



Sunvozertinib Plus Anlotinib as First-line Treatment for NSCLC with EGFR Sensitive Mutations and Co-mutations: Updated Phase II Data

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INTRODUCTION

- Advanced non-small cell lung cancer (NSCLC) patients with EGFR sensitive mutations (19del or L858R) frequently harbor concurrent co-mutations such as TP53, which are associated with genomic instability and early resistance. These co-alterations diminish the clinical benefit of standard EGFR tyrosine kinase inhibitor (TKI) monotherapy.
- Sunvozertinib (DZD9008) is a novel, irreversible, selective EGFR TKI with potent activity against a broad spectrum of EGFR mutations.
- Anlotinib is a multi-target TKI with anti-angiogenic effects that may synergize with EGFR TKI to alleviate resistance.
- Herein, we reported clinical data of sunvozertinib combined with anlotinib in NSCLC patients with EGFR sensitive mutation and co-mutations.

METHODS

- WU-KONG32 (NCT06348927) is a Phase II, open-label, single-arm, single-center study to evaluate the efficacy of sunvozertinib in combination with anlotinib in treatment naïve patients with locally advanced or metastatic NSCLC with EGFR L858R or exon 19del with co-mutations.
- Patients received sunvozertinib 300 mg QD continuously and anlotinib 8 mg QD (2 weeks on/1 week off) in 21-day cycles.
 - Tumor response was assessed by investigator per RECIST 1.1
 - Adverse events were graded according to CTCAE 5.0, and drug causality was assessed by investigators.

DEMOGRAPHICS AND BASELINE CHARACTERISTICS

- A total of 34 patients with advanced NSCLC harboring EGFR L858R or 19del and at least one co-mutations, who received at least one study treatment and completed post baseline tumor assessment, were included for efficacy analysis (**Table 1**). The Data cutoff date was July 16, 2026.

Table 1. Demographics and Baseline Characteristics (Efficacy Analysis Set)

Characteristics	DZD9008 300 mg + Anlotinib 8 mg (N = 34)
Median age, years (range)	62.0 (40, 76)
Female, n (%)	18 (52.9)
ECOG score of ≤ 1 , n (%)	34 (100.0)
Disease extension upon study entry, n (%)	
Stage IV	34 (100.0)
Baseline brain metastasis, n (%)	17 (50.0)
EGFR Mutation, n (%)	
Exon 19del	18 (52.9)
L858R	16 (47.1)
TP53 Mutation, n (%)	
Yes	28 (82.4)
No	6 (17.6)
Smoking Status, n (%)	
Yes	10 (29.4)
No	24 (70.6)

Abbreviation: ECOG, Eastern Cooperative Oncology Group; TP53, Tumor Protein 53.

