Essai Clinique

Généré le 08 mai 2024 à partir de

Titre	Étude en deux parties, ouverte et randomisée de phase II/III visant à comparer un traitement par dinutuximab et irinotécan avec un traitement par irinotécan seul pour le traitement de deuxième ligne chez des sujets atteints de cancer du poumon à petites cellules résistant ou récidivant.
Protocole ID	Distinct / DIV-SCLC-301
ClinicalTrials.gov ID	NCT03098030
Type(s) de cancer	Poumon à petites cellules
Phase	Phase II
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	dinutuximab et irinotécan
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	Montréal
Investigateur principal	Dre Vera Hirsh
Coordonnateur	Nicola Raby 514-934-1934 poste 34095
Statut	Actif en recrutement
But étude	This is a 2-part, multicenter, open-label, randomized study of dinutuximab and irinotecan versus irinotecan alone in subjects with relapsed or refractory small cell lung cancer (SCLC). Part 1 of the study involves intrasubject dose escalation to evaluate the safety and tolerability of dinutuximab in combination with irinotecan. Part 2 of the study is designed to determine whether dinutuximab plus irinotecan prolongs overall survival (OS) compared with irinotecan alone. Subjects in Part 2 will be randomized in a 2:2:1 fashion to 1 of 3 treatment groups: (A) irinotecan; (B) dinutuximab plus irinotecan; or (C) topotecan. Randomization will be stratified by duration of response to prior platinum therapy (relapse-free period <3 months or ≥3 months).
Critères d'éligibilité	• Have histologically or cytologically confirmed SCLC (undifferentiated small-cell carcinoma arising in or consistent with lung cancer origin). • Documented relapse or disease progression during or after first-line platinum-based therapy (subjects refractory to initial platinum-based therapy are eligible). • Have no curative therapy available. • Have a life expectancy of at least 12 weeks. • Have Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. • Have adequate bone marrow and hepatic function. • Have calculated creatinine clearance (CrCL) ≥30 mL/minute or serum creatinine ≤1.5 times below the upper limit of normal. • Women of reproductive potential must not be pregnant or breastfeeding and have a negative urine or serum pregnancy test obtained within 7 days prior to the first dose of study treatment. • Subjects must agree to consistently use 2 forms of highly effective contraception/birth control between signing of the informed consent and 60 days after the last study drug administration.

Critères d'exclusion	• Candidate for re-treatment with original platinum-based regimen as second-line therapy. • Prior treatment with irinotecan, topotecan, or dinutuximab. • Have active brain metastases. Subjects with brain metastases are allowed if they completed definitive brain therapy, are asymptomatic and radiologically stable, and if they are not currently receiving corticosteroids or radiation. • Have mixed small cell and non-small cell histologic features. • Have a previous or concurrent cancer that is distinct in primary site or histology from the cancer being evaluated in this study, except cervical carcinoma in situ, treated basal cell carcinoma, superficial bladder tumors (Ta and Tis [carcinoma in situ]) or any previous cancer curatively treated <3 years ago. • Have a history or current evidence of uncontrolled cardiovascular disease. • Have had a major surgery or significant trauma within 4 weeks of enrollment (Part 1) or randomization (Part 2). • Have had organ allograft or hematopoietic transplantation. • Have a history of hypersensitivity to any study drugs or their excipients, or intolerance to hydration due to preexisting pulmonary or cardiac impairment, or intolerance to opioid pain medications, or a history of severe hypersensitivity to any other antigen. • Have a history or current evidence of human immunodeficiency virus (HIV) infection. • Have active hepatitis B virus (HBV) or hepatitis C virus (HCV) infection requiring treatment or have an active infection that is clinically serious in the investigator's opinion. • Exposure to any investigational agent, systemic chemotherapy, or therapeutic radiation within 21 days of enrollment (Part 1) or randomization (Part 2). • Exposure to strong CYP3A4 and/or UGT1A1 inhibitors and strong CYP3A4 inducers within 14 days of enrollment (Part 1) or randomization (Part 2). • Have any clinical condition that is considered unstable or might jeopardize the safety of the subject and/or influence the subject's compliance in the study.