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POSTER SESSIONS
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P2.01-01
Cemiplimab, a Human PD-1 Monoclonal Antibody, Versus Chemotherapy in First-Line Treatment of Advanced NSCLC with PD-L1 ≥50%

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Background: Most patients (pts) with non-small cell lung cancer (NSCLC) present with advanced disease at diagnosis. Despite initial response to platinum-based doublet chemotherapy, an established first-line treatment for pts with advanced NSCLC whose tumours do not have *EGFR*, *ALK*, or *ROS 1* mutations, pts often progress and require additional treatment options. In recent years, anti-programmed death-1 (anti—PD-1) therapies have emerged as an effective treatment option for advanced NSCLC, potentially allowing some patients with PD-L1 expression ≥50% to avoid chemotherapy. However, there is currently only one PD-1 inhibitor approved as monotherapy in first-line treatment of NSCLC. In a Phase 1 trial of pts with advanced malignancies, including NSCLC, cemiplimab exhibited anti-tumour activity with a safety profile similar to those described for other anti—PD-1 agents. Cemiplimab-rwlc is the only Food and Drug Administration-approved treatment for patients with advanced cutaneous squamous cell carcinoma. **Method:** This is a randomised (1:1), multicentre, open-label, Phase 3 study of cemiplimab versus platinum-based doublet chemotherapy in systemic treatment-naïve pts (≥18 years) with stage IIIB, IIIC or IV squamous or non-squamous NSCLC whose tumours express PD-L1 in ≥50% of tumour cells (NCT03088540). Pts will be stratified by histology and geographic region. Pts will receive cemiplimab 350 mg every 3 weeks intravenously (for up to 108 weeks) or 4—6 cycles chemotherapy with (i) paclitaxel + cisplatin or carboplatin, (ii) pemetrexed + cisplatin or carboplatin with or without pemetrexed maintenance, (iii) or gemcitabine + cisplatin or carboplatin. Crossover from chemotherapy to cemiplimab and addition of chemotherapy to cemiplimab at the time of disease progression is allowed. The primary objective is to evaluate progression-free survival (PFS) as determined by blinded independent review committee. Key secondary objectives include assessment of overall survival and objective response rate. An independent data monitoring committee will monitor safety data during study conduct. **Result:** Section not applicable **Conclusion:** Section not applicable **Keywords:** non-small-cell lung cancer, anti—PD-1, cemiplimab

P2.01-02
CANOPY-A: A Phase 3 Study of Canakinumab as Adjuvant Therapy in Patients with Surgically Resected NSCLC

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Background: Overexpression of interleukin (IL)-1β has been described in solid tumors, including lung. IL-1β can promote angiogenesis, tumor invasiveness, and induces tumor-associated immunosuppression through myeloid-derived suppressor cell (MDSC) accumulation in tumors. Pre-clinical data has shown that IL-1β inhibition reduced tumor growth, by limiting pro-tumorigenic inflammation and polarization of MDSCs into M1 phenotype. Canakinumab is a human monoclonal antibody with high affinity and specificity for IL-1β. Recently, it was found that canakinumab was associated with a significant and dose-dependent reduction in incidence and mortality from lung cancer based on CANTOS study. **Method:** CANOPY-A (NCT03447769) is a phase III, randomized, double-blind, placebo-controlled study designed to evaluate efficacy and safety of adjuvant canakinumab versus placebo in patients with surgically resected NSCLC. This trial will enroll adult patients, with completely resected (R0) AJCC/UICC v.8 stages II-IIIA and IIIB (T >5 cm and N2) NSCLC, who have completed standard-of-care adjuvant treatments, including cisplatin-based chemotherapy and mediastinal radiation therapy (if applicable). Prior treatment with neoadjuvant chemotherapy or neoadjuvant radiotherapy is not permitted. Approximately 1500 patients will be randomized 1:1 to receive canakinumab (200 mg Q3W, s.c) or placebo (Q3W, s.c.) for 18 cycles or until disease recurrence, unacceptable toxicity, treatment discontinuation at the discretion of the investigator or patient, death, or loss to follow-up. Randomization will be stratified by AJCC/UICC v.8 stage, tumor histology, and region. The primary objective is disease-free survival, per investigator assessment. Secondary objectives include overall survival (key secondary objective), lung cancer-specific survival, safety, pharmacokinetics and immunogenicity of canakinumab, and patient-reported outcomes. Enrollment is ongoing. CANOPY-A (NCT03447769) is a phase III, randomized, double-blind, placebo-controlled study designed to evaluate efficacy and safety of adjuvant canakinumab versus placebo in patients with surgically resected NSCLC. This trial will enroll adult patients, with completely resected (R0) AJCC/UICC v.8 stages II-IIIA and IIIB (T >5 cm and N2) NSCLC, who have completed standard-of-care adjuvant treatments, including cisplatin-based chemotherapy and mediastinal radiation therapy (if applicable). Prior treatment with neoadjuvant chemotherapy or neoadjuvant radiotherapy is not permitted. Approximately 1500 patients will be randomized 1:1 to receive canakinumab (200 mg Q3W, s.c) or placebo (Q3W, s.c.) for 18 cycles or until disease recurrence,