KURZPROTOKOLL
ROCOCO

Öffentlicher Titel	Phase I Studie zu Rogaratinib und Copanlisib bei FGFR-positiven, fortgeschrittenen oder metastasierten soliden Tumoren
Wissenschaftl. Titel	A multicenter Phase 1 study to evaluate the safety, tolerability, pharmacokinetics, and maximum tolerated dose (MTD) and/or recommended Phase 2 dose (RP2D) of the combination of rogaratinib and copanlisib in patients with FGFR-positive, locally advanced or metastatic solid tumors
Kurztitel	ROCOCO
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase I
Erkrankung	Muskeln/Bewegungsapparat: Knochenkrebs (Sarkome): sonstige Therapiestudien Drüsen/Hormone/Stoffwechsel: Neuroendokrine Tumoren: sonstige Therapiestudien Geschlechtsorgane: Brustkrebs: sonstige Therapiestudien Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: sonstige Therapiestudien Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: sonstige Therapiestudien Haut: Hautkrebs: sonstige Therapiestudien Kopf-Hals: Kopf-Hals-Tumoren: sonstige Therapiestudien Lunge: Lungenkrebs: sonstige Therapiestudien Nervensystem: Gliome: sonstige Therapiestudien Niere/Harnwege: Harnblasenkrebs: sonstige Therapiestudien Niere/Harnwege: Nierenzellkrebs: sonstige Therapiestudien Verdauung: Analkrebs: sonstige Therapiestudien Verdauung: Gastrointestinale Stromatumoren (GIST): sonstige Therapiestudien Verdauung: Gallengangs-/Gallenblasenkrebs (maligne biliäre Tumoren): sonstige Therapiestudien Verdauung: Darmkrebs (Kolorektales Karzinom): sonstige Therapiestudien Verdauung: Leberkrebs (Hepatozelluläres Karzinom): sonstige Therapiestudien Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): sonstige Therapiestudien Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): sonstige Therapiestudien Weichteile: Sarkome: sonstige Therapiestudien
Einschlusskriterien	- High FGFR mRNA expression levels (RNAscope score of 3+ or 4+; measurement is part of this protocol) in archival or fresh tumor biopsy specimen. - Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 or 1. - At least 1 measurable lesion according to Response Evaluation Criteria in Solid Tumors (RECIST 1.1) in contrast enhanced (unless contraindicated) CT or MRI. - Adequate bone marrow, liver and renal function. - Glomerular filtration rate (GFR) >= 30 mL/min/1.73 m² according to the Modification of Diet in Renal Disease (MDRD) formula. - Left ventricular ejection fraction (LVEF) equal to or above the lower limit of normal (LLN) at the institution. - Life expectancy of at least 3 months. - For the dose escalation part: Patients with histologically confirmed, locally advanced or metastatic solid tumors who are not candidates for or refuse standard therapy or whose disease progressed and for which standard anti-cancer treatment is no longer effective, excluding primary brain or spinal tumors. - For the dose expansion part: Patients with histologically confirmed, locally advanced or metastatic urothelial carcinoma (transitional cell carcinoma) including urinary bladder, renal pelvis, ureters, urethra who are not candidates for or refuse standard therapy or whose disease progressed and for which standard anticancer treatment is no longer effective.

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Ausschlusskriterien	- Previous or concurrent cancer that is distinct from tumor for which the patient is enrolled in study, with exceptions - Ongoing or previous anti-cancer treatment within 4 weeks of study treatment start (or 6 weeks for mitomycin C, nitrosoureas and monoclonal antibodies); with exceptions. - Prior toxicity to anti-FGFR-directed or anti-PI3K-directed therapies leading to treatment discontinuation (previous exposure is allowed in other circumstances). - Symptomatic metastatic brain or meningeal tumors unless the patient is >6 months from definitive therapy, has no evidence of tumor growth on an imaging study and is clinically stable with respect to the tumor at the start of study treatment. Also the patient must not be undergoing acute steroid therapy or taper (chronic steroid therapy is acceptable provided that the dose is stable for one month prior to and following screening radiographic studies). - History or current condition of an uncontrolled cardiovascular disease including congestive heart failure NYHA > Class 2, unstable angina (symptoms of angina at rest) or new-onset angina (within last 3 months) or myocardial infarction within past 6 months and cardiac arrhythmias requiring anti-arrhythmic therapy (beta-blockers or digoxin are permitted). - Active hepatitis B (HBV) or C (HCV) infection. - Active clinically serious infections (>= CTCAE v4.03 Grade 2).
Alter	18 Jahre und älter
Molekularer Marker	FGFR
Sponsor	Bayer Healthcare
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03517956 (primäres Register) EudraCT 2018-000419-26

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