

Neoadjuvant EGFR-TKI in Stage I EGFR-Mutant NSCLC: Exploratory Randomized Results From the ANSWER Trial

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BACKGROUND

Randomized evidence for neoadjuvant EGFR-TKI remains limited in resectable stage I EGFR-mutant NSCLC, especially stage IA disease.

OBJECTIVE

To evaluate radiographic and pathological response, surgical feasibility, and early postoperative outcomes in the stage I cohort of ANSWER.

STUDY DESIGN

Multicenter, open-label randomized phase II trial

Enrollment: Mar 2022-Sep 2023

Stage I
n=13

Stage IA: 8 |
Stage IB: 5

Aumolertinib
n=8

Erlotinib
n=5

Median follow-up: 34.3 months (IQR 28.0-37.3)

KEY RESULTS

Radiographic shrinkage was common, while deep pathological regression was not observed.

61.5%

Radiographic PR
8/13 patients

38.5%

Stable disease
5/13 patients

Best radiographic response

13/13

Underwent planned surgery

100%

Minimally invasive approach

100%

R0 resection
0 perioperative deaths

PATHOLOGICAL RESPONSE

0%

pCR
0/13

0%

MPR
0/13

40-85%

Residual viable tumor range

EARLY ONCOLOGIC OUTCOMES

Descriptive only; the subgroup was not powered for between-arm comparisons.

Outcome	Aumolertinib n=8	Erlotinib n=5
Postoperative recurrence	0	1 (20.0%)
Deaths	0	0
Median DFS	Not reached	Not reached

OS was immature; no deaths had occurred at data cutoff.

INTERPRETATION

- Exploratory subgroup with a small sample (n=13).
- No formal efficacy comparison between the two EGFR-TKIs.
- Longer follow-up is required for DFS and OS.

KEY TAKEAWAY

Neoadjuvant EGFR-TKI was feasible and preserved surgery in stage I disease, but radiographic response did not translate into pCR or MPR.