# Clinical Trials Data BRAF - Document 29

# A Pharmacokinetics (PK) Study of the Effects Rabeprazole and Rifampin on Dabrafenib in Subjects With BRAF V600 Mutation Positive Tumors

## Clinical Trial: https://clinicaltrials.gov/study/NCT01954043

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Male or female at least 18 years of age at the time of signing the informed consent form.\n\* Provided signed written informed consent.\n\* Capable of compliance with the requirements and restrictions listed in the consent form.\n\* Body weight \\>=45 kilogram (kg) and a body mass index (BMI) \\>=19 Kilogram per meter squared (kg/m\\^2) and \\<40 kg/m\\^2 (inclusive).\n\* Able to swallow and retain oral medication.\n\* BRAF V600 mutation-positive tumor as confirmed in a Clinical Laboratory Improvement Amendments (CLIA)-approved laboratory or equivalent.\n\* Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.\n\* Adequate baseline organ function defined in study protocol.\n\* Women of child-bearing potential must be willing to practice acceptable methods of birth control. Additionally, women of childbearing potential must have a negative serum pregnancy test within 14 days prior to the first dose of study medication.\n\nExclusion Criteria:\n\n\* History of another malignancy with exceptions below, or any malignancy with confirmed activating RAS mutation. Exception: (a) Subjects who have been successfully treated and are disease-free for 5 years, (b) a history of completely resected non-melanoma skin cancer, (c) successfully treated in situ carcinoma, (d) CLL in stable remission, or (e) indolent prostate cancer (definition: clinical stage T1 or T2a, Gleason score \\<=6, and PSA \\<10 nanogram per milliliter \\[ng/mL\\]) requiring no or only anti-hormonal therapy, are eligible.\n\* Cancer therapy (chemotherapy with delayed toxicity, extensive radiation therapy, immunotherapy, biologic therapy, or major surgery) or investigational anti-cancer drugs within the last 3 weeks, or chemotherapy without delayed toxicity within the last 2 weeks, preceding the first dose of dabrafenib.\n\* Unresolved toxicity greater than Grade 2 from previous anti-cancer therapy except alopecia.\n\* Any serious and/or unstable pre-existing medical, psychiatric disorder or other conditions that could interfere with subject's safety, obtaining informed consent or compliance to the study procedures.\n\* Current use of therapeutic warfarin.\n\* Any prohibited medication(s) or herbal preparation as described in study protocol or requires any of these medications during the study.\n\* Have a known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to dabrafenib, rabeprazole and rifampin, or excipients that contraindicates their participation.\n\* Pregnant or nursing females.\n\* A history or evidence of cardiovascular risk including any of the following: a QT interval corrected for heart rate using the Bazett's formula (QTcB) \\>=480 milliseconds (msec); a history or evidence of current clinically significant uncontrolled arrhythmias; a history of acute coronary syndromes (including myocardial infarction or unstable angina), coronary angioplasty, or stenting within 6 months prior to randomization; a history or evidence of current \\>=Class II congestive heart failure (CHF) as defined by the New York Heart Association (NYHA) guidelines; Abnormal cardiac valve morphology (\\>=grade 2) documented by echocardiogram (subjects with grade 1 abnormalities \\[i.e., mild regurgitation/stenosis\\] can be entered on study). Subjects with moderate valvular thickening should not be entered on study.\n\* Presence of active gastrointestinal (GI) disease or other condition (e.g., small bowel or large bowel resection) that will interfere significantly with the absorption of drugs. If clarification is needed as to whether a condition will significantly affect absorption of drugs, contact the GSK Medical Monitor.\n\* A history of known Human Immunodeficiency Virus (HIV), Hepatitis B Virus, or Hepatitis C Virus infection.\n\* Subjects with brain metastases are excluded if their brain metastases are: Symptomatic, Treated (surgery, radiation therapy) but not clinically and radiographically stable one month after local therapy, or asymptomatic and untreated but \\>1 centimeter (cm) in the longest dimension. Subjects with small (\\<=1 cm in the longest dimension), asymptomatic brain metastases that do not need immediate local therapy can be enrolled. Subjects on a stable dose of corticosteroids for \\>1 month, or those who have been off corticosteroids for at least 2 weeks can be enrolled. Subjects must also be off of enzyme-inducing anticonvulsants for more than 4 weeks.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a BRAF gene mutation be eligible for the clinical trial?

Answer:  
Yes, a patient with a BRAF V600 mutation-positive tumor would be eligible for this trial \*provided they also meet all other inclusion criteria and do not meet any of the exclusion criteria.\* Specifically, the inclusion criteria explicitly states: "BRAF V600 mutation-positive tumor as confirmed in a CLIA-approved laboratory or equivalent."  
  
Having the BRAF mutation is just one requirement. They must also meet criteria related to age, performance status, organ function, etc., and \*not\* have any of the listed exclusionary conditions (prior malignancies, recent cancer therapy, specific health conditions, etc.).