



P2.336: Organ Preservation Exploratory Clinical Study in Stage II-III Non-Small Cell Lung Cancer (the Future Star)

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INTRODUCTION

- Surgical resection remains the primary treatment for locally advanced (stage II-III) non-small cell lung cancer (NSCLC).
- For early-stage patients who are unfit for surgery, radical radiotherapy is the standard of care, offering advantages such as preservation of lung function, avoidance of surgical trauma, and reduced perioperative risks and long-term impact on quality of life.
- This study aims to explore the feasibility of radiotherapy as an alternative to surgery in patients with stage II-III NSCLC who achieve >80% tumor regression following neoadjuvant therapy, as assessed by imaging.
- Almonertinib, a tyrosine kinase inhibitor of the epidermal growth factor receptor (EGFR-TKI), received approval from the National Medical Products Administration (NMPA) in 2025 for use as postoperative adjuvant therapy in patients with stage II-IIIB NSCLC^[1].
- In November 2025, the NMPA accepted the marketing authorization application for ensartinib, an ALK inhibitor, for use as postoperative adjuvant therapy in patients with anaplastic lymphoma kinase (ALK)-positive NSCLC at stages IB to IIIB^[2].
- Adebrelimab, a programmed death-ligand 1 (PD-L1) inhibitor, is indicated for use in neoadjuvant and adjuvant treatment settings for patients with resectable non-small cell lung cancer (NSCLC) at stages II to IIIB^[3].

Table 1. Study Objectives

Primary Endpoint

Event-Free Survival (EFS) per Investigator (INV)

Secondary Endpoints

- Overall Survival
- Quality of Life Score
- Organ Preservation Rate
- pathologic Complete Response (pCR) and Major Pathologic Response (MPR) per INV
- Safety

Exploratory Endpoints

Exploratory analysis of potential biomarkers in peripheral blood using ctDNA detection

REFERENCES & ACKNOWLEDGEMENTS

References:

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Artificial Intelligence (AI) Use Disclaimer

DeepSeek was utilized as a language polishing tool for the English writing throughout the preparation of this abstract.

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METHODS

This is a multicenter, prospective, open-label, randomized controlled trial.

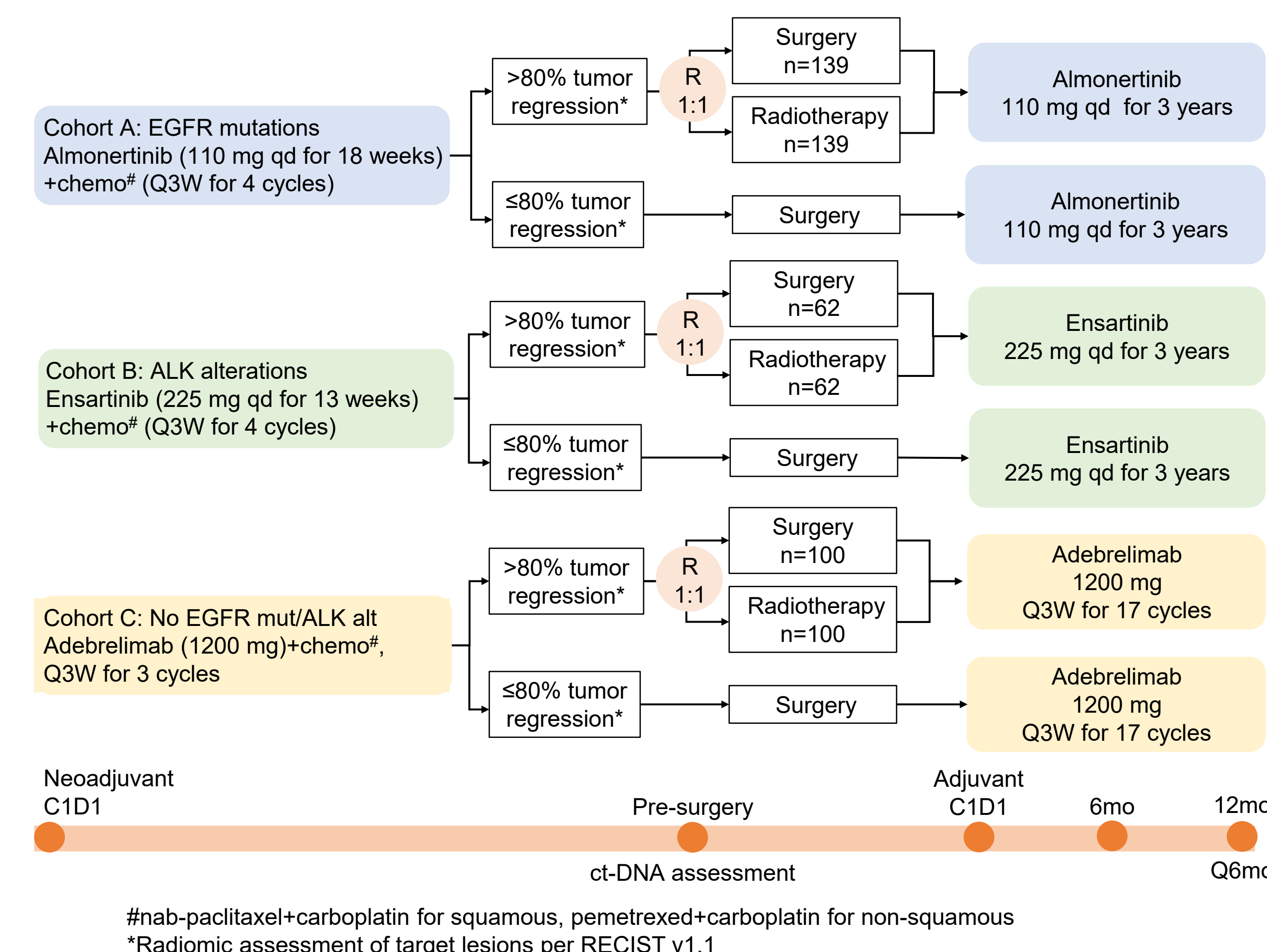


Table 2. Key Eligibility Criteria

Inclusion Criteria

- Age 18~75 years.
- Histologically or cytologically documented.
- Resectable stage II-III (IIIA/T3N2M0 IIIB) per AJCC v8.
- Confirmation by the central laboratory: Cohort A, the tumor harbors one of the 2 common EGFR mutations known to be associated with EGFR-TKI sensitivity (Ex19del, L858R), either alone or in combination with other EGFR mutations including T790M; Cohort B, the tumour harbours ALK positive; Cohort C, no EGFR mutations or ALK alterations, test PD-L1 expression.
- Measurable disease as defined by RECIST v1.1.
- ECOG PS of 0 or 1.
- No prior systemic anti-cancer treatment.
- Adequate bone marrow reserve and organ function.

Exclusion Criteria

- Major surgery (including primary tumor surgery, excluding placement of vascular access) within 3 weeks of the first dose of study drug.
- Any previous systematic anti-cancer therapy for lung cancer.
- Has or suspected has a history of pneumonitis /interstitial lung disease or any severe lung diseases which will influence the examination of lung function.
- Patients currently receiving medications or herbal supplements known to be strong inducers and inhibitors of cytochrome P450 (CYP) 3A4.
- Any evidence of severe or uncontrolled systemic diseases (including uncontrolled hypertension and active bleeding diatheses) or active infection (including hepatitis B, hepatitis C, and human immunodeficiency virus (HIV)).