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Firmonertinib 160 mg as First-Line Treatment for EGFR-Mutated NSCLC with Central Nervous System Metastases: The FAITH Phase 2 Study Cohort 1

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Background & Study Design

- Central nervous system (CNS) metastases in EGFR-mutated non-small cell lung cancer (NSCLC) are associated with poor outcomes, driven in part by the limited blood-brain barrier (BBB) penetration of standard-dose tyrosine kinase inhibitors (TKIs).
- We evaluated whether dose-intensified firmonertinib (160 mg), a highly CNS-penetrant third-generation TKI, could improve intracranial control as first-line therapy. Our real-world retrospective analyse has indicated the excellent CNS efficacy of high-dose firmonertinib (160mg) as first-line therapy in advanced NSCLC patients with EGFR mutations and CNS metastases (X. Li. et al.2023 WCLC).

Key Inclusion Criteria

- 18-75 years old
- Locally advanced or metastatic non-small-cell lung cancer (NSCLC)
- EGFR exon 19 deletion or L858R mutation, and other uncommon mutations
- No prior systemic therapy
- At least one measurable (≥ 10 mm) or evaluable (≥ 5 mm) intracranial lesion
- ECOG PS 0-3

N=42

Firmonertinib
160 mg QD

Continued until
PD, toxicity, or
consent
withdrawal

- **Primary endpoint:** iPFS
- **Secondary endpoint:** iORR, iDCR, PFS, OS, safety
- **Exploratory endpoints:** biomarker analysis

Extracranial lesions Assessed by RECIST 1.1, intracranial lesions assessed by RANO-BM. Tumor assessments were performed every 6–8 weeks until disease progression.
iPFS: intracranial Progression-Free Survival; iORR: intracranial Objective Response Rate; iDCR: intracranial Disease Control Rate; OS: Overall Survival ; QD: once daily

Baseline Characteristics

From Mar 2023 to Dec 2025, 42 patients were enrolled. Data cut-off time was July 17, 2026, median follow-up was 23.3 months.

Baseline Characteristics	n (%), N=42
Age, years	
Median (range)	57.0 (39.0-73.0)
Sex	
Male	20 (47.6)
Female	22 (52.4)
Smoking history	
Yes	13 (31.0)
No	29 (69.0)
ECOG PS	
0-1	32 (76.2)
≥2	10 (23.8)
Histology	
Adenocarcinoma	37 (88.1)
Adenosquamous carcinoma	2 (4.8)
Others	3 (7.1)
EGFR Mutations	
Exon 19 deletion (19DEL) mutation	17 (40.5)
L858R mutation	20 (47.6)
Other Uncommon mutations	5 (11.9)

Baseline Characteristics	n (%), N=42
TP53 Co-mutation	
Wild-type	20 (47.6)
Mutant	21 (50.0)
Unknown	1 (2.4)
Brain Metastases at Baseline	
Oligometastases (1-3 lesions)	26 (61.9)
Multiple metastases (≥4 lesions)	16 (38.1)
Neurological Symptoms, n (%)	
Yes	22 (52.4)
No	20 (47.6)
Prior Intracranial Local Therapy, n (%)	
Yes	21 (50.0)
No	21 (50.0)

Efficacy

Median follow-up was 23.3 months. In cFAS (n=42), the median iPFS was 26.6 months (15.4-NR), the median PFS was 25.0 months (15.4-27.1), ORR was 76.2%, DCR was 95.2%. In cEFR (n=29), iORR was 79.3%, iDCR was 93.1%.

	iPFS	PFS	OS
Median, months	26.6	25.0	Not reached
95% CI	15.4-NR	15.4-27.1	32.7-NR

Response	Intracranial, n (%), N=29	Systemic, n (%), N=42
CR	5 (17.4)	3 (7.1)
PR	18 (62.1)	29 (69.1)
SD	4 (13.8)	8 (19.0)
PD	2 (6.9)	2 (4.8)
NE	/	/
ORR/DCR	23 (79.3)/27 (93.1)	32 (76.2)/40 (95.2)

