

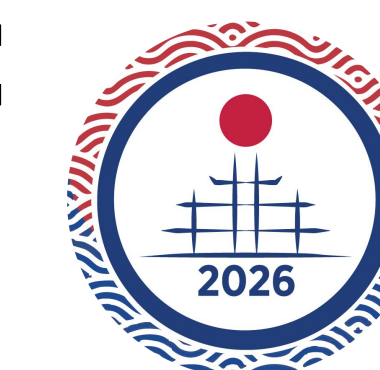


P1.121: Perioperative Cadonilimab and Chemotherapy in Stage II-IIIa Non-Small-Cell Lung Cancer: Primary Analysis of a Phase 2 Study

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INTRODUCTION

- Perioperative immune checkpoint inhibition has established a new paradigm for resectable non-small-cell lung cancer (NSCLC).
- Dual blockade of PD-1 and CTLA-4 elicits synergistic antitumour immunity, potentially translating into durable clinical benefit.
- Cadonilimab (AK104) is a humanized immunoglobulin G1 bispecific antibody that simultaneously targets PD-1 and CTLA-4.
- We report the primary efficacy and safety analyses of a prospective, single-arm, phase 2 trial evaluating perioperative cadonilimab, a novel PD-1/CTLA-4 bispecific antibody, combined with chemotherapy in resectable NSCLC.

METHODS

- This is a single-arm, multi-center, phase II study (NCT05377658).
- Eligible patients received AK104 (10 mg/kg) plus chemotherapy (carboplatin AUC 5 and nab-paclitaxel 260 mg/m²) every 3 weeks for 3 cycles, surgical resection was performed within 3-4 weeks post-neoadjuvant treatment, after re-assessment by investigator, AK104±CRT was administered after surgery.

Endpoints and Assessments:

- Primary endpoints:** pathological complete response (pCR).
- Secondary Endpoints:** major pathological response (MPR), objective response rate (ORR), R0 resection rate, event-free survival (EFS) and safety.

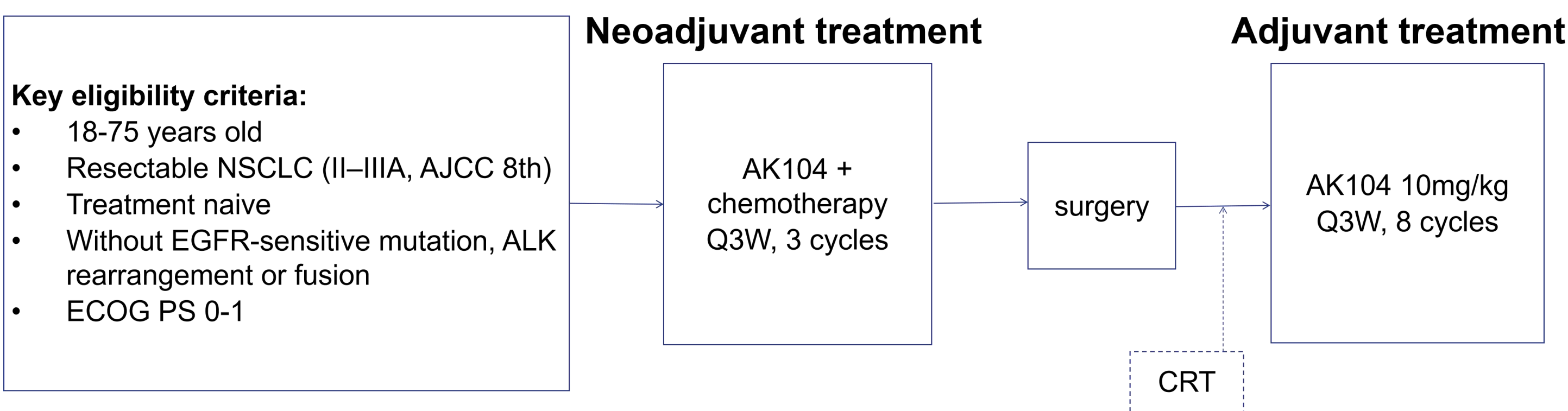


Figure 1. Study Design

BASELINE CHARACTERISTICS

- Between July 2022 and April 2025, a total of 43 patients were enrolled, 2 patients were excluded due to receiving AK104 neoadjuvant monotherapy treatment. 41 patients were included in efficacy and safety analysis. The baseline demographics and disease characteristics are reported in Table 1.
- Median age was 60 years (range: 34-75), 34 patients (82.9%) were male, and 22 patients (53.7%) had ECOG PS 0, 29 patients (70.7%) had history of smoking.
- Squamous NSCLC was observed in 31 (75.6%) patients, stage IIIa NSCLC was observed in 24 (58.5%) and lymph node metastases were observed in 33 (80.5%) patients.

CONCLUSION

- Perioperative cadonilimab combined with chemotherapy in resectable NSCLC demonstrated encouraging efficacy in this phase II study.
- Safety was manageable, grade ≥3 TRAEs occurred in 31.7% patients.

