Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	Étude de phase 1b/3 associant Bermarituzumab/Chimiothérapie/Nivolumab versus Bermarituzumab/Chimiothérapie/Placebo chez les patients avec un adénocarcinome gastrique ou de la JGE non-traité, de stade avancé et surexprimant FGFR2b
Protocole ID	FORTITUDE-102
ClinicalTrials.gov ID	NCT05111626
Type(s) de cancer	Estomac Oesophage
Phase	Phase I
Type étude	Clinique
Médicament	Bemarituzumab + chimiothérapie et nivolumab versus placebo + chimiothérapie et nivolumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	
Investigateur principal	Dr Maxime Chénard-Poirier
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Statut	Actif en recrutement
Date d'activation	23-11-2022
But étude	The main objective of Part 1 is to evaluate the safety and tolerability of bemarituzumab plus 5-fluorouracil, leucovorin, and oxaliplatin (mFOLFOX6) and nivolumab. The main objective Part 2 is to compare efficacy of bemarituzumab plus mFOLFOX6 and nivolumab to placebo plus mFOLFOX6 and nivolumab as assessed by overall survival.

Critères d'éligibilité	**Inclusion Criteria Part 1 and Part 2:**
	• Adult with unresectable, locally advanced or metastatic (not amenable to curative therapy) histologically documented gastric or gastroesophageal junction adenocarcinoma
	• Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1
	• Measurable disease or non-measurable, but evaluable disease, according to Response Evaluation Criteria in Solid Tumours version 1.1 (RECIST v1.1)
	• Participant has no contraindications to mFOLFOX6 chemotherapy or nivolumab
	• Adequate organ function as follows:
	  • Absolute neutrophil count ≥ 1.5 x 10^9/L
	  • Platelet count ≥ 100 x 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 aminotransaminase (AST) and Alanine aminotransaminase (ALT) <3 x upper limit of normal (ULN) (or < 5 x ULN if liver involvement)
	  • Total bilirubin <1.5 x ULN (or < 2 x ULN if liver involvement or Gilbert's disease)
	  • Calculated or measured creatinine clearance (CrCl) of ≥ 50 mL/minute calculated using the formula of Cockcroft and Gault
	  • International Normalized Ratio (INR) or prothrombin time (PT) < 1.5 × ULN except for participants receiving anticoagulation, who must be on a stable dose of anticoagulant therapy for 6 weeks prior to enrollment
	Additional Inclusion Criteria Part 2:

	• No prior treatment for metastatic or unresectable disease except for a maximum of 1 dose of mFOLFOX6 with or without nivolumab. Prior adjuvant, neo-adjuvant, and peri-operative therapy is allowed, provided it has been completed more than 6 months prior to the first dose of study treatment • 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.
Critères d'exclusion	• Prior treatment with any selective inhibitor of the fibroblast growth factor (FGF)-FGFR pathway • Known positive human epidermal growth factor receptor 2 (HER2) status • Untreated or symptomatic central nervous system disease metastases and leptomeningeal disease • Peripheral sensory neuropathy grade 2 or higher • Clinically significant cardiac disease • Other malignancy within the last 2 years (exceptions for definitively treated disease) • Chronic or systemic ophthalmologic disorders • Major surgery or other investigational study within 28 days prior to randomization • Palliative radiotherapy within 14 days prior to randomization • Abnormalities of the cornea that may pose an increased risk of developing a corneal ulcer • Active autoimmune disease that has required systemic treatment (except replacement therapy) within the past 2 years or any other diseases requiring immunosuppressive therapy while on study