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Abstract CT051: SKYSCRAPER-01: A phase III, randomized trial of tiragolumab (tira) + atezolizumab (atezo) versus placebo (pbo) + atezo in patients (pts) with previously-untreated PD-L1-high, locally advanced unresectable/metastatic NSCLC FREE

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Abstract

Background:

Tiragolumab (tira) + atezolizumab (atezo) has shown encouraging survival outcomes in pts with metastatic NSCLC, primarily in pts with PD-L1-high tumors (tumor proportion score [TPS] ≥50%). SKYSCRAPER-01 (NCT04294810) is a phase III, double-blind, placebo-controlled, randomized trial investigating the efficacy and safety of first-line tira + atezo in pts with PD-L1-high NSCLC.

Methods:

Eligible pts (previously untreated; PD-L1-high, locally advanced unresectable/metastatic NSCLC; *EGFR/ALK* wildtype) were randomized 1:1 to receive tira 600 mg IV + atezo 1200 mg IV or pbo + atezo 1200 mg IV every 3 weeks until disease progression, loss of clinical benefit, or unacceptable toxicity. Primary endpoints: investigator-assessed progression-free survival (INV-PFS) and overall survival (OS) in the primary analysis set (PAS; TPS ≥50%; 22C3 assay). Secondary endpoints: INV-objective response rate (INV-ORR) and INV-duration of response (INV-DOR) in the PAS; OS in the secondary analysis set (SAS; tumor cell [TC] ≥50%; SP263 assay).

Results:

A total of 534 pts were randomized (tira + atezo, n=266; pbo + atezo, n=268). Pt characteristics were balanced between treatment arms. At the final PFS analysis (data cut-off 12 Mar 2022; median follow-up 9.9 months), median INV-PFS was 7.0 months with tira + atezo and 5.6 months with pbo + atezo (HR 0.78; 95% CI 0.63, 0.97; p=0.02; PAS). At the final OS analysis (data cut-

off 24 Sep 2024; median follow-up 17.9 months), median OS was 23.1 months with tira + atezo and 16.9 months with pbo + atezo (HR 0.87; 95% CI 0.71, 1.08; p=0.22; PAS; **Table**). Tira + atezo demonstrated an acceptable safety profile, consistent with previous observations.

Table

PAS (TPS ≥50% per 22C3 assay)	**Tira + atezo**	**Pbo + atezo**
	(n=262)	**(n=259)**
Median PFS, months (95% CI)*†	7.0 (5.6, 9.8)	5.6 (4.4, 7.0)
HR (95% CI); p-value	0.78 (0.63, 0.97); p=0.02	
Median OS, months (95% CI)*†	23.1 (17.7, 28.8)	16.9 (14.6, 23.1)
HR (95% CI); p-value	0.87 (0.71, 1.08); p=0.22	
ORR, %*	45.8	35.1
Median DOR, months (95% CI)*	18.0 (13.6, 24.4)	14.6 (9.7, 18.6)
SAS (TC ≥50% per SP263 assay)	**Tira + atezo**	**Pbo + atezo**
	(n=211)	**(n=209)**
Median OS, months (95% CI)*	24.6 (17.9, 32.0)	20.6 (16.6, 29.3)
HR (95% CI)	0.93 (0.73, 1.18)	
Safety evaluable set‡	**Tira + atezo**	**Pbo + atezo**
	(n=267)	**(n=263)**
Any grade AEs, %	95.9	91.3
Grade 3-4 AEs, %	41.2	33.8
Grade 5 AEs, %	10.9	9.9
Treatment-related grade 5 AEs, %	1.5	0.8
AEs leading to treatment withdrawal, %	16.1	6.5
Any grade AESIs, %	70.0	50.6

* PFS analysis: data cut-off 12 Mar 2022 (PFS final analysis/first OS interim analysis); OS ORR, and DOR analysis: data cut-off 24 Sep 2024 (OS final analysis). PFS, ORR and DOR were assessed by the investigator.

† Primary endpoints.

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‡ All randomized patients who received ≥1 dose of study treatment. AE, adverse event; atezo, atezolizumab; AESIs, adverse events of special interest; CI, confidence interval; DOR, duration of response; HR, hazard ratio; ORR, objective response rate; OS, overall survival; PAS, primary analysis set; pbo, placebo; PFS, progression-free survival; SAS, secondary analysis set; TC, tumor cell; tira, tiragolumab; TPS, tumor proportion score.

Conclusion:

The primary endpoints of INV-PFS and OS were not met in the SKYSCRAPER-01 study. Numerical improvements in both PFS and OS with tira + atezo versus pbo + atezo suggest potential antitumor activity of TIGIT targeting in NSCLC.

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