A PHASE III, RANDOMIZED, DOUBLE-BLINDED, PLACEBO-CONTROLLED STUDY OF TIRAGOLUMAB, AN ANTI-TIGIT ANTIBODY, IN COMBINATION WITH ATEZOLIZUMAB COMPARED WITH PLACEBO IN COMBINATION WITH ATEZOLIZUMAB IN PATIENTS WITH PREVIOUSLY UNTREATED LOCALLY ADVANCED UNRESECTABLE OR METASTATIC PD-L1-SELECTED NON-SMALL CELL LUNG CANCER.

Published: 12-03-2020
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This study has been transitioned to CTIS with ID 2022-502482-17-00 check the CTIS register for the current data. This study will evaluate the efficacy and safety of tiragolumab plus atezolizumab compared with placebo plus atezolizumab in patients...

Ethical review	Approved WMO
Status	Completed
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON52819

Source
ToetsingOnline

Brief title
GO41717 / SCYSCRAPER1

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
lung cancer, Small cell lung cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anti-tigit, Atezolizumab, Dubbel blind, Non small cell lung cancer

Outcome measures

Primary outcome

-PFS after randomization, defined as the time from randomization to the first occurrence of disease progression or death from any cause (whichever occurs first), as determined by the investigator according to RECIST v1.1, in the primary analysis set

-OS after randomization, defined as the time from randomization to death from any cause, in the primary analysis set

Secondary outcome

1. Investigator assessed PFS according to RECIST v1.1 in the secondary analysis set

2. Investigator assessed OS according to RECIST v1.1 in the secondary analysis

set

3.Confirmed ORR, defined as the proportion of patients with a complete response (CR) or partial response (PR) on two consecutive occasions > 4 weeks apart, as determined by the investigator according to RECIST v1.1

4.DOR for patients with confirmed ORR, defined as the time from the first occurrence of a documented objective response to disease progression or death from any cause (whichever occurs first), as determined by the investigator according to RECIST v1.1

5.PFS rate at 6 months and 12 months, defined as the proportion of patients who have not experienced disease progression or death from any cause at 6 months and 12 months respectively, as determined by the investigator according to RECIST v1.1

6.OS rate at 12 months and 24 months, defined as the proportion of patients who have not experienced death from any cause at 12 and 24 months, respectively

7.Time to sustained deterioration (TTSD) in patient-reported physical functioning and global health status, as measured by the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire for Cancer (QLQ-C30)

8. Incidence and severity of adverse events, with severity determined according to the National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0

9. Minimum serum concentration (Cmin) and Maximum serum concentrate (Cmax) of tiragolumab

10. Cmin and Cmax of atezolizumab

11. Prevalence of ADAs to tiragolumab and atezolizumab at baseline and during

the study.

Study description

Background summary

Clinical data emerging in the field of tumor immunotherapy have demonstrated that therapies focused on enhancing T-cell responses against cancer can result in a significant survival benefit in patients with metastatic cancer, including NSCLC. PD-L1/PD-1 inhibitors in the 1L and 2L-plus settings have demonstrated significant improvement in survival compared with standard chemotherapy, which has led to the recent approvals of these agents for the treatment of NSCLC and validates the inhibition of the PD-L1/PD-1 pathway for achieving clinical benefit in NSCLC. Furthermore, the safety profile of PD-L1 and PD-1 antibodies as monotherapy appears to be more tolerable than many of the chemotherapy doublet combinations given in the front-line setting, which are associated with substantial toxicities and are often poorly tolerated by elderly and patients with poor performance status.

The results from the Phase II GO40290 study provide rationale to further evaluate the combination of tiragolumab and atezolizumab as a 1L treatment for NSCLC in a larger Phase III study. Therefore, this study (GO41717) is designed to evaluate whether the anti-tumor effects of atezolizumab, as measured by PFS and OS, may be improved with the addition of the anti-TIGIT antibody tiragolumab compared with placebo plus atezolizumab in patients with previously untreated, locally advanced or metastatic NSCLC

Study objective

This study has been transitioned to CTIS with ID 2022-502482-17-00 check the CTIS register for the current data.

