Essai Clinique

Généré le 18 mars 2025 à partir de

Titre	A Randomized, Multi-center, Double-blind, Placebo-controlled Phase 3 Study of Bemarituzumab Plus Chemotherapy Versus Placebo Plus Chemotherapy in Subjects With Previously Untreated Advanced Gastric or Gastroesophageal Junction Cancer With FGFR2b Overexpression
Protocole ID	FORTITUDE-101
ClinicalTrials.gov ID	NCT05052801
Type(s) de cancer	Estomac Oesophage
Phase	Phase III
Type étude	Clinique
Médicament	Bemarituzumab + chimiothérapie versus placebo + chimiothérapie
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL H HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
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Investigateur principal	Dr Petr Kavan
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Statut	Actif en recrutement
Date d'activation	05-01-2023
But étude	The main objective of this study is to compare efficacy of bemarituzumab combined with oxaliplatin, leucovorin, and 5-fluorouracil (5-FU) (mFOLFOX6) to placebo plus mFOLFOX6 as assessed by overall survival (OS).

Critères d'éligibilité	• Adults with unresectable, locally advanced or metastatic gastric or gastroesophageal junction cancer not amenable to curative therapy
	• Fibroblast growth factor receptor 2b (FGFR2b) overexpression positive as determined by centrally performed immunohistochemistry (IHC) testing, based on tumor sample either archival (obtained within 6 months/180 days prior to signing pre-screening informed consent) or a fresh biopsy
	• Eastern Cooperative Oncology Group (ECOG) less than or equal to 1
	• Measurable disease or non-measurable, but evaluable disease, according to Response Evaluation Criteria in Solid Tumors (RECIST) V 1.1
	• Participant has no contraindications to mFOLFOX6 chemotherapy
	• Adequate organ and bone marrow function:
	  • absolute neutrophil count greater than or equal to 1.5 times 10^9/L
	  • platelet count greater than or equal to 100 times 10^9/L
	  • hemoglobin ≥ 9 g/dL without red blood cell (RBC) transfusion within 7 days prior to the first dose of study treatment
	  • aspartate aminotransferase (AST) and alanine aminotransferase (ALT) less than 3 times the upper limit of normal (ULN) (or less than 5 times ULN if liver involvement). Total bilirubin less than 1.5 times ULN (or less than 2 times ULN if liver involvement); with the exception of participants with Gilbert's disease)
	  • calculated or measured creatinine clearance (CrCl) of ≥ 30 mL/minute calculated using the formula of Cockcroft and Gault ([140 - Age]) × Mass [kg]/[72 × Creatinine mg/dL]) (x 0.85 if female)
	  • international normalized ratio (INR) or prothrombin time (PT) less than 1.5 times ULN

	except for participants receiving anticoagulation, who must be on a stable dose of anticoagulant therapy for 6 weeks prior to enrollment
Critères d'exclusion	• Prior treatment for metastatic or unresectable disease (Note: prior adjuvant, neo-adjuvant, and peri-operative therapy is allowed if completed more than 6 months prior to first dose of study treatment) • Prior treatment with any selective inhibitor of fibroblast growth factor - fibroblast growth factor receptor (FGF-FGFR) pathway • Known human epidermal growth factor receptor 2 (HER2) positive • Untreated or symptomatic central nervous system (CNS) disease or brain metastases • Peripheral sensory neuropathy greater than or equal to Grade 2 • Clinically significant cardiac disease • Other malignancy within the last 2 years (exceptions for definitively treated disease) • Chronic or systemic ophthalmological disorders • Major surgery or other investigational study within 28 days prior to first dose of study treatment • Palliative radiotherapy within 14 days prior to the first dose of study treatment • Abnormalities of the cornea that may pose an increased risk of developing a corneal ulcer