Essai Clinique

Généré le 12 mai 2025 à partir de

Titre	A Phase III, Open-Label, Multicenter, Randomized, Study Evaluating the Safety and Efficacy of Polatuzumab Vedotin in Combination With Rituximab Plus Gemcitabine Plus Oxaliplatin (R-GEMOX) Versus R-GEMOX in Patients With Relapsed/Refractory Diffuse Large B-Cell Lymphoma
Protocole ID	POLARGO
ClinicalTrials.gov ID	NCT04182204
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase III
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	Polatuzumab védotine en association avec R-GEMOX versus R-GEMOX seul
Institution	CIUSSS DE LA MAURICIE-ET-DU-CENTRE-DU-QUEBEC CHAUR 1991 Boulevard du Carmel, Trois-Rivières, QC, G8Z 3R9
Ville	
Investigateur principal	Dr Jean-Sébastien Aucoin
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Statut	Fermé
Date d'activation	12-04-2022
But étude	This study is a multicenter, open-label study of polatuzumab vedotin administered by intravenous (IV) infusion in combination with rituximab, gemcitabine and oxaliplatin (R-GemOx) in participants with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). The study comprises of two stages: a safety run-in stage and a randomized controlled trial.
Critères d'éligibilité	• Histologically-confirmed diffuse large B-cell lymphoma, not otherwise specified (NOS) or history of transformation of indolent disease to DLBCL • Relapsed disease (disease that has recurred following a response that lasted ≥ 6 months from completion of the last line of therapy) or refractory disease (disease that progressed during therapy or progressed within 6 months (< 6 months) of prior therapy) • At least one (≥ 1) line of prior systemic therapy: • Patients may have undergone autologous hematopoietic stem cell transplantation (HSCT) prior to recruitment; chemotherapy followed by consolidative autologous HSCT will be counted as one line of therapy • Patients may have undergone allogeneic HSCT prior to recruitment, so long as they are off all immunosuppressive therapy and have no active GVHD; chemotherapy followed by allogeneic HSCT will be counted as one line of therapy • Local therapies (e.g., radiotherapy) will not be considered as lines of treatment • At least one bi-dimensionally measurable lesion, defined as > 1.5 cm in its longest dimension as measured by CT or MRI • Eastern Cooperative Oncology Group (ECOG) performance status of 0,1 or 2 • Adequate hematological function • For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception, and agreement to refrain from donating eggs • For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use

	contraceptive measures, and agreement to refrain from donating sperm
Critères d'exclusion	• History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies (or recombinant antibody-related fusion proteins) or known sensitivity or allergy to murine products • Contraindication to rituximab, gemcitabine or oxaliplatin • Peripheral neuropathy assessed to be > Grade 1 according to NCI CTCAE v5.0 • Prior use of polatuzumab vedotin or a gemcitabine plus platinum-based agent combination, recent participation in a clinical trial, and/or treatment with radiotherapy, chemotherapy, immunotherapy, immunosuppressive therapy within 2 weeks • Planned autologous or allogenic stem cell transplantation at time of recruitment • Primary or secondary central nervous system (CNS) lymphoma • Richter's transformation or prior CLL • Abnormal laboratory values or health conditions, as assessed by the investigator, any known conditions preventing adherence to protocol or active bacterial, viral, fungal, mycobacterial, parasitic, or other infection • Vaccination with a live vaccine within 4 weeks prior to treatment • Recent major surgery (within 6 weeks before the start of Cycle 1 Day 1) other than for diagnosis • Any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that may affect the interpretation of the results or render the patient at high risk from treatment complications • Pregnant or breastfeeding, or intending to become pregnant during the study or within 12 months after the last dose of study drug • Women of childbearing potential must have a negative serum pregnancy test result within 7 days prior to initiation of study drug