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Abstract CT053: Aumolertinib with or without chemotherapy as first line treatment in locally advanced or metastatic NSCLC with sensitizing EGFR mutations (AENEAS2) FREE

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Abstract

Introduction:

Aumolertinib, a third generation selective EGFR-TKI, is standard of care for the first-line treatment in advanced or metastatic NSCLC with sensitizing EGFR mutations in China. Evidence has shown that combining EGFR-TKIs with chemotherapy can improve outcomes compared to EGFR-TKIs monotherapy. AENEAS2 (NCT04923906) is a randomized, open-label, multicenter, phase 3 study assessing the efficacy and safety of aumolertinib plus chemotherapy versus aumolertinib alone as first-line treatment in locally advanced or metastatic NSCLC with sensitizing EGFR mutations.

Methods:

Patients who were naïve to treatment with locally advanced or metastatic NSCLC harboring EGFR mutations (exon 19 deletion or L858R mutation) were randomly assigned in a 1:1 ratio to receive aumolertinib 110 mg QD in combination with pemetrexed (500 mg/m^2) plus cisplatin (75 mg/m^2) or carboplatin (AUC5), versus to receive aumolertinib 110 mg QD monotherapy. The primary endpoint is progression free survival (PFS) assessed by IRC (Independent Review Committee) per RECIST v1.1. Data cutoff date: 2024/06/18.

Results:

A total of 624 patients were randomized to aumolertinib plus chemotherapy (n=310) or aumolertinib monotherapy (n=314) and stratified according to EGFR mutation status (Ex19del verse L858R) and CNS metastases at baseline (yes versus no). Baseline characteristics were balanced between treatment arms (aumolertinib plus chemotherapy versus aumolertinib): median age (range), 58.0 (30-84)/59.0 (31-81) years; 55.5/52.5 % female; 49.0/49.0% Ex19del; 51.0/51.0% L858R; 30.0/30.9% CNS metastases. Median follow-up was 23.4 months. Median PFS assessed by IRC was 28.9 months (95% CI, 26.3 to NA) in combination arm versus 18.9 months (95% CI, 17.8 to 21.1) in monotherapy arm; hazard ratio (HR) 0.471 (95% CI, 0.371 to 0.598; p<0.0001). The PFS benefit was consistent across pre-defined subgroups. The overall survival (OS) was immature with event-patient rate 21.6%; HR 0.442 (95% CI, 0.308 to 0.636; p<0.0001). Median cycles of pemetrexed exposure (range) were 20.0 (1-42) cycles, 88.8% of patients completed 4~6 cycles of platinum therapy. All causality grade ≥3 AEs (aumolertinib plus chemotherapy versus aumolertinib): 75.7%/23.7%; AEs leading to discontinuation of aumolertinib: 3.0%/1.3%. The safety profile of aumolertinib plus pemetrexed and platinum was consistent with the established profiles of the individual agent.

Conclusion:

Aumolertinib plus chemotherapy as a first-line treatment in advanced EGFR-mutant NSCLC demonstrated a statistically significant and clinically meaningful PFS improvement over aumoletinib monotherapy, with a manageable safety profile.

Citation Format:

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