RESULTS - EFFICACY

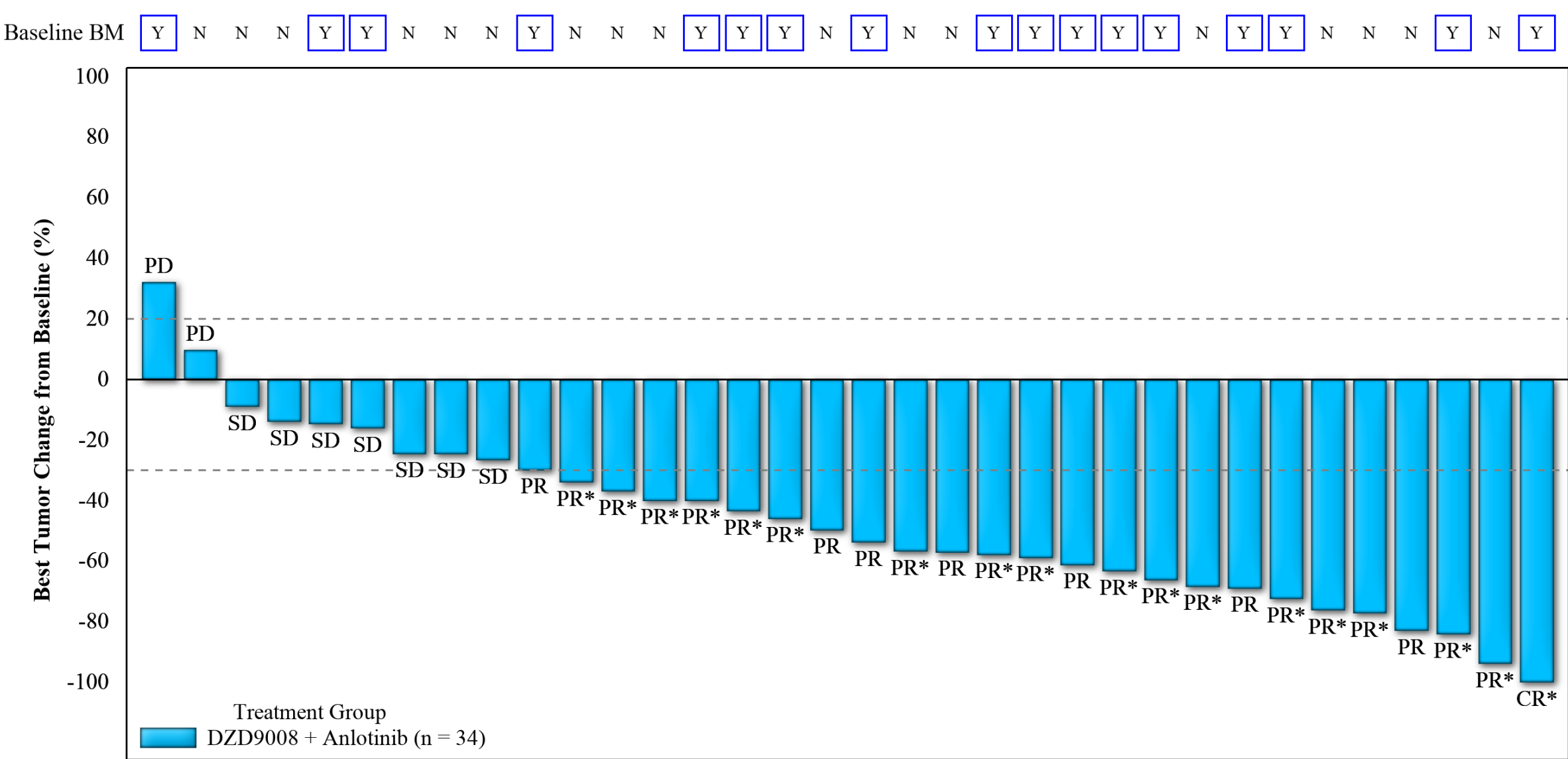
- Target tumor lesion shrinkage was observed in 94.1% (32/34) of patients with confirmed objective response rate (cORR) of 52.9% (18/34) and confirmed disease control rate (DCR) of 94.1% (32/34) (**Figure 1** and **Table 2**).
- The treatment benefit was durable. By the DCO date, 67.6% (23/34) of patients were treatment ongoing (**Figure 2**).
- With a median follow-up of 9.1 months, the median duration of response (DoR) was 12.6 months (95% CI, 10.4–NE), and 83.3% (15/18) responders were still responding.
- With a median follow-up of 6.6 months, the estimated median PFS was 14.7 months (95% CI, 12.4–NE), and 12-month PFS rate was 86.3% (**Figure 3**). The longest PFS was 17.2 months, and the patient was still on study treatment and deriving clinical benefit.

Table 2. Investigator-assessed Antitumor Efficacy per RECIST 1.1 (Efficacy Analysis Set)

	DZD9008 300 mg + Anlotinib 8 mg (N = 34)
ORR, % (95% CI)	73.5 (55.6, 87.1)
CR, n (%) *	1 (2.9)
PR, n (%)	24 (70.6)
PR, confirmed*	17 (50.0)
SD, n (%)	7 (20.6)
PD, n (%)	2 (5.9)
DCR, % (95% CI)*	94.1 (80.3, 99.3)

