or infections.