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# SKYSCRAPER-07: A phase III, randomised study of atezolizumab (atezo) with or without tiragolumab (tira) in patients (pts) with unresectable esophageal squamous cell carcinoma (ESCC) that has not progressed following definitive concurrent chemoradiotherapy (dCRT)

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## Background

Standard of care for unresectable locally advanced ESCC is dCRT; however, ≥50% of pts experience recurrence. SKYSCRAPER-07 (NCT04543617) assessed the efficacy and safety of tira + atezo or atezo + placebo (pbo) in pts with ESCC following dCRT.

## Methods

Eligible pts were aged ≥18 yrs with ECOG PS 0–1 and confirmed stage II–IVA (selected stage IVB) locally advanced ESCC who were ineligible for curative surgery and treated with dCRT. Pts were randomised 1:1:1 to receive tira 600 mg IV once every 3 weeks (Q3W) + atezo 1200 mg IV Q3W (arm A), atezo 1200 mg IV Q3W + pbo IV Q3W (arm B) or pbo + pbo IV Q3W (arm C) for 17 cycles, or until disease progression or unacceptable toxicity. Hierarchical testing of primary endpoints occurred in the order of: investigator-assessed progression-free survival (PFS; arms A vs C), overall survival (OS; A vs C) and OS (B vs C). If an endpoint did not reach statistical significance, only descriptive analyses were performed for subsequent endpoints.

## Results

As of 18 Feb 2025, 760 pts were enrolled; 257 pts in arm A, 250 pts in arm B and 253 pts in arm C (median follow-up 25.0 months [m]). Baseline characteristics were similar between arms. Median PFS was 20.8 m (95% CI 13.9–28.8) and 16.6 m (95% CI 11.2–19.4) for arms A and C, respectively (p=0.0947; Table). Median OS was 38.6 m (95% CI 28.8–not estimable [NE]) in arm A and 36.4 m (95% CI 25.8–NE) in arm C; median OS was not reached in arm B (Table). AEs were reported in 96.9%, 94.0% and 90.0% of pts in arms A, B and C, respectively; a higher number of pts reported treatment-related AEs in arm A vs B (74.8% vs 65.2%).

## Conclusions

SKYSCRAPER-07 did not meet its primary endpoint of PFS for tira + atezo vs pbo in pts with ESCC, and no OS benefit was observed vs pbo. However, results indicate a clinically meaningful improvement in PFS and OS with atezo + pbo vs pbo. No new safety signals were identified.Table: 2094O

| | PFS | | | OS | | |
|---|---|---|---|---|---|---|
| | A Tira + atezo (N=257) | B Atezo + pbo (N=250) | C Pbo + pbo (N=253) | A Tira + atezo (N=257) | B Atezo + pbo (N=250) | C Pbo + pbo (N=253) |
| Pts with event, n (%) | 141 (54.9) | 128 (51.2) | 157 (62.1) | 111 (43.2) | 88 (35.2) | 118 (46.6) |
| Median, m (95% CI) | 20.8 (13.9–28.8) | 29.1 (19.0–36.3) | 16.6 (11.2–19.4) | 38.6 (28.8–NE) | NR | 36.4 (25.8–NE) |
| Stratified HR* (95% CI) | 0.82 (0.65–1.03) | 0.74 (0.58–0.93)† | – | 0.91 (0.70–1.18)† | 0.69 (0.52–0.91)† | – |
| P-value* | 0.0947 | 0.0113† | – | 0.4772† | 0.0085† | – |
| 24 m rate, % (95% CI) | 46.7 (40.3–53.0) | 52.8 (46.4–59.2) | 40.9 (34.6–47.1) | 59.9 (53.6–66.1) | 69.1 (63.2–75.0) | 59.4 (53.1–65.7) |

*Vs placebo†Not formally tested as PFS (A vs C) not met, p-values are descriptive m, months; NE, not estimable; NR, not reached

## Clinical trial identification

NCT04543617.


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## Legal entity responsible for the study

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## Disclosure

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