



Real-World Efficacy of Firmonertinib as Adjuvant Therapy in Resectable Stage IA- IIIB EGFR-Mutated Non-Small Cell Lung Cancer

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Background

- The landmark ADAURA trial established third-generation EGFR tyrosine kinase inhibitors (TKIs) as the standard adjuvant therapy for Stage IB-IIIA NSCLC. However, whether adjuvant therapy is needed for Stage IA patients with high-risk histopathologic features—such as spread through air spaces (STAS) and high-grade components—remains an unresolved clinical dilemma. This study evaluates the real-world efficacy and safety of adjuvant Firmonertinib in an Asian cohort, with a focus on risk-stratified outcomes.

Methods

- This retrospective study included patients with stage I-IIIA EGFR-mutated lung adenocarcinoma who underwent surgery and received adjuvant firmonertinib (80 mg QD) treatment at the Affiliated Hospital of Qingdao University between August 2022 and November 2025.
- The clinical efficacy analysis for this study included disease-free survival (DFS), the 2/3-year DFS rate and the 2/3-year overall survival (OS) rate and safety. DFS was defined from the time of surgery to disease progression or death, while OS was defined from the time of surgery to death from any cause.

Results

Baseline characteristics

- We retrospectively reviewed 95 patients with completely resected (R0) Stage IA-IIIB EGFR-mutated lung adenocarcinoma who received adjuvant Firmonertinib (80 mg QD) between August 2022 and November 2025. There were 18 (18.95%) patients with stage IA, 11 (11.58%) with stage IB, 7 (7.37%) with stage II, and 10 (10.53%) with stage III. 63 patients (66.32%) had high-risk factors, among whom 41 (43.16%) with ≥ 2 high-risk factors. (Table 1)

Table 1. Patient Baseline Demographic and Clinical Characteristics

Characteristic	N=95
Age, years	
Median (Range)	61 (44, 78)
Sex, n (%)	
Female	29 (30.53)
Male	66 (69.47)
Smoking History, n (%)	
Yes	9 (9.47)
No	86 (90.53)
Pathological Stage (AJCC 8th), n (%)	
IA, n (%)	67 (70.53)
IB, n (%)	11 (11.58)
II, n (%)	7 (7.37)
III, n (%)	10 (10.53)
EGFR Mutation Subtype, n (%)	
Ex19del	36 (37.89)
L858R	50 (52.63)
EGFR 20ins	1 (1.05)
G719X	5 (5.26)
L861Q	4 (4.21)
T790M	1 (1.05)
High-risk Factor, n (%)	
≥ 1 High-risk factor	63 (66.32)
≥ 2 High-risk factors	41 (43.16)

- Among all patients with high-risk factors, pathological high-grade components* ($\geq 20\%$) accounted for 74.60%, spread through air spaces (STAS) for 85.71%, visceral pleural invasion (VPI) for 14.29%, and lymphovascular invasion (LVI) for 9.52%. (Table 2)

