

Research Area:

Gastric and Gastroesophageal Junction Cancer

FORTITUDE
102

Bemarituzumab

Amgen Study ID Number: 20210098

NCT Number: 05111626

FORTITUDE-102: A Phase 1b/3 Study of Bemarituzumab Plus Chemotherapy and Nivolumab Versus Chemotherapy and Nivolumab Alone in Subjects With Previously Untreated Advanced Gastric and Gastroesophageal Junction Cancer With FGFR2b Overexpression

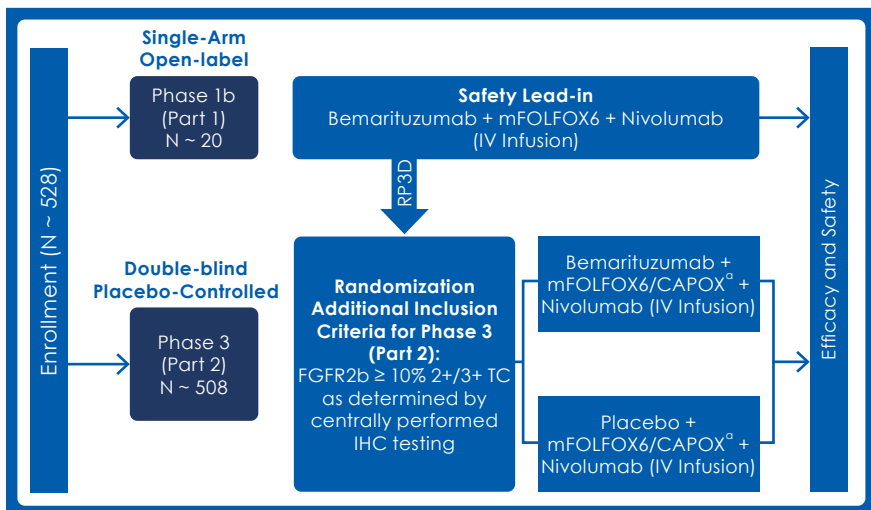
Primary Endpoints

- Phase 1b (part 1): Number of participants with DLTs; related TEAEs; TRAEs; and clinically significant changes in vital signs, visual acuity, physical examinations, and clinical laboratory tests
- Phase 3 (part 2): OS in participants with FGFR2b \geq 10% 2+/3+ TC staining

Key Secondary Endpoints

- Phase 1b (part 1): OR, DoR, DCR, PFS, OS, and PK profile of bemarituzumab
- Phase 3 (part 2): PFS and OR in participants with FGFR2b \geq 10% 2+/3+ TC staining

STUDY DESIGN



^aCapecitabine as oral administration and oxaliplatin as IV infusion.

CAPOX = capecitabine and oxaliplatin; DCR = disease control rate; DLT = dose-limiting toxicity; DoR = duration of response; FGFR2b = fibroblast growth factor receptor 2b; IHC = immunohistochemistry; IV = intravenous; mFOLFOX6 = modified 5-fluorouracil, leucovorin, and oxaliplatin; OR = objective response; OS = overall survival; PFS = progression-free survival; PK = pharmacokinetics; RP3D = recommended phase 3 dose; TC = tumor cell; TEAE = treatment-emergent adverse event; TRAE = treatment-related adverse event.

Products under investigational study have not been approved by the regulatory agencies for the use under investigation in this trial.

AMGEN

Bemarituzumab

Key Summary Point

This is a phase 1b/3 study of bemarituzumab plus chemotherapy and nivolumab versus chemotherapy and nivolumab alone in subjects with previously untreated advanced gastric and gastroesophageal junction cancer with FGFR2b overexpression (FORTITUDE-102)

Key Inclusion Criteria for Phase 1b (Part 1) and Phase 3 (Part 2)

- Adults with histologically documented gastric or gastroesophageal junction adenocarcinoma, where the disease is unresectable, locally advanced, or metastatic
- Measurable or nonmeasurable but evaluable disease according to RECIST v1.1
- Participants with no contraindications to nivolumab and either mFOLFOX6 or CAPOX chemotherapy
- ECOG PS of 0–1

Additional Inclusion Criteria for Phase 3 (Part 2)

- No prior treatment for metastatic or unresectable disease except for a maximum of one dose of chemotherapy (mFOLFOX6 or CAPOX) 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
- FGFR2b \geq 10% 2+/3+ TC as determined by centrally performed IHC testing based on a tumor sample that is either archival (obtained within 6 months/180 days prior to signing pre-screening informed consent) or a fresh biopsy

Key Exclusion Criteria for Phase 1b (Part 1) and Phase 3 (Part 2)

- Known positive HER2 status
- Abnormalities of the cornea that may pose an increased risk of developing a corneal ulcer
- History or evidence of systemic disease or ophthalmological disorders requiring chronic use of ophthalmic corticosteroids
- Evidence of any ongoing ophthalmologic abnormalities or symptoms that are acute (within 4 weeks) or actively progressing
- Untreated or symptomatic CNS metastases and leptomeningeal disease
- 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

Additional Information

- www.amgentrials.com Protocol Number: 20210098
- www.clinicaltrials.gov Identifier: NCT05111626

CAPOX = capecitabine and oxalipatin; CNS = central nervous system; ECOG = Eastern Cooperative Oncology Group; FGFR2b = fibroblast growth factor receptor 2b; HER2 = human epidermal growth factor receptor 2; IHC = immunohistochemistry; mFOLFOX6 = modified 5-fluorouracil, leucovorin, and oxalipatin; PS = performance status; RECIST v1.1 = Response Evaluation Criteria in Solid Tumors version 1.1; TC = tumor cell.