

Abstract #220015

FIGHT: A phase 3 randomized, double-blind, placebo controlled study evaluating (bemarituzumab) FPA144 and modified FOLFOX6 (mFOLFOX6) in patients with previously untreated advanced gastric and gastroesophageal cancer with a dose finding phase 1 lead-in.

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Background: FGFR2b overexpression and *FGFR2* gene amplification occurs in approximately 10% of patients with gastric cancer (GC) and is associated with a poor prognosis and the presence of metastases. Bemarituzumab, a first-in-class afucosylated, humanized IgG1 monoclonal antibody, selectively binds to FGFR2b, inhibiting ligand binding and blocking receptor activation and downstream signaling. Bemarituzumab is glycoengineered to enhance antibody-dependent cell-mediated cytotoxicity (ADCC). A phase 1 study of bemarituzumab monotherapy in solid tumors (Catenacci D, Rha S, Bang YJ, et.al. ASCO 2017) identified no dose-limiting toxicities. The reported response rate was 19% (4/21) with median duration of response of 15.4 weeks in patients with late-line GC and high FGFR2b overexpression. Based on the safety and activity profile of bemarituzumab monotherapy in GC, we designed a phase 3 trial with safety run-in of bemarituzumab in combination with mFOLFOX6. **Methods:** The FIGHT study (FPA144-004; NCT03343301) is a global, randomized, double-blind, placebo-controlled phase 3 trial evaluating bemarituzumab and mFOLFOX6 in first-line patients with advanced GC. Patients with unresectable locally advanced, or metastatic GC are eligible if tumors have *FGFR2* amplification by circulating tumor DNA (ctDNA) or FGFR2b overexpression by immunohistochemistry (IHC). Eligible patients are randomized 1:1 to bemarituzumab + mFOLFOX6 versus placebo + mFOLFOX6. Bemarituzumab or placebo dosing will continue every 2 weeks until radiographic or clinical disease progression, or intolerable toxicity. The primary endpoint is overall survival (OS) and key secondary endpoints include investigator-assessed progression-free survival (PFS) and objective response rate (ORR). The primary analyses will be event-based. The FIGHT Phase 3 trial is preceded by a Phase 1 safety evaluation in gastro-intestinal tumors without selection for FGFR2b. This portion of the trial initiated in December 2017 and is currently in progress with accrual to phase 3 expected in mid-2018.

Title:

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Yes

Is this clinical trial registered?

Yes

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