Protocol Version Date: 02/29/2024

NCI National Clinical Trials Network

ComboMATCH / EAY191-E5

For Patients with Advanced Solid Tumors

EAY191-E5 is Available Through the CTSU

ComboMATCH Treatment Trial E5:
A Randomized Phase II Study of AMG 510 (Sotorasib) with or without Panitumumab in Advanced Solid Tumors

Patient Population

See Section 3 for Complete Eligibility Details

- Must be enrolled on the ComboMATCH Registration Protocol (EAY191).
- Must be ≥ 18 years of age and have ECOG PS of ≤ 2 (or Karnofsky PS ≥ 60%).
- Must have a KRAS G12C alteration as determined by the ComboMATCH screening assessment.
- Must have disease that can be safely biopsied and agree to pre-treatment biopsy or have tissue available from within 12 months prior to the date of registration on EAY191. See 3.1.4.
- Must have cytologically/histologically confirmed advanced/ metastatic solid tumor.
- Must have progressed on at least one line of standard of care therapy in the advanced/metastatic setting. Note: Patients who progressed on prior EGFR inhibitor meet this criteria.
- Must have at least one measurable lesion as defined by RECIST, documented by imaging obtained within 28 days prior to registration/randomization.
- Must not have any serious active infection within 4 weeks prior to EAY191-E5 registration/randomization or currently receiving oral/IV antibiotics for infection.
- Must have ability to retain oral medication and not have any clinically significant GI abnormalities that might alter absorption.
- Must not have neuropathy ≥ grade 2 within 14 days prior to registration/randomization.
- Must have NYHA Functional Classification 2B or better.
- COHORT 1 ONLY: Must not have colorectal cancer or non-small cell lung cancer; must not have been previously treated with a KRAS G12C inhibitor.
- COHORT 2 ONLY: Must have progressed after treatment at the RP2D of any KRAS G12C inhibitor (see 3.3.1); must not have been previously treated with a KRAS G12C inhibitor in combination with an EGFR inhibitor.

Treatment Plan

See Sections 5 for Complete Treatment Details

Cohort 1 (KRAS G12C Inhibitor Naïve)

Regimen 1:
AMG 510 (Sotorasib):
- 960 mg PO daily once a day.

Panitumumab:
- 6 mg/kg IV on Days 1 and 15.

Regimen 2:
AMG 510 (Sotorasib):
- 960 mg PO daily once a day.

Cohort 2 (KRAS G12C Inhibitor Exposed)

Regimen 1:
AMG 510 (Sotorasib):
- 960 mg PO daily once a day.

Panitumumab:
- 6 mg/kg IV on Days 1 and 15.

1 Cycle = 28 days.
Repeat cycles every 28 days until progression or intolerable toxicity.

Patients on Cohort 1 Regimen 2 receiving AMG 510 (Sotorasib) who experience disease progression may be eligible to migrate to Cohort 2 and receive combination treatment with Panitumumab and AMG 510 (Sotorasib) upon documentation of disease progression. Cohort migration is dependent on availability of a slot on Cohort 2.

Number of Participants: 105

Protocol Chair:
Kristen Spencer, DO, MPH

Co-Chair:
Dustin Deming, MD

Patient Enrollment
All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org/open

Protocol Information
CTSU Help Desk: 1-888-823-5923, CTSUcontact@westat.com, www.ctsu.org

Please Enroll Your Eligible Patients!

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