

KURZPROTOKOLL **Fight**

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| Öffentlicher Titel | Phase III Studie zu Bemarituzumab und mFOLFOX6 bei unbehandeltem Magen- und Speiseröhrenkrebs |
| Wissenschaftl. Titel | A Phase 3 Randomized, Double-Blind, Controlled Study Evaluating FPA144 and Modified FOLFOX6 in Patients with Previously Untreated Advanced Gastric and Gastroesophageal Cancer: Phase 3 Preceded by Dose-Finding in Phase |
| Kurztitel | Fight |
| Studienart | multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig |
| Studienphase | Phase III |
| Erkrankung | Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie |
| Einschlusskriterien | <ul style="list-style-type: none">- Histologically documented gastric or gastroesophageal junctional adenocarcinoma (not amenable to curative therapy)- Eastern Cooperative Oncology Group (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 |
| Ausschlusskriterien | <ul style="list-style-type: none">- Untreated or symptomatic central nervous system (CNS) metastases- Clinically significant cardiac disease,- Peripheral sensory neuropathy \geq Common Terminology Criteria for Adverse Events (CTCAE) Grade 2- Active infection requiring systemic treatment- Known human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (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- Women who are pregnant or breastfeeding |
| Alter | 18 - 99 Jahre |
| Prüfzentren | Krankenhaus Nordwest GmbH (Rekrutierung beendet) Institut für klinisch-onkologische Forschung Steinbacher Hohl 2-26 60488 Frankfurt am Main Prof. Dr. med. Salah-Eddin Al-Batran Tel: 069 7601 4420 albatran@khnw.de |
| Sponsor | Five Prime Therapeutics Inc |
| Registrierung in anderen Studienregistern | ClinicalTrials.gov NCT03694522 (primäres Register) EudraCT 2017-003507-22 |