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EMPOWER-Lung 3: Cemiplimab in combination with platinum doublet chemotherapy for first-line (1L) treatment of advanced non-small cell lung cancer (NSCLC)

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Background

EMPOWER-Lung 3 is a randomised, 2-part, Phase 3 study of 1L treatment of patients (pts) with advanced (Stage III/IV) squamous (SQ) or non-squamous (NSQ) NSCLC without actionable mutations (NCT03409614). The double-blind Part 2 of the study enrolled pts irrespective of PD-L1 levels and compared clinical activity and safety of cemiplimab, an anti -PD-1, plus (+) platinum-based chemo, versus (vs) placebo (PBO)+chemo.

Methods

Pts were randomised (2:1; stratified by histology and PD-L1 expression) to receive cemiplimab 350 mg once every 3 weeks (Q3W) or PBO Q3W for 108 weeks (or until progression), plus up to 4 cycles of chemo (followed by mandatory pemetrexed maintenance for NSQ pts assigned to a pemetrexed-containing regimen). Primary endpoint was overall survival (OS). Key secondary endpoints include progression-free survival (PFS) and objective response rate (ORR) per blinded independent central review. Here we report Part 2 results from the pre-specified 2nd interim analysis. Data cut-off was 14 June 2021.

Results

Overall, 466 pts were eligible and randomised to cemiplimab+chemo (n=312) or PBO+chemo (n=154). Median (range) age was 63.0 (25-84) years; 57.1% had NSQ NSCLC; and 85.2% had Stage IV disease. Median OS was 21.9 months with cemiplimab+chemo vs 13.0 months with PBO+chemo (HR, 0.71; *P*=0.014). Cemiplimab+chemo was associated with superior median PFS (8.2 vs 5.0 months; HR, 0.56), higher ORR (43.3% vs 22.7%), and longer median duration of response (DOR) (15.6 months vs 7.3 months) vs PBO+chemo (Table). Incidence of Grade ≥3 adverse events was 43.6% in cemiplimab+chemo arm and 31.4% in PBO+chemo arm.Table: LBA51

	Cemiplimab+chemo (n=312)	PBO+chemo (n=154)	
Duration of follow-up, median (IQR), months	16.3 (13.9–19.1)	16.7 (14.2–19.0)	
OS, median (95% CI), months	21.9 (15.5–NE)	13.0 (11.9–16.1)	
HR (95% CI)			0.71 (0.53–0.93); *P*=0.014
PFS, median (95% CI), months	8.2 (6.4–9.3)	5.0 (4.3–6.2)	
HR (95% CI)			0.56 (0.44–0.70); *P*<0.0001
ORR, % (95% CI)	43.3 (37.7–49.0)	22.7 (16.4–30.2)	
Odds ratio (95% CI)			2.68 (1.72–4.19); *P*<0.0001
Complete response, n (%)	8 (2.6)	0 (0)	
Partial response, n (%)	127 (40.7)	35 (22.7)	
Kaplan-Meier estimated DOR, median (95% CI), months	15.6 (12.4–NE)	7.3 (4.3–12.6)	

Conclusions

In pts with advanced NSCLC, 1L cemiplimab+chemo demonstrated clinically meaningful and statistically significant improvement in OS, PFS, ORR and DOR vs chemo alone, with a safety profile consistent with cemiplimab monotherapy and platinum-based chemo.

Clinical trial identification

NCT03409614.

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Legal entity responsible for the study

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Disclosure

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