Research Area:

Gastric and Gastroesophageal Junction Cancer

Bemarituzumab

FORTITUDE 102

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

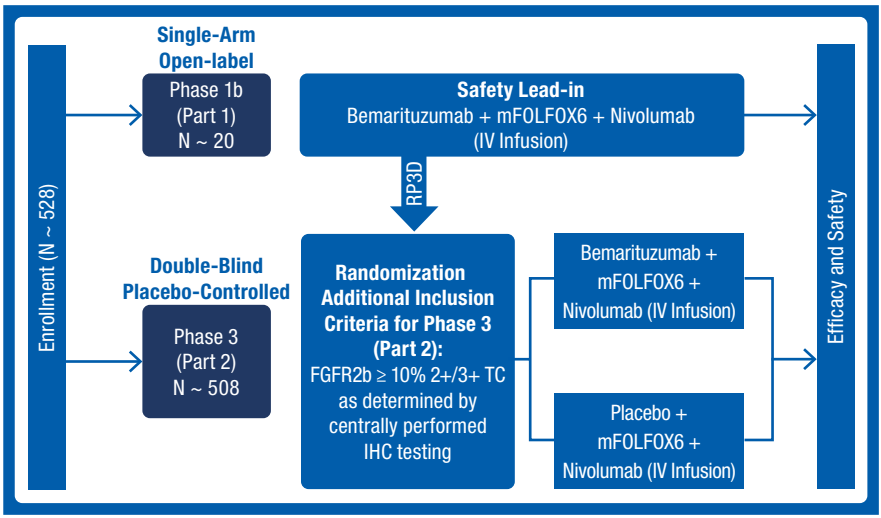
Primary Endpoints:

- Phase 1b (part 1): DLTs; 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 ≥ 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 ≥ 10% 2+/3+ TC staining

STUDY DESIGN:



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.

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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 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 disease, but evaluable disease, per RECIST v1.1
- Participants with no contraindications to mFOLFOX6 chemotherapy or nivolumab
- ECOG performance status of 0 to 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 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
- FGFR2b ≥ 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 Phase 1b (Part 1) and Phase 3 (Part 2):

- Known positive HER2 status
- Prior treatment with any selective inhibitor of the FGF-FGFR pathway
- Abnormalities of the cornea that may pose an increased risk of developing a corneal ulcer
- 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

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

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