TPS9161 **Poster Session**

LATIFY: Phase 3 study of ceralasertib + durvalumab vs docetaxel in patients with locally advanced or metastatic non-small-cell lung cancer that progressed on or after anti-PD-(L)1 and platinum-based therapy.

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Background: Following progression on first- or second-line immunotherapy ± platinum-based chemotherapy (CT), the prognosis for patients (pts) with metastatic non-small-cell lung cancer (NSCLC) is poor with limited alternative options to docetaxel. Ceralasertib is a selective inhibitor of Ataxia Telangiectasia and Rad3-related (ATR) protein kinase, which is activated in response to DNA damage. Clinical data suggest that ceralasertib may sensitize tumors to immunotherapy by biasing T cells to an immune-effective phenotype. Durvalumab is a selective, high-affinity human IgG1 monoclonal antibody that binds programmed cell death ligand-1 (PD-L1) and inhibits PD-L1-mediated suppression of T-cell activation. Combining ceralasertib with durvalumab may amplify the antitumor immune response, and potentially lead to durable tumor control. In the ongoing phase 2 HUDSON study in pts with locally advanced or metastatic NSCLC who progressed on anti-PD-(L)1 therapy and platinum-doublet regimen, ceralasertib + durvalumab showed promising efficacy with median progression-free survival (PFS) of 6.0 mos (80% CI, 4.6–7.5) and median overall survival (OS) of 15.9 mos (80% CI, 14.1–20.3). **Methods:** LATIFY is a phase 3, open-label, randomized, multicenter study in pts with NSCLC (NCT05450692). Key inclusion criteria are age ≥18 years; ECOG performance status 0–1; documented *EGFR* and *ALK* wild-type, and tumor cell PD-L1 status; and adequate organ and bone marrow function. Stable brain metastases are allowed. Pts should be eligible for second- or third-line therapy, and must have received an anti-PD-(L)1 therapy and a platinum-containing doublet regimen for locally advanced or metastatic NSCLC either separately or in combination, but no other prior therapies. Key exclusion criteria include mixed small-cell lung and NSCLC histology, unresolved toxicities of Grade ≥2 (NCI CTCAE v5.0) from prior therapy, active or prior autoimmune or inflammatory disorders, > 1 line of prior anti-PD-(L)1 therapy (alone or in combination), and > 1 line of platinum-based CT in a metastatic setting. Pts are randomized 1:1 to receive either oral ceralasertib 240 mg twice daily on Days (D) 1–7 with IV durvalumab 1500 mg on D8 (28-day cycle) or IV docetaxel 75 mg/m^2 (D1, 21-day cycle). The primary objective is to assess efficacy by OS. Secondary objectives include evaluating efficacy by PFS, objective response rate and disease control rate by RECIST v1.1; duration of, and time to, response; time to second progression or death; OS at 12 mos; time to deterioration of health-related quality of life and physical function; determining the pharmacokinetics of ceralasertib; and assessing safety. Approximately 580 pts will be recruited from around 21 countries in the Americas, Europe, and Asia Pacific. Clinical trial information: NCT05450692. Research Sponsor: AstraZeneca PLC.