A Phase 2 Study Evaluating the Efficacy, Safety, Tolerability, and Pharmacokinetics of Tarlatamab in Subjects with Relapsed/Refractory Small Cell Lung Cancer After Two or More Prior Lines of Treatment (DeLLphi-301)

Published: 29-09-2021
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Primary (Parts 1 and 2)• To evaluate safety and efficacy (per Response Evaluation Criteria in Solid Tumors version 1.1 [RECIST 1.1] by investigator) of 2 dose levels of tarlatamab Primary (Part 3)Evaluate safety of reduced mandatory monitoring...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54228

Source
ToetsingOnline

Brief title
20200491 - DeLLphi-301

Condition

- Other condition
- Respiratory tract neoplasms

Synonym

lung cancer, Small Cell Lung Cancer

Health condition

kleincellig longkanker

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Delta-like ligand 3 (DLL3), Phase 2, Small Cell Lung Cancer, Tarlatamab

Outcome measures

Primary outcome

Primary (Part 1 Only)

• objective response (OR) (complete response [CR] and partial response [PR])

• incidence of treatment-emergent adverse events (TEAEs)

• serum concentrations of tarlatamab

Primary (All Parts)

• OR (CR and PR)

Secondary outcome

Secondary (All parts):

1.

• duration of response (DOR)

• disease control (DC)

• duration of DC

• progression-free survival (PFS)

2.

• OR

• DOR

• DC

• duration of DC

• PFS

• overall survival (OS)

3.

• incidence of TEAEs

4.

• serum concentrations of tarlatamab

5.

• incidence of anti-tarlatamab antibody formation

Study description

Background summary

The phase 1 FIH Study 20160323 evaluating the safety, tolerability and anti-tumor activity of tarlatamab in SCLC is currently ongoing. The available safety and preliminary efficacy data from the dose exploration phase and the CRS mitigation cohort (with dexamethasone) demonstrate tarlatamab is well

tolerated, with a manageable safety profile and signs of preliminary efficacy.

There are currently no approved third-line therapies for relapsed ED SCLC, and third-line therapies used in this population typically have limited overall survival (OS) benefit .Thus, there is an urgent unmet medical need for new therapies in the third- and later-line setting.

A detailed description of the chemistry, pharmacology, efficacy, and safety of tarlatamab is provided in the Investigator*s Brochure.

Please refer to section 2.2 of the protocol.

Study objective

Primary (Parts 1 and 2)
• To evaluate safety and efficacy (per Response Evaluation Criteria in Solid Tumors version 1.1 [RECIST 1.1] by investigator) of 2 dose levels of tarlatamab

Primary (Part 3)
Evaluate safety of reduced mandatory monitoring period in cycle 1 at selected dose of tarlatamab

Primary (All Parts)
• Evaluate anti-tumor activity of tarlatamab as determined by objective response rate (ORR) per RECIST 1.1 by blinded independent central review (BICR)

Secondary (All parts):
• Evaluate anti-tumor activity of tarlatamab as determined by other measures per RECIST 1.1 by BICR
• Evaluate anti-tumor activity of tarlatamab as assessed by ORR and other measures per RECIST 1.1 by investigator
• Evaluate the safety and tolerability of tarlatamab
• Characterize the pharmacokinetics (PK) of tarlatamab
• Evaluate the immunogenicity of tarlatamab

Study design

Open-label, 2 part study evaluating tarlatamab monotherapy. Part 1: will evaluate 2 dose levels of tarlatamab (10 mg or 100 mg). Part 2 will be a dose expansion phase at the selected target dose (10 mg or 100 mg) based on an interim analysis of Part 1. Part 3 will be conducted after completing enrollment of Parts 1 and 2, and will enroll up to approximately 30 additional subjects at the selected dose, with modified cycle 1 monitoring criteria.

Intervention

Tarlatamab will be administered as a short-term IV infusion every 2 weeks in a 28-day cycle as monotherapy, with the exception in C1 (D1, D8, D15).

Study burden and risks

See section E of ABR-form.

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

o Male and female subjects (>= 18 years of age) at the time of signing the inform consent
o Histologically or cytologically confirmed relapsed/refractory SCLC

o Subject who progressed or recurred following 1 platinum-based regimen and at least 1 other prior line of therapy
(Note: [1] re-treatment with a platinum-based regimen is considered a second line of therapy; [2] platinum-based regimen followed by checkpoint inhibitor/anti-programmed death ligand 1 [PD-L1] as maintenance therapy is considered 1 line of therapy; [3] in countries where standard of care first line systemic treatment includes platinum
containing chemotherapy in combination with PD-L1 inhibitor, it is required that subjects have failed PD-L1 inhibitor as part of their first line systemic treatment or are ineligible to receive PDL1 inhibitor therapy.
For more information, see section 5.1 of the protocol.

Exclusion criteria

- Untreated or symptomatic brain metastases and leptomeningeal disease.
- Has evidence of interstitial lung disease or active, non-infectious pneumonitis.
- Subjects who experienced recurrent pneumonitis (grade 2 or higher) or severe, life-threatening immune-mediated adverse events or infusion-related reactions including those that lead to permanent discontinuation while on treatment with immuno-oncology agents.
- Unresolved toxicity from prior anti-tumor therapy, defined as not having resolved to Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 grade 1, or to levels dictated in the eligibility criteria with the exception of alopecia or toxicities from prior anti-tumor therapy that are considered irreversible (defined as having been present and stable for > 21 day) which may be allowed if they are not otherwise described in the exclusion criteria AND there is agreement to allow by both the investigator and Amgen.

For more information, see section 5.2 of the protocol.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-06-2022
Enrollment:	3
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tarlatamab
Generic name:	Tarlatamab

Ethics review

Approved WMO Date:	29-09-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-11-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-01-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-02-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-07-2022

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-08-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-10-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-01-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-01-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-05-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-07-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-09-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	11-01-2024
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2021-002566-40-NL
ClinicalTrials.gov	NCT05060016
CCMO	NL78140.056.21