

Aumolertinib: Adis Evaluation

Clinical Considerations

- Oral third-generation EGFR-TKI developed in China for the treatment of advanced EGFR mutation-positive NSCLC
- Selective for mutant over wild-type EGFR; high inhibitory activity against common EGFR sensitizing mutations and T790M resistance mutation
- Prolongs PFS and DoR relative to gefitinib as first-line treatment; good clinical activity (based on objective response rate, PFS, DoR and OS) as second-line treatment
- Tolerability profile similar to other EGFR-TKIs

Plain Language Summary

Background and rationale

- Non-small cell lung cancer (NSCLC), the most common type of lung cancer, is associated with a poor prognosis. In up to 50% of Asian patients and ≈ 17% of Caucasian patients with NSCLC, specific mutations in the epidermal growth factor receptor (EGFR) gene are responsible for tumour growth.
- Drugs that block the effects of EGFR [EGFR tyrosine kinase inhibitors (EGFR-TKIs)] improve survival in patients with NSCLC and EGFR mutations. Aumolertinib (Ameile®) is a third-generation EGFR-TKI that has been developed in China.

Clinical findings

- In previously untreated, advanced EGFR mutation-positive NSCLC, cancer progression was delayed by ≈ 9 months compared with the first-generation EGFR-TKI gefitinib.
- Good clinical activity as a second-line treatment in advanced EGFR mutation-positive NSCLC with resistance to earlier-generation EGFR-TKIs.
- Generally manageable tolerability profile; adverse events associated with wild-type EGFR inhibition (e.g. rash and diarrhoea) were less frequent than with gefitinib.

Conclusion

A promising new first- or second-line treatment option in advanced EGFR mutation-positive NSCLC

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