Cobolimab with dostarlimab and docetaxel in patients with advanced non-small cell lung cancer (NSCLC): COSTAR Lung

Methods

Study design

Key inclusion criteria

- ≥18 years old
- Pathologically proven advanced or metastatic NSCLC, and only squamous or adenocarcinoma histology
- Received 1 or 2 lines of therapy for advanced/metastatic disease
- Measurable disease per RECIST v1.1
- Documented radiographic disease progression on prior PEG-Flt3 or on prior anti-PD-L1 therapy
- Agrees to submit an archival FFPE tumor tissue specimen that was collected on baseline 250 Gy, or before prior treatment with an anti-PD-L1 or anti-PD-1 monoclonal antibody
- Patient has recovered from any prior treatment-related toxicities

Consent

- Written informed consent will be obtained from all participants

Objective

COSTAR Lung (NCT04655976) aims to compare the efficacy and safety of cobolimab plus dostarlimab plus docetaxel (docetaxel; Arm A) versus dostarlimab plus docetaxel (Arm B) and docetaxel alone (Arm C) in patients with PD-L1-positive or PD-L1-negative NSCLC.

Key exclusion criteria

- Previous treatment with an anti-PD-1/L1 agent that resulted in permanent discontinuation due to AE
- Previous treatment with an anti-CTLA-4 or anti-CTLA-4/L1 agent on docetaxel
- Documented seroconversion to anti-EGFR, BRAF, or ROS-1 mutation
- Radiographic, or clinical disease progression within 6 months after initiation of prior anti-PD-L1/PD-1 antibody treatment
- Bisphosphonates (other than zoledronic acid, denosumab, or pamidronate) within 14 days before randomization
- Current or active infection
- Current or active second primary lung cancer
- Current or active cardiac disease
- Uncontrolled hypertension
- Patients with pregnancy or breastfeeding

Figure: COSTAR Lung Study Schema

Figure: Trial Status

Study endpoints and assessments

Primary endpoints

- OS for Arms A or B vs C
- OS defined as survival from the date of randomization to the date of death by any cause

Secondary endpoints

- Arms A vs B: OS
- Arms A vs B, A vs C, and B vs C: confirmed ORR per investigator assessment based on RECIST v1.1
- DFS per RECIST v1.1
- TTD: defined as time from enrollment to meaningful deterioration on a composite endpoint of dyspnea, chest pain, and cough (from EORTC-QLQ-LC13 domains)
- Change from baseline as assessed by EORTC-QLQ-C30 and EORTC-QLQ-LC13 domains
- Arms A and B vs C: Safety and tolerability per incidence of TEAEs, SAEs, iAEs, AEs leading to death, and AEs leading to discontinuation

Exploratory endpoints

- Confirmed ORR per investigator assessment and PFS (RECIST)
- Pharmacokinetics
- Immunogenicity
- Biomarkers of response
- Patient-reported efficacy and tolerability
- Healthcare resource utilization

Statistical analyses

Futility analyses to assess ORR across the 3 arms in the Phase 2 portion. Conducted after 250 participants are enrolled in total (Arm A and B: 100 each). A sample size of 250 participants is planned to be enrolled in the Phase 3 portion. The analysis will be conducted on OS primary endpoint.