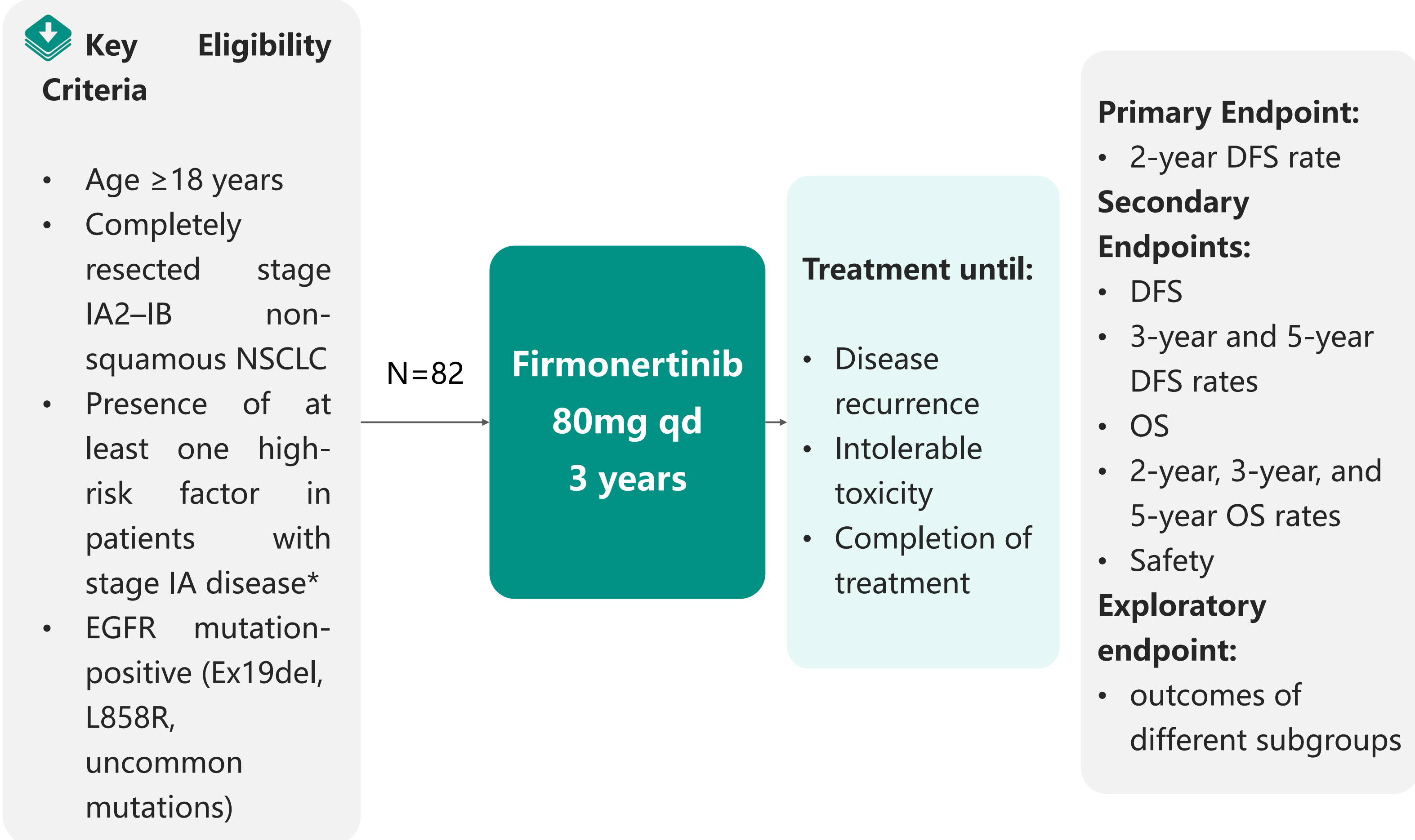


INTRODUCTION

- Firmonertinib (AST2818) is a highly brain-penetrant, third-generation EGFR tyrosine kinase inhibitor (TKI), which has been approved for the first-line treatment of patients with 19Del or L858R mutations and treatment of patients with T790M mutations whose disease has progressed on or after EGFR TKI therapy [1-2].
- FORWARD (NCT04853342), firmonertinib as adjuvant therapy for resected high-risk stage IA2, and stage IA3 to IIIA NSCLC patients with sensitive EGFR mutations is ongoing [3].
- Here we report the efficacy and safety of firmonertinib as adjuvant therapy for completely resected stage IA2-IA3 with high-risk factors and IB NSCLC patients with EGFR mutations in a real-world study (ChiCTR2500103374).

METHODS

Study design



- * **High-risk factor** : High-grade pattern , Micropapillary , Solid components , spread through air spaces (STAS) , Visceral pleural invasion , Vascular invasion
- The frequency of treatment visits and all safety monitoring and assessments shall be implemented in accordance with the standard clinical practice of the study center.

REFERENCES

- [1] Shi Y , et al. Lancet Respir Med. 2022 Nov ; 10(11):1019-1028.
- [2] Shi Y , et al. Lancet Respir Med. 2021 Aug ;9(8):829-839
- [3] FORWARD (NCT04853342)

DISCUSSION AND CONCLUSION

- Firmonertinib 80mg orally once daily has shown potential efficacy and excellent safety as adjuvant therapy for completely resected stage IA2-IA3 with high-risk factors and IB NSCLC patients with EGFR mutations.
- Patients were well tolerated and the TRAEs were consistent with previous studies.

RESULTS

Patients

- From July 2021 to Dec 2025, there were 82 patients enrolled. The median follow-up was 20 months.
- The baseline characteristics (Table 1) included ,the median age was 60.5 years (range: 37-75), female 79.3%. ,98.8% patients ECOG PS=0 , the Stage IA 58.5% (IA2 35.4%, IA3 23.2%), stage IB 41.5%, 92.1% patients had at least one high-risk factor. EGFR mutations were 19Del (37.8%), L858R (54.9%), G719A (2.4%), Ex20ins (2.4%), L861Q (1.2%) and others (1.2%), all 82 patients were adenocarcinoma.

