Patient-reported outcomes (PROs) with cemiplimab or placebo (PBO) plus platinum-doublet chemotherapy (chemo) for first-line (1L) treatment of advanced non-small cell lung cancer (asNSCLC): EMPORER-Lung 3 trial

Tamtak Makharadze, 1 Ruben GW Quek, 2 Tamr Melkadze, 3 Miranda Gogishvili, 3 Cristina Ivancu, 2 David Gorajda, 5 Mikhaili Dvorkin, 6 Konstantin Perik, 6 Konstantin Laktionov, 6 Gia Nemsadze, 6 Marina Nechaeva, 6 Irina Rozhkova, 6


**Background**

First-line chemotherapy (chemo) for first-line (1L) treatment of advanced non-small cell lung cancer (asNSCLC) is an area of intense interest, with the approval of an anti-PD-L1 therapy in the metastatic setting, cemiplimab, in combination with platinum-doublet chemotherapy (chemo). The EMPORER-Lung 3 trial evaluated the safety and efficacy of cemiplimab plus chemo (CEMI + CHEMO) versus placebo plus chemo (PBO + CHEMO) as a 1L treatment for advanced asNSCLC.

**Objective**

The primary objective of the EMPORER-Lung 3 trial was to determine if cemiplimab plus chemo would lead to an improvement in overall survival (OS) compared with placebo plus chemo.

**Key takeaways**

- **Significantly improved overall survival** and delay in time to treatment failure in the cemiplimab plus chemo group compared with the placebo plus chemo group.
- **Significant improvement** in QoL with cemiplimab plus chemo, with improved physical functioning and reduced symptoms of dyspnoea, nausea/vomiting, pain, constipation, and coughing.
- **Increased pain symptom reduction** with cemiplimab + chemo compared with PBO + chemo.
- **Statistically significant** improvement in time to disease progression (TTP) with cemiplimab + chemo compared with PBO + chemo.
- **Significantly reduced **number of treatment-emerging adverse events (TEAEs) with cemiplimab + chemo versus PBO + chemo.

**Methods**

**PROs assessment and scoring**

See Supplementary Appendix for details on PROs and scoring.

**Statistical analyses**

Treatment-emergent AEs (TEAEs) were performed to evaluate between-treatment arm differences in global health status quality of life (GHS/QoL), functioning, and symptoms, with variables of treatment, time, treatment by time, histology (homogeneous and squamous), level of programmed cell death ligand-1 (PD-L1) expression, baseline and baseline by time as covariates.

- Prespecified TTD was estimated using Kaplan-Meier methods and compared between groups using a stratified log-rank test and Cox proportional hazards model.
- No adjustment for multiple comparisons were made.

**Results**

**Baseline characteristics**

A total of 466 patients were randomised: 312 were assigned to receive cemiplimab + chemo and 154 to receive PBO + chemo (Supplementary Figure 1).

**Overall survival**

No significant overall difference between the two treatment arms. For every cycle from baseline to Cycle 21, 92% and 91% of patients in the cemiplimab + chemo and PBO + chemo arms, respectively, completed at least one question on the EORTC QLQ-C30 and POIS-Leipzig L13.

**QoL**

For every cycle in the first treatment cycle, QoL was improved in the cemiplimab + chemo arm compared with the PBO + chemo arm. For every cycle from baseline to Cycle 21, 92% and 91% of patients in the cemiplimab + chemo and PBO + chemo arms, respectively, completed at least one question on the EORTC QLQ-C30 and POIS-Leipzig L13.

**AEs**

No statistically significant between-treatment overall differences were observed on any other QLQ-C30 symptom scale (Supplementary Figure 1E).

**Time to definitive clinically meaningful deterioration**

A non-significant trend towards a delay in TTD in EMPORER-Lung 3 (asNSCLC), was observed in the cemiplimab + chemo arm versus PBO + chemo arm (Supplementary Figure 2A).

**Conclusion**

Among patients with asNSCLC, these favourable PRO results support the positive benefit-risk profile of cemiplimab + chemo.