Protocol Title: A Phase 3 Randomized, Double-Blind, Controlled Study Evaluating Bemarituzumab (FPA144) and Modified FOLFOX6 in Patients with Previously Untreated Advanced Gastric and Gastroesophageal Junction Cancer: Phase 3 Preceded by Dose-Finding in Phase 1 (FIGHT)

Target Population: Gastric Cancer

Summary: This is a global, randomized, double-blind, controlled study to evaluate the efficacy of Bemarituzumab (FPA144) + mFOLFOX6 versus Placebo + mFOLFOX6 in patients with FGFR2 selected Gastric Cancer (as determined by prospective IHC FGFR2b overexpression and/or a ctDNA blood assay demonstrating FGFR2 gene amplification).

Key Inclusion Criteria:
- Histologically documented Gastric or Gastroesophageal Junctional Adenocarcinoma (not amenable to curative therapy)
- ECOG performance status of 0 to 1
- Adequate hematological, liver and kidney function
- Measurable or non-measurable, but evaluable disease using RECIST v1.1
- FGFR2b overexpression as determined by a centrally performed IHC tissue test and/or FGFR2 gene amplification as determined by a centrally performed ctDNA blood based assay
- Candidate for mFOLFOX6 chemotherapy

Key Exclusion Criteria:
- Untreated or symptomatic Central Nervous System (CNS) metastases
- Clinically significant cardiac disease
- Peripheral sensory neuropathy ≥ Common Terminology Criteria for Adverse Events (CTCAE) Grade 2
- Active infection requiring systemic treatment
- Known HIV or AIDS-related illness, or known active or chronic Hepatitis B or C infection
- Prior treatment with any selective inhibitor of the Fibroblast Growth Factor (FGF)-FGFR Pathway
- Known abnormalities of the cornea that may pose an increased risk of developing a corneal ulcer
- Known positivity for HER2

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03694522