

P2.375: Neoadjuvant Sacituzumab Tirumotecan Plus Aumolertinib in Resectable EGFR-Mutant NSCLC: A Phase II Trial

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BACKGROUND

For resectable EGFR-mutant non-small cell lung cancer (NSCLC), neoadjuvant therapy plays a crucial role in improving surgical outcomes and reducing recurrence risk. The NeoADAURA study demonstrated that neoadjuvant third-generation EGFR-TKI therapy achieved a major pathological response (MPR) rate of 25%-26%, yet the pathological complete response (pCR) rate remained below 10%, indicating an unmet clinical need. Sacituzumab tirumotecan, a TROP2 antibody-drug conjugate (ADC), has shown promising efficacy in EGFR-TKI-resistant advanced NSCLC. The combination of EGFR-TKI and ADC theoretically offers synergistic antitumor activity through dual-target inhibition. This study aims to evaluate the efficacy and safety of Sacituzumab tirumotecan combined with aumolertinib as neoadjuvant therapy for stage II-IIIa EGFR-mutant NSCLC.

STUDY DESIGN

This multicenter, single-arm, phase II trial plans to enroll 64 patients with treatment-naïve, stage II-IIIa (AJCC 9th) EGFRm (19del/L858R) NSCLC, with an Eastern Cooperative Oncology Group performance status (ECOG PS) of 0-1. The treatment schema includes: 1) Neoadjuvant phase: Sacituzumab tirumotecan 4 mg/kg intravenously on days 1 and 15 of each cycle (q2w×4 cycles) combined with aumolertinib 110 mg orally once daily (for ≥9 weeks); 2) Surgery: radical resection within 4-6 weeks after completion of Sacituzumab tirumotecan neoadjuvant therapy; 3) Adjuvant phase: Aumolertinib 110 mg orally once daily for 3 years or until disease recurrence or other discontinuation criteria are met. The primary endpoint is MPR rate, defined as ≤10% residual viable tumor cells in the primary tumor bed, regardless of the presence of viable tumor cells in lymph nodes. Secondary endpoints include pCR rate, 3-year disease-free survival (DFS) rate, 3-year overall survival (OS) rate, DFS, OS, safety, and quality of life (QoL). Exploratory analyses will assess the correlation between ctDNA dynamics (before neoadjuvant therapy, after neoadjuvant therapy, and post-surgery) with pathological response and long-term outcomes. The sample size calculation is based on a one-sided α of 0.05 and 80% power, assuming a historical control MPR rate of 25% (NeoADAURA) and an expected MPR rate of 40% in the experimental group. Accounting for a 10% dropout rate, a total of 64 patients will be enrolled.

