Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	Étude multicentrique de phase 3 à répartition aléatoire, à double insu, contrôlée par placebo, avec comparateur actif, visant à évaluer le brentuximab védotine ou le placebo en association avec le lénalidomide et le rituximab chez des sujets atteints d'un lymphome diffus à grandes cellules B (LDGCB) récidivant ou réfractaire
Protocole ID	SGN35-031 (Echelon-3)
ClinicalTrials.gov ID	NCT04404283
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase III
Stade	Lymphome diffus à grandes cellules B
Type étude	Clinique
Médicament	Brentuximab védotine ou le placebo en association avec le lénalidomide et le rituximab
Institution	CIUSSS DU NORD-DE-L'ILE-DE-MONTREAL H HOPITAL DU SACRE-COEUR-DE-MONTREAL 5400 boul. Gouin Ouest, Montréal, QC, H4J1C5
Ville	
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Statut	Fermé
But étude	This study is being done to see if adding brentuximab vedotin helps two drugs work better to treat patients with diffuse large B-cell lymphoma (DLBCL). Participants in this study will have DLBCL that has come back or not gotten better with treatment.Patients will be randomly assigned to get either brentuximab vedotin or placebo. The placebo will look like brentuximab vedotin, but has no medicine in it. Since the study is "blinded," patients and their doctors will not know whether a patient gets brentuximab vedotin or placebo. All patients in the study will get rituximab and lenalidomide. These are drugs that can be used to treat DLBCL.
Critères d'éligibilité	• Participants with relapsed or refractory diffuse and transformed large B-cell lymphoma (R/R DLBCL). DLBCL and cell of origin (GCB versus non-GCB) will be histologically determined by local pathology assessment for the purposes of study eligibility and stratification. • Participants must have R/R disease following 2 or more lines of prior systemic therapy. • Participants must be HSCT or CAR-T ineligible according to the investigator and must meet at least one of the following criteria: 1. One or more co-morbidities, including cardiac, pulmonary, renal or hepatic dysfunction that in the opinion of the Investigator make the subject medically unfit to received HSCT or CAR-T therapy 2. Active disease following induction and salvage chemotherapy 3. Inadequate stem cell mobilization (for HSCT) 4. Relapse following prior HSCT or CAR-T 5. Unable to receive CAR-T therapy due to financial, geographic, or insurance issues • Participants will need to have a formalin-fixed paraffin-embedded tumor tissue (obtained ≤4 weeks before Day 1) submitted to the central pathology lab. • An Eastern Cooperative Oncology Group (ECOG) performance status score of 0 to 2 • Participants must have fluorodeoxyglucose (FDG)-avid disease by positron emission tomography (PET) and bidimensional measurable disease of at least 1.5 cm by computed tomography (CT), as assessed by the site radiologist within 28 days of Day 1.

	• Participants must be registered into the mandatory lenalidomide REMS® program and be willing to comply with its requirements. Per standard lenalidomide REMS® program requirements, all physicians who prescribe lenalidomide for research subjects enrolled into this trial, must be registered in, and must comply with, all requirements of the lenalidomide REMS® program.
Critères d'exclusion	• History of another malignancy within 2 years before the first dose of study drug or any evidence of residual disease from a previously diagnosed malignancy • History of progressive multifocal leukoencephalopathy (PML) • Active cerebral/meningeal disease related to the underlying malignancy. Subjects with a history of cerebral/meningeal disease related to the underlying malignancy are allowed if prior CNS disease has been effectively treated and without progression for at least 3 months. • Any uncontrolled Grade 3 or higher (per NCI CTCAE version 5.0) viral, bacterial, or fungal infection within 2 weeks prior to the first dose of study drug. Routine antimicrobial prophylaxis is permitted • Chemotherapy, radiotherapy, biologics, and/or other antitumor treatment with immunotherapy that is not completed 3 weeks prior to first dose of study drug, unless underlying disease has progressed on treatment • Participants who are breastfeeding • Known hypersensitivity to any study drug or excipient contained in the drug formulation of the study drugs • Known to be positive for hepatitis B by surface antigen expression. Known to be positive for hepatitis C infection (positive by polymerase chain reaction [PCR] or on antiviral therapy for hepatitis C within the last 6 months). Participants who have been treated for hepatitis C infection are permitted if they have documented sustained virologic response of 12 weeks. • Participants with previous allogeneic HSCT if they meet either of the following criteria: 1. <100 days from HSCT 2. Active acute or chronic graft-versus-host disease (GVHD) or receiving immunosuppressive therapy as treatment for or prophylaxis against GVHD • Previous treatment with brentuximab vedotin or lenalidomide • Current therapy with immunosuppressive medications (including steroids), other systemic anti-neoplastic, or investigational agentsa) Prednisone (or equivalent) ≤10 mg/day may be used for non-lymphomatous purposes • Documented history of a cerebral vascular event (stroke or transient ischemic attack), unstable angina, myocardial infarction, or cardiac symptoms consistent with New York Heart Association (NYHA) Class III-IV within 6 months prior to the first dose of study drugs • Congestive heart failure, Class III or IV, by the NYHA criteria • Grade 2 or higher peripheral sensory or motor neuropathy at baseline