

P1.128: A Phase II Study of Ensartinib as Neoadjuvant Therapy for Stage II-IIIB ALK-rearranged Non-Small Cell Lung Cancer (NEOEAST)



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INTRODUCTION

Neoadjuvant therapy has emerged as a promising strategy for improving outcomes in early-stage lung cancer. Although ALK inhibitors have demonstrated robust efficacy in advanced ALK-rearranged (ALK+) non-small cell lung cancer (NSCLC), their potential utility in the neoadjuvant setting remains largely underexplored. Ensartinib, a potent next-generation ALK inhibitor with established approval for first- and second-line treatment of advanced ALK+ NSCLC, offers a promising therapeutic option in this setting. Accordingly, this phase II NEOEAST study aimed to prospectively evaluate the feasibility, safety and efficacy of neoadjuvant ensartinib in patients with resectable stage II–IIIB ALK+ lung adenocarcinoma.

METHODS

Design:

- NEOEAST is an open-label, single-arm, prospective, phase II study (NCT05380024).
- Patients aged 18 to 75 years with histologically or cytologically confirmed, resectable, stage II-IIIB, ALK+ lung adenocarcinoma will be enrolled.
- Enrolled patients will receive ensartinib 225 mg orally once daily for 8 weeks as neoadjuvant therapy.
- Surgical resection will be scheduled within 3-21 days after the final dose of neoadjuvant therapy.
- After surgery, patients will be allowed to receive adjuvant therapy with 4 cycles of platinum-containing chemotherapy followed by up to 2 years of ensartinib, until disease recurrence, intolerable toxicity, death, withdrawal, or investigator decision.
- Primary endpoints: Major pathologic response (MPR, $\leq 10\%$ residual viable tumor). Secondary endpoints: pCR, ORR, DFS, OS, safety (CTCAE v5.0)

DISCUSSION AND CONCLUSION

- In patients with resectable stage II–IIIB ALK+ NSCLC, 8-week neoadjuvant ensartinib achieved an MPR rate of 40% and an R0 resection rate of 100% .The safety profile was consistent with the established toxicity profile of ensartinib; no new safety signals were observed.
- Clinicians can consider ensartinib as a safe and effective neoadjuvant bridge to surgery in this molecular subset.
- Mature DFS and OS data from NEOEAST will define the long-term survival benefit of this neoadjuvant approach.
- Biomarker exploration (e.g., ctDNA clearance, tumor microenvironment) is warranted to identify patients most likely to achieve pCR or MPR.
- Potential combination strategies in neoadjuvant setting.

REFERENCES & ACKNOWLEDGEMENTS

1. Reyes R, et al. Transl Lung Cancer Res 2021;10(1):607-621.
2. Blumenthal GM, et al. J Thorac Oncol 2018; 13(12):1818-1831.
3. Chia PL, et al. Clin Epidemiol 2014;6:423-432.
4. Wang B, et al. Sci Rep 2023;13(1):8317.
5. Horn L, et al. JAMA Oncol 2021;7(11):1617-1625.
6. Yang Y, et al. Lancet Respir Med 2020;8(1):45-53.

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RESULTS

- As of July 2026, a total of 10 patients with ALK+ NSCLC were enrolled. The median age was 58.5 years (range, 34–69). 10 patients have undergone surgical resection, and all patients (100%) achieved R0 resection. The MPR and pCR rates were 40.0% (4/10) and 10.0% (1/10), respectively.
- Radiographic assessment revealed no complete responses; however, 9 patients achieved a partial response, yielding an ORR of 90% (9/10).
- Treatment-related adverse events (AEs) occurred in 10 patients (100%),most adverse events were grade 1 or 2 in severity, only one patient (10%) experienced grade ≥ 3 transaminase elevation.

Table 1. Baseline Characteristics

Characteristics	All patients (n=10)
Median age (range), years	58.5 (34, 69)
Sex-male/female, n (%)	3 (30.0%) / 7 (70.0%)
ECOG PS, n (%)	
0/1	10 (100.0%)/0
Smoking status, n (%)	
Never/Former/Current	7 (70.0%) / 3(30.0%) / 0
Baseline clinical stage, n (%)	
IIB/IIIA	3 (30.0%) / 7 (70.0%)

