# Essai Clinique

Généré le 12 mai 2025 à partir de

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| 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<br>Oesophage |
| Phase | Phase I |
| Type étude | Clinique |
| Médicament | Bemarituzumab + chimiothérapie et nivolumab versus placebo + chimiothérapie et nivolumab |
| Institution | CHU DE QUEBEC – UNIVERSITE LAVAL<br>L'HOTEL-DIEU DE QUEBEC ET CRCEO<br>11 Côte du Palais, Québec, QC, G1R 2J6 |
| Ville | |
| Investigateur principal | Dr Maxime Chénard-Poirier |
| Coordonnateur | Maryse Gingras<br>418-691-5781 |
| Statut | Fermé |
| 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:**<br>• Adult with unresectable, locally advanced or metastatic (not amenable to curative therapy) histologically documented gastric or gastroesophageal junction adenocarcinoma<br>• Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1<br>• Measurable disease or non-measurable, but evaluable disease, according to Response Evaluation Criteria in Solid Tumours version 1.1 (RECIST v1.1)<br>• Participant has no contraindications to mFOLFOX6 chemotherapy or nivolumab<br>• Adequate organ function as follows:<br>  • Absolute neutrophil count ≥ 1.5 x 10^9/L<br>  • Platelet count ≥ 100 x 10^9/L<br>  • Hemoglobin ≥ 9 g/dL without red blood cell (RBC) transfusion within 7 days prior to the first dose of study treatment<br>  • Aspartate aminotransaminase (AST) and Alanine aminotransaminase (ALT) <3 x upper limit of normal (ULN) (or < 5 x ULN if liver involvement)<br>  • Total bilirubin <1.5 x ULN (or < 2 x ULN if liver involvement or Gilbert's disease)<br>  • Calculated or measured creatinine clearance (CrCl) of ≥ 50 mL/minute calculated using the formula of Cockcroft and Gault<br>  • 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<br>**Additional Inclusion Criteria Part 2:** |

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| | • 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<br>• 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<br>• Known positive human epidermal growth factor receptor 2 (HER2) status<br>• Untreated or symptomatic central nervous system disease metastases and leptomeningeal disease<br>• Peripheral sensory neuropathy grade 2 or higher<br>• Clinically significant cardiac disease<br>• Other malignancy within the last 2 years (exceptions for definitively treated disease)<br>• Chronic or systemic ophthalmologic disorders<br>• Major surgery or other investigational study within 28 days prior to randomization<br>• Palliative radiotherapy within 14 days prior to randomization<br>• Abnormalities of the cornea that may pose an increased risk of developing a corneal ulcer<br>• 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 |