



P2.100: Dacomitinib in advanced NSCLC patients with uncommon EGFR mutations: a multicenter, single-arm, phase II study and biomarker analysis (DANCE study)

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INTRODUCTION

Uncommon epidermal growth factor receptor (EGFR) mutations can be detected in 10–15% of patients with non-small cell lung cancer. Dacomitinib, a second-generation EGFR-TKI, is effective in patients with common EGFR mutations, but its efficacy and safety in patients with uncommon EGFR mutations remain unclear.

METHODS

We conducted a single-arm, prospective, phase II study. Pathologically confirmed locally advanced or metastatic non-small cell lung cancer (NSCLC) patients harboring uncommon *EGFR* mutations (exon 20 insertions were excluded) were included in the study. Eligible patients were orally administered 45 mg of dacomitinib once daily until disease progression, unacceptable toxicity, death, or withdrawal of consent. The primary endpoint of the trial was the objective response rate (ORR) assessed by investigators. The disease control rate (DCR), progression-free survival (PFS), overall survival (OS) and safety were secondary endpoints. Biomarker analysis was exploratory analysis.

DISCUSSION AND CONCLUSION

Actionable Take Away Message

- Dacomitinib has high anti-tumor activity and response duration with manageable toxicity in NSCLC patients with uncommon EGFR mutations. The results support the administration of dacomitinib as a treatment option for these patients.

Future Direction for Research

- Prospective RCT study to validate the efficacy of dacomitinib in uncommon EGFR mutation and brain metastasis
- Prospective study to evaluate ctDNA-guided treatment intensification in patients with persistent detectable mutant EGFR at first assessment.

REFERENCES & ACKNOWLEDGEMENTS

List the most critical references and recognize any support or contributions from others.

- Use QR code to save space and to link to more extensive lists or related works.



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RESULTS

Between December 2020 and December 2022, 48 patients were screened for eligibility, and 30 patients were enrolled for analysis. The median age was 66 years, and 26 (86.7%) patients were diagnosed with metastatic disease. The most frequent uncommon type of *EGFR* mutation was compound mutation (12 cases, 40%), followed by 21L861Q (10 cases, 33.3%).

- The ORR and DCR were 80.0% (95% CI, 61.4–92.3%) and 100.0% (95% CI, 88.4–100.0%), respectively. The median best response depth of the target lesion from baseline was –48.40%.
- The median PFS was 14.3 months (95% CI, 10.8–20.9 months), and the 24-month PFS rate was 28.9%.
- The median OS was 44.2 months (95% CI, 30.6-NE), and the three-year OS rate was 59.2%.
- All patients (100%) experienced at least one adverse event (AE) of any grade or cause, and the most common AE was rash (86.7%; Grade 3: 23.3%). Grade 3 or higher AEs were reported in 12 (40.0%) patients. No unexpected safety signal was observed.

Table1. Baseline characteristics

Characteristic	N=30 (%)
Age, median(range), y	66 (44-75)
Female, No. (%)	14 (47.0%)
Smoking status	
Current/former	7 (23.3%)
Never	23 (76.7%)
Stage	
Locally advanced	4 (13.3%)
Metastatic	26 (86.7%)
Histologic subtype	
Adenocarcinoma	29 (96.7%)
NOS	1 (3.3%)
PD-L1 expression	
<1%	9 (30.0%)
1%-49%	7 (23.3%)
≥50%	3 (10.0%)
Unknown	11 (36.7%)
EGFR mutation type	
complex mutation	12 (40.0%)
21L861Q	10 (33.3%)
18G719X	7 (23.3%)
other mutation	1 (3.3%)
Performance status	
0	7 (23.3%)
1	23 (76.7%)
Treatment line	
First-line	26 (86.7%)
Second-line	4 (13.3%)

