Research Area:

Solid Tumors

FORTITUDE 301

Amgen Study ID Number: 20210104
NCT Number: 05325866

Bemarituzumab

FORTITUDE-301: A Phase 1b/2, Multicenter, Open-label Basket Study Evaluating the Safety and Efficacy of Bemarituzumab Monotherapy in Solid Tumors With FGFR2b Overexpression

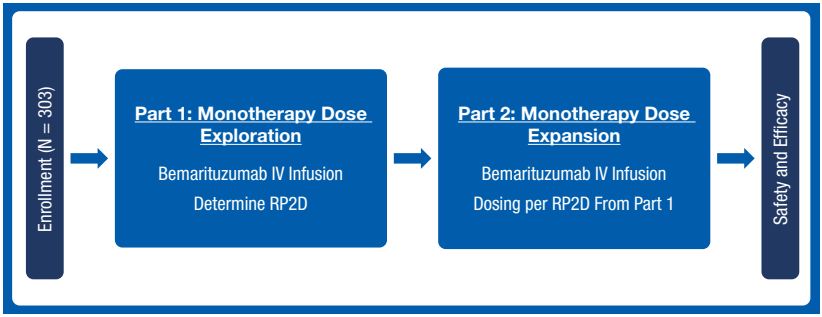
Primary Endpoints:

- Part 1: Incidence of DLTs, TEAEs (including clinically significant changes in vital signs, visual acuity, and clinical laboratory tests), and TRAEs
- Part 2: Objective response rate

Secondary Endpoints:

- Part 1: Objective response rate
- Parts 1 and 2: DCR, DOR, time to response, PFS, OS, and PK parameters for bemarituzumab (including AUC, C_{max}, and C_{trough})
- Part 2: Incidence of TEAEs (including clinically significant changes in vital signs, visual acuity, and clinical laboratory tests) and TRAEs

Study Design:



AUC = area under the concentration-time curve; C_{max} = maximum observed concentration; C_{trough} = observed concentration at the end of a dose interval; DCR = disease control rate; DLT = dose-limiting toxicity; DOR = duration of response; FGFR2b = fibroblast growth factor receptor isoform 2b; IV = intravenous; OS = overall survival; PFS = progression-free survival; PK = pharmacokinetics; RP2D = recommended phase 2 dose; TEAE = treatment-emergent adverse event; TRAE = treatment-related adverse event.

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Key Summary Point:

This is a phase 1b/2 study to evaluate the safety and efficacy of bemarituzumab monotherapy in solid tumors with FGFR2b overexpression.

Key Inclusion Criteria:

- Age ≥ 18 years with histologically or cytologically confirmed cancer of one of the following types, relapsed or refractory after at least 1 prior therapeutic regimen in advanced/metastatic setting, as specified below:
  - ≥ 1 line of therapy for HNSCC, intrahepatic cholangiocarcinoma, platinum-resistant ovarian epithelial cell carcinoma (including fallopian tube cancers and primary peritoneal cancers), endometrial adenocarcinoma, cervical carcinoma, and other solid tumors
  - ≥ 2 lines of therapy for TNBC
  - Lung adenocarcinoma: at least platinum-based chemotherapy, checkpoint inhibitor, and targeted therapy
- Disease that is unresectable, locally advanced, or metastatic (not amenable to curative therapy)
- FGFR2b overexpression as determined by centrally performed IHC testing
- Measurable disease by RECIST v1.1
- ECOG PS ≤ 1

Key Exclusion Criteria:

- Untreated or symptomatic CNS metastases or leptomeningeal disease
- Other solid tumor cohort excludes primary tumors of the CNS, squamous NSCLC, gastric adenocarcinoma, and gastroesophageal junction adenocarcinoma
- Impaired cardiac function or clinically significant cardiac disease
- History of systemic disease or ophthalmologic disorders requiring chronic use of ophthalmic steroids
- Recent history (within 6 months) or evidence of corneal defects, corneal ulcerations, keratitis, or keratoconus
- Evidence of any ongoing ophthalmologic abnormalities or acute (within 4 weeks) or actively progressing symptoms
- Recent (within 6 months) corneal surgery or ophthalmic laser treatment
- Prior treatment with any selective inhibitor of the FGF/FGFR pathway

Additional Information:

- www.amgentrials.com Protocol Number: 20210104
- www.clinicaltrials.gov Identifier: NCT05325866

CNS = central nervous system; ECOG PS = Eastern Cooperative Oncology Group performance status; FGF/FGFR = fibroblast growth factor/fibroblast growth factor receptor; FGFR2b = fibroblast growth factor receptor isoform 2b; HNSCC = head and neck squamous cell carcinoma; IHC = immunohistochemistry; NSCLC = non–small-cell lung cancer; RECIST v1.1= Response Evaluation Criteria in Solid Tumors Version 1.1; TNBC = triple-negative breast cancer.

Products under investigational study have not been approved by any regulatory authority.

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