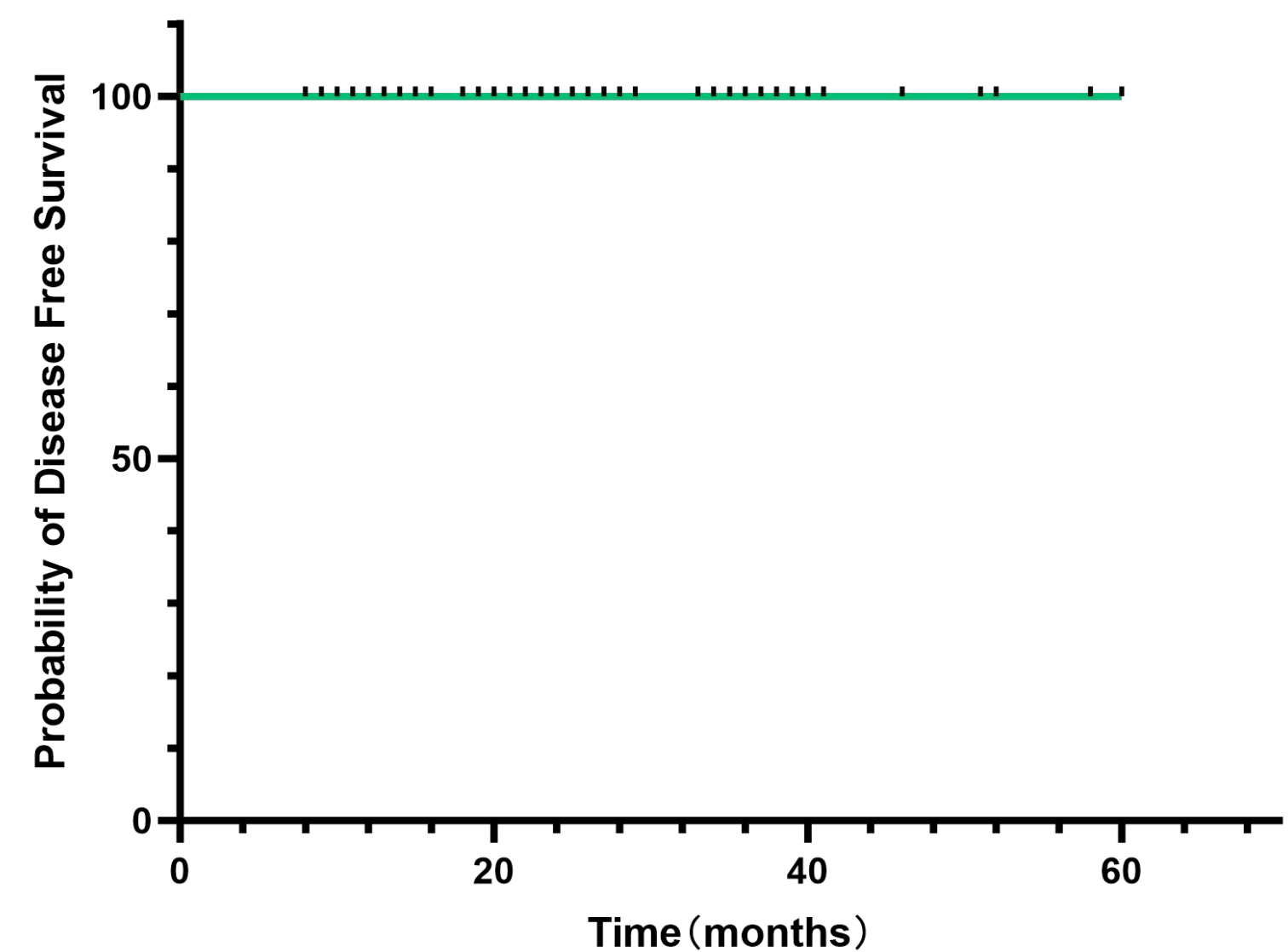
Table 1. Baseline characteristics of patients

Characteristics	Firmonertinib (N=82)
Age (range) , years	60.5 (37-75)
female/male, %	79.3/20.7
Smoking history, %	
Yes	15.9
No	84.1
ECOG, %	
0	98.8
1	1.2
TNM stage , %	
IA2	35.4
IA3	23.2
IB	41.5
High-risk factor, %	
high-grade pattern	62.2
micropapillary	40.2
spread through air spaces	32.9
visceral pleural invasion	31.7
solid components	30.5
EGFR mutations, %	
19Del	37.8
L858R	54.9
G719A	2.4
Ex20ins	2.4
L861Q	1.2
others	1.2

Efficacy

- At data cut-off (DCO) was August 1 , 2026, all patients continued to receive firmonertinib and no disease recurrence, the primary endpoint 2-year disease-free survival rate was 100% (Figure 1).

Figure 1: Kaplan-Meier curve of DFS assessed by investigator



Safety

- The rate of treatment related adverse events (TRAEs) was 12.2%, there were no grade 3 or higher TRAEs occurred. There were no incidence of dose interruption, dose reductions, treatment discontinuation or deaths due to TRAEs. (Table 2)
- The most common TRAEs were rash 7.3%, abnormal liver function 3.7%, and oral ulcer 1.2% (Figure 2).

Table 2. Overview of TRAEs

Adverse Event	n (%)
TRAE	10 (12.2)
Grade ≥3 TRAE	0 (0)
Dose interruption	0 (0)
Dose reduction	0 (0)
Discontinuation	0 (0)

Figure 2: most common TRAEs

