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	- 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	- 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 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