Randomized, Open Label Phase 3 study of SAR408701 versus Docetaxel in Previously Treated metastatic Non-Squamous Non-Small Cell Lung Cancer patients with CEACAM5 positive tumors

Published: 16-10-2019
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON54679

Source
ToetsingOnline

Brief title
CARMEN-LC03

Condition

- Metastases

Synonym
metastatic lung cancer, Metastatic non-squamous non-small cell lung cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Docetaxel, Metastatic, Non-small cell lung cancer, SAR408701

Outcome measures

Primary outcome

- Progression free survival

- Overal survival

Secondary outcome

- Objective response rate will be defined as the proportion of participants who have a complete response (CR) or partial response (PR), as best overall response derived from Overall Response (OR) determined by the IRC per RECIST 1.1

- Health related quality of life by means of questionnaires EORTC QLQ-LC13 and EORTC QLQ C-30

- Incidence of TEAEs and SAEs and laboratory abnormalities according to NCI CTCAE V5

- Duration of response (DOR) is defined as the time from first documented evidence of CR or PR until progressive disease (PD) determined per RECIST 1.1 or death from any cause

Study description

Background summary

A protein called CEACAM5 is expressed at the surface of some types of cancer including lung cancer. SAR408701 consists of a drug component called DM4. DM4 is linked to an antibody; this is a protein in the blood that protects the body against bacteria and viruses. It can recognize abnormal cells and binds to the surface of these cells. The antibody component of SAR408701 binds to the CEACAM5 antigen expressed at the surface of the tumor cell. Then SAR408701 enters the tumor cells and the drug DM4 kills the cell.

Study objective

The primary objectives of this study are to assess if SAR408701 has a better progression free survival and general overall survival compared to docetaxel, and main secondary endpoints are objective response rate, time to deterioration on health related quality of life, safety and duration of response. Also only for SAR408701 arm, pharmokinetics and development of antibody to SAR408701 will be analyzed.
The crossover phase only has tertiary endpoints: to assess the safety and objective response rate of crossover SAR408701 treatment after documented disease progression on docetaxel treatment

Study design

Phase 3, randomized, open label, parallel.

Intervention

SAR408701, intravenous infusion, once every two weeks.
Docetaxel, intravenous infusion, once every three weeks.
Cross-over treatment after docetaxel (optional): SAR408701, intravenous infusion, once every 2 weeks.

Study burden and risks

Burden and risks are related to the blood sampling, CT or MRI scan (radation burden), biopsy and possible side effects of the study medication.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• At least 18 years of age or above (or countries legal age of maturity if above 18 years) and signed the informed consent.
• Histologically or cytologically proven diagnosis of non-squamous NSCLC with metastatic disease progression after platinum-based chemotherapy and immune checkpoint inhibitor.
• Participants with carcinoembryonic antigen-related cell adhesion molecule (CEACAM) 5 expression of >=2+ in archival tumor sample (or if not available, fresh biopsy sample) involving at least 50 % of the tumor cell population as demonstrated prospectively by central laboratory via immune histochemistry (IHC).
• At least one measurable lesion by RECIST v1.1 as determined by local site investigator /radiologist assessment.
• Eastern Cooperative Oncology Group (ECOG) performance status 0-1.
• A female participant who agrees to use effective contraceptive methods during and for at least 7 months after the last dose of study intervention.
• A male participant who agrees to use effective contraception methods during and for at least 6 months after the last dose of study intervention.

Exclusion criteria

• Patients with untreated brain metastases and history of leptomeningeal disease. if previously treated brain metastases no documentation of non-progressive disease in brain within 4 weeks prior to the first dose of study intervention.
• Significant concomitant illnesses, including all severe medical conditions that would impair the patient*s participation in the study or interpretation of the results.
• History within the last 3 years of an invasive malignancy other than the one treated in this study, with the exception of resected/ablated basal or squamous-cell carcinoma of the skin or carcinoma in situ of the cervix, or other local tumors considered cured by local treatment.
• Non-resolution of any prior treatment related toxicity to < grade 2 according to NCI CTCAE V5.0, except for alopecia, vitiligo and active thyroiditis controlled with hormonal replacement therapy
• History of known acquired immunodeficiency syndrome (AIDS) related illnesses or known HIV disease requiring antiretroviral treatment, or unresolved viral hepatitis
• Previous history of and/or unresolved corneal disorders. The use of contact lenses is not permitted.
• Concurrent treatment with any other anticancer therapy.
• Prior treatment with docetaxel or maytansinoid derivatives (DM1 or DM4 antibody drug conjugate) or any drug targeting CEACAM5.
• Contraindication to use of corticosteroid premedication.
• Previous enrollment in this study and current participation in any other clinical study involving an investigational study treatment or any other type of medical research.
• Poor bone marrow, liver or kidney functions
• Hypersensitivity to any of the study interventions, or components thereof (EDTA), or drug (paclitaxel, polysorbate 80) or other allergy that, in the opinion of the Investigator, contraindicates participation in the study.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2020
Enrollment:	19
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nvt
Generic name:	Tusamitamab ravtansine
Product type:	Medicine
Brand name:	Taxotere
Generic name:	Docetaxel
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	16-10-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	17-12-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	09-03-2020
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-03-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-06-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-07-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-10-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-11-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-01-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-01-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	05-05-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-05-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-11-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-11-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-01-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-03-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
Other	2019-001273-81
EudraCT	EUCTR2019-001273-81-NL
CCMO	NL71128.100.19