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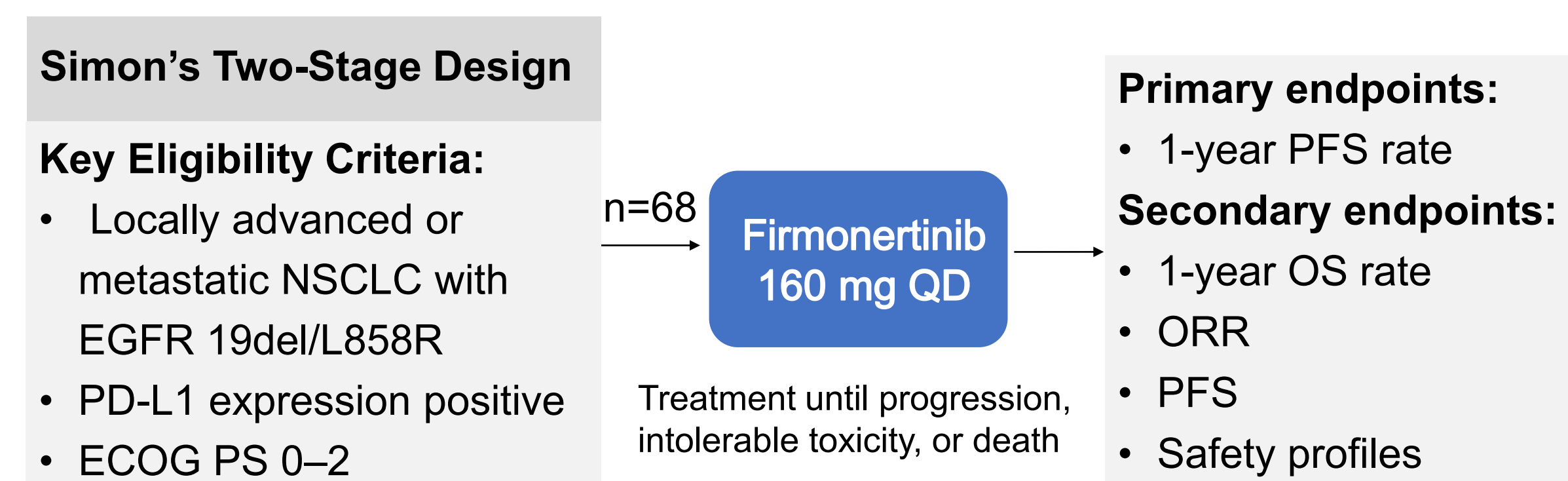
INTRODUCTION

- The ECTOP-1031 (FUTURE) study is a prospective, multicenter phase II trial evaluating firmonertinib (160 mg QD) in locally advanced or metastatic NSCLC with EGFR-sensitizing mutations and PD-L1 expression.
- It employs a Simon's two-stage design. First-stage data were previously presented at WCLC 2025. Here we update the analysis of the second-stage cohort.

METHODS

- In the first stage, 30 patients were enrolled, the objective response rate (ORR) was 86.7%, the disease control rate (DCR) was 96.7%, and the 1-year progression-free survival (PFS) rate reached 73.3%, meeting the primary endpoint of the first stage.
- An additional 32 patients were subsequently enrolled, totaling 62 patients. The trial will be deemed successful if the pooled 1-year PFS rate exceeds 70%. Assuming a 10 % dropout rate, a total of 68 patients will be enrolled.

Design (NCT05255406)



RESULTS

Baseline Characteristics

- At the data cutoff of March 2026, 62 patients were enrolled. Baseline characteristics were shown in *Table 1*.

RESULTS

Table 1 Baseline Characteristics

Baseline Characteristics	N (%)
Age (years)	
Median (range)	57.5 (30-80)
Sex	
Female	31 (50.0)
Male	31 (50.0)
PD-L1 status, %	
Low expression (TPS < 50%)	40 (64.5)
High expression (TPS ≥ 50%)	22 (35.4)
Metastatic sites	
Brain	18 (29.0)
Bone	31 (50.0)
Liver	5 (8.1)
Pleura	17 (27.4)
Adrenal gland	5 (8.1)
EGFR mutation type	
L858R	27 (43.5)
19del	35 (56.5)
ECOG PS	
0	19 (30.6)
1-2	43 (69.4)
Smoking history	
Yes	14 (22.6)
No	48 (77.4)
Stage	
III	8 (12.9)
IV	54 (87.1)

Efficacy

- The median follow-up was 23.7 months (ranging from 2.0 to 48.3 months).
- Investigator-assessed efficacy demonstrated a cORR of 79.0% and a DCR of 93.6%(*Figure 1*).
- The 1-year PFS rate reached 72.4%, with a median PFS (mPFS) of 20.0 months (*Figure 2*).

