

KURZPROTOKOLL **Fight**

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
Sponsor	Five Prime Therapeutics Inc
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03694522 (primäres Register) EudraCT 2017-003507-22