Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	A Phase Ib/II, Open-Label, Multicenter, Randomized, Controlled Study Investigating the Safety, Tolerability, Pharmacokinetics, and Efficacy of Mosunetuzumab (BTCT4465A) in Combination With CHOP or CHP-Polatuzumab Vedotin in Patients With B-Cell Non-Hodgkin Lymphoma
Protocole ID	GO40515
ClinicalTrials.gov ID	NCT03677141
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase I-II
Type étude	Traitement
Médicament	Mosunetuzumab avec CHOP ou CHP-Polatuzumab Vedotine
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dre Sarit Assouline
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Statut	Actif en recrutement
But étude	This study will evaluate the safety, pharmacokinetics, and preliminary efficacy of mosunetuzumab in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (M-CHOP) and, subsequently, in combination with cyclophosphamide, doxorubicin, and prednisone (CHP) plus polatuzumab vedotin (CHP-pola) in participants with relapsed or refractory (R/R) B-cell non-Hodgkin lymphoma (NHL), and in previously untreated participants with diffuse large B-cell lymphoma (DLBCL).
Critères d'éligibilité	**Inclusion Criteria for Phase Ib and Phase II Portions** • At least one bi-dimensionally measurable nodal lesion, defined as > 1.5 cm in its longest dimension, or one bi-dimensionally measurable extranodal lesion, defined as > 1.0 cm in its longest diameter • Eastern Cooperative Oncology Group Performance Status of 0, 1, or 2 • Adequate hematologic function **Inclusion Criteria for Phase Ib Portion** • Participants must also meet the following criteria for study entry in the Phase Ib portion: • Histologically confirmed B-cell NHL according to the World Health Organization (WHO) 2016 classification expected to express the cluster of differentiation-20 (CD20) antigen • Relapsed or refractory (R/R) B-cell NHL after at least one prior systemic lymphoma therapy • Treatment with at least one prior CD20-directed therapy • Group B only: no prior treatment with polatuzumab vedotin **Inclusion Criteria for Phase II Portion** • Participants must also meet the following criteria for study entry in the Phase II portion: • Previously untreated, histologically confirmed DLBCL according to WHO 2016 classification • International Prognostic Index (IPI) score of 2−5

Critères d'exclusion	• Prior treatment with mosunetuzumab • Prior allogenic stem-cell transplant • Current Grade >1 peripheral neuropathy • Participants with history of confirmed progressive multifocal leukoencephalopathy (PML) • Known or suspected chronic active Epstein Barr virus (CAEBV), hepatitis B, hepatitis C (HCV), or Human Immunodeficiency Virus (HIV) • Prior solid organ transplantation • History of autoimmune disease • Current or past history of central nervous system (CNS) lymphoma • Current or past history of CNS disease, such as stroke, epilepsy, CNS vasculitis, or neurodegenerative disease • Significant cardiovascular disease or pulmonary disease • Clinically significant history of liver disease • Recent major surgery within 4 weeks before the start of C1D1, other than superficial lymph node biopsies for diagnosis **Exclusion Criteria for Phase Ib Portion** • Participants who also meet any of the following criteria will be excluded from study entry in the Phase Ib portion: • Prior treatment with chemotherapy, immunotherapy, and biologic therapy 4 weeks prior to C1D1 • Prior treatment with radiotherapy within 2 weeks prior to C1D1 • Adverse events from prior anti-cancer therapy resolved to ≤Grade 1 (with the exception of alopecia and anorexia) • Prior treatment with >250 mg/m^2 doxorubicin (or equivalent anthracycline dose) **Exclusion Criteria for Phase II Portion** • Participants who also meet any of the following criteria will be excluded from study entry in the Phase II portion: • Participants with transformed lymphoma • Prior therapy for B-cell NHL