



Preliminary analysis of efficacy and safety of tislelizumab plus chemotherapy in resectable KRAS-mutant NSCLC

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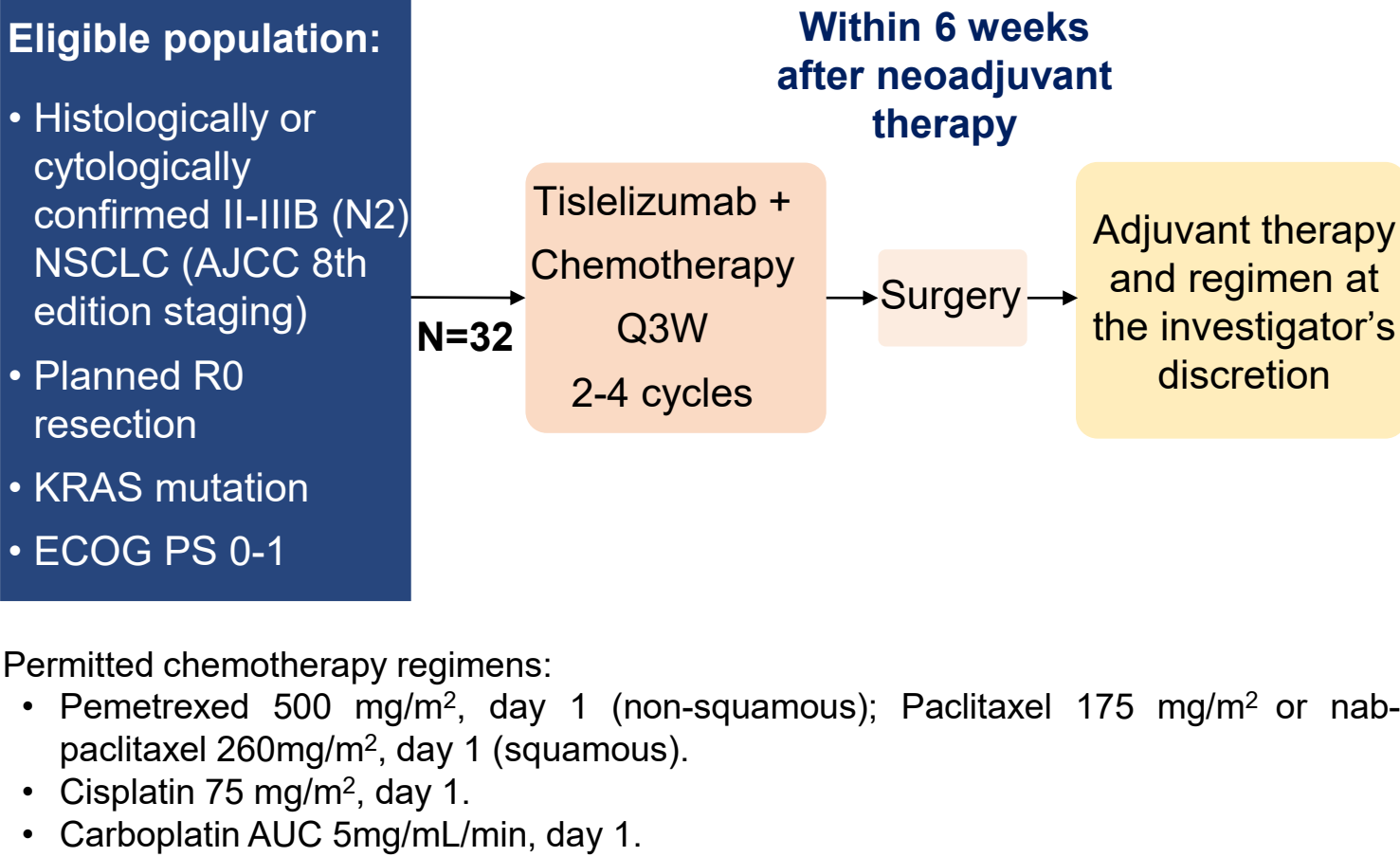
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BACKGROUND

- Perioperative immunochemotherapy has been recommended as a promising treatment option for resectable non-small cell lung cancer (NSCLC) with negative EGFR/ALK mutations based on phase III clinical trials¹⁻⁶.
- KRAS-mutant advanced NSCLC may represent a population that derives greater benefit from immunotherapy⁷. However, whether perioperative immunochemotherapy is suitable for patients harboring KRAS mutations remains unclear.
- We conducted a phase 2 study to evaluate the efficacy and safety of tislelizumab plus chemotherapy in patients with resectable stage II-IIIB (N2) KRAS-mutant NSCLC. Here, we report the preliminary analysis of this trial.

