

PATIENT-REPORTED OUTCOMES WITH CEMPLIMAB VERSUS CHEMOTHERAPY IN ADVANCED NON-SMALL CELL LUNG CANCER (ANSLC): EASTERN COOPERATIVE ONCOLOGY GROUP (ECOG) PERFORMANCE STATUS SUBGROUPS IN EMPOWER-LUNG 1

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Background Subgroup analysis of EMPOWER-Lung 1, a 1:1 randomized, open-label Phase 3 study, showed improvements in overall survival (OS) and progression-free survival with cemiplimab monotherapy (CEMI, n=283) versus platinum-doublet chemotherapy (CHEMO, n=280) in patients with an ECOG performance status (PS) score 0 and 1 (OS: PS 0: hazard ratio [HR] 0.77, 95% confidence interval [CI] 0.41, 1.44; PS 1: HR 0.54, 95% CI 0.38, 0.76) in patients with aNSCLC with programmed cell death-ligand 1 \geq 50%.¹ Post-hoc analyses evaluated patient-reported outcomes (PROs) in both ECOG PS subgroups.

Methods PROs were assessed at baseline and Day 1 of each treatment cycle for the first 6 cycles, and then on Day 1 of every third cycle using the European Organization for Research and Treatment of Cancer Quality of Life-Core 30 (QLQ-C30) and Lung Cancer Module (QLQ-LC13) questionnaires. Higher scores indicate better functioning and global health status (GHS)/quality of life (QoL), or worse symptom severity. Mixed-model repeated-measures analyses were performed to compare overall change from baseline scores between the two treatment arms while controlling for baseline characteristics. Time to definitive clinically meaningful deterioration (TTD) per 10-point threshold was analyzed using a stratified log-rank test and proportional hazards model.²

Results Baseline PRO scores were broadly similar between treatment arms. Statistically significant difference in overall change from baseline in GHS/QoL favoring CEMI versus CHEMO occurred in the ECOG PS score 1 subgroup (mean treatment difference 5.03, 95% CI 1.90, 8.15, $P=0.0017$). CEMI also resulted in statistically significant favorable differences in both ECOG subgroups in overall change from baseline in physical and social functioning; fatigue, nausea/vomiting, and constipation symptoms per QLQ-C30; and peripheral neuropathy and alopecia symptoms per QLQ-LC13. There was a statistically significant delay in TTD in physical functioning in the ECOG PS score 1 subgroup, favoring CEMI (HR 0.59, 95% CI 0.37, 0.95, $P=0.028$). Statistically significant delays in TTD favoring CEMI occurred in both ECOG subgroups in social functioning, fatigue and nausea/vomiting symptoms per QLQ-C30; peripheral neuropathy and alopecia symptoms per QLQ-LC13. When comparing between arms, no analyses yielded statistically significant PRO results favoring CHEMO for any QLQ-C30 or QLQ-LC13 scale.

Conclusions In this post-hoc analysis of patients with aNSCLC across both ECOG PS subgroups, CEMI resulted in significant overall improvement and delayed TTD relative to CHEMO in multiple patient-reported cancer-related and lung cancer-specific functions and symptoms. Positive PRO results further support the favorable benefit-risk profile of CEMI versus CHEMO in aNSCLC in both PS subgroups.

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Ethics Approval The protocol and all amendments were approved by the appropriate institutional review board or independent ethics committee at each participating study site. The study was conducted in accordance with the principles of the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practice guidelines.

Consent Written informed consent was obtained for publication of this abstract.

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