CodeBreaK 300

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Study Factsheet

Protocol title
A Phase 3, Multicenter, Randomized, Open-label, Active-controlled Study of Sotorasib and Panitumumab Versus Investigator's Choice (Trifluridine and Tipiracil, or Regorafenib) for the Treatment of Previously Treated Metastatic Colorectal Cancer Subjects with *KRAS* G12C Mutation

Sponsor
Amgen Inc.

ClinicalTrials.gov Identifier
NCT05198934 (https://clinicaltrials.gov/ct2/show/NCT05198934)

Protocol Number
20190172

Key inclusion criteria*
- Age ≥ 18 years
- Pathologically documented metastatic colorectal adenocarcinoma harboring a *KRAS* G12C mutation identified through molecular testing
- Received at least 1 prior line of therapy for metastatic disease. Participants must have received and progressed or experienced disease recurrence on or after fluoropyrimidine, irinotecan, and oxaliplatin
- ECOG PS ≤ 2
- Measurable disease per RECIST 1.1 criteria

Key exclusion criteria*
- Active brain metastases
- History or presence of hematological malignancies unless curatively treated with no evidence of disease ≥ 2 years
- Significant GI disorder that results in significant malabsorption, requirement for IV alimentation, or inability to take oral medication
- History of interstitial pneumonitis or pulmonary fibrosis or evidence of interstitial pneumonitis or pulmonary fibrosis
- Leptomeningeal disease
- Previous treatment with a $KRAS^{G12C}$ inhibitor

Study design
- Screening (up to 28 days)
- Study treatment until disease progression, unacceptable toxicity, withdrawal of informed consent, or death
  In select cases, subjects may continue on treatment following radiologic progression if they are continuing to demonstrate clinical benefit
- Safety follow-up (28 ± 7 days after end of treatment)
- Long-term follow-up (up to 1 year after last subject enrolled)

Primary and secondary endpoints
Primary: PFS
Secondary: OS, ORR, DOR, TTR, DCR, investigator-assessed ORR, investigator-assessed PFS

** additional criteria apply*

DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; GI, gastrointestinal; IV, intravenous; KRAS, Kirsten rat sarcoma; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; RECIST, Response Evaluation Criteria In Solid Tumors; TTR, time to response

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