Study of Chemotherapy Plus Ipatasertib for People With Solid Tumors With PTEN/AKT Mutations, 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-S3 based on the presence of an actionable mutation as defined in EAY191 * GENERAL COMBOMATCH EAY191 REGISTRATION INCLUSION CRITERIA: * Participants must be enrolled on the ComboMATCH Master Registration Trial EAY191 * Participants must have an activating AKT mutation (a known mutation in AKT1, AKT2, or AKT3, a single nucleotide variant, insertion, or deletion), PTEN mutation (a known mutation in PTEN, a single nucleotide variant, insertion, or deletion), or genomic deletion loss of PTEN as determined by the ComboMATCH screening assessment * GENERAL COMBOMATCH EAY191 REGISTRATION EXCLUSION CRITERIA: * Participants must not have an activating KRAS, NRAS, HRAS, or BRAF mutation (a single nucleotide variant, insertion, or deletion) as determined by the ComboMATCH screening assessment * Participants must have disease that can be safely biopsied and agree to a pre-treatment biopsy or have archival tissue available from within 12 months prior to the date of registration on the ComboMATCH Registration Trial (EAY191) * Participants must have a histologically confirmed non-breast solid malignancy * Participants must have locally advanced, unresectable, or metastatic disease in the opinion of the treating investigator * Participants must have measurable disease documented by CT or MRI. Measurable disease must be assessed within 28 days prior to registration. Non-measurable disease must be assessed within 42 days prior to registration. The CT from a combined positron emission tomography (PET)/CT may be used only if it is of diagnostic quality. All known sites of disease must be assessed and documented on the Baseline Tumor Assessment Form (Response Evaluation Criteria in Solid Tumors \[RECIST\] 1.1). Participants whose only measurable disease is within a previous radiation therapy port must demonstrate clearly progressive disease (in the opinion of the treating investigator) prior to registration * Participants with known brain metastases must have a CT/MRI scan to evaluate for central nervous system (CNS) disease and show no evidence of progression within 42 days prior to registration * Participants must have completed any CNS-directed therapy and/or local therapy for spinal cord compression at least 28 days prior to registration * Participants must not have spinal cord compression or brain metastases unless: (1) metastases have been locally treated and have remained clinically controlled and asymptomatic for at least 14 days prior to registration, AND (2) participant has no residual neurological dysfunction and has been off corticosteroids for at least 24 hours prior to registration * Participants must not have leptomeningeal disease * Participants must have progressed on or within 6 months of taxane-based therapy in the neoadjuvant/adjuvant or metastatic setting prior to registration * Participants must not have received any prior AKT inhibitor (e.g., capivasertib or ipatasertib); prior PI3K/mTOR inhibitor is acceptable * Participants must not have received cancer-directed therapy prior for at least 14 days prior to initiation of treatment on study * Participants must not be planning to receive any concurrent chemotherapy, immunotherapy, biologic, radiation, or hormonal therapy for cancer treatment while receiving treatment on this study * Participants must be \>= 18 years of age * Participants must be able to swallow oral medications whole * Participants must have a pre-study history and physical exam done within 28 days prior to registration * Participants must have a Zubrod performance status of 0-2 within 28 days prior to registration * Participants must have adverse events resolved =\< grade 1 related to any prior therapy, except alopecia within 14 days prior to registration * Participants with neuropathy must have resolved to \< grade 2 within 14 days prior to registration * Leukocytes \>= 3 x 10\^3/uL (within 28 days prior to registration) * Absolute neutrophil count \>= 1.5 x 10\^3/uL (within 28 days prior to registration) * Platelets \>= 100 x 10\^3/uL (within 28 days prior to registration) * Total bilirubin =\< institutional upper limit of normal (ULN) unless history of Gilbert's disease. Participants with history of Gilbert's disease must have total bilirubin =\< 5 x institutional ULN (within 28 days prior to registration) * Aspartate aminotransferase (AST) \& alanine aminotransferase (ALT) =\< 3 x institutional ULN (within 28 days prior to registration) * Participants must have adequate cardiac function, class IIB (2B) or better. Participants with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, must have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification * Participants must have a measured OR calculated creatinine clearance \>= 50 mL/min using the following Cockcroft-Gault formula. This specimen must have been drawn within 28 days prior to registration * Participants with known human immunodeficiency virus (HIV)-infection