333P Efficacy and safety of immune checkpoint inhibitors alone or combined with chemotherapy in pulmonary sarcomatoid carcinoma

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Background: Pulmonary sarcomatoid carcinoma (PSC) is a rare subtype of lung cancer, associated with a worse prognosis and resistance to platinum-based chemotherapy. Immune checkpoint inhibitors (ICI) alone or in combination with chemotherapy are the standard of care for non-small cell lung cancer, yet the benefit of ICI in patients with PSC remains unclear.

Methods: This multicenter retrospective study evaluated patients with advanced or recurrent PSC treated with ICI included therapy between Dec 2015 and Sep 2021. Patients were divided into three cohorts: cohort A (ICI plus chemotherapy as first-line therapy), cohort B (ICI as first-line therapy), and cohort C (ICI as second- or later-line therapy). Clinical efficacy and immune-related adverse events (irAEs) were evaluated.

Results: A total of 124 patients were included. The patients' characteristics were as follows: male/female, 97/27; median age (range), 69 (35-84); PS 0-1/≥2, 103/21; advanced/recurrent, 76/48. Most patients had pleomorphic carcinoma (n = 92, 74.2%) and tumor PD-L1 expression ≥50% (n = 81, 65.3%). The overall response rate (ORR), median progression-free survival (PFS), and median overall survival (OS) were 59.0%, 10.5 months, and 32.8 months, respectively. Similar results were observed regardless of tumor PD-L1 expression. The PFS and OS rates at 24 months were 35.3% and 51.5%. There was no significant difference in the ORR, PFS, or OS between the three cohorts (Table). IrAEs were observed in 67 patients (54.0%), including 27 patients (21.8%) with grade 3-5 events. Patients with grade 1-2 irAEs showed higher ORR, longer PFS and OS than those with no irAEs or grade 3-5 irAEs.

Table: 333P

Cohort	N	ORR (%) (95% CI)	PFS (months) (95% CI)	OS (months) (95% CI)
A	40	66.7 (49.0 - 81.4)	9.2 (5.8 - 22.4)	24.9 (15.7 - NA)
B	56	56.6 (42.3 - 70.2)	11.2 (5.6 - 37.7)	20.1 (10.5 - NA)
C	28	53.6 (33.9 - 72.5)	12.0 (3.4 - NA)	44.0 (7.2 - NA)

Conclusions: ICI therapy for PSC showed promising efficacy regardless of the treatment line and PD-L1 expression.

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334P Patient-reported outcomes with cemiplimab versus chemotherapy in advanced non-small cell lung cancer (aNSCLC): Geographic region subgroups in EMPOWER-Lung 1

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Background: Previously reported subgroup analysis of EMPOWER-Lung 1 (NCT03088540), a randomised 1:1 open-label Phase 3 study, showed overall survival improvement trends with cemiplimab monotherapy (CEMI, n=283) versus platinum-doublet chemotherapy (CHEMO, n=280) in geographic region subgroups (Europe: hazard ratio [HR] 0.54, 95% confidence interval [CI] 0.39—0.77; Asia: HR 0.76, 95% CI 0.24—2.41; rest of world [ROW]: HR 0.59, 95% CI 0.26—1.33) in patients with aNSCLC and programmed cell death-ligand 1 (PD-L1) ≥50%. With post-hoc exploratory analyses, patient-reported outcomes (PROs) were also evaluated in these three subgroups.

Methods: PROs were assessed at baseline and Day 1 of each treatment cycle for the first 6 cycles, then on Day 1 of every third cycle using the European Organisation for Research and Treatment of Cancer Quality of Life-Core 30 (QLQ-C30) and Lung Cancer Module (QLQ-LC13) questionnaires. Mixed-model for repeated measures analyses compared overall change from baseline scores between the two treatment arms while controlling for baseline characteristics.

Results: Baseline PRO scores were broadly similar between treatment arms across geographical regions. A statistically significant difference in overall change from baseline in global health status/quality of life favoured CEMI versus CHEMO in two subgroups (Asia: 12.61, 95% CI 4.44—20.77, P=0.0032; ROW: 9.09, 95% CI 0.89—17.29, P=0.0305). CEMI led to statistically significant favourable differences in all three subgroups in nausea/vomiting and constipation symptoms and in Europe and Asia subgroups in physical and role functioning, fatigue, and appetite loss symptoms per QLQ-C30, and alopecia per QLQ-LC13. When comparing between treatment arms, no analyses yielded statistically significant PRO results favouring CHEMO on any QLQ-C30 or QLQ-LC13 scale.

Conclusions: In patients with aNSCLC and PD-L2 ≥50% across three geographic region subgroups, CEMI led to significant overall improvement in multiple patient-reported cancer-related and lung cancer-specific functions and symptoms. Positive PRO results further support the favourable benefit-risk profile of CEMI versus CHEMO across these subgroups.

Clinical trial identification: NCT03088540.

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