

P2.367: Prospective Observational Study of Patients with Completely Resected *EGFR* mutation-positive NSCLC
— AURORA (WJOG17023L) —



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Elucidating Long-Term Prognosis and Real-World Evidence on the Safety of Osimertinib as Adjuvant Therapy in Japanese Patients

INTRODUCTION

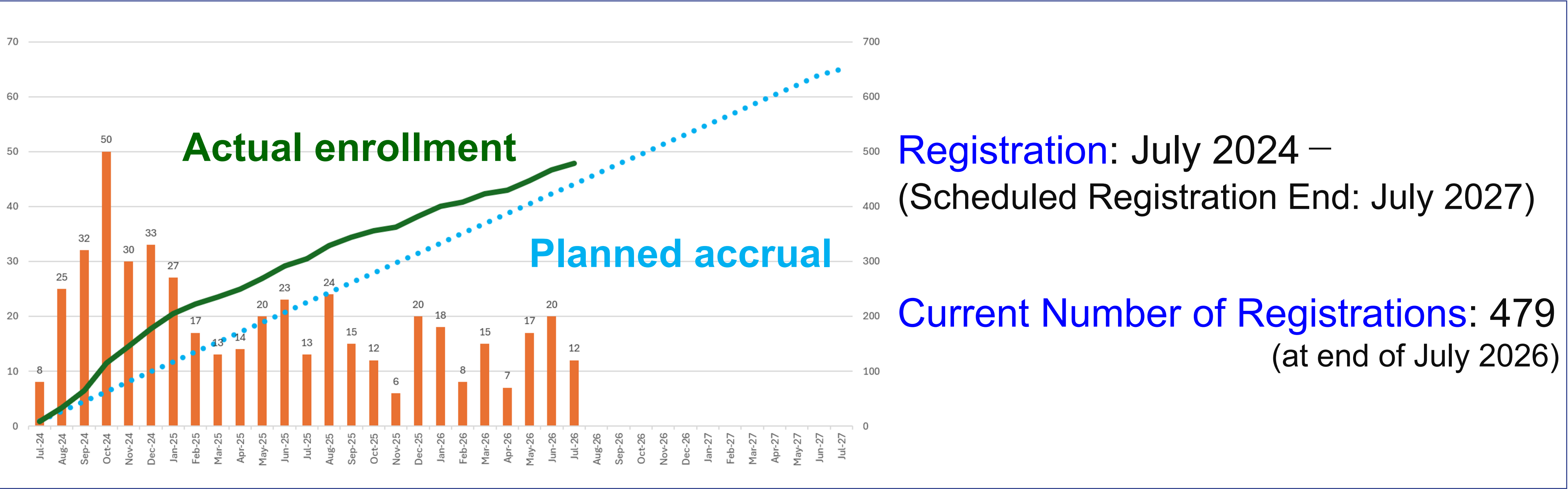
▸ The phase III ADAURA trial demonstrated the efficacy and safety of three years of oral osimertinib as adjuvant therapy for pathological stage II–III* non-small-cell lung cancer (NSCLC) harboring common epidermal growth factor receptor (*EGFR*) mutations^{1,2}.

(*No Japanese patients with Stage IB [UICC 7th edition] were enrolled in the ADAURA trial.)

▸ However, the number of Japanese patients participating in the trial was limited.

▸ We aimed to investigate the selection of adjuvant therapy, its impact on long-term prognosis, and the safety of osimertinib adjuvant therapy in patients with NSCLC harboring *EGFR* mutation in clinical practice (UMIN000054402).

TRIAL IN PROGRESS



Registration: July 2024 –
(Scheduled Registration End: July 2027)

Current Number of Registrations: 479
(at end of July 2026)

