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Study Factsheet

Brief Summary
A Phase 1/2 Study to Evaluate Sotorasib (AMG 510) Monotherapy and Combination Therapy in Subjects With Advanced Solid Tumors With *KRAS G12C* Mutation

Sponsor
Amgen Inc.

ClinicalTrials.gov identifier
NCT03600883 (https://clinicaltrials.gov/ct2/show/NCT03600883)

Protocol Number
20170543

Key inclusion criteria*
- Subjects age ≥ 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 ≥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

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