



EP12.12: First-line oral vinorelbine plus furmonertinib in refractory EGFR-mutated NSCLC: safety run-in data from a two-cohort study

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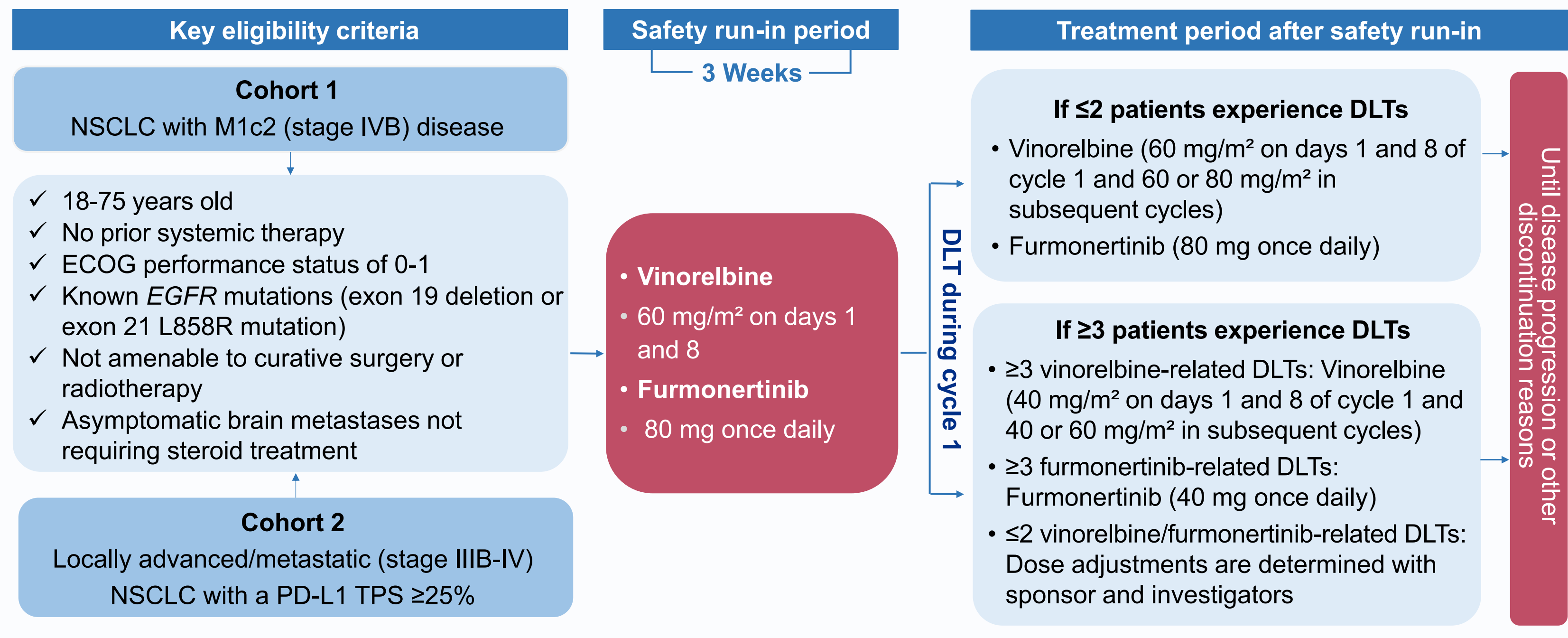
INTRODUCTION

- For patients with *EGFR*-mutated advanced or metastatic NSCLC, third-generation *EGFR*-TKI monotherapy is the standard first-line treatment¹⁻⁴.
- However, acquired resistance inevitably develops after a median PFS of 19-22 months¹⁻⁶.
- Although combinations of *EGFR*-TKIs with chemotherapy or amivantamab significantly improve both PFS and OS versus *EGFR*-TKI monotherapy, their clinical applicability is limited by increased toxicity and the requirement for intravenous administration⁷⁻¹⁰.
- The presence of M1c2 disease or elevated PD-L1 ($\geq 25\%$) expression is associated with poorer prognosis, highlighting the need for more effective combination strategies in this refractory subgroup¹¹⁻¹³.
- In this context, this prospective, two-cohort study was conducted to evaluate a first-line all-oral regimen of vinorelbine plus furmonertinib (a third-generation *EGFR*-TKI) in *EGFR*-mutated locally advanced or metastatic NSCLC with M1c2 disease or elevated PD-L1 expression.
- Only clinical outcomes from the safety run-in period were reported here.

METHODS

- In this open-label, non-randomized, two-cohort study (ChiCTR2500111096), systematic treatment-naïve patients with histopathology confirmed locally advanced or metastatic NSCLC harboring *EGFR* mutations (exon 19 deletion and exon 21 L858R mutation) were enrolled from two centers in China.
- Cohort 1 included patients with M1c2 disease and Cohort 2 included those with a PD-L1 tumor proportion score of $\geq 25\%$.
- The study began with a 3-week safety run-in period, in which 6 patients receive oral vinorelbine (60 mg/m² on days 1 and 8) plus furmonertinib (80 mg once daily) as the starting dose.
- Dosing regimen for subsequent expansion cohort was determined based on DLT observed during the safety run-in period. The primary endpoint was investigator-assessed PFS.

