1210P Neoadjuvant pembrolizumab (pembro) or placebo (pbo) plus chemotherapy and adjuvant pembro or pbo for early stage NSCLC: Subgroup analyses of the phase III KEYNOTE-671 study

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Background: Neoadjuvant pembro + chemo followed by adjuvant pembro significantly improved event-free survival (EFS) and OS vs neoadjuvant chemo alone in patients (pts) with resectable NSCLC in the phase III KEYNOTE-671 study. At interim analysis 2 (IA2), HRs (95% CI) were 0.59 (0.48–0.72) for EFS and 0.72 (0.56–0.93) for OS. We present EFS and OS results for key pt subgroups based on IA2.

Methods: Eligible pts with resectable stage II, IIIA, or IIIB (N2) NSCLC per AJCC 8 were randomized 1:1 to 4 cycles of pembro 200 mg or pbo + cisplatin-based chemo followed by surgery and adjuvant pembro or pbo for up to 13 additional cycles. Dual primary endpoints were EFS by investigator assessment per RECIST v1.1 and OS. Randomization was stratified by disease stage (II vs III), PD-L1 TPS (<50% vs ≥50%), histology (squamous vs nonsquamous), and region (East Asia vs non–East Asia). Exploratory analyses of EFS and OS were done using a Cox regression model with treatment as a covariate for preplanned subgroups based on PD-L1 TPS, disease stage, nodal involvement, and histology at baseline. Landmark analyses of EFS and OS from time of initiation of adjuvant therapy were also done.

Results: 797 pts were randomized to the pembro arm (N = 397) or the pbo arm (N = 400). Median study follow-up at IA2 (data cutoff, July 10, 2023) was 36.6 mo (range, 18.8–62.0). HRs for EFS and OS favored the pembro arm across all subgroups evaluated (**Table**). Among pts who started adjuvant therapy, HRs (95% CI) for EFS and OS from the start of adjuvant therapy were 0.55 (0.42–0.72; N = 548) and 0.71 (0.49–1.03; N = 557), respectively.

Table: 1210P

	N	EFS HR (95% CI)	OS HR (95% CI)
Stage II at baseline	239	0.59 (0.40–0.88)	0.67 (0.41–1.10)
Stage III at baseline	558	0.58 (0.46–0.72)	0.74 (0.55–0.98)
Squamous histology	344	0.51 (0.38–0.69)	0.71 (0.51–0.99)
Nonsquamous histology	453	0.66 (0.51–0.86)	0.73 (0.50–1.06)
PD-L1 TPS ≥50%	266	0.48 (0.33–0.71)	0.55 (0.33–0.92)
PD-L1 TPS 1%–49%	242	0.52 (0.36–0.73)	0.69 (0.44–1.07)
PD-L1 TPS ≥1%	508	0.51 (0.39–0.66)	0.62 (0.45–0.87)
PD-L1 TPS <1%	289	0.75 (0.56–1.01)	0.91 (0.63–1.32)
N0 status at baseline	290	0.58 (0.41–0.80)	0.70 (0.46–1.05)
N1 status at baseline	152	0.56 (0.35–0.91)	0.74 (0.41–1.33)
N2 status at baseline	355	0.63 (0.48–0.82)	0.74 (0.51–1.07)

Conclusions: Perioperative pembro provided a clinically meaningful improvement in EFS and OS across subgroups vs neoadjuvant chemo alone in pts with resectable stage II, IIIA, or IIIB NSCLC. Results from the landmark analyses from time of adjuvant therapy start suggest adjuvant therapy adds clinical benefit in this setting.

Clinical trial identification: NCT03425643; EudraCT 2017-001832-21.

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1211P IMpower010: ctDNA status and 5y DFS follow up in patients (pts) with resected NSCLC who received adjuvant chemotherapy (chemo) followed by atezolizumab (atezo) or best supportive care (BSC)

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Background: In IMpower010 (NCT02486718), ctDNA+ status after surgery (post-op) was associated with poor prognosis; atezo was beneficial vs BSC regardless of post-op ctDNA status (Zhou ESMO-IO 2021). Post-chemo, ctDNA clearance (ctDNA−; 62% of post-op ctDNA+ pts) was associated with improved DFS; ctDNA levels were maintained in ctDNA+ pts, and conversion to ctDNA+ was delayed with atezo in ctDNA− pts (Felip ESMO-IO 2022). At final DFS and 2nd IA of overall survival (OS) with ≥5y of follow up, DFS benefit with atezo continued to translate into a positive OS trend vs BSC in PD-L1 tumour cell (TC) ≥1% and TC ≥50% stage II-IIIA pts. We report updated DFS and OS by ctDNA and PD-L1 status.

Table: 1211P DFS and OS by ctDNA and PD-L1 status in stage II-IIIA ctDNA-evaluable pts

Group	ctDNA status	PD-L1 status	Median DFS, mo		HR (95%CI)
			Atezo	BSC	
Post-op	−	All	n=218 NE	n=204 60.6	0.74 (0.56, 0.98)
		TC ≥1%	n=124 NE	n=98 52.6	0.60 (0.40, 0.89)
		TC <1%	n=94 63.1	n=106 66.7	0.97 (0.65, 1.44)
	+	All	n=53 19.1	n=59 7.9	0.64 (0.42, 0.98)
		TC ≥1%	n=36 21.8	n=37 7.2	0.58 (0.34, 0.98)
		TC <1%	n=15 5.0	n=22 8.0	0.81 (0.38, 1.73)
Post-chemo[a]	−	All	n=36 34.2	n=28 13.3	0.68 (0.37, 1.26)
	+	All	n=19 4.2	n=20 4.0	0.64 (0.32, 1.26)
			Median OS, mo		**HR (95%CI)**
Post-op	−	TC ≥1%	n=124 NE	n=98 NE	0.68 (0.39, 1.19)
	+	TC ≥1%	n=36 68.5	n=37 32.4	0.58 (0.32, 1.05)

[a] In 103 evaluable post-op ctDNA+ pts CI, confidence interval; HR, hazard ratio; NE, not estimable