

## **KURZPROTOKOLL ROCOCO**

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| <b>Öffentlicher Titel</b>   | Phase I Studie zu Rogaratinib und Copanlisib bei FGFR-positiven, fortgeschrittenen oder metastasierten soliden Tumoren                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Wissenschaftl. Titel</b> | 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Kurztitel</b>            | ROCOCO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Studienart</b>           | multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Studienphase</b>         | Phase I                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Erkrankung</b>           | <p>Muskeln/Bewegungsapparat: Knochenkrebs (Sarkome): sonstige Therapiestudien</p> <p>Drüsen/Hormone/Stoffwechsel: Neuroendokrine Tumoren: sonstige Therapiestudien</p> <p>Geschlechtsorgane: Brustkrebs: sonstige Therapiestudien</p> <p>Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: sonstige Therapiestudien</p> <p>Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: sonstige Therapiestudien</p> <p>Haut: Hautkrebs: sonstige Therapiestudien</p> <p>Kopf-Hals: Kopf-Hals-Tumoren: sonstige Therapiestudien</p> <p>Lunge: Lungenkrebs: sonstige Therapiestudien</p> <p>Nervensystem: Gliome: sonstige Therapiestudien</p> <p>Niere/Harnwege: Harnblasenkrebs: sonstige Therapiestudien</p> <p>Niere/Harnwege: Nierenzellkrebs: sonstige Therapiestudien</p> <p>Verdauung: Analkrebs: sonstige Therapiestudien</p> <p>Verdauung: Gastrointestinale Stromatumoren (GIST): sonstige Therapiestudien</p> <p>Verdauung: Gallengangs-/Gallenblasenkrebs (maligne biliäre Tumoren): sonstige Therapiestudien</p> <p>Verdauung: Darmkrebs (Kolorektales Karzinom): sonstige Therapiestudien</p> <p>Verdauung: Leberkrebs (Hepatozelluläres Karzinom): sonstige Therapiestudien</p> <p>Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): sonstige Therapiestudien</p> <p>Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): sonstige Therapiestudien</p> <p>Weichteile: Sarkome: sonstige Therapiestudien</p> |
| <b>Einschlusskriterien</b>  | <ul style="list-style-type: none"> <li>- High FGFR mRNA expression levels (RNAscope score of 3+ or 4+; measurement is part of this protocol) in archival or fresh tumor biopsy specimen.</li> <li>- Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 or 1.</li> <li>- At least 1 measurable lesion according to Response Evaluation Criteria in Solid Tumors (RECIST 1.1) in contrast enhanced (unless contraindicated) CT or MRI.</li> <li>- Adequate bone marrow, liver and renal function.</li> <li>- Glomerular filtration rate (GFR) <math>\geq 30</math> mL/min/1.73 m<sup>2</sup> according to the Modification of Diet in Renal Disease (MDRD) formula.</li> <li>- Left ventricular ejection fraction (LVEF) equal to or above the lower limit of normal (LLN) at the institution.</li> <li>- Life expectancy of at least 3 months.</li> <li>- 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.</li> </ul>                                                                                                                                                                                                                                                                   |

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| <b>Ausschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- 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.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|                                                  | <ul style="list-style-type: none"><li>- Previous or concurrent cancer that is distinct from tumor for which the patient is enrolled in study, with exceptions</li><li>- 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.</li><li>- Prior toxicity to anti-FGFR-directed or anti-PI3K-directed therapies leading to treatment discontinuation (previous exposure is allowed in other circumstances).</li><li>- Symptomatic metastatic brain or meningeal tumors unless the patient is &gt;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).</li><li>- History or current condition of an uncontrolled cardiovascular disease including congestive heart failure NYHA &gt; 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).</li><li>- Active hepatitis B (HBV) or C (HCV) infection.</li><li>- Active clinically serious infections (<math>\geq</math> CTCAE v4.03 Grade 2).</li></ul> |
| <b>Alter</b>                                     | 18 Jahre und älter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Molekularer Marker</b>                        | FGFR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Prüfzentren</b>                               | <b>Krankenhaus Nordwest GmbH</b> (Rekrutierung beendet)<br>Klinik für Onkologie und Hämatologie<br>Steinbacher Hohl 2-26<br>60488 Frankfurt am Main<br>Dr. med Thorsten Götze<br>Tel: 069 7601-4187<br>Fax: 069 069-7601-3655<br><a href="mailto:goetze.thorsten@khnw.de">goetze.thorsten@khnw.de</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Sponsor</b>                                   | Bayer Healthcare                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Registrierung in anderen Studienregistern</b> | ClinicalTrials.gov NCT03517956 (primäres Register)<br>EudraCT 2018-000419-26                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |