ARTEMIDE (Astrazeneca)

A Study to Assess the Safety and Efficacy of AZD2936 in Participants With Advanced or Metastatic Non-small Cell Lung Cancer (NSCLC). This is the trial summary as assessed on clinicaltrials.gov on 17/11/2021.

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: Dose Escalation Part Checkpoint inhibitor (CPI) experienced NSCLC	AZD2936 IV monotherapy
Experimental: Dose Expansion Part B: CPI experienced NSCLC	AZD2936 IV monotherapy
Experimental: Dose Expansion Part C: CPI Naive NSCLC	AZD2936 IV monotherapy
Experimental: Dose Expansion Part D: To be confirmed through a protocol amendment	AZD2936 IV monotherapy

Inclusion criteria:

- Written informed consent
- Aged 18 or above
- Unresectable stage III or 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
- Confirmed progression during treatment with a CPI-including regimen
- ECOG performance status of 0 or 1 at enrolment
- Life expectancy of ≥ 12 weeks at enrolment
- 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
- 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