This study will evaluate the efficacy and safety of tiragolumab plus atezolizumab compared with placebo plus atezolizumab in patients with previously untreated locally advanced, unresectable or metastatic PD-L1 selected NSCLC, with no EGFR mutation or ALK translocation.

Study design

This is a Phase III, randomized, double-blinded, placebo-controlled, global, multicenter study designed to evaluate the efficacy, safety, of tiragolumab plus atezolizumab compared with placebo plus atezolizumab in patients with

previously untreated locally advanced, unresectable or metastatic PD-L1 selected NSCLC.

After a screening period, eligible patients will be in a randomized 1:1 ratio to receive either tiragolumab plus atezolizumab or placebo plus atezolizumab.

Please refer to figure 1 and appendix 1 in the protocol, where the study design is shown and the schedule of assessments is provided respectively.

Intervention

In the experimental arm, patients will receive atezolizumab at a fixed dose of 1200 mg administered by IV infusion Q3W on Day 1 of each 21-day cycle, followed by tiragolumab at a fixed dose of 600 mg administered to patients by IV infusion Q3W on Day 1 of each 21-day cycle.

In the control arm, patients will receive atezolizumab at a fixed dose of 1200 mg administered by IV infusion Q3W on Day 1 of each 21-day cycle, followed by placebo administered by IV infusion Q3W on Day 1 of each 21-day cycle.

Study burden and risks

The general burden for the patient consists of (a.o.) the withdrawal of blood samples, possible collection of tumor sample, administration of investigational products (intravenously) which may lead to various adverse events.

Contacts

Public
Roche

Beneluxlaan 2A
Woerden 3446GR
NL
Scientific
Roche

Beneluxlaan 2A
Woerden 3446GR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age > 18 years
- Eastern Cooperative Oncology Group Performance Status of 0 or 1
- Histologically or cytologically documented locally advanced or recurrent NSCLC
- No prior systemic treatment for metastatic NSCLC
- Tumor PD-L1 expression as determined by PD-L1 IHC assay TPS >= 50% as determined by 22C3 pharmaDx assay TC3 or IC3 as determined by the VENTANA PD-L1 Assay (SP142), or TC >= 50% as determined by the investigational VENTANA PD-L1 CDx Assay (SP263) of tumor tissue
- Measurable disease per Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1)
- Adequate hematologic and end-organ function.

Exclusion criteria

- Known to have a mutation in the EGFR gene or an ALK fusion oncogene
- Symptomatic, untreated, or actively progressing central nervous system metastases
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis
- Significant cardiovascular disease
- History of malignancy other than NSCLC within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death
- Severe infection within 4 weeks prior to initiation of study treatment
- Current treatment with anti-viral therapy for HBV or HCV
- Treatment with investigational therapy within 28 days prior to initiation of

study treatment
- Prior treatment with CD137 agonists or immune checkpoint blockade therapies
- Treatment with systemic immunostimulatory agents or anticipation of need for systemic immunosuppressive medication during study treatment prior to initiation of study treatment.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-08-2020
Enrollment:	26
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tecentriq
Generic name:	Atezolizumab
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	tiragolumab
Generic name:	tiragolumab

Ethics review

Approved WMO Date:	12-03-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-05-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-08-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-10-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-12-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-12-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-12-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	08-06-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-09-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-10-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-11-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-12-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-06-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-08-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-11-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	02-12-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-12-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-05-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-06-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-08-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-10-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-12-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-12-2023

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	31-01-2024
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-02-2024
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	CTIS2022-502482-17-00
EudraCT	EUCTR2019-002925-31-NL
CCMO	NL72441.056.20

Study results

Date completed: 31-12-2024

Summary results

Trial ended prematurely