Table2. AEs Regardless of Relationship With Dacomitinib

Adverse Event	All grades	Grades 1-2	Grades 3	Grades 4	Grades 5
Any adverse event	30 (100%)	18 (60.0%)	11 (36.7%)	0	1 (3.3%)
rash	26 (86.7%)	19 (63.3%)	7 (23.3%)	0	0
diarrhea	17 (56.7%)	15 (50.0%)	2 (6.7%)	0	0
paronychia	13 (43.3%)	13(43.3%)	0	0	0
Mucositis oral	13 (43.3%)	12 (40.0%)	1 (3.3%)	0	0
Prolonged QT interval	11 (36.7%)	0	0	0	0
anemia	10 (33.3%)	0	0	0	0
Elevated bilirubin	9 (30.0%)	0	0	0	0
hepatic dysfunction	7 (23.3%)	0	0	0	0
Elevated uric acid	4 (13.3%)	4 (13.3%)	0	0	0
lymphocyte count decreased	4 (13.3%)	0	0	0	0
Elevated creatinine	3 (10.0%)	3(10.0%)	0	0	0
hemorrhage	3 (10.0%)	0	0	0	0
pulmonary infection	2 (6.7%)	0	1 (3.3%)	0	1 (3.3%)
Platelet count decreased	2 (6.7%)	0	0	0	0
vomit	1 (3.3%)	0	0	0	0
pancreatitis	1 (3.3%)	0	1 (3.3%)	0	0
edema	1 (3.3%)	0	0	0	0
Elevated blood glucose	1 (3.3%)	0	0	0	0
WBC count decreased	1 (3.3%)	0	0	0	0
Neutrophil count decreased	1 (3.3%)	0	0	0	0