must be receiving anti-retroviral therapy and have an undetectable viral load test on the most recent test results obtained within 6 months prior to registration * Participants with evidence of chronic hepatitis B virus (HBV) infection must have undetectable HBV viral load on suppressive therapy within 28 days prior to registration * Participants with a history of hepatitis C virus (HCV) infection must have been treated and cured. Participants with HCV infection who are currently on treatment must have an undetectable HCV viral load within 28 days prior to registration * Participants must have an electrocardiography (ECG) performed (if clinically indicated with a corrected QTc interval of =\< 470 msec) within 28 days prior to registration * Participants must not have a history of allergic reactions attributed to compounds of similar chemical or biologic composition to ipatasertib and/or paclitaxel * Participants must not have an active small/large bowel inflammation such as ulcerative colitis or Crohn's disease * Participants must not have grade 2 or higher uncontrolled intercurrent illness * NOTE: To receive an agent, participant must not have any uncontrolled intercurrent illness requiring antibiotic/antiviral/antifungal therapy or interventional procedures. Participants with infections unlikely to be resolved within 2 weeks following registration should not be considered for the trial * Participants must not have a known grade 2 or higher uncontrolled or untreated hypercholesterolemia or hypertriglyceridemia * Participants must not have any of the following: * Cirrhosis at a level of Child-Pugh B (or worse), * Cirrhosis (any degree) and a history of hepatic encephalopathy, or * Clinically meaningful ascites resulting from cirrhosis. Clinically meaningful ascites is defined as ascites from cirrhosis requiring diuretics or paracentesis * Participants must not be receiving any medications or substances that are inhibitors or inducers of CYP3A. Treatment with strong CYP3A inhibitors or strong CYP3A inducers within 2 weeks or 5 drug-elimination half-lives, whichever is longer, prior to initiation of study drug is prohibited. * NOTE: Because the lists of these agents are constantly changing, it is important to regularly consult a frequently updated medical reference. As part of the enrollment/informed consent procedures, the participant will be counseled on the risk of interactions with other agents, and what to do if new medications need to be prescribed or if the participant is considering a new over-the-counter medicine or herbal product. The participant wallet card should be presented to the participant * Participants must not have baseline fasting glucose (after 8-hour fast) \> 160 mg/dL (8.9 mmol/L) within 28 days prior to registration * Participants with known diabetes mellitus must not require insulin therapy or have a baseline fasting glucose \>150 mg/dL (8.3 mmol/L) or high glycosylated hemoglobin (Hb)A1c, (\>= 8.0%), suggesting poorly controlled diabetes * Participants who are on a stable dose of oral diabetes medication \>= 2 weeks prior to initiation of study drug treatment are eligible for enrollment * Participants with a prior or concurrent malignancy whose natural history or treatment (in the opinion of the treating physician) must not have a potential to interfere with the safety or efficacy assessment of the investigational regimen * Participants must not have lung disease requiring active systemic therapy or placing participants at increased risk of toxicity related to study-directed therapy including, but not limited to pneumonitis, interstitial lung disease, idiopathic pulmonary fibrosis, cystic fibrosis, aspergillosis, active tuberculosis, or history of opportunistic infections (pneumocystis pneumonia or cytomegalovirus pneumonia) * Participants must not be pregnant or nursing. Individuals who are of reproductive potential must have agreed to use an effective contraceptive method with details provided as a part of the consent process. A person who has had menses at any time in the preceding 12 consecutive months or who has semen likely to contain sperm is of "reproductive potential". In addition to routine contraceptive methods, "effective contraception" also includes surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) including hysterectomy, bilateral oophorectomy, bilateral tubal ligation/occlusion, and vasectomy with testing showing no sperm in the semen * Participants must not have psychiatric illness/social situations that would limit compliance with study requirements

Conditions & Interventions

Interventions:

Interventions:
PROCEDURE: Biopsy Procedure, PROCEDURE: Biospecimen Collection, PROCEDURE: Computed Tomography, DRUG: Ipatasertib, PROCEDURE: Magnetic Resonance Imaging, DRUG: Paclitaxel
Conditions:
Locally Advanced Malignant Solid Neoplasm, Metastatic Malignant Solid Neoplasm, Unresectable Malignant Solid Neoplasm

More Information

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Number:
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