A Phase 1b Study Evaluating the Safety and Efficacy of First-Line Tarlatamab in Combination With Carboplatin, Etoposide, and PD-L1 Inhibitor in Subjects with Extensive Stage Small Cell Lung Cancer

Published: 04-04-2022
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This study has been transitioned to CTIS with ID 2024-511021-58-00 check the CTIS register for the current data. Primary Objective:- Number of participants with dose limiting toxicity - Number of participants with treatment-related adverse events -...

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

Summary

ID

NL-OMON53561

Source
ToetsingOnline

Brief title
20200469 (DeLLphi-303)

Condition

- Other condition
- Respiratory tract neoplasms

Synonym

extensive stage small cell lung cancer, 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), ES-SCLC, Extensive stage small cell lung cancer, Tarlatamab

Outcome measures

Primary outcome

Dose-limiting toxicities (DLTs), treatment-emergent and treatment-related

adverse events, changes in vital signs, electrocardiograms (ECGs), and clinical

laboratory tests.

Secondary outcome

- Progression free survival, will be based on modified Response Evaluation

Criteria in Solid Tumors version 1.1 (RECIST v1.1).

- Objective response, based on modified RECIST v1.1

- Duration Of Response, and Disease control, as per modified RECIST v1.1.

- Overall survival (OS) as per modified RECIST v1.1

- Serum concentrations of tarlatamab.

Study description

Background summary

Small cell lung cancer is accounting for 10% to 15% cases of lung cancer and strongly associated with smoking. It is characterized by an aggressive course; fast time doubling, high fraction of growth and emergence distant metastases within a short time from diagnosis. While 30% of patients present with disease limited to 1 hemithorax - half breast (limited disease [LD]), the majority have extensive disease [ED]. Small cell lung cancer is exquisitely sensitive to first-line chemotherapy and to radiation but is subsequently resistant to second-line and subsequent therapies after disease recurrence. Patients with ED develop drug resistance and die as a result of disease at a median time of 10 to 12 months from diagnosis.

Study objective

This study has been transitioned to CTIS with ID 2024-511021-58-00 check the CTIS register for the current data.

Primary Objective:
- Number of participants with dose limiting toxicity
- Number of participants with treatment-related adverse events
- Number of participants with treatment-emergent adverse events
- Number of participants with changes in vital signs
- Number of participants with changes in electrocardiogram
- Number of participants with changes in clinical laboratory tests

Secondary Objective:
- 6-month progression free survival per modified Response Evaluation Criteria in Solid Tumors version 1.1
- Objective response per modified Response Evaluation Criteria in Solid Tumors version 1.1
- Duration of response per modified Response Evaluation Criteria in Solid Tumors version 1.1
- Disease control per modified Response Evaluation Criteria in Solid Tumors version 1.1
- Overall survival per modified Response Evaluation Criteria in Solid Tumors version 1.1
- Characterization of pharmacokinetics of Tarlatamab in combination with anti-PDL1 with or without chemotherapy

Study design

This is a phase 1b study evaluating the safety, tolerability, and preliminary efficacy of first-line tarlatamab (study drug under investigation) in combination with standard of care chemo-immunotherapy in subjects with Extensive Stage Small Cell Lung Cancer. This study is open label, subject and

study staff will know the treatment received on study.

Intervention

Tarlatamab will be evaluated
- in combination with chemo-immunotherapy followed by maintenance cycles of tarlatamab plus PD-L1 inhibitor, and
- as maintenance only in combination with tarlatamab plus PD-L1 inhibitor following standard of care chemo-immunotherapy.
Both atezolizumab and durvalumab separately will be evaluated in combination with tarlatamab.

Study burden and risks

There is an unmet need to provide further therapeutic options for patients diagnosed with extensive stage small cell lung cancer. Based on ongoing experince with tarlatamab in a phase 1, first-in-human, setting, safety data has been generated to proceed in combination with standard of care.

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

• Participant has provided informed consent/assent prior to initiation of any study specific activities/procedures
• Age greater than or equal to 18 years old at the same time of signing the informed consent
• Participants with histologically or cytologically confirmed Extended Stage Small Cell Lung Cancer (ES-SCLC) and no prior systemic treatment for ES-SCLC other than protocol defined standard of care first line therapy prior to enrollment. Subjects with prior treatment for limited stage SCLC (LS-SCLC) are permitted.
• Eastern Cooperative Oncology Group (ECOG) 0 to 1
• Participants with treated asymptomatic brain metastases are eligible provided they meet defined criteria
• Adequate organ function as defined in protocol

Please refer to section 5.1 of the protocol for the full list of inclusion criteria and any changes in these following protocol amendment 3.

Exclusion criteria

• History of other malignancy within the past 2 years with exceptions
• Major surgery within 28 days of study day 1
• Untreated or symptomatic brain metastases and leptomeningeal disease

Please refer to section 5.2 of the protocol for the full list of exclusion criteria and any changes in these following protocol amendment 3.

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-01-2023
Enrollment:	4
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Imfinzi
Generic name:	Durvalumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Tarlatamab
Generic name:	Tarlatamab

Ethics review

Approved WMO

Date:	04-04-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	19-08-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	07-09-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	14-12-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-01-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-04-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-04-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-08-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-08-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-11-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-03-2024
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-04-2024
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
EU-CTR	CTIS2024-511021-58-00
EudraCT	EUCTR2021-005462-17-NL
ClinicalTrials.gov	NCT05361395
CCMO	NL79883.056.22