

CodeBreak 100

Study Factsheet

Brief Summary

A Phase 1/2 Study to Evaluate Sotorasib Monotherapy and Combination Therapy in Subjects With Advanced Solid Tumors that Harbor a *KRAS G12C* Mutation

Sponsor

Amgen Inc.

ClinicalTrials.gov identifier

NCT03600883 (<https://clinicaltrials.gov/ct2/show/NCT03600883>)

Protocol Number

20170543

Key inclusion criteria*

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

Key exclusion criteria*

- Active brain metastases from non-brain tumors
- Myocardial infarction within 6 months of study day 1
- Gastrointestinal tract disease causing the inability to take oral medication

* additional criteria apply

Study design

- Phase 1/2 multicenter, open-label study
- Phase 1: dose exploration/expansion study (monotherapy and combination therapy)
- Phase 2: sotorasib as monotherapy in NSCLC, CRC, and other solid tumors

Primary and Secondary Endpoints**

TEAEs, TRAEs, Number of grade \geq 3 TEAEs, serious AEs, AEs of interest, clinically significant changes in vital signs, ECGs, and clinical laboratory tests, DLT, ORR, DOR, DCR, PFS, duration of SD, TTR, OS

** Endpoints vary by study phase/part

AE, adverse event; CRC, colorectal cancer; DCR, disease control rate; DLT, dose-limiting toxicity; DOR, duration of response; ECG, electrocardiogram; KRAS, Kirsten rat sarcoma; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; SD, stable disease; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event; TTR, time to response