



Updated Results From the OSTAR Trial: Efficacy and Safety of Adjuvant Osimertinib in High-Risk Stage I EGFRm NSCLC After R0 Resection

C. Chen, J. Xie, B. Zhang, C. Wang, Q. Zhang, Z. Zhang, L. Zhang, S. Wang, X. Wang, R. Jiang, D. Yue
Tianjin Medical University Cancer Institute and Hospital, Tianjin, China
Correspondence: chen_checn@tmu.edu.cn



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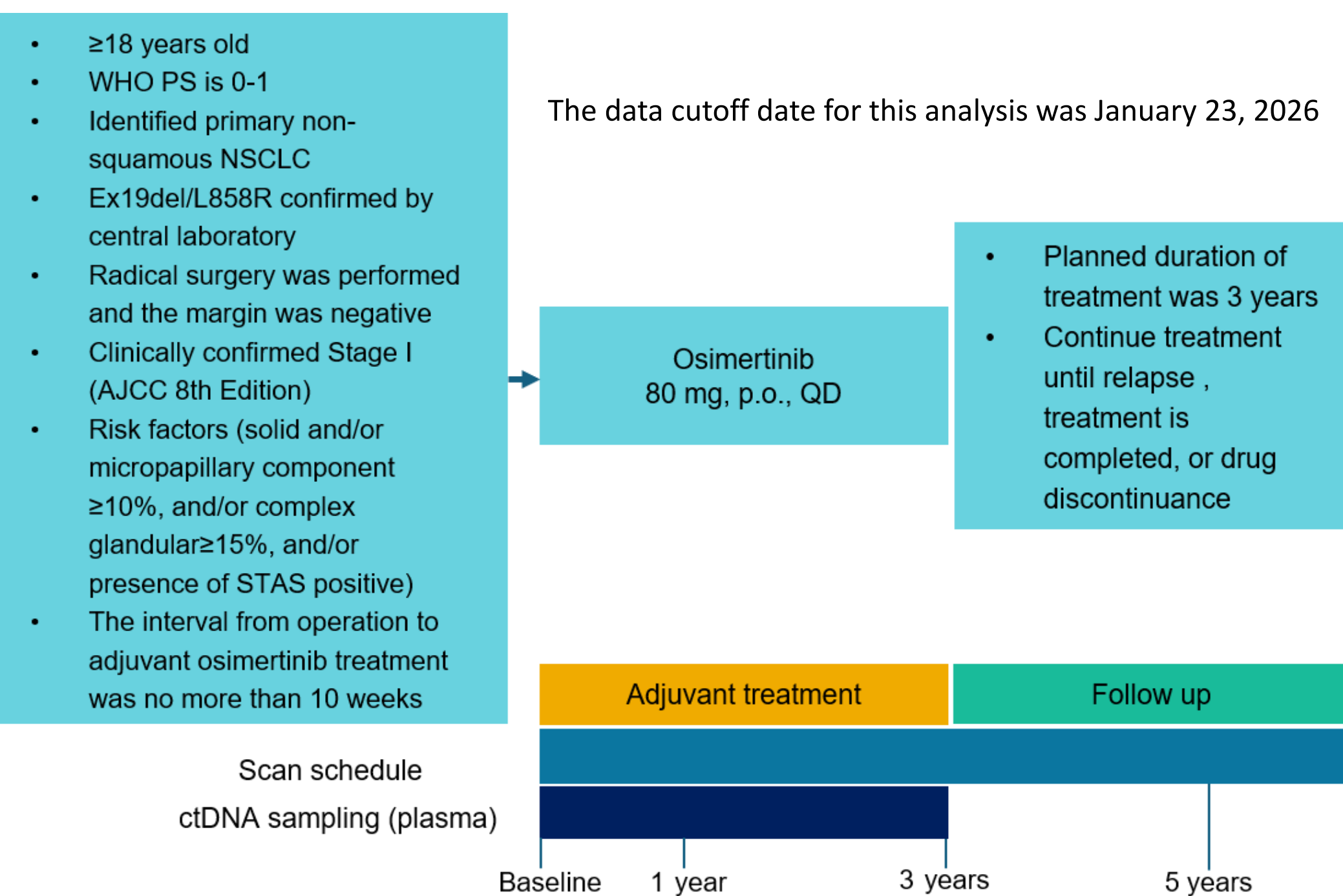
INTRODUCTION

- Patients with completely resected stage I non-small cell lung cancer (NSCLC) harboring high-risk histopathologic features (including solid and/or micropapillary components $\geq 10\%$, complex glands $\geq 15\%$, and/or spread through air space (STAS)) demonstrate an elevated risk of recurrence while deriving limited benefit from adjuvant chemotherapy.
- The ADAURA trial established that adjuvant osimertinib significantly reduced the risk of disease recurrence or death by 59% in the stage IB subgroup (HR = 0.41; 95% CI: 0.23-0.69).
- However, the therapeutic efficacy of adjuvant osimertinib in patients with stage I NSCLC characterized by these specific high-risk pathological features remains to be elucidated.

