

## Health-related quality of life (HRQoL) outcomes from the randomized, double-blind phase 3 KEYNOTE-671 study of perioperative pembrolizumab for early-stage non-small-cell lung cancer (NSCLC).

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**Background:** Neoadjuvant pembrolizumab + cisplatin-based chemotherapy (neoadj pembro + chemo), resection, and adjuvant (adj) pembro (pembro arm; n=397) significantly improved EFS, OS, pCR, and mPR and had an expected safety profile versus neoadj placebo (pbo) + chemo, resection, and adj pbo (pbo arm; n=400) in patients (pts) with resectable stage II, IIIA, or IIIB (N2) NSCLC. We present prespecified pt-reported outcome (PRO) endpoints from KEYNOTE-671. **Methods:** Pts completed EORTC QLQ-C30 and QLQ-LC13 questionnaires at baseline (BL), the last scheduled presurgery visit, adj cycles 1-4, 7, 10, and 13, and each post treatment visit. A constrained longitudinal data analysis model was used to estimate least squares mean (LSM) score changes from BL to neoadj wk 11 and adj wk 10 (latest time of  $\geq 60\%$  completion and  $\geq 80\%$  compliance) in QLQ-C30 global health status (GHS)/QoL, physical functioning (PF), role functioning (RF), and dyspnea and QLQ-LC13 cough and chest pain in all treated pts who completed  $\geq 1$  PRO assessment. Data are from interim analysis 2 (10 Jul 2023 cutoff). **Results:** Across arms, questionnaire completion was  $\geq 87\%$  at neoadj wk 11 and  $\geq 62\%$  at adj wk 10; compliance was  $\geq 87\%$  and  $\geq 92\%$ , respectively. There were no differences in LSM change from BL in the neoadj or adj phase for any PRO score (Table). **Conclusions:** Adding perioperative pembro maintained HRQoL in both the neoadj and adj settings versus neoadj chemo and surgery alone in pts with resectable early-stage NSCLC. Together with the significant efficacy improvements and absence of new safety signals, HRQoL data support the perioperative pembro regimen as a new standard of care. Clinical trial information: NCT03425643. Research Sponsor: Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

	LSM (95% CI) Change from BL to Neoadj wk 11, Pembro Arm N=390	LSM (95% CI) Change from BL to Neoadj wk 11, Pbo Arm N=395	Difference (95% CI), Neoadj Phase	LSM (95% CI) Change from BL to Adj wk 10, Pembro Arm N=395	LSM (95% CI) Change from BL to Adj wk 10, Pbo Arm N=397	Difference (95% CI), Adj Phase
QLQ-C30						
GHS/QoL	-9.31 (-11.67, -6.94)	-10.73 (-13.07, -8.40)	1.43 (-1.64, 4.49)	-1.52 (-3.67, 0.63)	-3.74 (-5.96, -1.52)	2.22 (-0.58, 5.02)
PF	-6.30 (-8.00, -4.60)	-6.65 (-8.32, -4.97)	0.35 (-1.99, 2.68)	-5.06 (-6.77, -3.35)	-5.81 (-7.58, -4.04)	0.75 (-1.63, 3.13)
RF	-9.43 (-12.00, -6.87)	-10.47 (-13.00, -7.94)	1.04 (-2.41, 4.49)	-4.86 (-7.39, -2.34)	-7.00 (-9.62, -4.39)	2.14 (-1.33, 5.61)
Dyspnea	2.16 (-0.35, 4.67)	3.94 (1.46, 6.42)	-1.77 (-5.10, 1.55)	5.78 (2.96, 8.59)	9.64(6.73, 12.55)	-3.86 (-7.63, -0.09)
QLQ-LC13						
Cough	-11.40 (-13.92, -8.88)	-9.57 (-12.07, -7.08)	-1.82 (-5.01, 1.36)	-6.78 (-9.73, -3.84)	-4.63 (-7.67, -1.59)	-2.15 (-5.95, 1.65)
Chest pain	1.13 (-1.02, 3.28)	0.41 (-1.72, 2.54)	0.72 (-2.03, 3.47)	2.99 (0.38, 5.59)	6.03 (3.33, 8.73)	-3.04 (-6.53, 0.45)

Increases in GHS/QoL and functioning scores indicate improvement. Decreases in symptom scores indicate improvement.