Figure 1. Study design



RESULTS

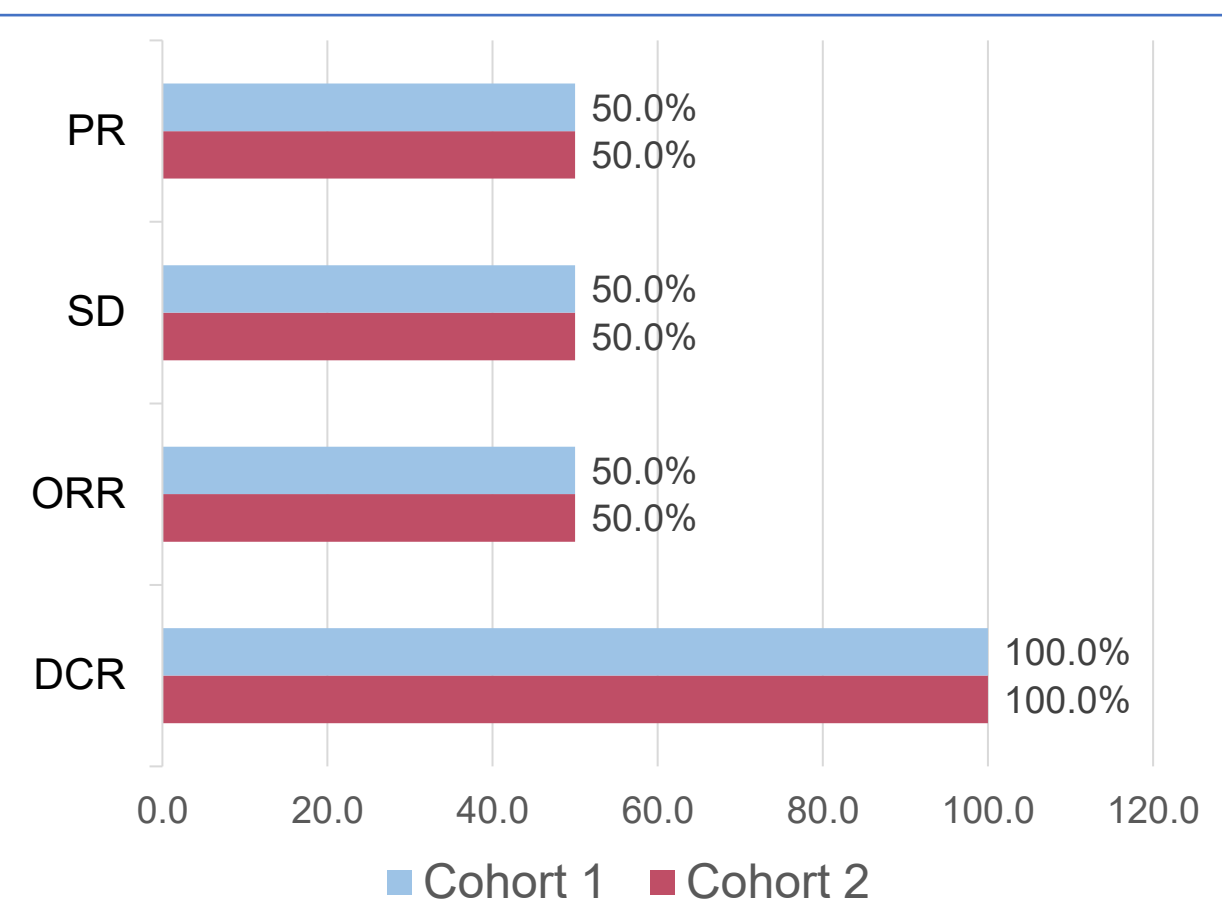
Patient characteristics and efficacy

- Between December 12, 2025, and January 27, 2026, 6 patients (4 in Cohort 1 and 2 in Cohort 2) were enrolled in the safety run-in period.
- No patients experienced DLTs during the safety run-in period.
- During treatment period, 3 (50.0%) of 6 patients achieved PR and 3 (50.0%) had a SD as the best response.
- The ORR and DCR were 50.0% (95% CI, 11.8-88.2) and 100.0% (95% CI, 54.1-100.0), respectively.

Table 1. Patient characteristics

Characteristics	Total (n=6)
Median age, year (range)	60.5 (43-63)
Sex, n (%)	
Male	4 (66.7)
Female	2 (33.3)
ECOG performance status score, n (%)	
0	0
1	6 (100.0)
Ethnicity, n (%)	
Han	6 (100.0)
Smoking history, n (%)	
Never	4 (66.7)
Former	2 (33.3)

Figure 2. Tumor response



Safety

- TRAEs of any grade were reported in 83.3% (5/6) of patients. The most common TRAEs were diarrhea (66.7%), white-cell count decreased (50.0%), anemia (50.0%), and electrocardiogram QT prolonged (50.0%).
- No patients experienced grade ≥ 3 TRAEs or treatment-related death.
- The safety profile of vinorelbine plus furmonertinib was consistent with the individual agents, with no new safety signals identified.

Table 2. TRAE occurring in $>20\%$ of patients

Adverse events, n (%)	Any grade	Grade ≥ 3
Haematological events		
White-cell count decreased	3 (50.0)	0
Anemia	3 (50.0)	0
Neutrophil count decreased	2 (33.3)	0
Non-haematological events		
Diarrhea	4 (66.7)	0
Electrocardiogram QT prolonged	3 (50.0)	0

CONCLUSION

- The all-oral combination of vinorelbine plus furmonertinib as first-line treatment was well tolerated and showed preliminary antitumor activity in *EGFR*-mutated locally advanced or metastatic NSCLC with M1c2 disease or elevated PD-L1 expression.
- More clinical data will be updated from this ongoing study.

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Abbreviations: CR, complete response; DCR, disease control rate; DLT, dose-limiting toxicity; ECOG, Eastern Cooperative Oncology Group; *EGFR*, epidermal growth factor receptor; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD, progressive disease; PD-L1, programmed death-ligand 1; PFS, progression-free survival; PR, partial response; SD, stable disease; TKI, tyrosine kinase inhibitor; TPS, tumor proportion score; TRAE, treatment-related adverse events.

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