Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial of Nirogacestat Versus Placebo in Adult Patients With Progressing Desmoid Tumors/Aggressive Fibromatosis (DT/AF)
Protocole ID	NIR-DT-301
ClinicalTrials.gov ID	NCT03785964
Type(s) de cancer	Sarcome
Phase	Phase III
Stade	Sarcome des tissus mous
Type étude	Traitement
Médicament	Nirogacestat
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Thierry Alcindor
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Statut	Fermé
But étude	Desmoid tumors, also referred to as aggressive fibromatosis, are rare, locally invasive, slow growing soft tissue tumors. Although considered benign because of their inability to metastasize, desmoid tumors can cause significant morbidity and occasionally mortality in patientsNirogacestat (PF-03084014) is a potent, small molecule, selective, reversible, noncompetitive inhibitor of γ-secretase (GS) with a potential antitumor activity.Nirogacestat is being investigated for the treatment of desmoid tumors due to its ability to bind to GS, blocking proteolytic activation of Notch receptors. Previous clinical study data have shown that Notch signaling plays an important role in cancer development. Hence, inhibition of Notch signaling is an important strategy for therapeutic treatment.
Critères d'éligibilité	• Participant has DT/AF that has progressed by ≥20% as measured by RECIST Version 1.1 Criteria within the 12-month period prior to first dose of study treatment. • Participant has newly diagnosed, measurably progressing DT/AF that is not amenable to surgical resection or radiation therapy; OR recurrent, progressing DT/AF following CR to initial therapy; OR preexisting DT/AF and has previously received therapy and the residual tumor has progressed. • Participant agrees to provide archival or new tumor tissue for confirmation of disease. • If participant was previously treated with an investigational therapy for treatment of DT/AF, participant must have completed prior therapy at least 28 days prior to signing informed consent. • Participants who are receiving nonsteroidal anti-inflammatory drugs (NSAIDs) as treatment for conditions other than DT/AF. • Participant has an Eastern Cooperative Oncology Group (ECOG) performance status ≤2 at screening. • Participant has adequate organ and bone marrow function.

Critères d'exclusion	• Participant has known malabsorption syndrome or preexisting gastrointestinal conditions that may impair absorption of nirogacestat. • Participant has experienced any of the following within 6 months of signing informed consent: clinically significant cardiac disease (New York Heart Association Class III or IV), myocardial infarction, severe/unstable angina, coronary/peripheral artery bypass graft, symptomatic congestive heart failure, cerebrovascular accident, transient ischemic attack, or symptomatic pulmonary embolism. • Lymphoma, leukemia, or any malignancy within the past 5 years except for basal cell or squamous epithelial carcinomas of the skin that have been resected with no evidence of metastatic disease for 3 years. • Current or chronic history of liver disease or known hepatic or biliary abnormalities (except for Gilbert's syndrome or asymptomatic gallstones). • Participant previously received or is currently receiving therapy with GS inhibitors or anti-Notch antibody therapy. • Participant is currently using or anticipates using a tyrosine kinase inhibitor within 28 days of study treatment. • Participant is currently using or anticipates using food or drugs that are known strong/moderate cytochrome P450 3A4 (CYP3A4) inhibitors or strong inducers within 14 days prior to the first dose of study treatment. • Participant is currently using or anticipates using chronic daily NSAIDs for treatment of DT/AF within 28 days of study treatment. • Participant is unable to tolerate MRI or for whom MRI is contraindicated. • Participant has experienced other severe acute or chronic medical or psychiatric conditions within 1 year of study start.