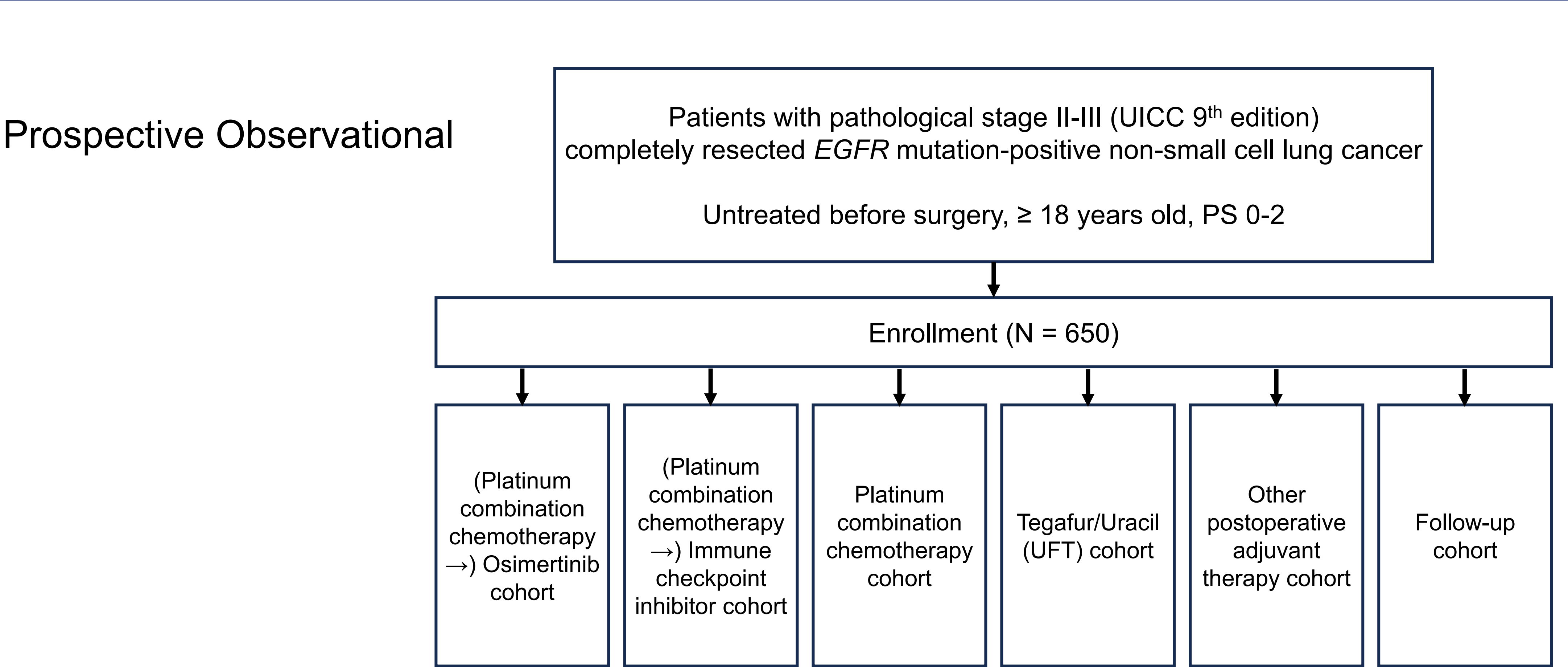
REFERENCES & ACKNOWLEDGEMENTS

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References
1. Wu YL and Tsuboi M, et al. Osimertinib in Resected EGFR-Mutated Non-Small-Cell Lung Cancer. The New England journal of medicine. 2020;383:1711–23.
2. Tsuboi M, et al. Overall Survival with Osimertinib in Resected EGFR-Mutated NSCLC. The New England journal of medicine. 2023.

Artificial Intelligence (AI) Use Disclaimer
We did not use AI for this contents

METHODS



Follow-up Duration: 8 years
(primary and final analyses scheduled at 5 and 8 years, respectively)

Primary Endpoint: disease-free survival

Secondary Endpoints: overall survival, central nervous system disease-free survival, adverse events due to osimertinib, details about the interstitial lung disease due to osimertinib, details of treatment after recurrence, progression-free survival with first-line treatment after recurrence

SAMPLE SIZE : 650 patients

The sample size was determined on the assumption that the real-world-5-year disease-free survival rate with adjuvant osimertinib therapy would be 50%, slightly lower than that observed in the ADAURA trial, with a 95% confidence interval width of approximately 10%. This takes into account 10% attrition rate and an estimated 60% adoption rate of osimertinib adjuvant therapy in clinical practice.