Aumolertinib as Adjuvant Therapy in Postoperative EGFR-Mutated Non–Small-Cell Lung Cancer

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Introduction

Aumolertinib (HS-10296) is a novel, promising oral third-generation Epidermal Growth Factor Receptor (EGFR) tyrosine kinase inhibitor (TKI), which has demonstrated efficacy in tumours harbouring sensitive EGFR mutations and T790M resistance mutation. Aumolertinib also has been shown to be efficacy in CNS metastasis. However, the efficacy and safety of aumolertinib as adjuvant therapy in postoperative patients remain unknown.

Methods

Patients who underwent radical lung cancer surgery with EGFR-sensitizing mutations were enrolled and received aumolertinib 110 mg daily, the medication time (6months-36months) depended on pathology stage and physical conditions. The disease-free survival (DFS), safety and tolerability were evaluated.

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Results

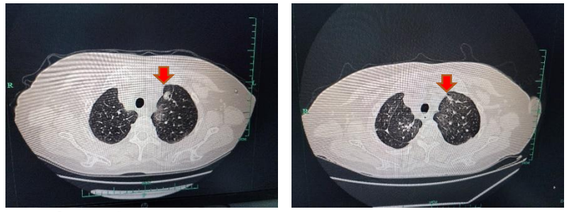
The study analyzed 66 patients with pathologically confirmed adenocarcinoma, EGFR mutation positive (exon 19 deletion or L858R), stage I–III NSCLC. At the data cutoff, all patients have no symptoms of tumor recurrence, 25(37.9%) patients have been followed up for over 1 year. At 12 months, 100% patients were alive and disease-free. None of these patients have central nervous system disease. During aumolertinib therapy, 34.8% of patients had adverse treatment-related adverse events of any grade, there was no grade ≥3 adverse events occurred(Table 1). Aumolertinib was also effective in multiple primary lung cancer. (Figure 1)

Table 1: Adverse events possibly causally-related to treatment

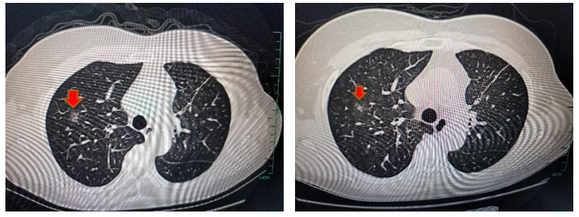
AE, n (%)	Total (n=66)	
	Any grade	Grade ≥3
Any AEs	23 (34.8)	0(0)
Rash	15 (22.7)	0(0)
Oral ulcer	7 (10.6)	0(0)
Diarrhea	5 (7.6)	0(0)

Figure 1: CT changes of lesions when aumolertinib was effective on patients.

Patient 1



Patient 2



Conclusions

This is the first study to demonstrate that aumolertinib has preliminary efficacy and a tolerable safety profile in patients with completely resected stage Ⅰ-Ⅲ NSCLC harboring EGFR mutations. This study is still in progress and further analyses are undergoing to determine longer-term outcomes.