

**LBA51**

**KEYNOTE-024 5-year OS update: First-line (1L) pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score (TPS) ≥50%**

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**Background**

Superiority of 1L pembro monotherapy vs chemo in pts with metastatic NSCLC with PD-L1 TPS ≥50% and no sensitizing *EGFR/ALK* alterations was demonstrated in KEYNOTE-024 (NCT02142738). We report updated efficacy and safety from KEYNOTE-024 with 5 years follow-up.

**Methods**

Eligible pts were randomized to pembro (200 mg Q3W for up to 35 cycles [×2 years]) or chemo. Randomization was stratified by ECOG PS (0/1), histology (squamous/nonsquamous), and region (East Asia/other). Pts randomized to chemo who had PD and met eligibility criteria could cross over to pembro monotherapy. Pts randomized to pembro who completed 2 years of therapy or who stopped pembro after achieving CR and then had PD were eligible for a second course of pembro monotherapy. Endpoints included PFS (primary); OS, ORR, and safety (secondary); and duration of response (exploratory). For this analysis, response/PD was assessed by investigators per RECIST v1.1.

**Results**

305 pts were randomized (pembro, 154; chemo, 151). As of June 1, 2020, median (range) time from randomization to data cutoff was 59.9 (55.1–68.4) mo. 83 (55.0%) pts randomized to chemo crossed over to pembro. Efficacy in the ITT population and in 39/154 (25.3%) pts in the pembro arm who completed 35 cycles of pembro are shown in the Table. 12/154 pts started second course pembro; outcomes in these pts will be presented. Among all treated pts, incidence of treatment-related grade 3–5 AEs was 31.2% with pembro vs 53.3% with chemo. Table: LBA51

Efficacy

	Pembro (N = 154)	Chemo (N = 151)
Median OS, mo (95% CI)	26.3 (18.3–40.4)	13.4 (9.4–18.3)
- HR (95% CI)	0.62 (0.48–0.81)	
Kaplan-Meier estimate of 5-year OS rate, %	31.9	16.3
	Pts who completed 35 cycles (N = 39)	
ORR, n (%) <sup>a</sup>	32 (82.1)	
- CR	4 (10.3)	
- PR	28 (71.8)	
- SD	6 (15.4)	
Pts alive at data cutoff, n/N (%)	32/39 (82.1) <sup>b</sup>	
Kaplan-Meier estimate of 3-year OS rate after completing pembro, %	81.4	

<sup>a</sup>At data cutoff, 18/39 pts were alive and had not experienced PD per investigator assessment. <sup>b</sup>7 patients died due to PD; 2 did

not receive any additional treatment.

## Conclusions

Pembro continues to show improvements in OS vs chemo as 1L treatment for metastatic NSCLC with PD-L1 TPS  $\geq$ 50%. Despite the high crossover rate, 5-year OS was approximately doubled among pts who received pembro (31.9% vs 16.3%). Fewer pts who received pembro experienced grade 3–5 AEs vs those who received chemo. Long-term OS and durable responses were observed with pembro monotherapy.

## Clinical trial identification

NCT02142738.

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## Legal entity responsible for the study

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