# Essai Clinique

Généré le 25 avr. 2024 à partir de

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| Titre | An Open-Label, Multicenter, Phase I Trial Evaluating the Safety and Pharmacokinetics of Escalating Doses of BTCT4465A, WITH OR WITHOUT SINGLE-DOSE OBINUTUZUMAB PRETREATMENT, in Patients with Relapsed or Refractory B Cell Non-Hodgkin's Lymphoma (FL and DLBCL) |
| Protocole ID | GO29781 |
| ClinicalTrials.gov ID | NCT02500407 |
| Type(s) de cancer | Lymphome non-hodgkinien (LNH) |
| Phase | Phase I |
| Stade | Maladie réfractaire |
| Type étude | Traitement |
| Médicament | BTCT4465A et Obinutuzumab |
| Institution | CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL<br>HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS<br>3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2 |
| Ville | Montréal |
| Investigateur principal | Dre Sarit Assouline |
| Coordonnateur | Amine Saad<br>514-340-8222 poste 24599 |
| Statut | Fermé |
| But étude | This is a Phase 1/1b dose-escalation study of BTCT4465A administered as a single agent and in combination with atezolizumab in participants with relapsed or refractory B-cell NHL and CLL. The study will consist of a dose-escalation stage and an expansion stage where participants will be enrolled into indication-specific cohorts. |
| Critères d'éligibilité | • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1<br>• B-cell lymphoma expected to express the cluster of differentiation 20 (CD20) antigen who have relapsed after or failed to respond to at least one prior treatment regimen and for whom there is no available therapy expected to improve survival<br>• Adequate hepatic, hematologic, and renal function |
| Critères d'exclusion | • Pregnant or lactating women<br>• Monoclonal antibody, radioimmunoconjugate, antibody-drug conjugate, chemotherapy, or other investigational anti-cancer agent within 4 weeks prior to study drug<br>• Treatment with radiotherapy within 2 weeks prior to the first BTCT4465A administration<br>• Systemic immunosuppressive medication within 2 weeks prior to study drug<br>• Autologous stem cell transplantation (SCT) within 100 days prior to study drug, or any prior allogeneic SCT or solid organ transplantation<br>• Autoimmune disease with the exception of controlled/treated hypothyroidism, disease-related immune thrombocytopenic purpura, or hemolytic anemia<br>• History of central nervous system (CNS) lymphoma or other CNS disease<br>• Significant cardiovascular or pulmonary disease<br>• Hepatitis B or C or human immunodeficiency virus (HIV)<br>• Receipt of a live attenuated vaccine within 4 weeks prior to study drug |