Essai Clinique

Généré le 04 mai 2024 à partir de

Titre	A Phase 2/3 Study to Evaluate the Efficacy and Safety of Unesbulin in Unresectable or Metastatic, Relapsed or Refractory Leiomyosarcoma
Protocole ID	PTC596-ONC-008-LMS
ClinicalTrials.gov ID	NCT05269355
Type(s) de cancer	Sarcome
Phase	Phase II-III
Type étude	Clinique
Médicament	Unesbulin
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	
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Statut	Actif en recrutement
But étude	This study will compare the efficacy and safety of unesbulin plus dacarbazine versus placebo plus dacarbazine in participants with unresectable or metastatic, relapsed or refractory LMS who have received at least 1 prior line of systemic therapy.
Critères d'éligibilité	• Histological or cytological confirmation of LMS arising at any anatomic site except bone sarcoma, unresectable or metastatic, relapsed or refractory disease measurable per RECIST 1.1 criteria • Disease progression on previous treatment before screening or intolerability to other oncology treatments • Participants with liver metastases may be enrolled • Participants with well-controlled asthma or chronic obstructive pulmonary disease may be enrolled. • Toxicity from prior therapies recovered to Grade ≤1 or participant's baseline, except for alopecia. In addition, endocrinopathies associated with prior immunotherapy-based treatments that are well controlled on replacement medication are not exclusionary. • At least 1 prior systemic cytotoxic or targeted therapy regimen for LMS • At least 4 weeks since prior surgery and recovered in the opinion of investigator
Critères d'exclusion	• Received temozolomide or dacarbazine at any time • Any other systemic anticancer therapy including investigational agents ≤3 weeks before initiation of study treatment. Additionally, participants may not have received radiation ≤3 weeks before initiation of study treatment. • Known intolerance to dacarbazine or one or more of the excipients in unesbulin. • Co-existing active infection or any co-existing medical condition likely to interfere with study procedures • Gastrointestinal disease or other conditions that could affect absorption. Active peptic ulcer disease or previous history of gastric perforation within the last 2 years • Major surgery, open biopsy, or significant traumatic injury that has not recovered, in the opinion

of the investigator, within 28 days of baseline
- Prior malignancies, other than LMS, that required treatment or have shown evidence of recurrence (except for non-melanoma skin cancer or adequately treated cervical carcinoma in situ, prostate cancer in situ or any other low risk malignancy that is approved by the medical monitor) during the 5 years before initiation.
- Prior or ongoing clinically significant illness, medical or psychiatric condition, medical history, physical findings, electrocardiogram (ECG) findings, or laboratory abnormality that, in the investigator's opinion, could affect the safety of the participant, or alter the absorption, distribution, metabolism, or excretion of the study drugs, or could impair the assessment of study results.