ARTEMIDE-01 (AstraZeneca)

Study to Assess the Safety and Efficacy of AZD2936 in Participants With Advanced or Metastatic Non-small Cell Lung Cancer

This is the trial summary as assessed on clinicaltrials.gov on 10/03//2023.

Minor changes in the protocol may occur. You can check this on this direct link: https://clinicaltrials.gov/ct2/show/NCT04995523.

Trial Design:

ARM	INTERVENTION
Experimental: PART D CPI naïve NSCLC (PDL1 >50% and HLA-negative)	IV AZD2936, Anti-TIGIT/Anti-PD-1 Bispecific Antibody

Inclusion criteria:

- Written informed consent
- Aged 18 or above
- Part C and Part D: Stage IV squamous or non-squamous NSCLC not amenable to curative surgery or radiation.
- Documented PD-L1 expression by PD-L1 IHC per local report.
- Part C and Part D: No prior I/O treatment for NSCLC.
- ECOG performance status of 0 or 1 at enrolment.
- Life expectancy of ≥ 12 weeks at enrolment.
- Have at least 1 measurable lesion per RECIST v1.1.
- Adequate bone marrow, liver and kidney function

Exclusion criteria:

- Sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) fusion.
- Documented test result for any other known genomic alteration for which a targeted therapy is approved in first line per local standard of care (e.g. ROS1, NTRK fusions, BRAF, V600E mutation).
- Previous treatment with an anti-TIGIT therapy.
- Any concurrent chemotherapy, radiotherapy, investigational, biologic, or hormonal therapy for cancer treatment.
- Part C and Part D: Any prior systemic treatment with an immune-oncology agent (Treatment with one previous systemic chemotherapy will be allowed).
- Primary or secondary resistance after treatment with 2 or more regimens including a CPI.

- Symptomatic central nervous system (CNS) metastasis.
- Thromboembolic event within 3 months prior to enrolment.
- Other invasive malignancy within 2 years prior to screening.