

OBJECTIVE RESPONSE IMPACT ON PATIENT REPORTED OUTCOMES (PROS) IN PATIENTS WITH ANSCLC WITH PD-L1 \geq 50% RECEIVING CEMIPIMAB VERSUS CHEMOTHERAPY: EMPOWER-LUNG 1

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Background In EMPOWER-Lung 1 (NCT03088540), a randomized 1:1 phase 3 open-label study comparing cemiplimab versus chemotherapy in patients with advanced NSCLC (aNSCLC) with PD-L1 \geq 50%, clinically meaningful and statistically significant improvements in OS and PFS were observed. Better objective responses were observed with cemiplimab monotherapy versus platinum-doublet chemotherapy (odds ratio 2.53; 95% CI: 1.74–3.69; $P < 0.0001$). To evaluate the effects of objective response on PROs, we performed exploratory analyses of patients with and without objective response, based on treatment arms combined and for each treatment arm separately.

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 EORTC QLQ-C30 and QLQ-LC13 questionnaires. Higher scores indicated better global health status (GHS)/QoL. Patients were grouped by their RECIST-based objective response status (with versus without objective response) within each treatment arm. Mixed-effects model for repeated measures were performed to compare overall change from baseline GHS/QoL scores while controlling for baseline. Time to definitive clinically meaningful deterioration (TTD) (decrease of ≥ 10 points) for GHS/QoL was compared between patients with and without objective response using a stratified log-rank test and Cox proportional hazards model.

Results For the 2 treatment arms combined, an overall change from baseline in GHS/QoL significantly favored patients with versus those without objective response (9.71; 95% CI: 6.90–12.52). Overall change from baseline significantly favored patients with versus those without objective response in both the cemiplimab arm (9.36; 95% CI: 5.76–12.95) and chemotherapy arm (7.68; 95% CI: 3.65–11.71).

For the 2 treatment arms combined, a significantly greater delay in TTD in GHS/QoL was observed in patients with objective response (median: not yet reached [NYR]) versus those without objective response (11.89 months; HR 0.29; 95% CI: 0.18–0.47). Likewise, a significantly greater delay in TTD in patients with versus those without objective response was also observed in both the cemiplimab arm (median: both NYR; HR 0.33; 95% CI: 0.18–0.58) and the chemotherapy arm (median: NYR for patients with objective response) versus those without objective response (11.89 months; HR 0.25; 95% CI: 0.11–0.60).

Conclusions In patients with aNSCLC with PD-L1 \geq 50%, overall change from baseline and TTD in GHS/QoL significantly favored patients with versus those without objective response. These results suggest that an objective response may lead to more favorable overall change from baseline and a greater delay in TTD in GHS/QoL among these patients.

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Trial Registration NCT03088540

Ethics Approval All studies were approved by the institutional review board or ethics committee at each participating site. Informed written consent was obtained from all individual participants included in the studies.

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