METHODS

Study Design

- This is an ongoing, single-center, phase II study that enrolled 70 patients between October 2022 and June 2024.
- Eligible patients harboring EGFR-sensitive mutations underwent complete surgical resection and were diagnosed with stage I NSCLC (AJCC 8th edition) with high-risk histopathologic features.
- All participants received adjuvant osimertinib at a dose of 80 mg once daily for a planned duration of 3 years.
- The primary endpoint is the 3-year disease-free survival (DFS) rate.



Study endpoint

Primary : 3-year DFS rate
Secondary : DFS, 3-year OS rate and 5-year OS rate, OS, safety, health-related quality of life assessment
Exploratory : the relationship between genomic changes (mutations, copy number changes (CNVs), structural changes, etc.), genomic expression profiles of plasma ctDNA (during treatment), the tumour lesions (before treatment and at relapse), and efficacy of Osimertinib adjuvant therapy in stage I NSCLC.

DISCUSSION AND CONCLUSION

Actionable Take Away Message

- Adjuvant osimertinib at a dose of 80 mg once daily demonstrated promising efficacy in patients with completely resected stage I EGFR-mutated NSCLC harboring high-risk pathological features.

Future Direction for Research

- This study employed a single-arm design with a small sample size, necessitating larger randomized controlled trials to confirm these findings.

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RESULTS

- The data cutoff date for this analysis was January 23, 2026. Median follow-up was 27.3 months (95% CI, 23.8-30.5). Until data cutoff, Twenty-two (31.4%) patients discontinued osimertinib therapy, comprising 5 patients who completed the planned 3-year treatment duration and 17 patients who discontinued prematurely due to financial constraints or adverse events.
- The 1-year disease-free survival (DFS) rate was 100%, while the 2-year DFS rate was 98.6% and 3-year DFS rate was 95.5%, with two patients experiencing disease progression. The 1- and 2-year overall survival (OS) rates were both 100%, and the 3-year OS rate was 96.0%, with only one patient death (without progression).