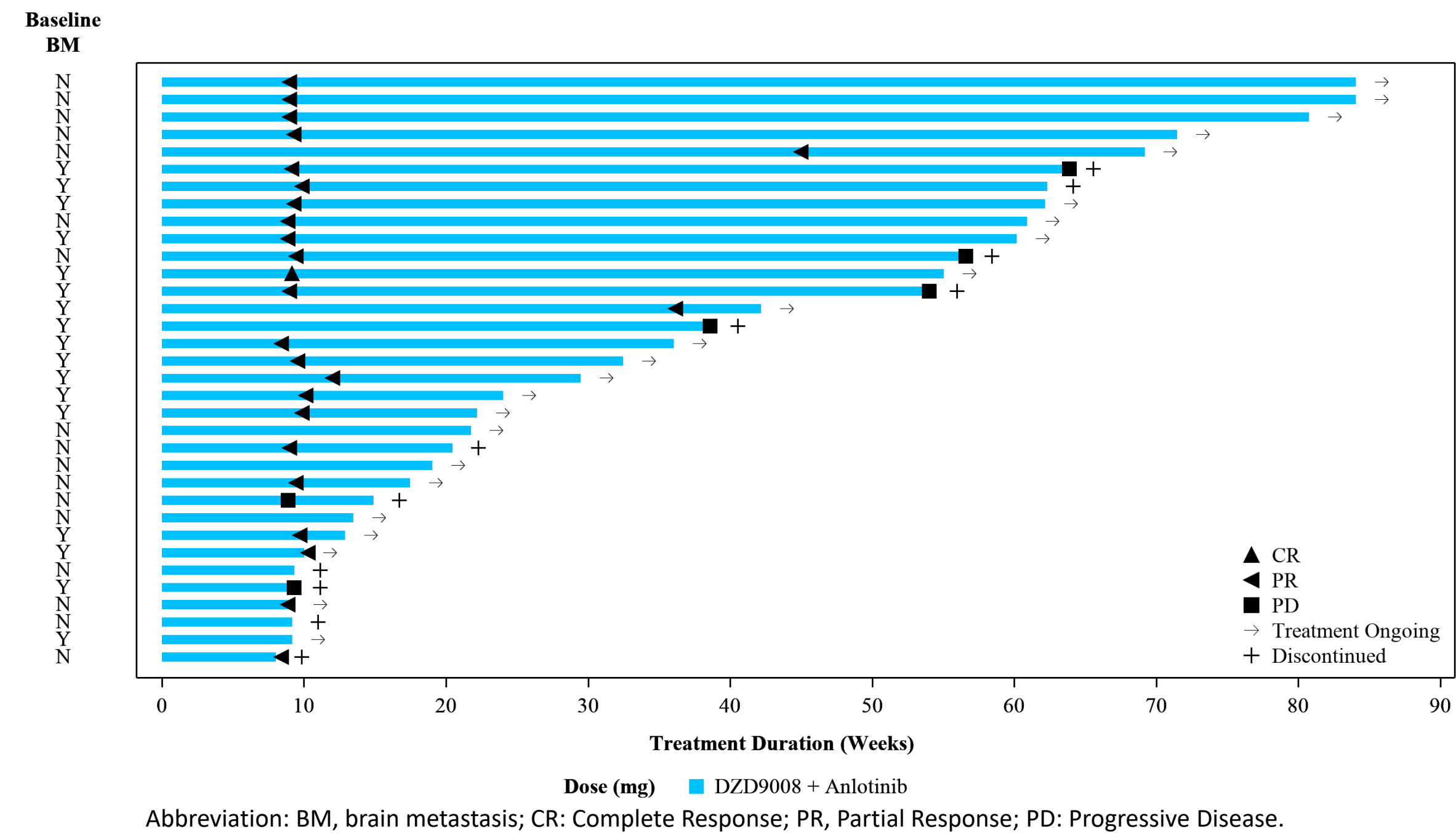
Abbreviation: CI: Confidence Interval. N: Number of participants in the analysis set for each treatment group; the percentage was calculated based on N as the denominator; CR: Complete Response; PR, Partial Response; PD: Progressive Disease; SD, Stable Disease; * confirmed tumor response.

Figure 1. Best Tumor Size Changes from Baseline of Target Lesions (Efficacy Analysis Set)



Abbreviation: BM, brain metastasis; CR: Complete Response; PR, Partial Response; PD: Progressive Disease; SD, Stable Disease.
*confirmed tumor response.