Figure1. The response depth from baseline

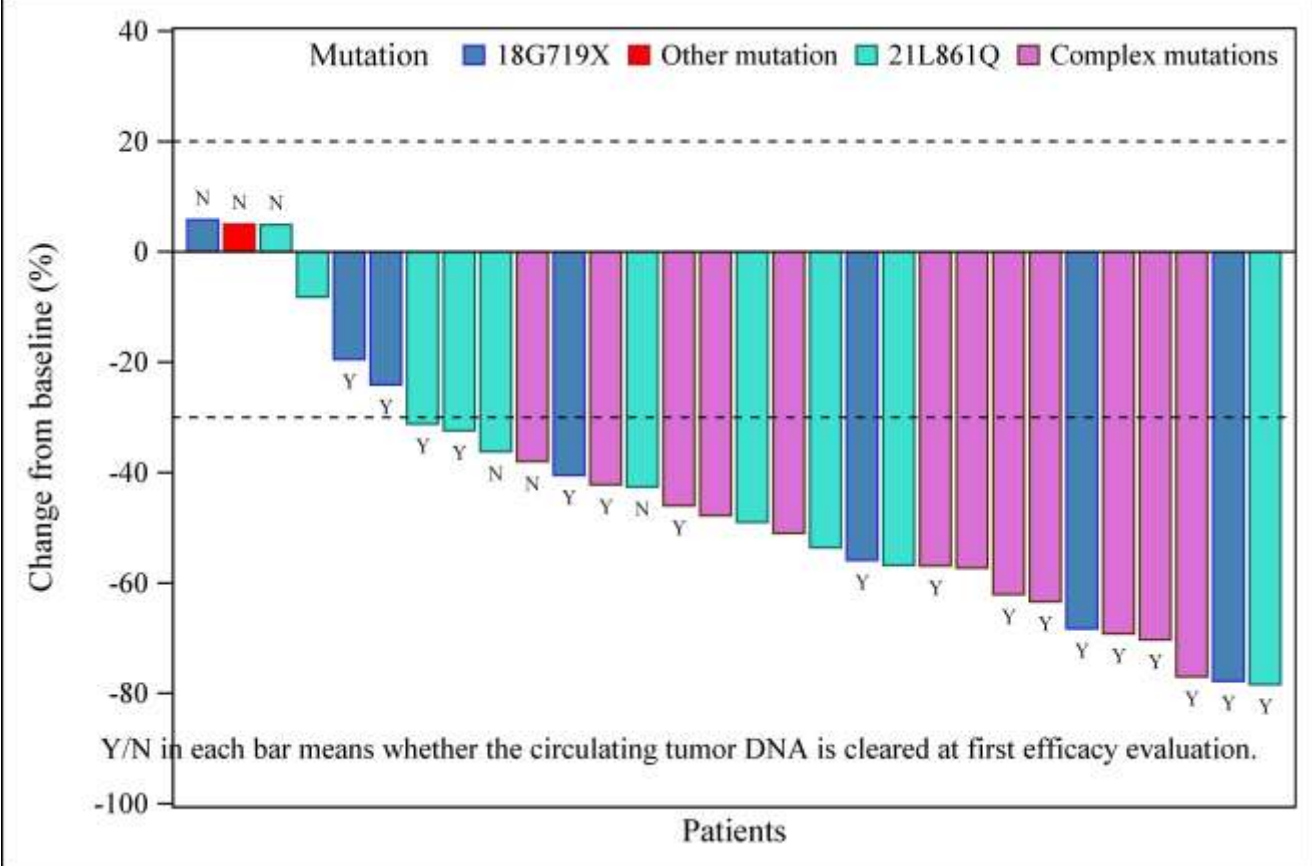


Figure2a. PFS on FAS population

