Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	A Phase 3, Randomized, Placebo-controlled, Double-blind Study of Vimseltinib to Assess the Efficacy and Safety in Patients With Tenosynovial Giant Cell Tumor
Protocole ID	DCC-3014-03-001 (MOTION)
ClinicalTrials.gov ID	NCT05059262
Type(s) de cancer	Sarcome
Phase	Phase III
Type étude	Clinique
Médicament	Vimseltinib
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
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Investigateur principal	Dr Thierry Alcindor
Coordonnateur	
Statut	Fermé
But étude	This is a multicenter Phase 3 clinical study, which aims to evaluate the effectiveness of an investigational drug called vimseltinib for the treatment of tenosynovial giant cell tumor (TGCT) in cases where surgical removal of the tumor is not an option.The study consists of two parts. In Part 1, eligible study participants will be assigned to receive either vimseltinib or matching placebo for 24 weeks. A number of assessments will be carried out during the course of the study, including physical examinations, blood tests, imaging studies, electrocardiograms, and questionnaires. MRI scans will be used to evaluate the response of the tumors to the treatment. Participants assigned to placebo in Part 1 will have the option to receive vimseltinib for Part 2. Part 2 is a long-term treatment phase in which all participants receive open-label vimseltinib.
Critères d'éligibilité	• Patients ≥18 years of age • TGCT for which surgical resection is not an option (tumor biopsy to confirm diagnosis required if no histology/pathology available at screening) • Symptomatic disease as defined as at least moderate pain per BPI Worst Pain or at least moderate stiffness per Worst Stiffness NRS item (defined as a score of 4 or more, with 10 describing the worst condition) within the screening period, prior to the first dose, and documented in the medical record • Participants should complete 14 consecutive days of questionnaires during the screening period and must meet minimum requirements as outlined in study protocol • Must have stable analgesic regimen, as judged by the investigator, for at least 2 weeks prior to first dose of study drug • Must have at least 1 measurable lesion according to RECIST Version 1.1, with a minimum tumor size of 2cm • Adequate organ and bone marrow function • If a female of childbearing potential, must have a negative pregnancy test prior to enrollment and agree to follow the contraception requirements • Must provide signed consent to participate in the study and is willing to comply with study-specific procedures • Willing and able to complete the patient-reported outcome (PRO) assessments on an electronic device

Critères d'exclusion	• Previous use of systemic therapy targeting colony stimulating factor 1 (CSF1) or CSFR1 receptor (CSF1R); previous therapy with imatinib and nilotinib is allowed • Received therapy for TGCT, including investigational therapy within 14 days prior to the administration of study drug or within 28 days for therapies with a half-life longer than 3 days or an unknown half-life prior to the administration of study drug • Known metastatic TGCT or other active cancer that requires concurrent treatment (exceptions will be considered on a case-by-case basis) • QT interval corrected by Fridericia's formula (QTcF) >450 ms in males or >470 ms in females or history of long QT syndrome • Concurrent treatment with any study-prohibited medications • Major surgery within 14 days of the first dose of study drug • Any clinically significant comorbidities • Active liver or biliary disease including evidence of fatty liver, nonalcoholic steatohepatitis (NASH), or cirrhosis • Malabsorption syndrome or other illness that could affect oral absorption • Known active human immunodeficiency virus (HIV), active or chronic hepatitis B, active or chronic hepatitis C, or known active mycobacterium tuberculosis infection • If female, the participant is pregnant or lactating • Known allergy or hypersensitivity to any component of the study drug • Contraindication to MRI