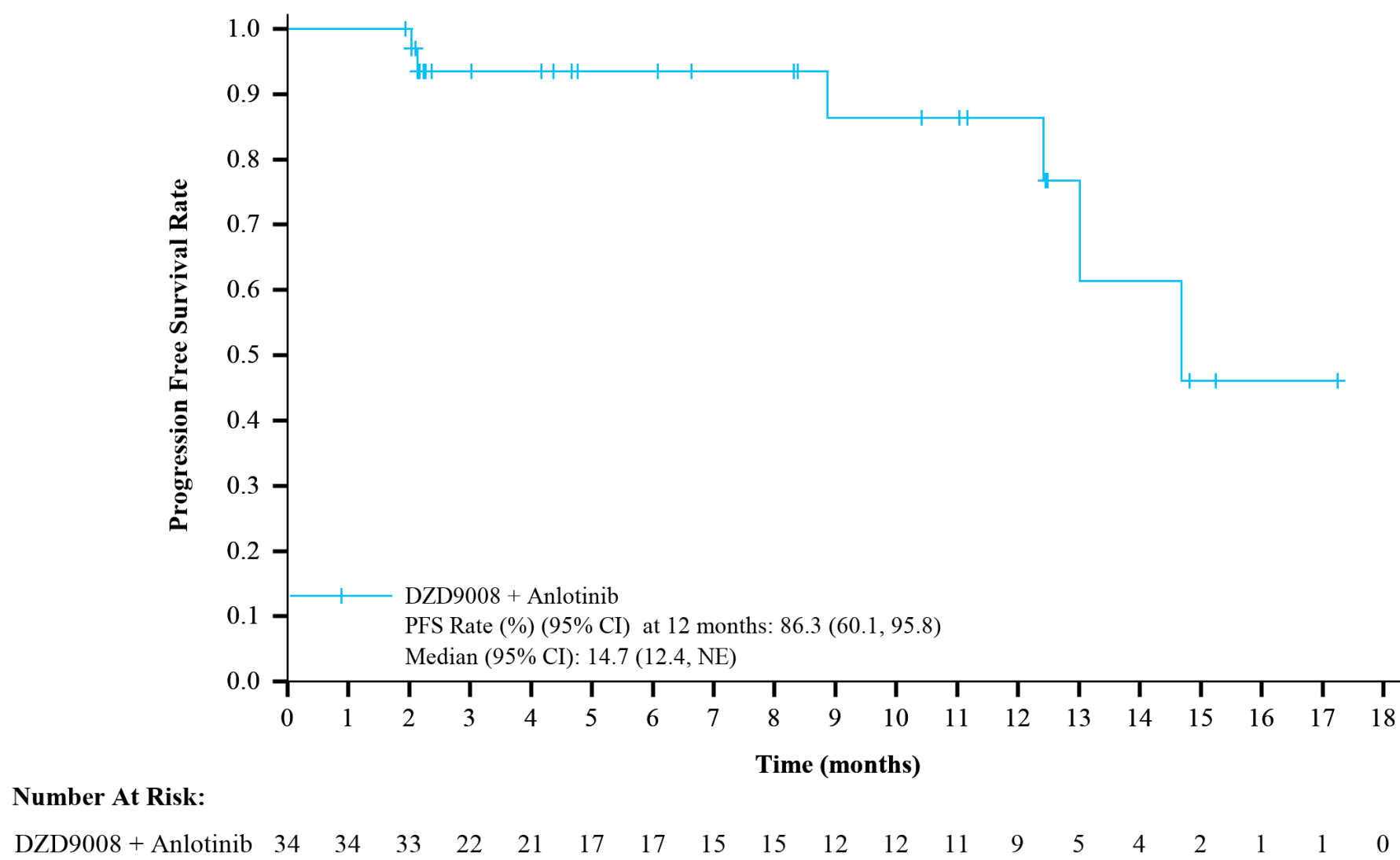
Figure 2. Duration on Treatment (Efficacy Analysis Set)



Abbreviation: BM, brain metastasis; CR: Complete Response; PR, Partial Response; PD: Progressive Disease.

