# Phase 2, Open-Label Safety and Efficacy Study of Telisotuzumab Vedotin (ABBV-399) in Subjects with Previously Treated c-Met+ Non-Small Cell Lung Cancer

Published: 21-02-2020
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To evaluate whether Telisotuzumab Vedotin improves response rate and survival in participants who are c-Met+ with NSCLC. For the additional monotherapy cohort :Primary objective is to evaluate the safety and tolerability of telisotuzumab vedotin...

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

## Summary

### ID

NL-OMON52936

**Source**
ToetsingOnline

**Brief title**
M14-239

### Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

**Synonym**
advanced or metastisc lungcancer, Non small cell lung cancer, squamous or non squamous

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** AbbVie Deutschland GmbH & Co. KG
**Source(s) of monetary or material Support:** AbbVie

## Intervention

**Keyword:** c-MET, NSCLC

## Outcome measures

### Primary outcome

The primary objective is to determine the overall response rate (ORR) of

Telisotuzumab Vedotin in participants with c-Met+ NSCLC.

### Secondary outcome

The secondary objectives are to determine:

• Duration of response (DoR)

• Disease control rate (DCR)

• Progression Free Survival (PFS)

• Overall Survival (OS)

For the additional monotherapy cohort

Secondary objective is to evaluate the preliminary efficacy of telisotuzumab

vedotin monotherapy

# Study description

### Background summary

There are two main types of lung cancer: Small Cell Lung Cancer (SCLC) and Non-Small Cell Lung Cancer (NSCLC). NSCLC is a disease in which cancer cells form in the tissues of the lung and is more common of the two types, accounting

for 80% to 85% of lung cancers. In many NSCLC and other tumors, there is involvement of a protein known as c-Met+, which is a cell surface receptor that is overexpressed. Telisotuzumab Vedotin (ABBV-399 or Teliso-V) is an antibody drug conjugate that specifically targets cells that express c-Met+ and delivers a cytotoxin to the cancer cell resulting in the death of the cancer cell.

### Study objective

To evaluate whether Telisotuzumab Vedotin improves response rate and survival in participants who are c-Met+ with NSCLC.

For the additional monotherapy cohort :
Primary objective is to evaluate the safety and tolerability of telisotuzumab vedotin monotherapy

### Study design

Open Label, non-randomized, single group assignment.

### Intervention

Telisotuzumab Vedotin given intravenously (IV) every 2 weeks with tumor assessment every 6 weeks.

### Study burden and risks

There will be a higher treatment burden for participants in this trial compared to their standard of care. Participants will attend regular visits during the study at a hospital or clinic. The effect of the treatment will be checked by medical assessments, blood tests, computed tomography (CT)/Magnetic Resonance Imaging (MRI) scan, tumor biopsy, checking for side effects and completing questionnaires.

## Contacts

**Public**
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**Scientific**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

• Histologically confirmed non-small cell lung cancer (NSCLC) with known epidermal growth factor receptor (EGFR) status (wild type; with site documented status). Subjects in Monotherapy Cohort 1.6 mg/kg Q2W must have non-squamous EGFR wild type NSCLC.
• Has locally advanced or metastatic NSCLC.
• Has c-Met+ NSCLC as assessed by an AbbVie designated immunohistochemistry (IHC) laboratory. Subject must submit archival or fresh tumor material for assessment of c-Met levels during the prescreening period. Tumor material from the primary tumor site and/or metastatic sites are allowed. If archival tissue is negative for c-Met overexpression, fresh biopsy material may be submitted for reassessment of c-Met expression.
•If a subject meets eligibility criteria for c-Met protein expression level based on archival tumor material, fresh tumor material for assessment of c-Met expression levels should be submitted prior to dosing of telisotuzumab vedotin. If it is determined that a pre-dose fresh biopsy is not appropriate for a given subject, the subject may still be enrolled at the investigator's discretion. AbbVie must be informed of this decision before dosing.
• Subjects who have progressed on systemic cytotoxic chemotherapy (or are ineligible for systemic cytotoxic chemotherapy) and an immune checkpoint inhibitor (as monotherapy or in combination with systemic cytotoxic chemotherapy, or ineligible for an immune checkpoint inhibitor), and prior anti-cancer therapies targeting driver gene alterations (if applicable).
• Subject must have received no more than 2 lines of prior systemic therapy

(including no more than 1 line of prior systemic cytotoxic chemotherapy) in the locally advanced or metastatic setting.
• Subjects should not have received prior cMET-targeted antibody therapies.
• Has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1.
• No known active severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. If a subject has signs/symptoms suggestive of SARS-CoV-2 infection, the subject must have a negative molecular (e.g., polymerase chain reaction [PCR]) test result or 2 negative antigen test results at least 24 hours apart.
• Subjects who do not meet SARS-CoV-2 infection eligibility criteria must be screen failed and may only rescreen after they meet the following SARS-CoV-2 infection viral clearance criteria:
- At least 10 days since first positive PCR test result have passed in asymptomatic patients or 10 days since recovery, defined as resolution of fever without use of antipyretics and improvement
in symptoms.

## Exclusion criteria

• Has adenosquamous histology.
• Has received anti-cancer therapy including chemotherapy, radiation therapy, immunotherapy, biologic, or any investigational therapy as described in the protocol.
• Subjects with metastases to the central nervous system (CNS) are eligible only after definitive therapy (such as surgery or radiotherapy) is provided and:
* - There is no evidence of progression of CNS metastases at least 4 weeks after definitive therapy.
* - They are asymptomatic and off or on a stable or reducing dose of systemic steroids and/or anticonvulsants for at least 2 weeks prior to first dose of telisotuzumab vedotin.
• Has a clinically significant condition(s) described in the protocol.
• Has unresolved clinically significant adverse events grade 2 from prior anticancer therapy, except for alopecia or anemia.
• Had major surgery within 21 days prior to the first dose of telisotuzumab vedotin.
• Subject must not have a history of interstitial lung disease or pneumonitis that required treatment with systemic steroids.
• Subjects must not have any evidence of pulmonary fibrosis on screening imaging assessment or any history of pneumonitis or interstitial lung disease within 3 months of the planned first dose of the study drug. For imaging findings deemed clinically insignificant by the treating physician, subject may be eligible after discussion with and approval from the AbbVie medical monitor.
• Subjects must not have received radiation therapy to the lung <6 months prior to the first dose of telisotuzumab vedotin.
• Subjects must not have received any live vaccine within 30 days of the first

dose of investigational product.

# Study design

## Design

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

## Recruitment

NL

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| Recruitment status: | Completed |
| Start date (anticipated): | 23-10-2020 |
| Enrollment: | 5 |
| Type: | Actual |

## Medical products/devices used

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| Product type: | Medicine |
| Generic name: | ABBV-399 |

# Ethics review

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| Approved WMO Date: | 21-02-2020 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 24-02-2020 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

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| Approved WMO Date: | 14-04-2020 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 23-11-2020 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 09-12-2020 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 06-01-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 20-01-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 22-02-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 17-04-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 17-05-2021 |
| Application type: | Amendment |

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|---|---|
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 20-05-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 17-05-2022 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 20-05-2022 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 03-10-2022 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 01-11-2022 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 08-11-2022 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 13-12-2022 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO | |

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|---|---|
| Date: | 06-01-2023 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 12-05-2023 |
| 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 | EUCTR2018-001772-38-NL |
| ClinicalTrials.gov | NCT03539536 |
| CCMO | NL72477.056.20 |