A Phase 2, Multicenter, Open-label Study of Sotorasib (AMG 510) in Subjects with Stage IV NSCLC Whose Tumors Harbor a KRASG12C Mutation in Need of First-Line Treatment (CodeBreaK 201)

Published: 30-08-2021
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Primary- To evaluate the tumor objective response rate (ORR) assessed by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 criteria in subjects who receive sotorasib at either 960 mg daily (QD) or 240 mg QD whose tumors are PD-L1 Tumor…

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON51994

Source
ToetsingOnline

Brief title
20190288 - CodeBreak 201

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
Lung cancer, non small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Amgen
Source(s) of monetary or material Support: Amgen

Intervention

Keyword: Non small cell lung cancer, Phase 2, Sotorasib

Outcome measures

Primary outcome

Objective response (OR) (OR = complete response [CR] + partial response [PR]), measured by computed tomography (CT) or magnetic resonance imaging (MRI) and assessed per RECIST v1.1 per Blinded Independent Central Review (BICR)

Secondary outcome

- Disease control (CR + PR + stable disease [SD])

- Duration of response (DOR)

- Time to response (TTR)

- Progression-free survival (PFS)

- Overall survival (OS)

- Treatment-emergent adverse events, treatment-related adverse events, and changes in vital signs, electrocardiogram [ECGs], and clinical laboratory tests.

Study description

Background summary

Lung cancer was the most common cause of cancer related death in 2020 and has

been traditionally treated with platinum-based chemotherapy. More recently immunotherapy has resulted in substantial improvements in survival for patients with Non-Small Cell Lung Cancer (NCSCLC) but despite these improvements many patients still do not respond to immunotherapy, with successful treatment ranging from 40%-60% in the patient population.

Prior to sotorasib, there was no anticancer therapy specifically targeting tumors that harbor the KRAS p.G12C mutation. We are looking into the safety and effectiveness of sotorasib in patients who have been diagnosed with NSCLC that are known to have the KRAS p.G12C mutation and have <1% PD-L1 and/or a STK11 mutation in their tumour cells.

Please refer to C4.

Study objective

Primary
- To evaluate the tumor objective response rate (ORR) assessed by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 criteria in subjects who receive sotorasib at either 960 mg daily (QD) or 240 mg QD whose tumors are PD-L1 Tumor Proportion Score (TPS) < 1% and/or harbor a STK11 co-mutation, in a subgroup of subjects with PD-L1 < 1% and in a subgroup of subjects with STK11 co-mutation.

Secondary
- To evaluate other measures of efficacy.
- To evaluate the safety and tolerability of sotorasib.

Study design

This is an open-label, multicenter phase 2 study to explore the anti-tumor effect of sotorasib monotherapy in subjects with metastatic non-small cell lung cancer (NSCLC) with a specific mutation, called KRAS p.G12C, whose tumors express < 1% PD-L1 (a specific protein) and/or have a another specific mutation called STK11, in need of first line treatment.
Participants will be randomized in a 1:1 design for treatment with sotorasib at 960 mg orally (PO) daily (QD) or 240 mg PO QD.
An independent Data Review Team (DRT) will monitor the study. Participants will be treated until disease progression as determined by blinded independent central review (BICR), unacceptable toxicity, withdrawal of informed consent, or death, whichever occurs first.

Intervention

Sotorasib will be administered orally.

Study burden and risks

Please refer to section E2 and E9.

Contacts

Public
Amgen

Minervum 7061
Breda 4817 ZK
NL
Scientific
Amgen

Minervum 7061
Breda 4817 ZK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Untreated stage IV (per AJCC v8) NSCL
• Pathologically documented diagnosis of untreated metastatic stage IV NSCLC with KRAS p.G12C mutation
• Aged over 18
• Life expectancy of at least 3 months
• A willingness to undertake the study procedures

• Subjects will undergo a pre-treatment tumor biopsy if medically feasible, unless a sample is available within 3 months of enrollment. If a tumor biopsy prior to treatment is not medically feasible and recent sample is not available, subjects and investigators must be willing to provide archived tumor tissue samples (formalin-fixed paraffin-embedded [FFPE]) sample collected within 5 years.
• Measurable disease per investigator interpretation using RECIST 1.1
• Eastern Cooperative Oncology Group (ECOG) Performance Status of <= 1.

Refer to section 5.1 of the protocol.

Exclusion criteria

• Must not have a history of mixed small cell and NSCLC
• Must not have a spinal cord compression or active brain metastases and/or carcinomatous meningitis.
• Must not have HIV, hepatitis B and hepatitis C
• Myocardial infarction within 6 months of study day 1, symptomatic congestive heart failure (New York Heart Association > Class II), unstable angina, or cardiac arrythmia requiring medication.

Refer to section 5.2 of het protocol.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Sotorasib
Generic name:	Sotorasib

Ethics review

Approved WMO Date:	30-08-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-11-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-12-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	10-01-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-04-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-06-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-08-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	06-09-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2021-002638-18-NL
ClinicalTrials.gov	NCT04933695
CCMO	NL78141.028.21