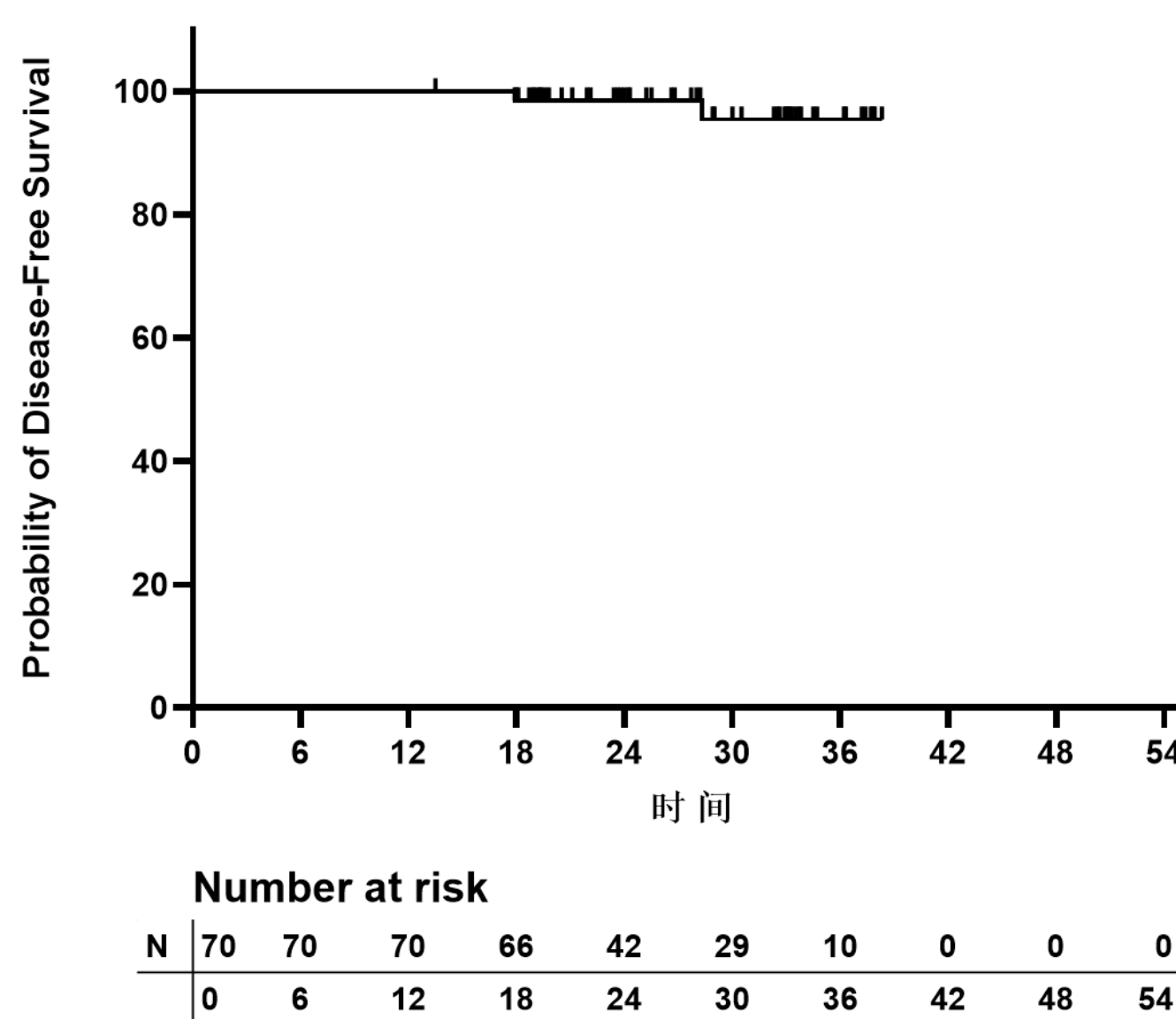


Figure 1: DFS in All patients

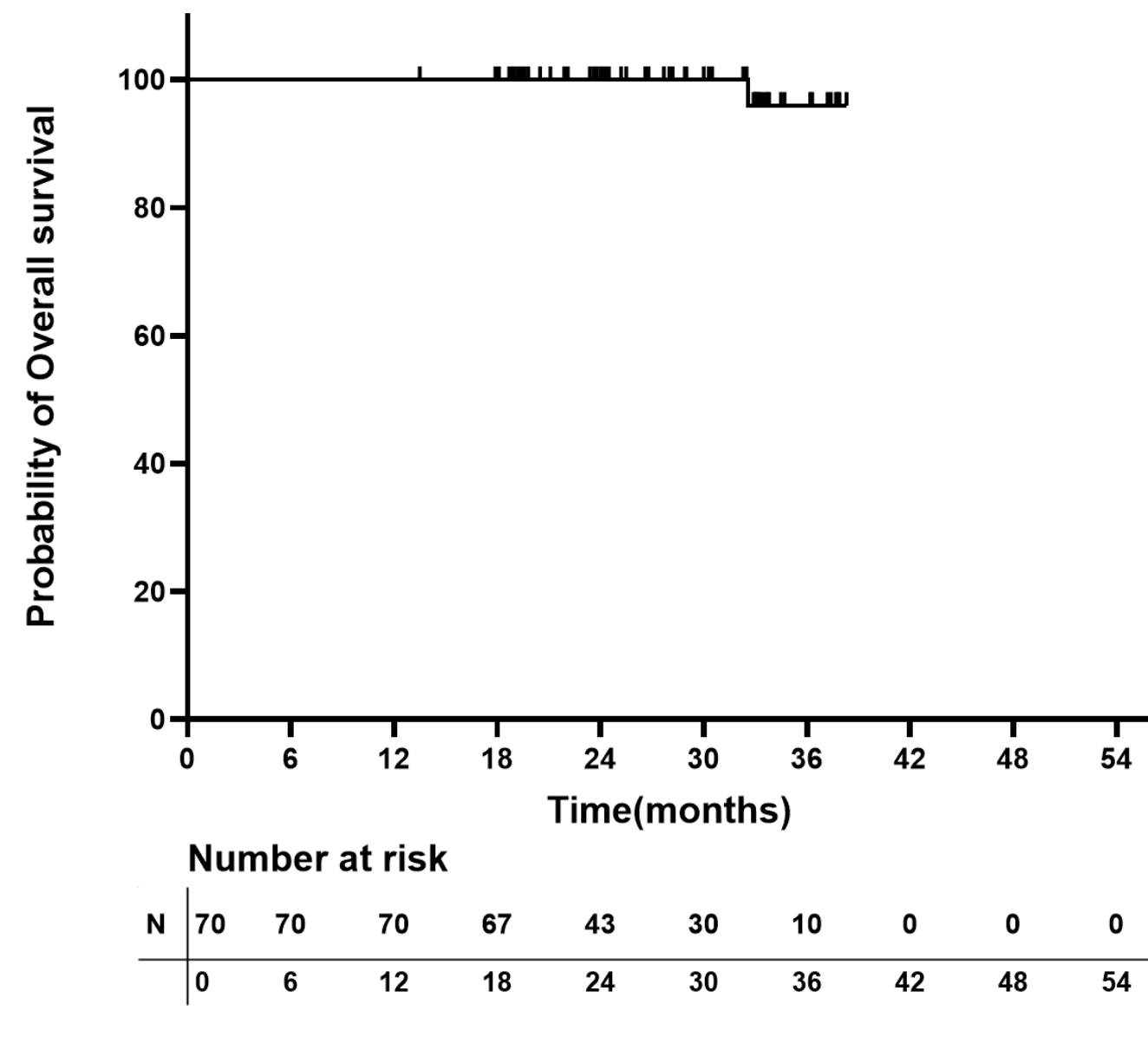


Figure 2: OS in All patients

Figure 3: 2025 AACR Poster CT164 Presentation

