Carmen (Sanofi)

SAR408701 Versus Docetaxel in Previously Treated Carcinoembryonic Antigen-related Cell Adhesion Molecule 5 (CEACAM5) Positive Metastatic Non-squamous Non-small Cell Lung Cancer Patients.

This is the trial summary as assessed on clinicaltrials.gov on 25/02/2020.

Minor changes in the protocol may occur. You can check this on this direct link:

https://clinicaltrials.gov/ct2/show/NCT04154956?term=EFC&cond=Lung+Cancer&draw=2&rank=3

Trial Design:

Arm	Intervention
SAR408701	SAR408701 Administered intravenously once every 2 weeks
Docetaxel	Docetaxel Administered intravenously once every 3 weeks

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.
- The above information is not intended to contain all considerations relevant to a patient's potential participation in a clinical trial.