Table 2. Antitumor Activity in Efficacy Analysis Set

Pathological assessment	Surgery population ,n=10(%)
R0 resection	10 (100%)
Major pathologic response (MPR)	4 (40.0%)
Pathologic complete response (pCR)	1 (10.0%)
Radiological assessment	Neoadjuvant population ,n=10(%)
Complete response (CR)	0
Partial response (PR)	9 (90.0%)
Stable disease (SD)	1 (10.0%)
Progressed disease (PD)	0
Objective response rate (CR+PR)	9 (90.0%; 55.5%-99.7%)
Disease control rate (CR+PR+SD)	10 (100%; 69.2%-100%)

Figure 1. Pathological response

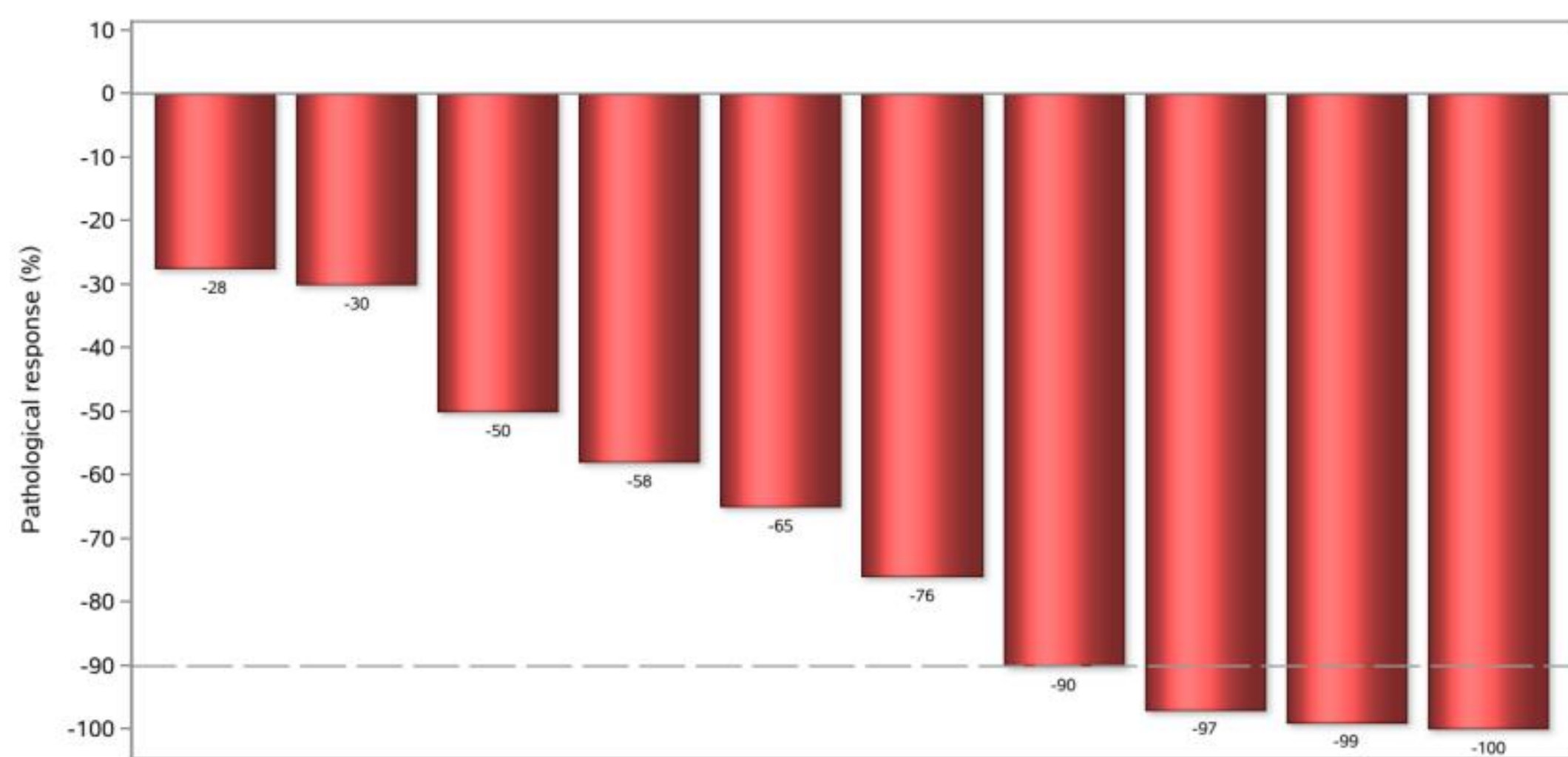


Figure 2. Radiological response

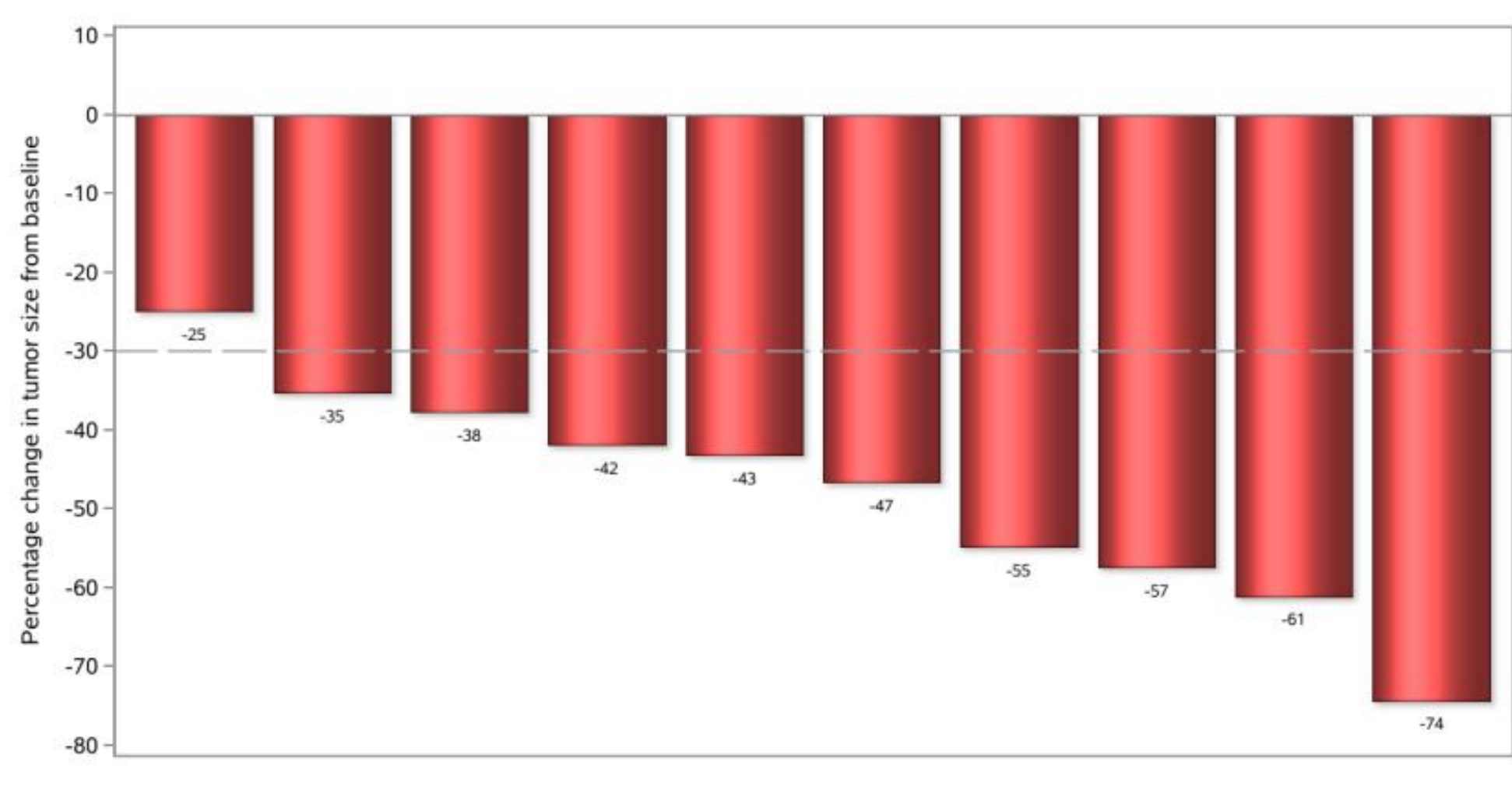


Table3 . Adverse Events in Safety Analysis Set (n=10)

Events, n (%)	Any grade	Grade 1-2	Grade 3
Any TRAEs	10 (100%)	9 (90%)	1 (10%)
Rash	8(80%)	8 (80.0%)	0
Transaminases increased	7 (70.0%)	6 (60.0)	1 (10%)
Edema	1 (10.0%)	1 (10.0%)	0
Diarrhoea	1 (10.0%)	1 (10.0%)	0
Fatigue	1 (10.0%)	1(10.0%)	0
Constipation	1 (10.0%)	1 (10.0%)	0