KURZPROTOKOLL
BAY 73-4506 / 16674

Öffentlicher Titel	Effekt von Regorafenib auf Transportproteine P-gp und BCRP in Patienten mit soliden Tumoren in einer Phase I Studie
Wissenschaftl. Titel	A Phase I, multi-center, non-randomized, open label, drug-drug-interaction study to determine the effect of multiple doses of regorafenib (BAY 73-4506) on the pharmacokinetics of probe substrates of transport proteins P-gp (digoxin; Group A) and BCRP (sulfasalazine; Group B) in patients with advanced solid malignant tumors
Kurztitel	BAY 73-4506 / 16674
Studienart	multizentrisch, prospektiv, offen/unverblindet, Pharma-Studie, mehrarmig
Studienphase	Phase I
Ziele	- Area under the plasma concentration-time curve from time zero to 24 hours (AUC(0-24)) for Digoxin - Maximum drug concentration (Cmax) in plasma for Digoxin - Area under the plasma concentration-time curve from time zero to 24 hours (AUC(0-24)) for rosuvastatin - Maximum drug concentration (Cmax) in plasma for rosuvastatin - Tumor Response following RECIST criteria - Number of participants with adverse events as a measure of safety and tolerability - Number of participants with drug related adverse events as a measure of safety and tolerability
Einschlusskriterien	- The following criteria apply to ALL patients starting the study treatment: - 1. Patients with histologically confirmed, locally advanced or metastatic solid tumors refractory to standard therapy or in whom regorafenib is considered a standard treatment. - 2. Male or Female Caucasian patients >/= 18 years of age - 3. Women of childbearing potential and men must agree to use adequate contraception before entering the program until at least 8 weeks after the last study drug administration. - 4. Life expectancy of at leat 12 weeks - 5. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 - 6. Adequate bone marrow and liver function - 7. Estimated creatinine clearance (CLcr) 30 mL/min as calculated using the Cockroft-Gault (C-G) equation. - 8. Thyroid Stimulating Hormone(TSH) within normal ranges. - The following inclusion criteria apply to Group A (digoxin + regorafenib) patients ONLY: Potassium, magnesium and calcium blood levels within normal range according to the local laboratory. - The following inclusion criteria apply to Group B (rosuvastatin + regorafenib) patients ONLY: Signed genetic informed consent. Patients must be able to understand and willing to sign the written informed consent intended to screen for BCRP and OATP1B1 polymorphisms.
Ausschlusskriterien	- For ALL patients - Major surgical procedure, open biopsy, or significant traumatic injury within 28 days before start of study medication. - Non-healing wound, skin ulcer, or bone fracture. - Ongoing or active infection. - Other anticancer treatment. - Patients unable to swallow oral medications - For Group A (digoxin + regorafenib): Family history of sudden cardiac death.

	- For Group B (rosuvastatin + regorafenib): a) Patients with porphyria; b) Patients with intestinal or urinary obstructions.
Alter	18 Jahre und älter
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	Bayer Healthcare
Förderer	Bayer Healthcare
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02106845 EudraCT 2013-003613-18