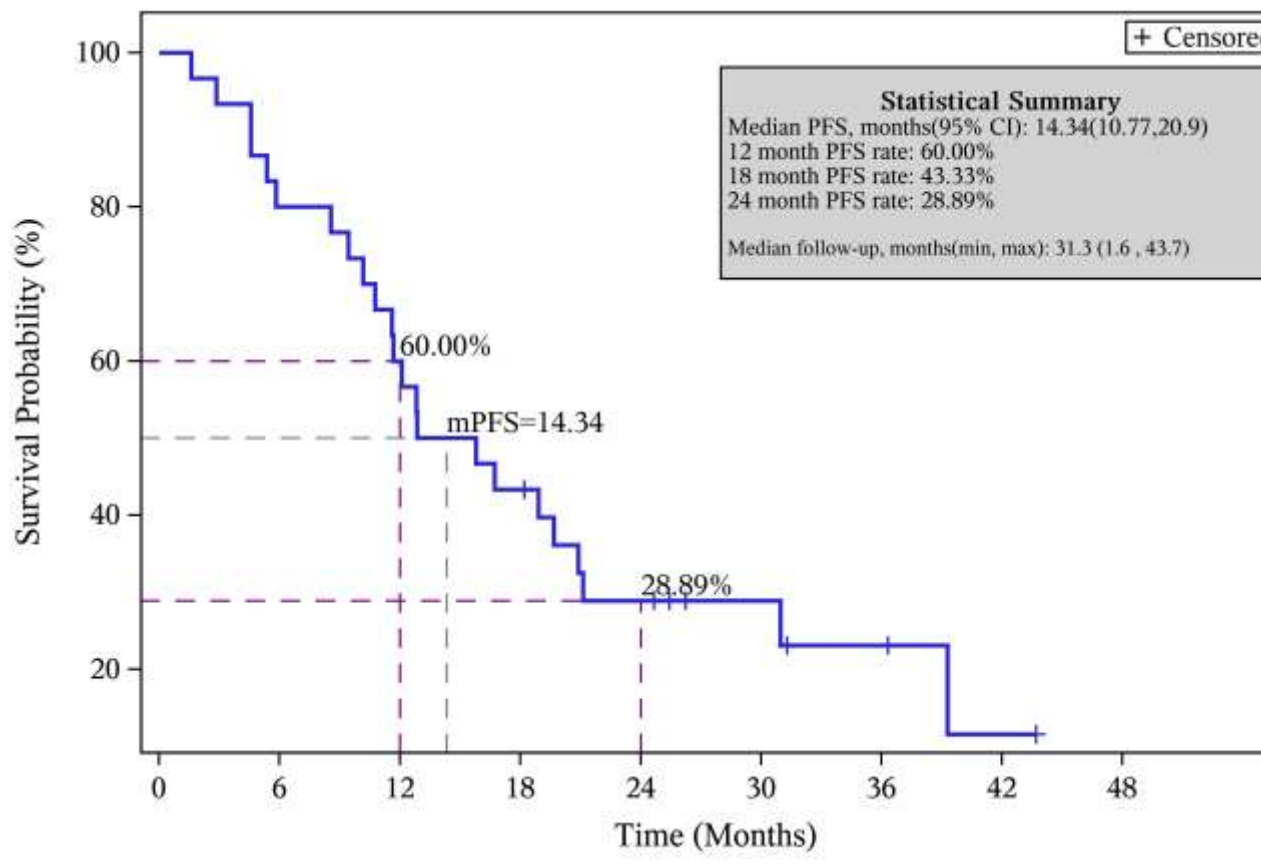


Figure2b. OS on FAS population

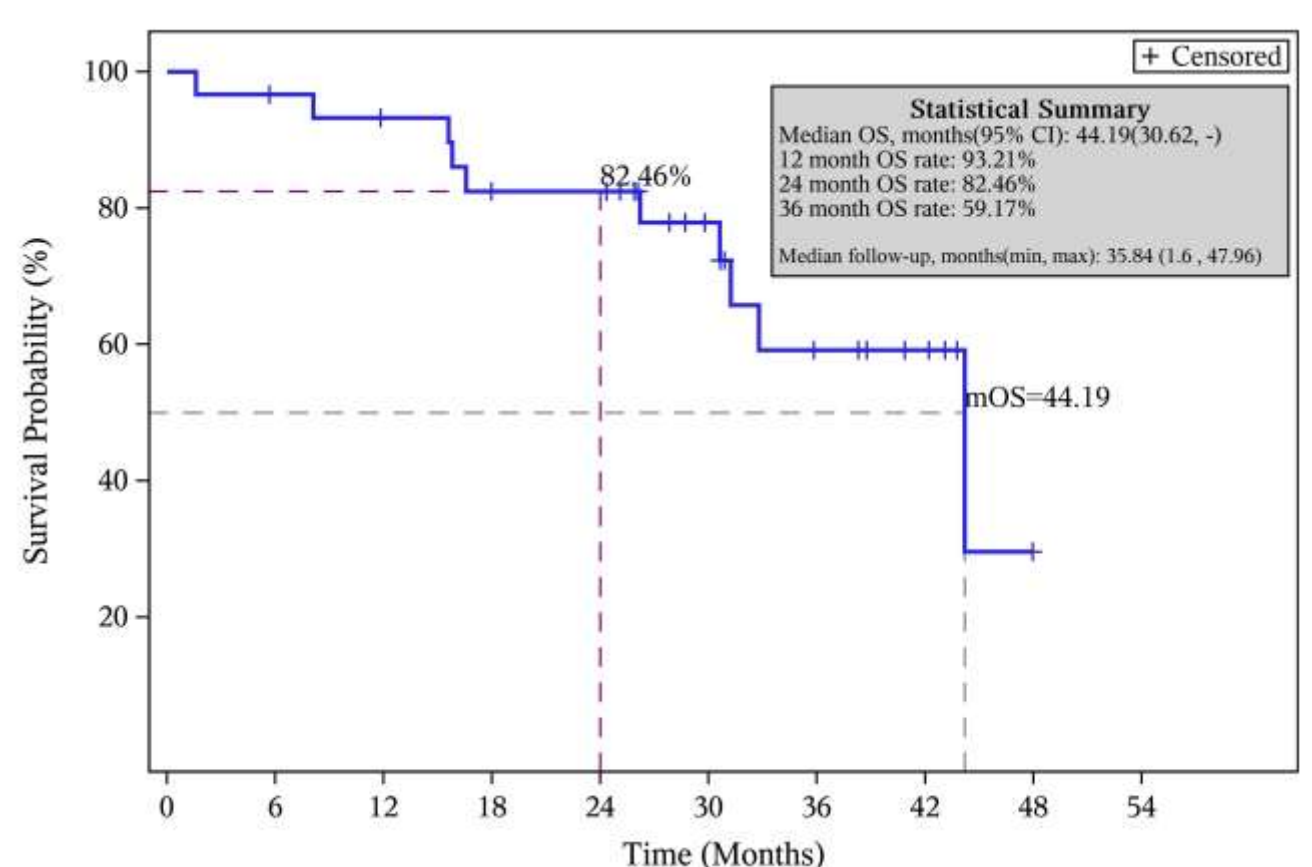


