Essai Clinique

Généré le 19 mai 2025 à partir de

Titre	A Phase 3 Randomized, Open-Label, Multicenter Clinical Study of CGT9486+Sunitinib vs. Sunitinib in Subjects With Locally Advanced, Unresectable, or Metastatic Gastrointestinal Stromal Tumors
Protocole ID	Peak
ClinicalTrials.gov ID	NCT05208047
Type(s) de cancer	Tumeur stromale gastro-intestinale
Phase	Phase III
Médicament	CGT9486+Sunitinib versus 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	Actif en recrutement
Date d'activation	29-09-2023
But étude	This is a Phase 3, open-label, international, multicenter study of CGT9486 in combination with sunitinib. This is a multi-part study that will enroll approximately 426 patients. Part 1 consists of two evaluations: 1) confirming the dose of an updated formulation of CGT9486 to be used in subsequent parts in approximately 20 patients who have received at least one prior line of therapy for GIST and 2) evaluating for drug-drug interactions between CGT9486 and sunitinib in approximately 18 patients who have received at least two prior tyrosine kinase inhibitors (TKIs) for GISTs. The second part of the study will enroll approximately 388 patients who are intolerant to, or who failed prior treatment with imatinib only and will compare the efficacy of CGT9486 plus sunitinib to sunitinib alone with patients being randomized in a 1:1 manner.

Critères d'éligibilité	• Histologically confirmed locally advanced, metastatic, and/or unresectable GIST. Molecular pathology report must be available for Part 2; if molecular pathology report is unavailable or inadequate, an archival or fresh tumor tissue sample will be required to evaluate mutational status prior to randomization.
	• Documented disease progression on or intolerance to imatinib
	• Subjects must have received the following treatment:
	  • Part 1a: Treatment with ≥1 prior lines of therapy for GIST
	  • Part 1b: Treatment with ≥2 prior TKI for GISTs
	  • Part 2: Prior treatment with imatinib only
	• Have at least 1 measurable lesion according to mRECIST v1.1
	• ECOG - 0 to 2
	• Have clinically acceptable local laboratory screening results (clinical chemistry and hematology) within certain limits

Critères d'exclusion	• Known PDGFR driving mutations or known succinate dehydrogenase deficiency • Clinically significant cardiac disease • Major surgeries (eg, abdominal laparotomy) within 4 weeks of the first dose of study drug • Gastrointestinal abnormalities including, but not limited to, significant nausea and vomiting, malabsorption, external biliary shunt, or significant bowel resection that would preclude adequate absorption • Any active bleeding excluding hemorrhoidal or gum bleeding

- Seropositive for HIV 1 or 2, or positive for hepatitis B surface antigen or hepatitis C virus (HCV) antibody.
- Active, uncontrolled, systemic bacterial, fungal, or viral infections at Screening
- Received strong CYP3A4 inhibitors or inducers
- Received sunitinib within 3 weeks (Part 1a, Part 1b)