Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	Étude de phase III ouverte, multicentrique, interventionnelle et à répartition aléatoire sur le DCC-2618 par rapport au sunitinib chez des patients atteints de tumeurs stromales gastro-intestinales avancées après un traitement par l'imatinib
Protocole ID	intrigue (DCC-2618-03-002)
ClinicalTrials.gov ID	NCT03673501
Type(s) de cancer	Tumeur stromale gastro-intestinale
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Ripretinib (DCC-2618) vs Sunitinib
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	
Investigateur principal	Dr Jonathan Noujaim
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Statut	Fermé
But étude	This is a 2-arm, randomized, open-label, international, multicenter study comparing the efficacy of DCC-2618 to sunitinib in GIST patients who progressed on or were intolerant to first-line anticancer treatment with imatinib. Approximately 358 patients will be randomized in a 1:1 ratio to DCC-2618 150 mg once daily (QD) (continuous dosing for 6 week cycles) or sunitinib 50 mg QD (6 week cycles, 4 weeks on, 2 weeks off).
Critères d'éligibilité	• Patients ≥ 18 years of age at the time of informed consent. • Histologic diagnosis of GIST and must be able to provide an archival tumor tissue sample, otherwise, a fresh biopsy is required. • Molecular pathology report must be available. If molecular pathology report is not available or insufficient, an archival tumor tissue sample or fresh biopsy is required for mutation status confirmation by the central laboratory prior to randomization. • Patients must have progressed on imatinib or have documented intolerance to imatinib. • Eastern Cooperative Oncology Group (ECOG) PS of ≤ 2 at screening. • Female patients of childbearing potential must have a negative serum beta-human chorionic gonadotropin (β-hCG) pregnancy test at screening and negative pregnancy test at Cycle 1 Day 1 prior to the first dose of study drug. • Patients of reproductive potential must agree to follow the contraception requirements outlined in the study protocol. • Patients must have at least 1 measurable lesion according to mRECIST Version 1.1 (non nodal lesions must be ≥ 1.0 cm in the long axis or ≥ double the slide thickness in the long axis) within 21 days prior to the first dose of study drug. • Adequate organ function and bone marrow reserve as indicated by the central laboratory assessments performed at screening. • Resolution of all toxicities from prior therapy to ≤ Grade 1 (or patient baseline) within 1 week prior to the first dose of study drug (excluding alopecia and ≤ Grade 3 clinically asymptomatic lipase, amylase, and creatine phosphokinase [CPK] laboratory abnormalities). • The patient is capable of understanding and complying with the protocol and has signed the

	informed consent document. Signed informed consent form (ICF) must be obtained before any study-specific procedures are performed.
Critères d'exclusion	• Treatment with any other line of therapy in addition to imatinib for advanced GIST. • Patients with a prior or concurrent malignancy whose natural history or treatment have the potential to interfere with the safety or efficacy assessment of this clinical trial are not eligible. • Patient has known active central nervous system metastases. • New York Heart Association class II-IV heart disease, myocardial infarction within 6 months of cycle 1 day 1, active ischemia or any other uncontrolled cardiac condition such as angina pectoris, clinically significant cardiac arrhythmia requiring therapy, uncontrolled hypertension or congestive heart failure. • Left ventricular ejection fraction (LVEF) < 50% at screening. • Arterial thrombotic or embolic events such as cerebrovascular accident (including ischemic attacks) or hemoptysis within 6 months before the first dose of study drug. • Venous thrombotic events (e.g. deep vein thrombosis) or pulmonary arterial events (e.g. pulmonary embolism) within 1 month before the first dose of study drug. Patients on stable anticoagulation therapy for at least one month are eligible. • 12-lead ECG demonstrating QT interval corrected (QTc) by Fridericia's formula > 450 ms in males or > 470 ms in females at screening or history of long QTc syndrome • Use of known substrates or inhibitors of BCRP transporters within 14 days or 5 x the half-life (whichever is longer) prior to the first dose of study drug. • Major surgeries (e.g. abdominal laparotomy) within 4 weeks of the first dose of study drug. All major surgical wounds must be healed and free of infection or dehiscence before the first dose of study drug. • Any other clinically significant comorbidities. • Known human immunodeficiency virus or hepatitis C infection only if the patient is taking medications that are excluded per protocol, active hepatitis B, or active hepatitis C infection. • If female, the patient is pregnant or lactating. • Known allergy or hypersensitivity to any component of the study drug. • Gastrointestinal abnormalities including but not limited to: • inability to take oral medication • malabsorption syndromes • requirement for intravenous (IV) alimentation • Any active bleeding excluding hemorrhoidal or gum bleeding.