CARMEN-LC06 (Sanofi)

Open label, Phase 2 study, evaluating the efficacy and safety of tusamitamab ravtansine in participants with CEACAM5 negative-moderate expression and high circulating CEA non-squamous non-small-cell lung cancer (NSQ NSCLC)

This is the trial summary as assessed on clinicaltrials.gov on 21/06/2022.

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

https://clinicaltrials.gov/ct2/show/NCT05245071

Trial Design:

This is an open label single group, Phase 2, 1-arm study for treatment to evaluate efficacy, safety, and Pharmacokinetic (PK) of tusamitamab ravtansine in nonsquamous non-small-cell-lung-cancer (NSQ NSCLC) participants with negative or moderate CEACAM5 expression tumors and high circulating carcinoembryonic antigen (CEA).

Participants who will be enrolled, will receive tusamitamab ravtansine as monotherapy every two weeks (Q2W) until disease progression, unacceptable adverse event (AE), initiation of a new anticancer therapy, or the participant's or investigator's decision to stop the treatment, whichever comes first. A total of approximately 38 participants are planned to be treated.

Inclusion criteria:

Histologically or cytologically proven diagnosis of NSQ NSCLC metastatic disease at study entry; progression after platinum-based chemotherapy and immune checkpoint inhibitor.

Participants with moderate or negative CEACAM5 expression as demonstrated prospectively by central laboratory via immune histochemistry (ICH) and high circulating CEA levels (≥100 ng/mL). Moderate CEACAM5 expression is defined as intensity ≥ 2 + in ≥ 1% and <50 % of tumor cells. Negative CEACAM5 expression is defined as intensity of 1 + whatever the percentage of stained tumor cells or <1% of tumor cells.

At least one measurable lesion by RECIST v1.1

Eastern Cooperative Oncology Group (ECOG) performance status 0-1.

Women of childbearing potential or male patient with women of childbearing potential who agree to use highly effective method of birth control.

Exclusion criteria:

Patients with untreated brain metastases or history of leptomeningeal disease.

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.

History of known uncontrolled infection with human immunodeficiency virus (HIV), or unresolved viral hepatitis

Significant concomitant illness that could impair the participation in the study or interpretation of the results or any major surgery with 3 weeks prior treatment administration

Nonresolution of any prior treatment-related toxicity to <Grade 2 according to NCI CTCAE v5.0, with the exception of alopecia, vitiligo, or active thyroiditis controlled with hormone replacement therapy.

Previous history of and/or unresolved corneal disorders. The use of contact lenses is not permitted.

Prior treatment with maytansinoid derivatives (DM1 or DM4 antibody drug conjugate) or any drug targeting CEACAM5.

Concurrent treatment with any other anticancer therapy

Poor bone marrow, liver or kidney functions.