# 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

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### 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.
- **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.

**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.

**Regimen 2:**

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

**Number of Participants:** 105

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### Patient Enrollment

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

### Protocol Information

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

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Please Enroll Your Eligible Patients!
EAY191-E5
ComboMATCH Treatment Trial E5:
A Randomized Phase II Study of AMG 510 (Sotorasib) with or without Panitumumab in Advanced Solid Tumors

Schema

- **Cohort 1**
  - EAY191-E5.C1
  - People who have had a prior KRAS G12C inhibitor or have one of the following: CRC, NSCLC
  - N = 66

- **Cohort 2**
  - EAY191-E5.C2
  - People who have progressed on a KRAS G12C inhibitor
  - N = 39

- **Stratum 1**
  - EAY191-E5.C1.S1
  - People who have pancreatic cancer
  - N ≥ 16

- **Stratum 2**
  - EAY191-E5.C1.S2
  - People who have all other cancers

- **Stratum 3**
  - EAY191-E5.C2.S3
  - People who have pancreatic cancer
  - N ≤ 15

- **Stratum 4**
  - EAY191-E5.C2.S4
  - People who have NSCLC
  - N ≤ 15

- **Stratum 5**
  - People who have CRC
  - N ≤ 15

- **Stratum 6**
  - EAY191-E5.C2.S6
  - People who have all other cancers

- **Treatment Regimen 1**
  - EAY191-E5.C1.S1.R1
  - AMG 510 (Sotorasib) + Panitumumab

- **Treatment Regimen 2**
  - Sotorasib

- **Treatment Regimen 1**
  - EAY191-E5.C1.S2.R1
  - AMG 510 (Sotorasib) + Panitumumab

- **Treatment Regimen 2**
  - EAY191-E5.C1.S2.R2
  - Sotorasib

- **Treatment Regimen 1**
  - EAY191-E5.C2.S3.R1
  - AMG 510 (Sotorasib) + Panitumumab

- **Treatment Regimen 1**
  - AMG 510 (Sotorasib) + Panitumumab

- **Treatment Regimen 1**
  - EAY191-E5.C2.S5.R1
  - AMG 510 (Sotorasib) + Panitumumab

- **Treatment Regimen 1**
  - AMG 510 (Sotorasib) + Panitumumab

**Protocol E5**
- EAY191.E5
- People with KRAS G12C mutated advanced solid tumors
- N = 165

**KEY**
- S: Stratification
- R: Randomization