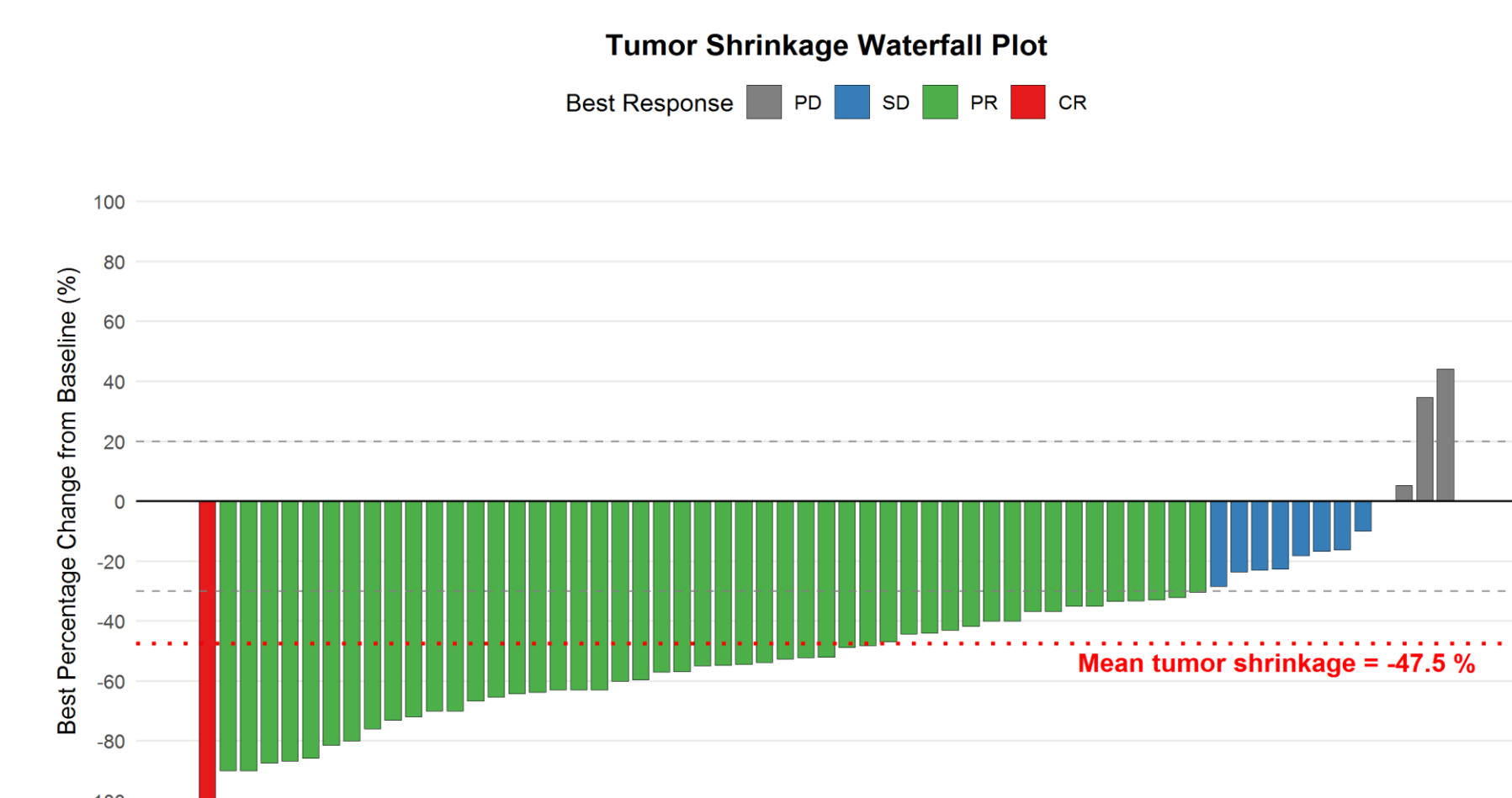


Figure 1 Waterfall plot of best change from baseline

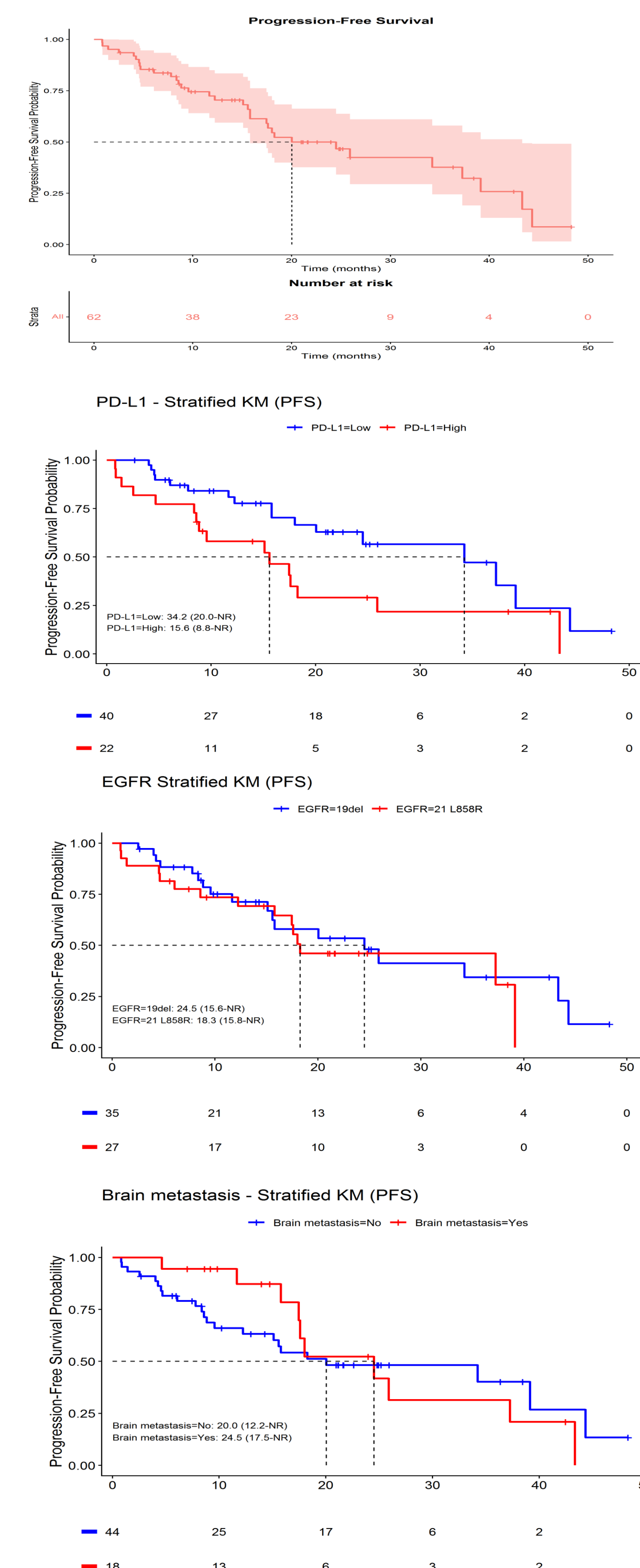


Figure 2 Kaplan-Meier Estimates of PFS

- Patients with high PD-L1 expression (TPS≥50%) had a significantly shorter mPFS (15.6 months) compared to those with low PD-L1 expression (1%≤TPS<50%) (34.2 months, $P=0.035$).
- No significant difference in mPFS was observed between L858R and 19 deletion (18.3 vs 24.5 months, $P = 0.55$), or between patients with and without brain metastases (24.5 vs 20.0 months, $P = 0.83$) (*Figure 2*).

Safety

- The incidence of all-grades TRAEs was 46.8%. Grade≥3 TRAEs were observed in 4.8% of patients (*Table 2*).
- One patient experienced an SAE (1.6%).
- Dose interruption and dose reduction occurred in 1.6% and 11.3% of patients, respectively.

Table 2 Treatment Related Adverse Events(TRAEs)*

TRAEs, n (%)	N=62	
	All grades	Grade ≥3
Rash	8 (12.9)	0 (0)
Diarrhea	8 (12.9)	0 (0)
Paronychia	7 (11.3)	1 (1.6)
Elevated ALT/ AST	4 (6.5)	1 (1.6)
Pruritus	3 (4.8)	0 (0)
Dry skin	2 (3.2)	0 (0)
Oral ulcer	2 (3.2)	0 (0)
Hepatic dysfunction	2 (3.2)	1 (1.6)
Cough	2 (3.2)	0 (0)
Elevated myocardial enzymes	1 (1.6)	1 (1.6)

*All grades TRAEs incidences≥3% or grade ≥3 TRAEs incidences≥1%.

CONCLUSION

- The ECTOP-1031 study demonstrates that double-dose firmonertinib offers promising efficacy and a manageable safety profile as first-line treatment in patients with EGFR-mutant and PD-L1-positive advanced NSCLC.