Research Area:

Non-Small Cell Lung Cancer

CodeBreaK 200

Sotorasib* (AMG 510)
**Proposed INN*

- Amgen Study: 20190009
- NCT: 04303780
- EudraCT: 2019-003582-18

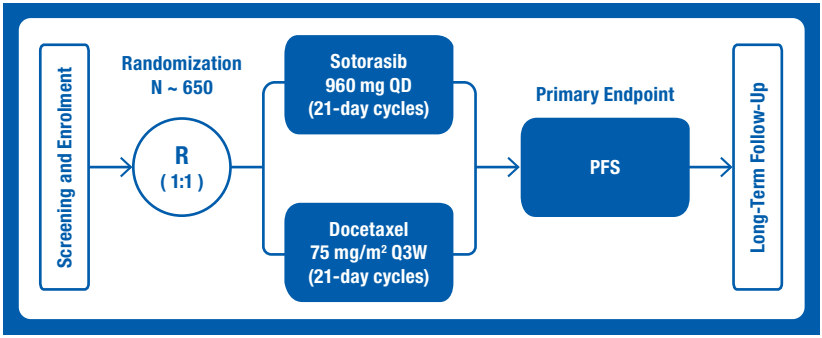
A Phase 3 Multicenter, Randomized, Open Label, Active-Controlled, Study of Sotorasib Versus Docetaxel for the Treatment of Previously Treated Locally Advanced and Unresectable or Metastatic Non-Small Cell Lung Cancer (NSCLC) Subjects with Mutated *KRAS p.G12C*

Primary Endpoint:

- Progression-free survival (PFS)

Secondary Endpoints:

- OS, ORR, DOR, TTR, DCR
- Quality of life assessment, PRO
- Safety and tolerability
- PK



Key Inclusion Criteria:

- Adults with pathologically documented, previously treated, locally-advanced and unresectable or metastatic NSCLC with *KRAS p.G12C* mutation confirmed through molecular testing
- ECOG PS ≤ 1
- ≥ 1 prior systemic therapy including platinum-based doublet chemotherapy and checkpoint inhibitor

Key Exclusion Criteria:

- Active brain metastases
- Prior docetaxel treatment
- Gastrointestinal tract disease causing the inability to take oral medication
- Major surgery within 28 days of study day 1

DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; INN, international nonproprietary name; *KRAS*, Kirsten rat sarcoma viral oncogene homolog; ORR, objective response rate; OS, overall survival; PK, pharmacokinetics; PRO, patient-reported outcomes; Q3W, every 3 weeks; QD, every day; R, randomization; TTR, time to response.

Product has not been authorised by regulatory agencies for marketing and is only authorised for investigational use in this trial.

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Key Summary Points:

CodeBreak 200 is a Phase 3 study to compare sotorasib to docetaxel for the treatment of subjects with previously treated locally advanced and unresectable or metastatic non-small cell lung cancer (NSCLC) with mutated *KRAS p.G12C*.

The primary outcome measure is progression-free survival (PFS) defined as time from randomization until disease progression or death from any cause, whichever occurs first.

Additional Information:

- www.clinicaltrials.gov
  Identifier - NCT: 04303780
- www.amgentrials.com
  Protocol Number: 20190009
- www.clinicaltrialsregister.eu
  EudraCT: 2019-003582-18

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