




Essai Clinique

Généré le 29 avr. 2024 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  HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
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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	<ul style="list-style-type: none">Adults with unresectable, locally advanced or metastatic gastric or gastroesophageal junction cancer not amenable to curative therapyFibroblast 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 biopsyEastern Cooperative Oncology Group (ECOG) less than or equal to 1Measurable disease or non-measurable, but evaluable disease, according to Response Evaluation Criteria in Solid Tumors (RECIST) V 1.1Participant has no contraindications to mFOLFOX6 chemotherapyAdequate organ and bone marrow function:<ul style="list-style-type: none">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 treatmentaspartate 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 ($[140 - \text{Age}] \times \text{Mass [kg]} / [72 \times \text{Creatinine mg/dL}]$) (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	<ul style="list-style-type: none">• 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