



Poster #: P2.309: Efficacy and Safety of Different Dosing Regimens of Befotertinib in EGFR-mutant NSCLC Patients With Brain Metastases

Huijuan Wang¹, Xiaojuan Zhang¹, Ke Shang², Jing Wang³, Hong Lu⁴, Yinghua Ji⁵, Yong Liu⁶

¹Henan Cancer Hospital, Zhengzhou, China, ²Xinyang Central Hospital, Xinyang, China, ³The Affiliated Hospital of Qingdao University, Qingdao, China, ⁴Huaihe Hospital of Henan University, Kaifeng, China, ⁵The First Affiliated Hospital of Xinxiang Medical University, Xinxiang, China, ⁶Zhoukou Central Hospital, Zhoukou, China
Correspondence: Huijuan Wang, 18638561588@163.com



INTRODUCTION

Non-small cell lung cancer (NSCLC) accounts for 85% of lung cancer cases. Epidermal growth factor receptor (EGFR) mutations are the most common mutations in advanced NSCLC among Asian populations, with an incidence of 30% to 50%. EGFR-tyrosine kinase inhibitors (EGFR-TKIs) have demonstrated significant efficacy in EGFR-mutant NSCLC and have become the standard first-line treatment. Brain metastases (BM) occur in 10%-20% of NSCLC patients and are associated with poorer quality of life (QoL) and unfavorable prognosis. Befotertinib is a third-generation TKI targeting classic EGFR mutations, which has been approved for first-line treatment of advanced NSCLC with sensitive EGFR mutations. This study aims to evaluate the efficacy and safety of different dosing regimens of befotertinib in EGFR-mutant NSCLC with brain metastases.

KEYWORDS

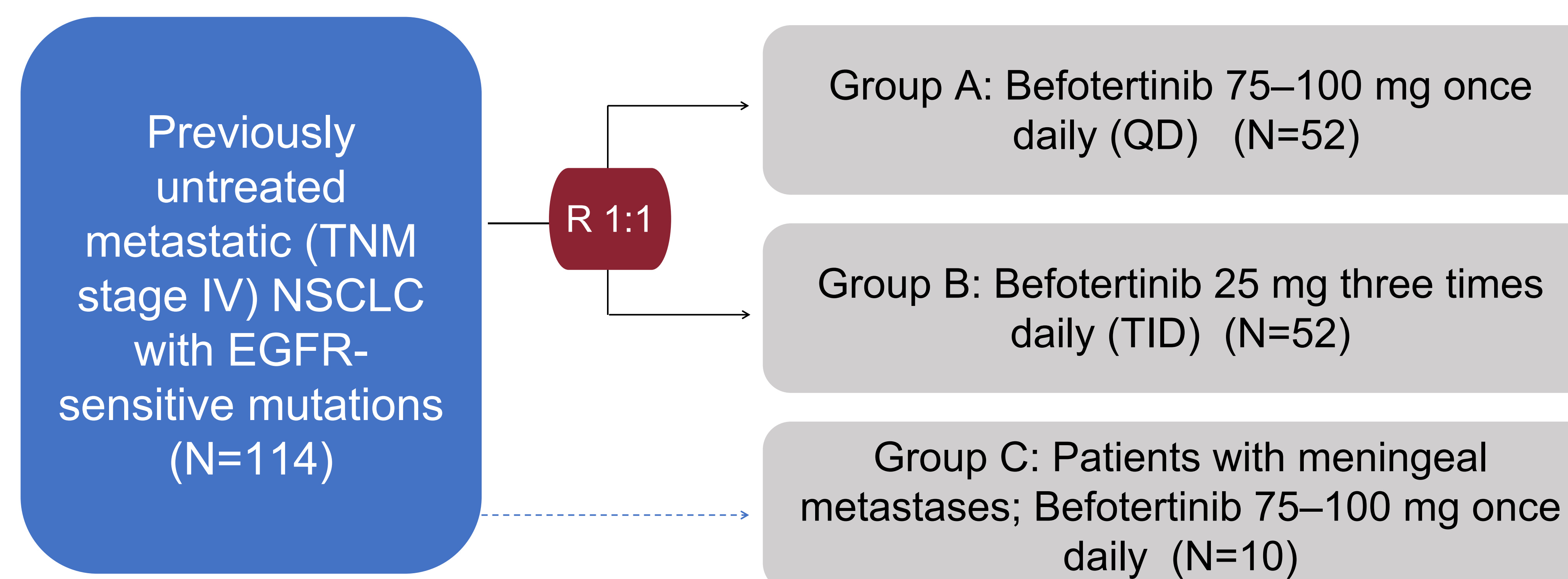
EGFR-mutant NSCLC;
Brain Metastases; Befotertinib

METHODS

This study comprises two patient cohorts: one with brain metastases (BM) and one with leptomeningeal metastases (LM).

- The BM cohort is designed as a randomized, open-label, multicenter clinical trial, while the LM cohort is a single-arm study. For the BM cohort, patients with stage IV EGFR-mutant NSCLC and brain metastases will be randomized into two groups. One group receives befotertinib 75-100 mg once daily (QD), and the other receives befotertinib 25 mg three times daily (TID). Treatment continues until disease progression. Each group plans to enroll 52 patients.
- The primary endpoint is progression-free survival (PFS). Secondary endpoints include intracranial PFS (iPFS), overall survival (OS), objective response rate (ORR), intracranial ORR (iORR), and safety assessments.
- The LM cohort will enroll 10 patients with stage IV EGFR-mutant NSCLC and leptomeningeal metastases. This cohort will evaluate the efficacy and safety of befotertinib 75-100 mg QD.

TRIAL DESIGN



KEY ENDPOINTS

- Primary endpoint: PFS
- Secondary endpoints: iPFS, OS, ORR, iORR, safety

REGISTRATION DETAILS

- Patient enrollment is currently ongoing.
- Clinical Trial Registration Number: ChiCTR2400085346.

REFERENCES & ACKNOWLEDGEMENTS

- Janne PA, Yang JC, Kim DW, et al. AZD9291 in EGFR inhibitor-resistant non-small-cell lung cancer[J]. *N Engl Med*, 2015, 372(18):1689-1699.
- Soria J C, Ohe Y, Vansteenkiste J, et al. Osimertinib in untreated EGFR-mutated advanced non-small-cell lung cancer[J]. *New England Journal of Medicine*, 2018, 378(2):113-125.
- De Carlo E, et al. Brain Metastases Management in Oncogene-Addicted Non-Small Cell Lung Cancer in the Targeted Therapies Era. *Int J Mol Sci*. 2022 Jun 9;23(12):6477.