Figure2c. PFS according to mutation type

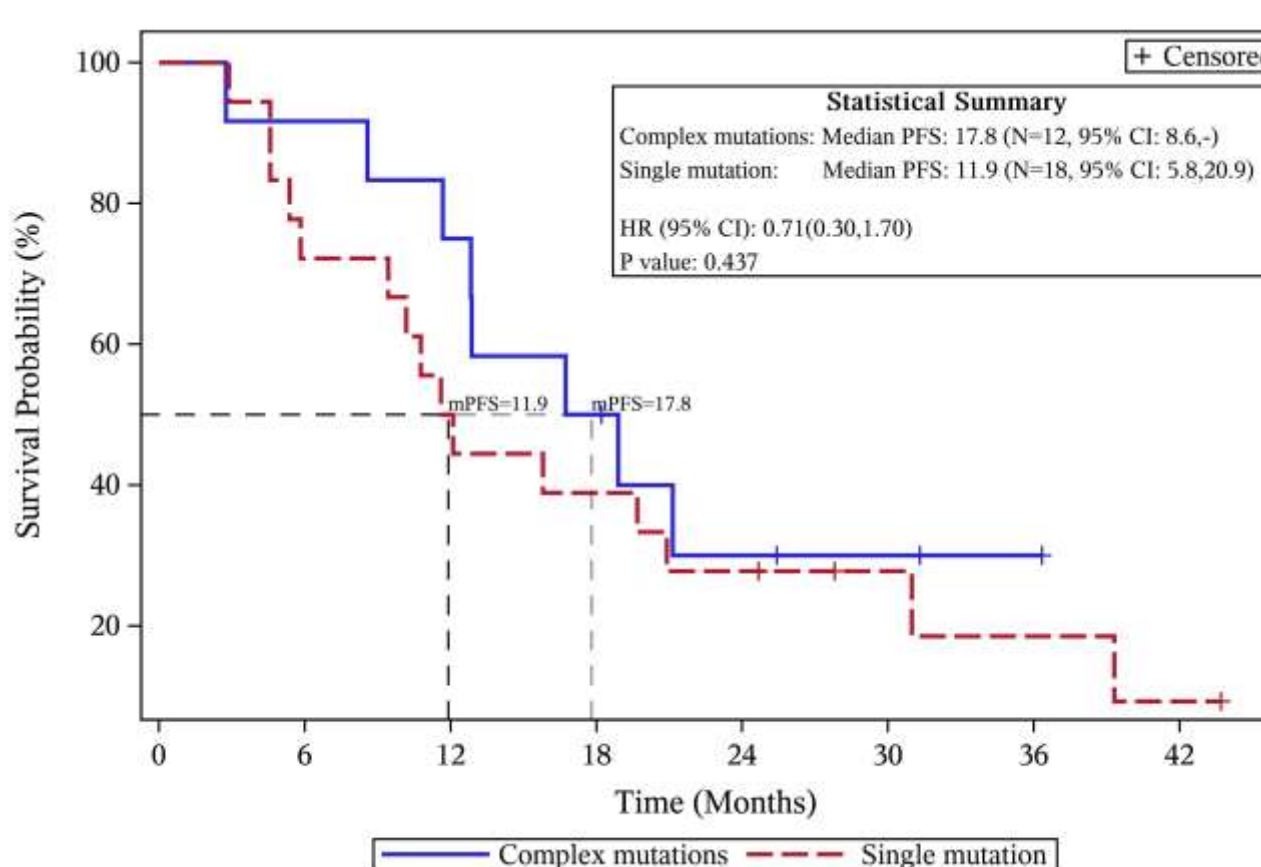


