Testing the Use of Neratinib or the Combination of Neratinib and Palbociclib Targeted Treatment for HER2+ Solid Tumors (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-N5 based on the presence of an actionable mutation as defined in EAY191 * Patients must have a HER2 amplified solid tumor except breast cancer. Patient's cancer must have HER2 amplification as defined with ≥ 7 copies by next generation sequencing (NGS) testing * Patients must have recurrent or persistent disease * No known evidence of RB1 loss or deletion including copy number loss or deleterious mutation * Patients must have disease that can be safely biopsied and agree to a pre-treatment biopsy or, if disease cannot be safely biopsied, have archival tissue available from within 12 months prior to the date of registration on the ComboMATCH Registration Trial (EAY191) * Patients must have measurable disease based on RECIST 1.1. A second measurable lesion outside of the biopsiable lesion is required * Patients with treated brain metastases are eligible if follow up brain imaging after central nervous system (CNS) directed therapy shows no evidence of progression for 3 months or more and patient is not on steroids and is asymptomatic * No known leptomeningeal disease * Patients may have received up to 5 prior lines of systemic therapy * Prior therapy with trastuzumab or pertuzumab, either alone or in combination, antibody drug conjugates (ADC) such as DS8201a or T-DM1 is allowed * Prior therapy with tyrosine kinase inhibitors (TKI) such as neratinib or tucatinib is not allowed * No prior therapy with CDK4/6 inhibition * No cancer directed therapy within 3 weeks prior to registration. For oral therapy, the washout can be reduced to greater than or equal to 5 half lives of the drug. No HER2 targeting ADCs within 30 days prior to registration * Age ≥ 18 * Eastern Cooperative Oncology Group (ECOG) Performance Status of ≤ 2 * Not pregnant and not nursing * Absolute neutrophil count (ANC) ≥ 1,500 cells/mm\^3 * Platelets ≥ 100,000 cells/mm\^3 * Hemoglobin ≥ 9 g/dl (Note: The use of transfusion or other intervention to achieve hemoglobin (Hgb) ≥ 9 g/dl is acceptable) * Creatinine clearance (CrCL) of ≥ 30 mL/min by the Cockcroft-Gault formula * Total bilirubin level ≤ 1.5 x institutional upper limit of normal (ULN) (patients with known Gilbert's disease who have bilirubin level ≤ 3 x institutional ULN may be enrolled) * Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤ 3 x institutional upper limit of normal (ULN) * Patients with known history or current symptoms of cardiac disease, 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 * No active infection requiring parenteral antibiotics * No current evidence of intra-abdominal abscess, abdominal/pelvic fistula (not diverted), gastrointestinal perforation, gastrointestinal (GI) obstruction, and/or need for drainage nasogastric or gastrostomy tube * No current evidence of malabsorption or chronic diarrhea or any other significant gastro-intestinal disease (e.g gastrectomy, ileal bypass, Crohn's disease, gastroparesis), associated with moderate to severe diarrhea (grade 2 or more) or inability to tolerate oral therapy * No lung disease causing dyspnea at rest * No interstitial lung disease with ongoing signs and symptoms at the time of registration * No history of allergic reaction to the study agents, compound of similar chemical or biologic composition of the study agents or any of their excipients

Conditions & Interventions

Interventions:
PROCEDURE: Biopsy Procedure, PROCEDURE: Biospecimen Collection, PROCEDURE: Computed Tomography, PROCEDURE: Echocardiography Test, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Multigated Acquisition Scan, DRUG: Neratinib Maleate, DRUG: Palbociclib

Conditions:
Malignant Female Reproductive System Neoplasm, Malignant Solid Neoplasm, Recurrent Malignant Female Reproductive System Neoplasm, Recurrent Malignant Solid Neoplasm

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: PHASE2
IRB
Number:
System ID: NCT06126276

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