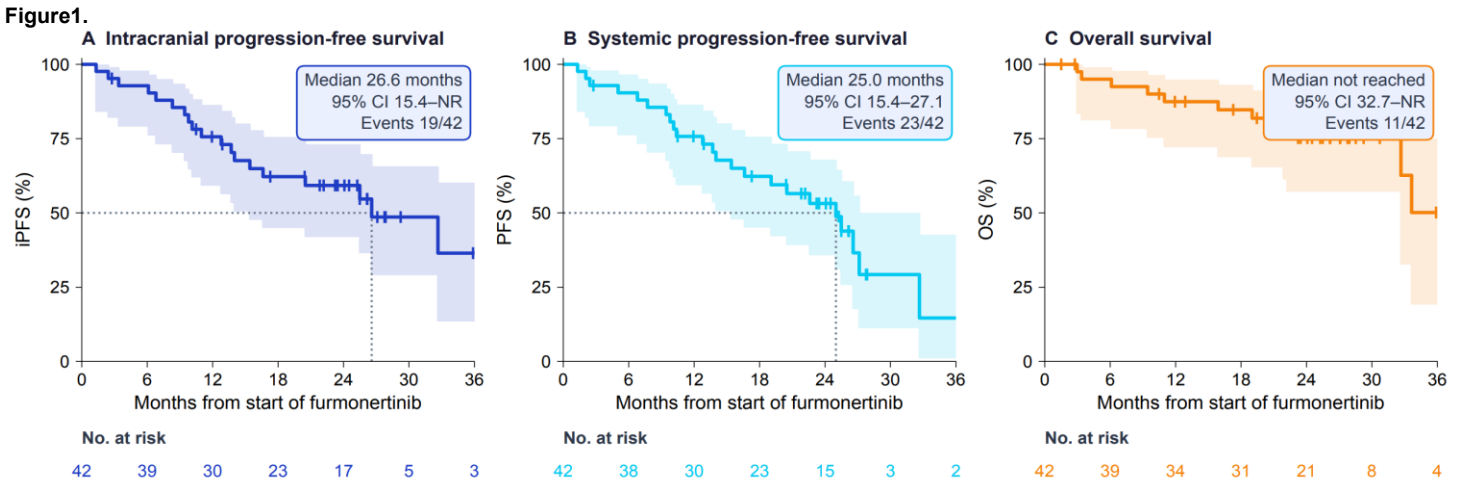
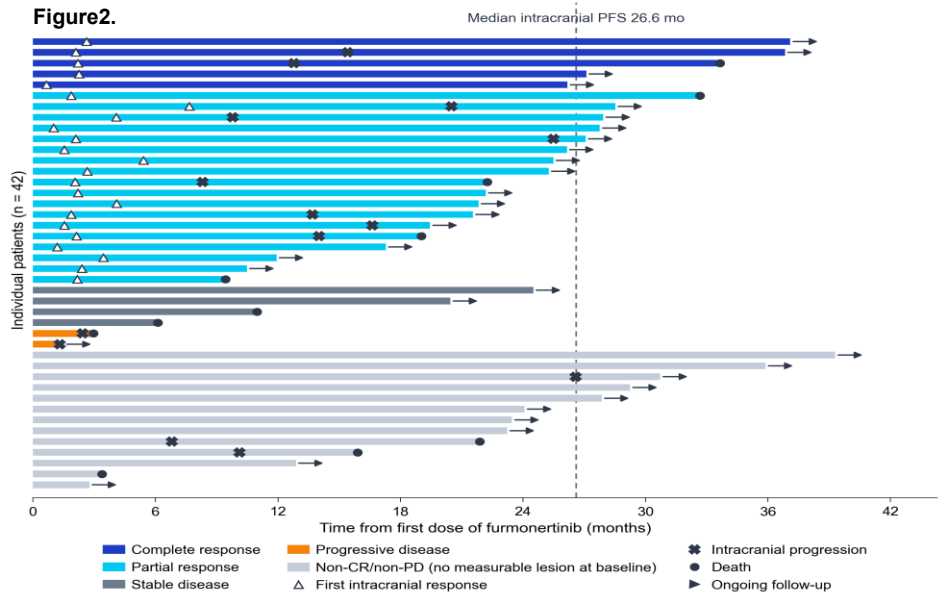


Figure1. Kaplan–Meier estimates of intracranial progression-free survival (A), systemic progression-free survival (B) and overall survival (C) in patients with EGFR-mutant non-small-cell. Tick marks indicate censored observations; shaded areas denote 95% confidence intervals.

Figure2. Individual patient responses and follow-up in patients with EGFR-mutant non-small-cell lung cancer and brain metastases treated with first-line furmonertinib 160 mg (n = 42). Each bar represents one patient, with bar length indicating time from the first dose of furmonertinib to death or last follow-up. Bars are coloured by best intracranial response assessed per RANO-BM and ordered by response category and duration of follow-up. Triangles denote the first documented intracranial response, crosses intracranial progression, and circles death; arrowheads indicate patients still under follow-up at data cut-off.

Patients with measurable and non-measurable CNS lesions at baseline were defined as CNS FAS (cFAS). Patients with measurable CNS lesions at baseline were defined as CNS evaluable for response set (cEFR).



Safety

All 42 patients were included in the safety analysis. TRAEs of any grade were reported in 38 of 42 patients (90.5%). Grade 3 or higher TRAEs occurred in 2 patients (4.8%), with no grade 4 or 5 treatment-related events observed. The most frequent TRAEs of any grade were rash (19 [45.2%]), diarrhea (11 [26.2%]).

AE, n=42	n (%)
Any Grades TRAEs	38 (90.5)
Grade ≥ 3 TRAEs	2 (4.8)
Treatment related death	0 (0)
TRAEs leading to dose discontinuation	1 (2.4)
TRAEs leading to dose interruption / reduction	4 (9.5)

TRAEs, n=42	n (%)
Rash	19 (45.2)
Diarrhea	11 (26.2)
Paronychia	6 (14.3)
Decreased white blood cell count	5 (11.9)
AST increased / ALT increased	5 (11.9)

Abbreviations: ALT=alanine aminotransferase. AST=aspartate aminotransferase. TRAE=treatment-related adverse event. Adverse events graded per CTCAE v5.0. Events occurring in $\geq 10\%$ of patients

Conclusion: Firmonertinib 160 mg as first-line therapy was associated with promising intracranial activity and a manageable safety profile in patients with untreated EGFR-mutant NSCLC and brain metastases.