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LBA69

SKYSCRAPER-03: Phase III, open-label, randomised study of atezolizumab (atezo) + tiragolumab (tira) vs durvalumab (durva) in locally advanced, unresectable, stage III non-small cell lung cancer (NSCLC) after platinum-based concurrent chemoradiation (cCRT)

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Background

SKYSCRAPER-03 (NCT04513925) is a phase 3 study that evaluated atezo + tira in the consolidation setting for patients (pts) with unresectable, stage III NSCLC without progression after cCRT.

Methods

Eligible pts were randomised 1:1 to receive atezo (1680mg q4w) + tira (840mg q4w) or durva (10mg/kg q2w or 1500mg q4w) for 13 x 28-day cycles. Pts were enrolled irrespective of programmed death-ligand 1 (PD-L1) expression. The primary endpoint was independent review facility-assessed progression-free survival (IRF-PFS) in pts with PD-L1+ NSCLC (tumour cells [TC] ≥1% by central SP263 assay). Secondary endpoints included overall survival (OS) and safety.

Results

Of 829 pts enrolled (PD-L1 all-comers), 413 pts were randomised to atezo + tira and 416 to durva. In total, 419 pts had PD-L1+ NSCLC (n=209 received atezo + tira, n=210 received durva). Median IRF-PFS in pts with PD-L1+ NSCLC was 19.4 months (mo) with atezo + tira vs 16.6 mo with durva (stratified hazard ratio [HR] 0.96; 95% confidence interval [CI] 0.75–1.23; p=0.76; Table). In the PD-L1 all-comers group, median IRF-PFS was 14.2 vs 13.8 mo, respectively (stratified HR 1.00; 95% CI 0.84–1.19). Median OS in pts with PD-L1+ NSCLC was not estimable with atezo + tira vs 54.8 mo with durva (stratified HR 0.99, 95% CI 0.73–1.34). In the PD-L1 all-comers group, median OS was 45.6 vs 45.8 mo, respectively (stratified HR 0.98; 95% CI 0.80–1.20). Among safety-evaluable pts (n=820), grade 3–4 adverse events (AEs) occurred in 26.5% of pts who received atezo + tira vs 25.7% of pts who received durva. AEs led to treatment withdrawal in 15.5% vs 9.0% of pts, respectively.Table: LBA69

Efficacy	PD-L1+ (TC ≥1%)		PD-L1 all-comers	
	Atezo + tira (n=209)	Durva (n=210)	Atezo + tira (n=413)	Durva (n=416)
Median IRF-PFS, mo (95% CI)	19.4 (13.8–29.5)	16.6 (11.1–22.8)	14.2 (12.6–19.2)	13.8 (10.9–17.0)
Stratified HR (95% CI)	0.96 (0.75–1.23)	1.00 (0.84–1.19)		

Efficacy	PD-L1+ (TC ≥1%)		PD-L1 all-comers	
	Atezo + tira (n=209)	Durva (n=210)	Atezo + tira (n=413)	Durva (n=416)
P-value	0.76	–		
	Safety-evaluable pts			
Safety, %[☒]	Atezo + tira (n=407)	Durva (n=413)		
All-grade AEs	97.5	97.3		
Grade 3–4	26.5	25.7		
Grade 5	6.6	7.5		
All-grade treatment-related AEs	80.3	67.1		
Grade 3–4	13.8	10.7		
Grade 5	0.5	1.7		
All-grade AEs of special interest	76.4	62.2		

Median follow-up: 33.0 mo (PD-L1+), 30.7 mo (PD-L1 all-comers). Median treatment duration: 11.0 mo in both study arms. *9 pts (6 atezo + tira, 3 durva) did not receive study therapy.

Conclusions

Atezo + tira did not offer additional benefit over durva in pts with unresectable, stage III NSCLC. The safety profile of atezo + tira was consistent with prior observations.

Clinical trial identification

NCT04513925.

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