Research Area:

Non-Small Cell Lung Cancer

CodeBreaK 202

Sotorasib

- Amgen Study ID Number: 20190341
- NCT: NCT05920356
- EudraCT: 2022-501863-41

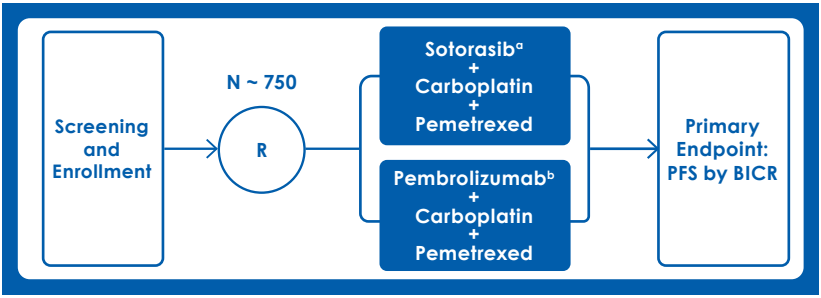
CodeBreaK 202: A Phase 3, Multicenter, Randomized, Open-label Study Evaluating Efficacy of Sotorasib Platinum Doublet Combination Versus Pembrolizumab Platinum Doublet Combination as a Front-Line Therapy in Subjects With Stage IV or Advanced Stage IIIB/C Nonsquamous Non-Small Cell Lung Cancer (NSCLC), Negative for PD-L1, and Positive for *KRAS* G12C.

Primary Endpoint:

- PFS by BICR

Key Secondary Endpoints:

- OR, OS, PFS2, DOR, TTR, DC, changes in QLQ-C30, and changes in QLQ-LC13
- Safety and tolerability
- PK



Inclusion Criteria:

- Histologically or cytologically confirmed diagnosis of nonsquamous stage IV or advanced Stage IIIB or IIIC NSCLC with *KRAS* G12C mutation and negative for PD-L1 expression by central testing or local laboratory testing confirmed through central testing
- No history of systemic anticancer therapy in metastatic/non-curable settings
- ECOG ≤ 1

[a]Oral administration
[b]Intravenous administration
BICR, Blinded Independent Central Review; DC, disease control; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; KRAS, Kirsten rat sarcoma viral oncogene homolog; NSCLC, non-small cell lung cancer; OR, objective response; OS, overall survival; PD-L1, programmed cell death ligand 1; PFS, progression-free survival; PFS2, time from randomization to progression on second-line therapy; PK, pharmacokinetics; QLQ-C30, quality-of-Life questionnaire core 30; QLQ-LC13, quality-of-life questionnaire lung cancer 13; R, randomization; TTR, time to response.

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Key Summary Point:

- CodeBreaK 202 is a phase 3 study to compare PFS in participants who receive sotorasib with platinum doublet chemotherapy versus participants who receive pembrolizumab with platinum doublet chemotherapy

Exclusion Criteria:

- Mixed histology NSCLC with either small-cell or large-cell neuroendocrine cell component or predominant squamous cell histology
- Participants with tumors known to harbor molecular alterations for which targeted therapy is locally approved
- Symptomatic (treated or untreated) brain metastases
- GI tract disease causing the inability to take oral medication
- Myocardial infarction within 6 months of randomization, unstable arrhythmias, or unstable angina
- Prior therapy with a $KRAS^{G12C}$ inhibitor

Additional Information:

- www.clinicaltrials.gov
  Identifier - NCT: 05920356
- www.amgentrials.com
  Amgen Study ID Number: 20190341
- www.clinicaltrialsregister.eu
  EudraCT: 2022-501863-41

GI, gastrointestinal; KRAS, Kirsten rat sarcoma viral oncogene homolog; NSCLC, non-small cell lung cancer; PFS, progression-free survival.

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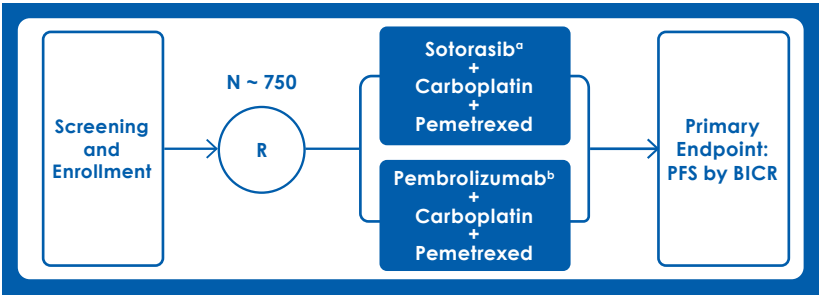

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