Table 1. Patient Baseline Characteristics

	N=41
Age, years median (range)	60 (34-75)
Sex, n(%)	
Male	34 (82.9)
ECOG, n(%)	
PS 0	22 (53.7)
Smoking status, n(%)	
Never	12 (29.3)
Current/former	29 (70.7)
Histology, n(%)	
Squamous	31 (75.6)
Nonsquamous	9 (22.0)
Other	1 (2.4)
Disease stage, n(%)	
II	17 (41.5)
IIIa	24 (58.5)
cN stage, n(%)	
N0	8 (19.5)
N1	21 (51.2)
N2	12 (29.3)

RESULTS

- As of data cut-off on Feb 28, 2026, 30 of 41 patients (73.2%) underwent surgery, pCR rate was 36.7%, MPR rate was 66.7%. (Table 2, Figure 2)
- The ORR was 63.4%, 1 patient (2.4%) was complete response (CR), 25 patients (61.0%) were partial response (PR), and 6 patients (14.6%) were stable disease (SD). (Table 3)
- 25 patients (83.3%) received R0 resection, 3 patients (10.0%) received R1 resection. (Table 4)

Table 2. Pathological Response

	N=30
pCR	11(36.7%,[19.9% to 56.1%])
MPR (RVT*≤10%)	20(66.7%,[47.2% to 82.7%])
-RVT≤5%	16(53.3%,[34.7% to 71.1%])

*RVT: residual viable tumor cells in both primary tumor and lymph nodes.

Table 3. Efficacy after neoadjuvant therapy

Patients, n (%)	N=41
ORR	26 (63.4,[46.7 to 78.2])
Best overall response	
CR	1 (2.4)
PR	25 (61.0)
SD	6 (14.6)

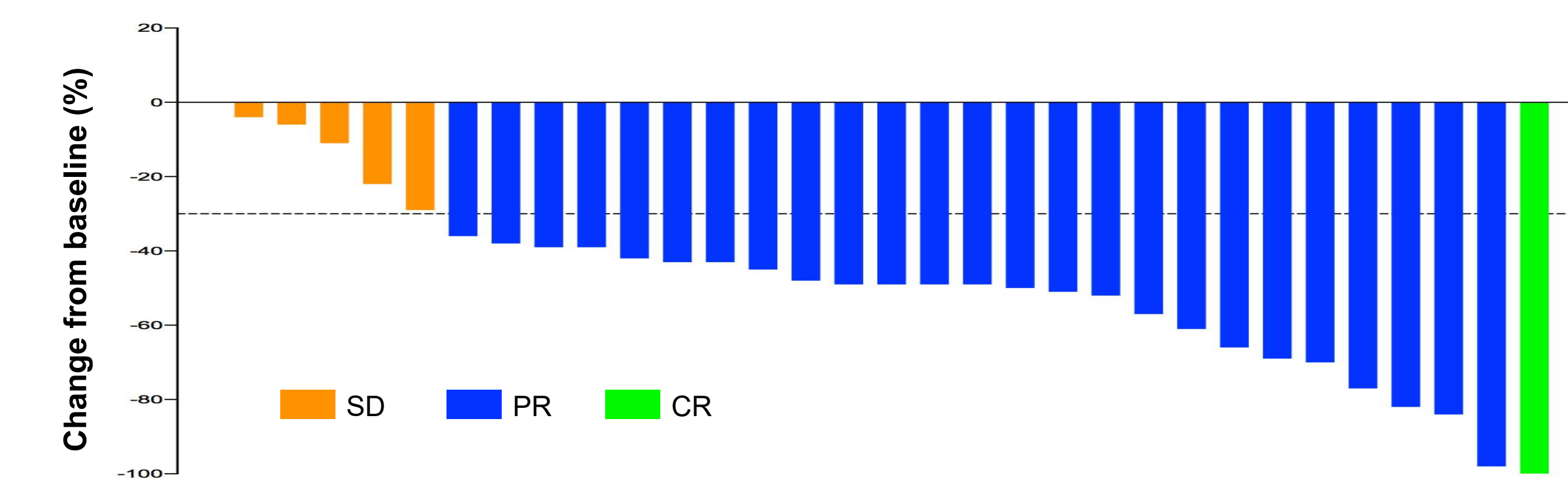


Figure 2. Best change from baseline

Table 4. Summary of surgical results

	N=30
Resection extent	
R0 resection, n(%)	25 (83.3,[65.3 to 94.4])
R1 resection, n(%)	3 (10.0)
Rx resection, n(%)	2 (6.7)
Resection extent	
Lobectomy, (%)	30 (100.0)
Surgical Methods	
Minimally Invasive, n(%)	25 (83.3)
Thoracotomy, n(%)	5 (16.7)

- Grade ≥3 TRAEs occurred in 31.7% of patients, SAEs occurred in only 4.9% of patients.
- TRAEs leading to delayed or cancelled surgery occurred in only 1 patients (2.4%), no drug-related death occurred.

Table 5. Safety Summary

TRAEs, n (%)	N=41
Any grade	37 (90.2)
Grade ≥3	13 (31.7)
SAE	2 (4.9)
irAE	13 (31.7)
Grade ≥3 irAE	3 (7.3)
Infusion related reaction	13 (31.7)
Grade ≥3 infusion-related reaction	6 (14.6)
Leading to treatment discontinuation	13 (31.7)
Leading to death	0 (0)
Leading to delayed or cancelled surgery	1 (2.4)