



P1.159: Efficacy and Safety of Sunvozertinib as Adjuvant Treatment in Resected stage IB-IIIB EGFR Exon 20 Insertion mutated NSCLC

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INTRODUCTION

The role of epidermal growth factor receptor (EGFR) exon 20 insertion (exon20ins) mutation-targeted therapy in the adjuvant setting for non-small cell lung cancer (NSCLC) remains unexplored. Sunvozertinib, an oral inhibitor targeting EGFR exon20ins, has shown promising antitumor efficacy in patients with advanced NSCLC^[1]. This study aims to evaluate the efficacy and safety of sunvozertinib as adjuvant therapy in patients with completely resected stage IB-IIIB NSCLC harboring EGFR exon20ins mutation.

METHODS

Design: phase II, single-arm, prospective study

This phase II, single-arm, prospective study (Registration number: ChiCTR2400094167) was designed to enroll 25 patients with pathologically confirmed, completely resected stage IB (with high-risk factors) to IIIB NSCLC harboring EGFR exon20ins mutation. Following optional investigator-determined adjuvant chemotherapy, all enrolled patients received adjuvant sunvozertinib for 3 years. The initial sunvozertinib dose of 300 mg once daily was amended to 200 mg once daily based on treatment-related adverse events (TRAEs) and evidence from WU-KONG1B study^[2]. The primary endpoint is the 3-year disease-free survival (DFS) rate. Secondary endpoints include DFS, overall survival and safety.

DISCUSSION AND CONCLUSION

Actionable Take Away Message

- Preliminary results indicate that adjuvant sunvozertinib therapy demonstrated a promising efficacy and manageable safety in patients with completely resected EGFR exon20ins-mutant NSCLC. The long-term survival benefits still require final assessment upon completion of patient enrollment and with longer-term follow-up.

Future Direction for Research

- This study provides preliminary evidence to support the exploration of postoperative adjuvant targeted therapy for this specific patient population.

REFERENCES & ACKNOWLEDGEMENTS

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Artificial Intelligence (AI) Use Disclaimer

No artificial-intelligence-based tools were utilized in the development, drafting or revision of this manuscript. All content, data analysis, interpretation and conclusions were independently completed by the authors.

RESULTS

As of March 20, 2026, a total of 21 eligible patients had been enrolled. The median age was 62 years, and 66.7% (14/21) of the patients were male. Visceral pleural invasion, spread through air spaces, and lymphovascular invasion were observed in 5 (23.8%), 17 (81.0%), and 9 (42.9%) patients, respectively. The distribution of pathological stages were as follows: high-risk stage IB (28.6%, 6/21), stage II (28.6%, 6/21), and stage III (42.9%, 9/21). All patients with stage II to IIIA disease and two patients with stage IB disease (33.3%, 2/6) received adjuvant platinum-based chemotherapy. After a median follow-up of 13.6 months, no deaths were observed. TRAEs of any grade occurred in 100% of patients; grade 3 TRAEs occurred in 33.3% (7/21) of patients, and no grade >3 TRAEs were observed. The most common grade 3 TRAEs included blood creatine phosphokinase increased, decreased appetite, paronychia, diarrhea, etc. Discontinuation of the trial regimen owing to adverse events occurred in 3 (14.3%) patients; one of whom experienced disease relapse one month after discontinuation. No new safety signals occurred and most adverse events can be controlled with symptomatic treatment or dosage adjustment.