Figure2d. OS according to mutation type

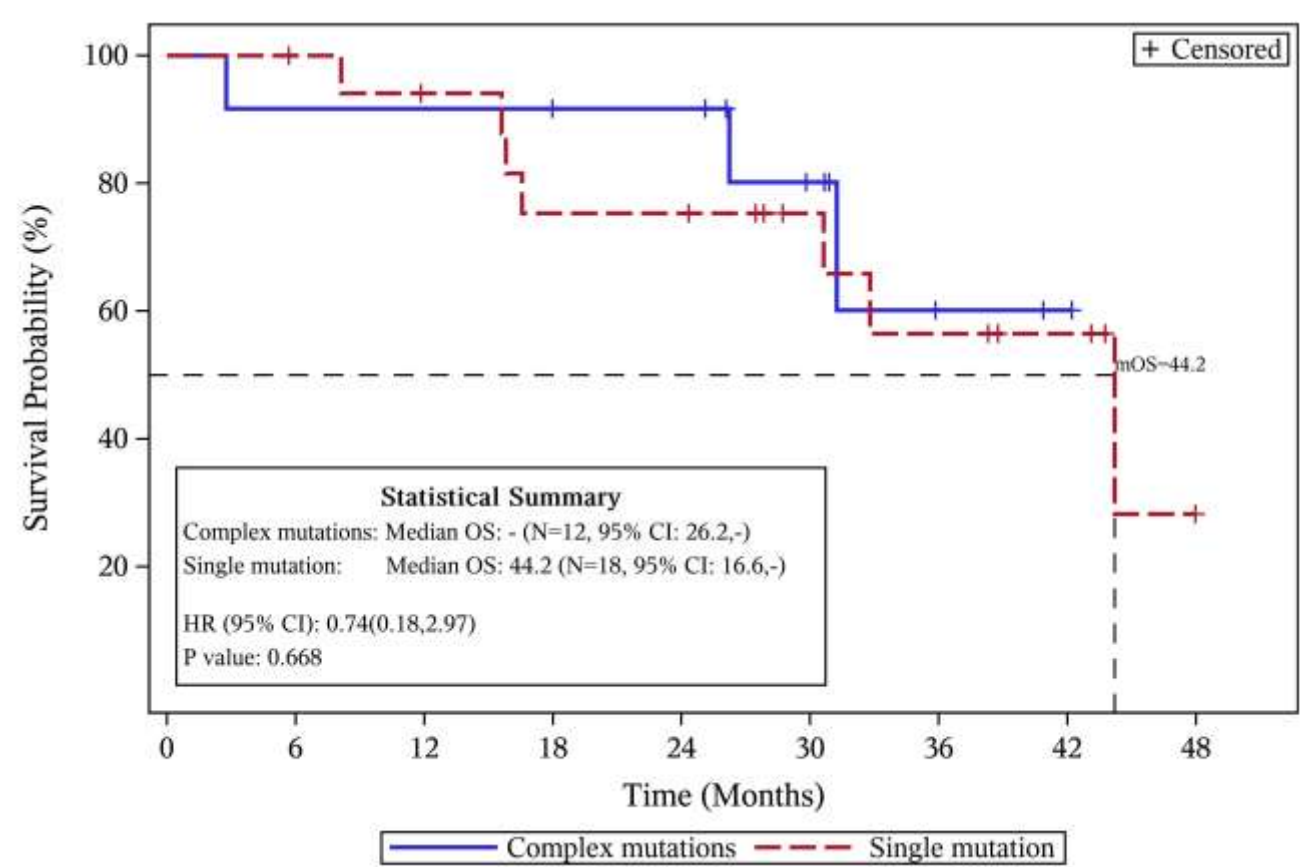


Figure3. PFS according on ct-DNA status

