Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	A Randomized, Open-Label, Phase 3 Trial of Epcoritamab vs Investigator's Choice Chemotherapy in Relapsed/Refractory Diffuse Large B-cell Lymphoma
Protocole ID	GCT3013-05
ClinicalTrials.gov ID	NCT04628494
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase III
Stade	Lymphome diffus à grandes cellules B
Type étude	Clinique
Médicament	Epcoritamab versus une chimiothérapie au choix de l'investigateur (R-GemOx ou BR)
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Jean-François Larouche
Coordonnateur	Philippe Nadeau 418-649-0252 poste 63115
Statut	Actif en recrutement
But étude	The purpose of this trial is to evaluate the efficacy of epcoritamab (GEN3013 DuoBody®-CD3xCD20) compared to investigator's choice of chemotherapy in patients with relapsed, refractory diffuse large B-Cell Lymphoma who have failed or are ineligible for HDT-ASCT. Eligible patients will be randomized (1:1) to either epcoritamab or investigator's choice of chemotherapy: R-GemOx (rituximab, gemcitabine and oxaliplatin) or BR (bendamustine and rituximab).

Critères d'éligibilité	• Relapsed or refractory disease and previously treated with at least 1 line of systemic antineoplastic therapy including anti-CD20 mAb-containing combination chemotherapy since lymphoma diagnosis
	• One of the confirmed histologies below with CD20-positivity:
	  • DLBCL, NOS, including de novo or histologically transformed from FL
	  • "Double-hit" or "triple-hit" DLBCL (technically classified in WHO 2016 as HGBCL, with MYC and BCL2 and/or BCL6 translocations), including de novo or histologically transformed from FL
	  • FL Grade 3B
	• ECOG PS score of 0-2
	• Failed previous HDT-ASCT or not eligible for HDT-ASCT at screening
	• Patients must have detectable disease by PET scan and measurable by CT scan or MRI
	• Acceptable renal and liver function
	• Life expectancy >2 months on SOC treatment

Critères d'exclusion	• Primary CNS tumor or known CNS involvement • Any prior therapy with a bispecific antibody targeting CD3 and CD20 • Major surgery within 4 weeks prior to randomization • Chemotherapy and other non-investigational antineoplastic agents (except CD20 mAbs) within 4 weeks or 5 half-lives (whichever is shorter) prior to randomization • Any investigational drug within 4 weeks or 5 half-lives, whichever is longer, prior to randomization • ASCT within 100 days of randomization

- Treatment with CAR-T therapy within 100 days prior to randomization
- Seizure disorder requiring anti-epileptic therapy
- Clinically significant cardiac disease,