



A Single-Arm Confirmatory Trial Evaluating Adjuvant Alectinib 300 mg Twice Daily in Japanese Patients With ALK+ Resected NSCLC: JACTOP-02/ J-ALINA

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INTRODUCTION

- In Japan, alectinib 300 mg twice daily demonstrated efficacy in advanced ALK+ NSCLC in the J-ALEX trial and was approved at this dose, whereas the global approved dose is 600 mg twice daily.
- Although adjuvant alectinib has recently been approved in Japan, the approved adjuvant dose is 600 mg twice daily, which is higher than the dose approved for advanced disease in Japan.
- Therefore, we conducted a confirmatory phase III trial to evaluate adjuvant alectinib at 300 mg twice daily in Japanese patients with resected ALK-positive NSCLC.

METHODS

- This study is a prospective, single-arm phase III trial conducted by the Japan Cancer Treatment Optimization Group (JACTOP) at 66 institutions across Japan group.

Statistical Plan

- Based on the ALINA trial, the expected 3-year DFS was set at **88%**, with a threshold value of **78%**.
- Assuming a one-sided alpha of 0.05 and a power of 85%, the required sample size was calculated to be 101 patients based on the arcsine square-root transformation of the Kaplan–Meier estimator.
- The planned sample size was set at 112 patients to allow for ineligible patients.

DISCUSSION AND CONCLUSION

Actionable Take Away Message

- The J-ALINA (JACTOP-02) study is the first prospective interventional trial to investigate dose optimization of adjuvant alectinib in Japanese patients with ALK-positive NSCLC.

Future Direction for Research

- Demonstration of efficacy comparable to that of the ALINA trial would support a lower-dose treatment strategy that may reduce treatment-related toxicity while maintaining clinical efficacy.
- Such an approach has the potential to improve the tolerability of adjuvant therapy and substantially reduce healthcare costs, thereby addressing an important socioeconomic challenge.

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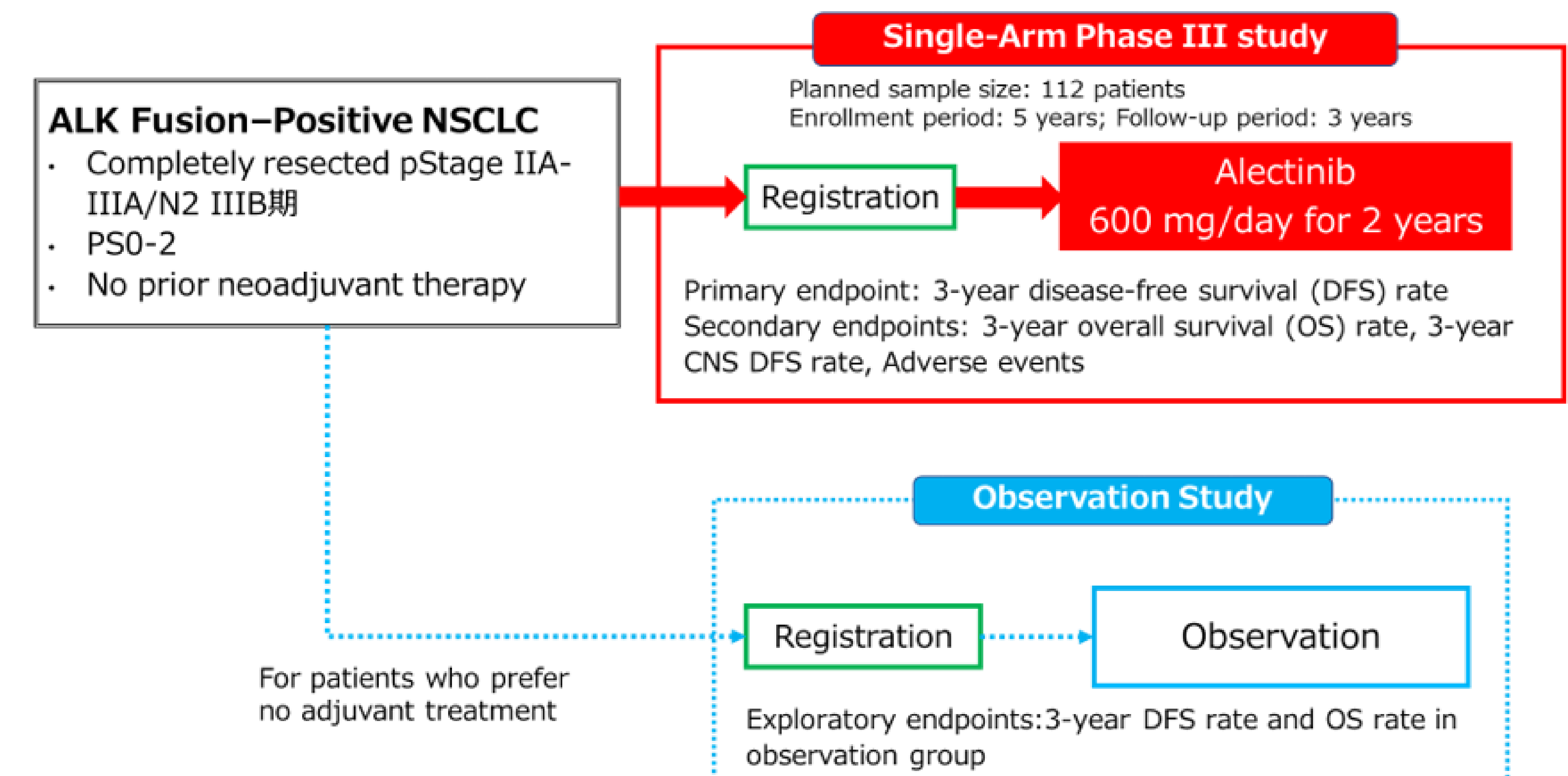


STUDY DESIGN AND TRIAL PROGRESS

Study Schema: A Single-Arm Confirmatory Phase III Trial

Primary Endpoint: 3-year DFS

Planned Sample Size: 112 patients



Trial Progress

