

Testing the Use of AMG 510 (Sotorasib) and Panitumumab as a Targeted Treatment for KRAS G12C Mutant Solid Tumor Cancers (A ComboMATCH Treatment Trial)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patient must have enrolled onto EAY191 and must have been given a treatment assignment to ComboMATCH to EAY191-E5 based on the presence of an actionable mutation as defined in EAY191 * Patient must be enrolled on the ComboMATCH Registration Protocol (EAY191) at the time of registration/randomization to the EAY191-E5 study * Patient must be \geq 18 years of age * Patient must have a KRAS G12C alteration as determined by the ComboMATCH screening assessment * Patient must have disease that can be safely biopsied and agree to a pre-treatment biopsy or have tissue available from within 12 months prior to the date of registration on the ComboMATCH Registration Trial (EAY191-E5) * NOTE: The current actionable marker of interest (aMOI)/actionable alteration list for this treatment trial can be found on the Cancer Trials Support Unit (CTSUS) website: www.ctsu.org (final URL pending) * NOTE: Novel/Dynamic aMOI can be submitted for review per the process described in the ComboMATCH registration protocol * Patient must have cytologically/histologically confirmed advanced/metastatic solid tumor * Patient must have progressed on at least one line of standard of care therapy in the advanced/metastatic setting * NOTE: Patients who have progressed on a prior human epidermal growth factor receptor (EGFR) inhibitor will meet this criterion * Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of \leq 2 (or Karnofsky performance status \geq 60%) * Patient must have at least one measurable lesion as defined by Response Evaluation Criteria in Solid Tumors (RECIST) documented by imaging obtained within 28 days prior to registration/randomization * Patient must not have any serious active infection within 4 weeks prior to EAY191-E5 registration/randomization (e.g., requiring hospitalization and/or intravenous [IV] antibiotics) or currently receiving oral or IV antibiotics for the treatment of infection. Patients receiving prophylactic antibiotics are eligible * Patient must have the ability to retain oral medication and not have any clinically significant gastrointestinal abnormalities that might alter absorption * Patient must not have any history of or current evidence of non-infectious interstitial lung disease (ILD)/pneumonitis * Patient must not have a history of allergic reactions attributed to either of the study agents or to agents of similar chemical or biologic composition * Patient must have completed full treatment cycle 21 days prior to EAY191-E5 registration/randomization if they have received prior chemotherapy, biological cancer therapy, radiation therapy or an investigational agent/device. Patients must have recovered to Common Terminology Criteria for Adverse Events (CTCAE) grade 1 or better from any adverse events due to prior cancer therapy (with the exception of alopecia) * Patient must not be pregnant or breast-feeding due to the potential harm to an unborn fetus and possible risk for adverse events in nursing infants with the treatment regimens being used. All patients of childbearing potential must have a blood test or urine study within 14 days prior to registration/randomization to rule out pregnancy. A patient of childbearing potential is defined as anyone, regardless of sexual orientation or whether they have undergone tubal ligation, who meets the following criteria: 1) has achieved menarche at some point, 2) has not undergone a hysterectomy or bilateral oophorectomy; or 3) has not been naturally postmenopausal (amenorrhea following cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months) * Patient must not expect to conceive or father children by using accepted and effective method(s) of contraception or by abstaining from sexual intercourse for the duration of their participation in the study and for at least 6 months after the last dose of protocol treatment. Patients must not breastfeed while receiving protocol treatment and for one week (7 days) after the last dose of AMG 510 (sotorasib) and 2 months after the last dose of panitumumab * Patients must not have neuropathy \geq grade 2 within 14 days prior to registration/randomization * Patients with treated brain metastases are eligible if follow-up brain imaging after central nervous system (CNS)-directed therapy shows no evidence of progression * Human immunodeficiency virus (HIV)-infected patients no effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial * Patients with known history or current symptoms of cardiac history, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better * Total bilirubin \leq 1.5 x institutional upper limit of normal (ULN) (obtained \leq 28 days prior to protocol registration/randomization) * Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase [SGOT])/alanine aminotransferase (ALT) (serum glutamic pyruvic transaminase [SGPT]) $<$ 3 x institutional upper limit of normal (obtained \leq 28 days prior to protocol registration/randomization) * Creatinine \leq 1.5 x institutional ULN OR creatinine clearance $>$ 50 mL/min/1.73 m² for patients with creatinine levels $>$ 1.5 mg/dL as per Cockcroft-Gault (obtained \leq 28 days prior to protocol registration/randomization) * COHORT I: Patient must not have colorectal cancer or non-small cell lung cancer * COHORT I: Patient must not have been previously treated with a KRAS G12C inhibitor * COHORT II: Patient must have progressed after treatment at the recommended phase II dose (RP2D) of any KRAS G12C inhibitor * NOTE: Patients on cohort 1 who experience progression on Regimen 2 (AMG 510 [sotorasib] alone) may be eligible to enroll on cohort 2 and receive combination treatment with panitumumab and AMG 510 (sotorasib). Patients must meet performance status requirements and laboratory values as above and must begin treatment within 7 days of enrollment. Migration to cohort 2 must take place within 6 months of progression, with no intervening anti-cancer therapy given. * NOTE: Cohort migration following disease progression is dependent on a slot being available. MATCHBox makes the new treatment assignment following initiation of a step 2 registration for this treatment trial * COHORT II: Patient must not have been previously treated with a KRAS G12C inhibitor in combination with an EGFR inhibitor

Conditions & Interventions

Interventions:

PROCEDURE: Biopsy Procedure, PROCEDURE: Biospecimen Collection, PROCEDURE: Computed Tomography, PROCEDURE: Magnetic Resonance Imaging,

BIOLOGICAL: Panitumumab, DRUG: Sotorasib

Conditions:

Advanced Malignant Solid Neoplasm, Metastatic Malignant Solid Neoplasm

More Information

Contact(s): ctrrecruit@vcu.edu

Principal Investigator:

Phase: PHASE2

IRB

Number:

System ID: NCT05638295

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