CodeBreaK 201

Study Factsheet

Protocol Title

A Phase 2, Multicenter, Open-label Study of Sotorasib in Subjects With Stage IV NSCLC Whose Tumors Harbor a *KRAS* G12C Mutation in Need of First-Line Treatment (CodeBreaK 201)

Sponsor

Amgen Inc.

ClinicalTrials.gov identifier

NCT04933695 (https://clinicaltrials.gov/ct2/show/NCT04933695)

Protocol Number

20190288

Key inclusion criteria*

- Untreated stage IV NSCLC
- *KRAS* G12C mutation identified through molecular testing
- Age ≥ 18 years
- PD-L1 TPS score < 1% and/or *STK11* loss of function mutation

Key exclusion criteria*

- Mixed small-cell lung cancer and NSCLC histology
- Prior treatment for metastatic NSCLC unless adjuvant/neoadjuvant therapy was completed 12 months before metastatic disease
- Active brain metastases from non-brain tumors
- Myocardial infarction within 6 months of study Day 1
- Unable to take or absorb (for example, gastrointestinal tract disease) oral medication
- Co-administration of proton-pump inhibitors (PPIs) and histamine 2 (H2) receptor antagonists (H2RA)

** additional criteria apply*

Study design

- Participants randomized in a 1:1 design for treatment with sotorasib at 960 mg PO daily or 240 mg PO daily, stratified by *STK11*m
- 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.
- SFU visit approximately 30 days after last dose
- LTFU visits (in clinic or via telephone) every 12 weeks starting from date of last dose

Primary and secondary endpoints

Primary: Objective Response (OR = CR + PR)

Secondary: Disease control (CR + PR + SD); DOR; TTR; PFS; OS; TEAEs; TRAEs; Changes in vital signs, ECGs, and clinical laboratory tests

CR, complete response; DOR, duration of response; ECG, electrocardiogram; KRAS, Kirsten rat sarcoma; LTFU, long-term follow-up; NSCLC, non-small cell lung cancer; OR, objective response; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; PO, orally; PR, partial response; QD, daily; SD, stable disease; SFU, safety follow-up; *STK11*, serine/threonine kinase 11; TEAE, treatment-emergent adverse event; TPS, tumor proportion score; TRAE, treatment-related adverse event; TTR, time to response

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