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Abstract CT126: Aumolertinib as adjuvant therapy in patients with stage II-IIIB EGFR-mutated NSCLC after complete tumor resection: A randomized, double-blind, placebo-controlled, phase 3 trial (ARTS) FREE

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Abstract

Background:

Lung cancer is the primary cause of cancer-related morbidity and mortality globally. Approximately 30% of patients with EGFR mutation (EGFRm) in NSCLC are diagnosed at an early stage and are candidates for curative-intent surgical resection; however, disease recurrence remains a substantial clinical challenge. Aumolertinib is a third-generation EGFR TKI that potently inhibits both sensitizing EGFR mutations (ex19del/L858R) and the resistance mutation T790M. ARTS (NCT04687241) is a randomized, double-blind, placebo-controlled, multicenter, phase 3 trial designed to evaluate the efficacy and safety of adjuvant aumolertinib versus placebo in patients with stage II-IIIB EGFRm NSCLC after complete resection, with or without adjuvant chemotherapy.

Methods:

Inclusion criteria included patients aged ≥18 years, ECOG PS 0-1, primary non-squamous stage II/IIIA/IIIB (T3N2M0) NSCLC, confirmed EGFRm (ex19del or L858R), complete resection with full postsurgical recovery, with or without postoperative adjuvant chemotherapy. Patients were randomized in a 1:1 ratio to receive aumolertinib (110 mg orally, once daily) or matched placebo for a planned treatment duration of 3 years. Stratification was based on stage (II, IIIA N2-, IIIA/B N2+) and mutation type (ex19del, L858R). The primary endpoint was disease-free survival (DFS), assessed by blinded independent central review (BICR). Secondary endpoints included

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investigator-assessed DFS, overall survival (OS), and safety profile. Data cutoff (DCO): April 15, 2024.

Results:

A total of 214 patients from China were randomized to treatment (Aumolertinib n=107, Placebo n=107). Baseline characteristics were balanced across treatment arms (aumolertinib/placebo): female 55.1%/57.0%, ever-smokers 28.0%/29.9%, stage II 44.9%/44.9%, stage III 54.2%/52.3%, ex19del 47.7%/50.5%, L858R 52.3%/49.5%, ECOG PS 0 36.4%/41.1%, ECOG PS 1 63.6%/58.9%. Median follow-up for DFS was 27.6 months. The mDFS assessed by BICR was not reached (95% CI, 29.1 to NA) in the aumolertinib arm versus 19.4 months (95% CI, 11.2 to 26.2) in the placebo arm; hazard ratio (HR) 0.166 (95% CI, 0.094 to 0.294); p<0.0001. The 2-year DFS rate was 88.2% in the aumolertinib arm versus 40.6% in the placebo arm. Investigator-assessed DFS was concordant with BICR assessment. OS data were immature at DCO (aumolertinib/placebo OS maturity: 2.8%/3.8%). The incidence of AEs leading to dose interruptions, dose reductions, and discontinuation in the aumolertinib/ placebo arm was 12.3%/ 17.8%, 9.4%/ 1.9%, and 0.9%/ 0, respectively. No new safety risks were observed.

Conclusions:

Adjuvant aumolertinib demonstrates a statistically significant and clinically meaningful improvement in DFS in patients with stage II-IIIB EGFRm NSCLC following complete tumor resection and adjuvant chemotherapy, when indicated. This DFS benefit underscores the promise of aumolertinib in fulfilling an unmet need for effective adjuvant EGFR-targeted therapy in early-stage NSCLC.

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