RESULTS - EFFICACY

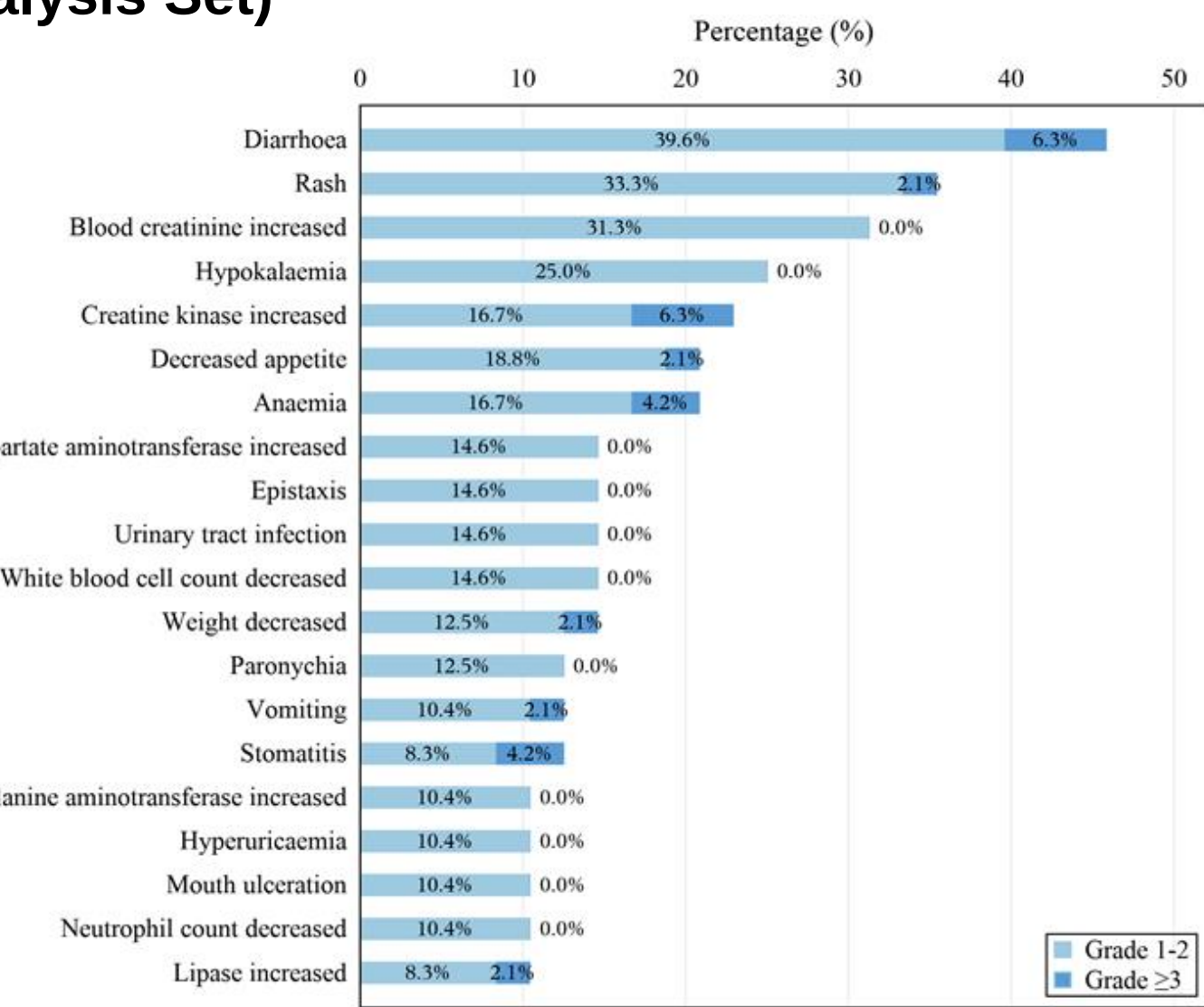
Figure 3. Kaplan-Meier Plot of Progression-free Survival (Efficacy Analysis Set)



RESULTS - SAFETY

- A total of 48 patients who had received at least one dose of study treatment were included in the safety analysis set.
- Sunvozertinib combined with anlotinib was well-tolerated, with most patients received both drugs throughout their treatment course.
- Common treatment-related AEs include diarrhoea, rash, blood creatinine increased, hypokalaemia, creatine kinase increased, decreased appetite, and anaemia. Most AEs were CTCAE Grade 1 or 2.
- Safety profile is similar to sunvozertinib or anlotinib. No unexpected AEs were observed. (**Figure 4**).

Figure 4. Most Common Drug-Related TEAE by Preferred Term and CTCAE Grade ($\geq 10\%$) (Safety Analysis Set)



Abbreviation: AE: Adverse Event; CTCAE: Common Terminology Criteria for Adverse Events; TEAE: Treatment-Emergent Adverse Event.

CONCLUSION

Sunvozertinib in combination with anlotinib demonstrates promising antitumor efficacy and a manageable safety profile as first-line treatment for patients with advanced NSCLC carrying EGFR sensitive mutation with high-risk co-mutations, supporting its potential as a clinical treatment option for this patient population.

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