CodeBreaK 101
Study Factsheet

Brief Summary: A Phase 1b/2 Study Evaluating Sotorasib in Combination With Anti-Cancer Therapies in Subjects With Advanced Solid Tumors With *KRAS G12C* Mutation

Sponsor: Amgen Inc.

ClinicalTrials.gov identifier: NCT04185883 (https://clinicaltrials.gov/ct2/show/NCT04185883)

Protocol Number: 20190135

Key inclusion criteria*

- Subjects age ≥ 18 years old
- Pathologically documented, locally-advanced or metastatic malignancy with *KRAS G12C* mutation identified through molecular testing

**additional criteria apply*

Key exclusion criteria*

- Primary brain tumor
- Spinal cord compression or untreated or symptomatic brain metastases or leptomeningeal disease from non-brain tumors
- Myocardial infarction within 6 months of study day 1
- Gastrointestinal tract disease causing the inability to take oral medication

Study design

- Multicenter, open-label, phase 1b/2 study
- Primary endpoints: DLTs, TEAEs, TRAEs, and clinically significant changes in vital signs, ECGs, and clinical laboratory tests, and ORR
- Key secondary endpoints: PK parameters of sotorasib and anti-cancer treatments, ORR, DOR, OS, PFS, DCR, and duration of SD

Treatment Arms

Sotorasib + pembrolizumab (PD-1 inhibitor)
Sotorasib + trametinib (MEK inhibitor)
Sotorasib + RMC-4630 (SHP2 allosteric inhibitor)
Sotorasib + afatinib (pan-ErbB tyrosine kinase inhibitor)
Sotorasib + atezolizumab (PD-L1 inhibitor)
Sotorasib + panitumumab + FOLFIRI (EGFR inhibitor + chemotherapy)
Sotorasib + carboplatin, pemetrexed, or docetaxel (chemotherapy)
Sotorasib + AMG 404 (PD-1 inhibitor)
Sotorasib + everolimus (mTOR inhibitor)
Sotorasib + palbociclib (CDK inhibitor)
Sotorasib + bevacizumab (VEGF inhibitor)

CDK, Cyclin-dependent kinase; DCR, disease control rate; DLT, dose-limiting toxicity; DOR, duration of response; ECG, electrocardiogram; EGFR, epidermal growth factor receptor; ErbB, erythroblastic leukemia viral oncogene homolog; KRAS, Kirsten rat sarcoma; MEK, mitogen-activated protein kinase; mTOR, mammalian target of rapamycin; ORR, objective response rate; OS, overall survival; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1; PFS, progression-free survival; PK, pharmacokinetic; SD, stable disease; SHP2, src homology region 2-containing protein tyrosine phosphatase 2; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event; VEGF, vascular endothelial growth factor