Table 2. High-risk pathological characteristics

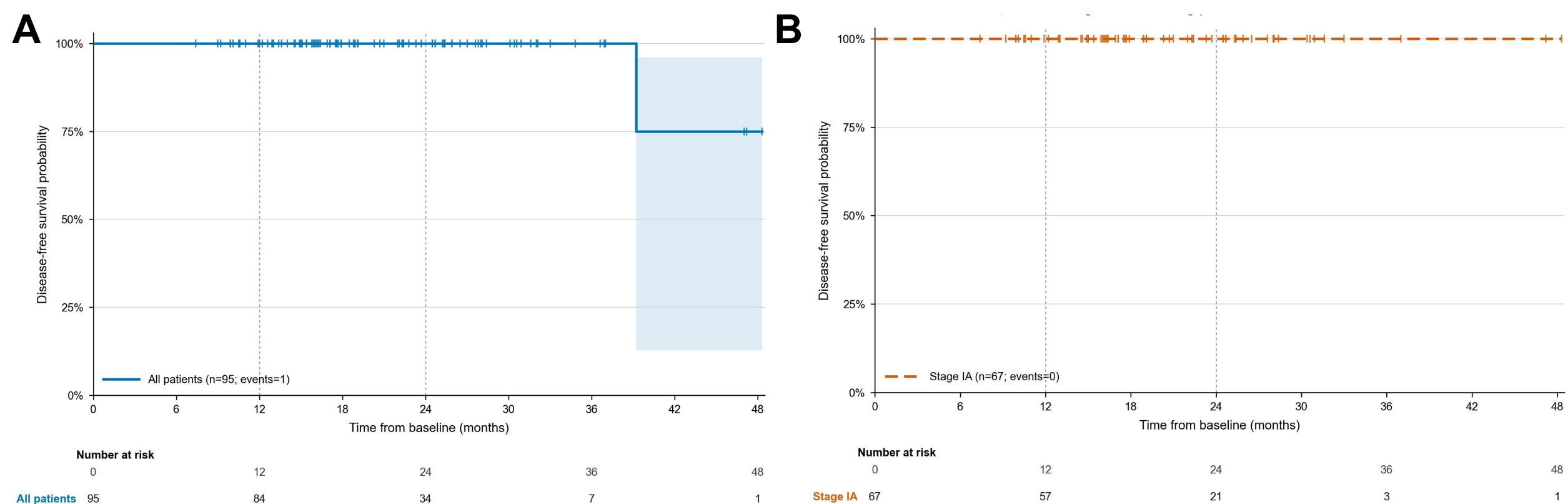
High-risk factors	Overall (N = 63)	Stage IA (N = 38)	Stage IB-III (N = 25)
High-grade components, n (%)*	47 (74.60%)	26 (68.42%)	21 (84.00%)
Spread through air spaces (STAS), n (%)	54 (85.71%)	32 (84.21%)	22 (88.00%)
Visceral pleural invasion (VPI), n (%)	9 (14.29%)	0 (0.00%)	9 (36.00%)
Lymphovascular invasion (LVI), n (%)	6 (9.52%)	3 (7.89%)	3 (12.00%)

*Defined as $\geq 20\%$ micropapillary, solid, or complex glandular components.

Efficacy

- As of August 6, 2026, all patients were followed up for more than 6 months, with a median follow-up time of 18.9 months. Among them, 34 cases (35.79%) were followed up for more than 24 months, and the duration of medication was 3-38 months. Only 1 patient relapsed. The median DFS and OS of the entire group of patients have not yet been reached, and the 1-year and 2-year DFS rates are both 100%. (Figure 1A)
- As of August 6, 2026, the median follow-up time for stage IA patients (n=67) was 18.9 months, with 21 cases (31.34%) followed up for more than 24 months. All patients survived without imaging recurrence, and the 1-year and 2-year DFS rates were both 100%. (Figure 1B)

Figure 1. DFS in the overall population (A) and IA stage population (B)



Safety

- Safety analysis revealed that the incidence of treatment - related adverse events (TRAEs) was 9.5% (9/95), with all events being Grade 1.
- Common TRAEs included rash (4.2%, 4/95), ALT increase (4.2%, 4/95), AST increase (4.2%, 4/95), and Blurred vision (1.1%, 1/95). There was no incidence of dose reductions, treatment discontinuation or deaths due to TRAEs. (Table 3)

Table 3. Treatment-Related Adverse Events

Events (n=95)	Any grade n (%)
Any TRAEs	9(9.5)
Grade ≥ 3 TRAEs	0 (0)
Rash	4 (4.2)
ALT increase	4 (4.2)
AST increase	4 (4.2)
Blurred vision	1 (1.1)

Conclusion

- Adjuvant Firmonertinib demonstrates remarkable early efficacy and a superior safety profile in resected EGFR-mutated NSCLC. The absence of recurrence in a cohort heavily enriched with STAS and high-grade components—even in Stage IA disease—suggests that a biology-driven adjuvant approach may mitigate the high recurrence risk associated with aggressive pathological phenotypes. These data support the exploration of Firmonertinib in risk-stratified adjuvant trials for early-stage NSCLC.

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