METHODS

Figure 1. Study design



- Primary endpoint:** pCR rate
- Secondary endpoints:** MPR rate, ORR, EFS, OS, downstaging rate, safety

Statistical considerations:

- Simon's two-stage design was applied, assuming a pCR rate of 20% versus a historical control rate of 3.5%. With a one-sided $\alpha=0.025$ and 80% power, 27 evaluable patients are required; allowing for a 15% dropout rate, 32 patients will be enrolled.
- In stage 1, 13 patients will be enrolled; if ≥ 1 patient achieves pCR, the study proceeds to stage 2; if >3 patients achieve pCR, the primary endpoint is met.

RESULTS

Treatment disposition and baseline characteristics

- Between Nov 28, 2024 and March 20, 2026, 16 pts were enrolled (Figure 2, Table 1).

Figure 2. Patient flow

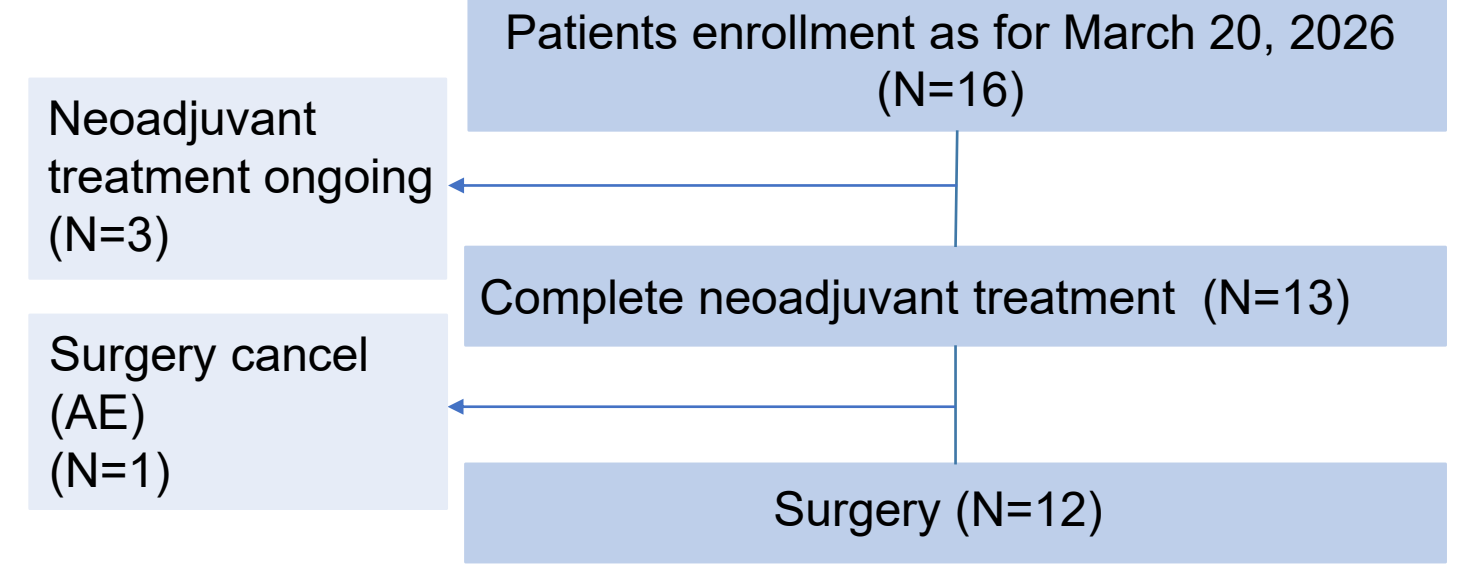


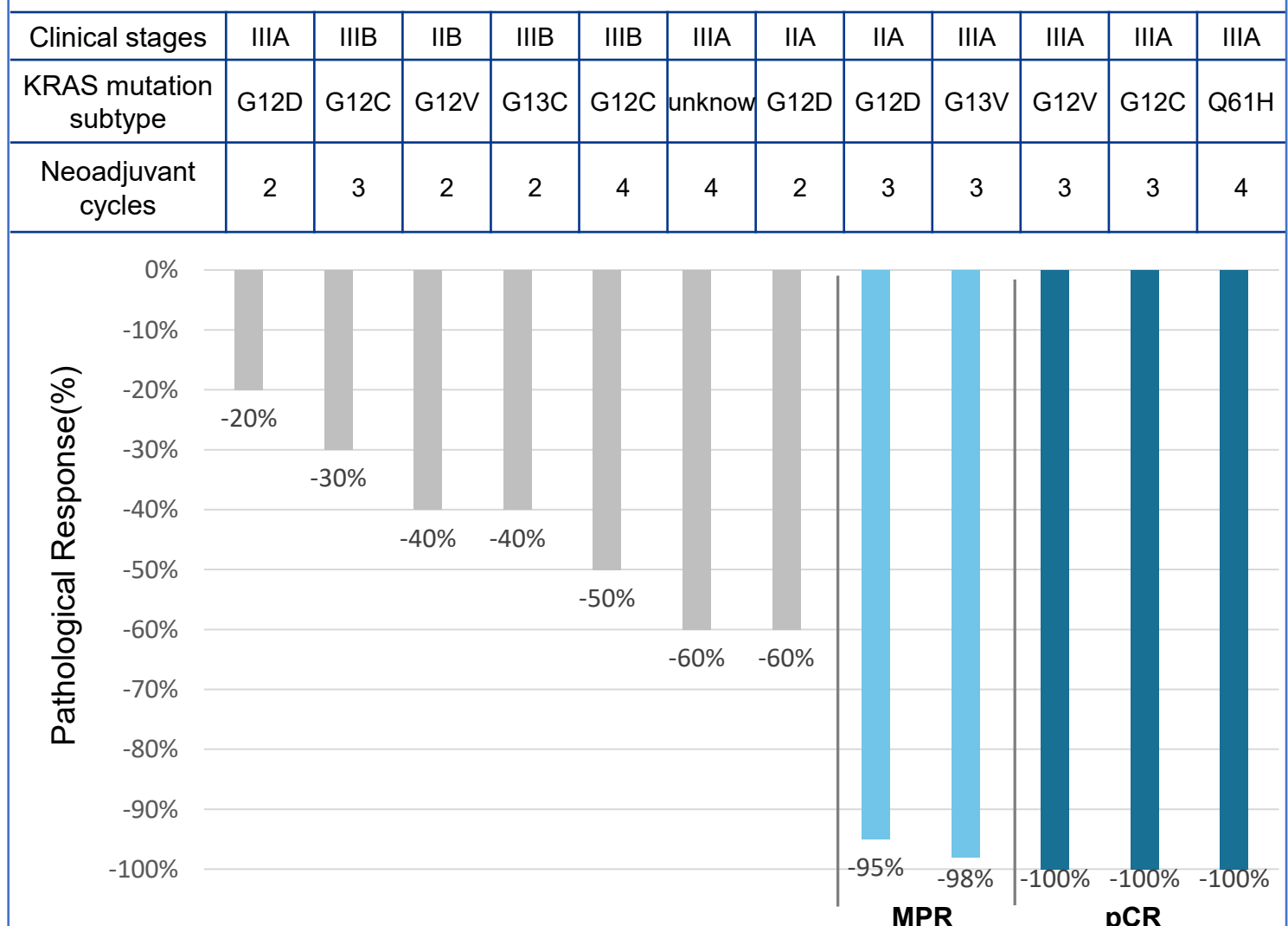
Table1. Baseline characteristics

Characteristics	Patients (n=16)
Age (median-yr)	63 (59-79)
Male/Female, n (%)	12 (75.0) /4 (25.0)
ECOG PS, n (%)	
0/1	5 (31.3) /11 (68.7)
Clinical stage , n (%)	
IIA/IIIB	2 (12.5) /2 (12.5)
IIIA/IIIB	8 (50.0) /4 (25.0)
Histology , n (%)	
Adenocarcinoma	14 (87.5)
Squamous /Adenosquamous Carcinoma	1 (6.25) /1 (6.25)
PD-L1 expression, n (%)	
<1%	3 (18.8)
1-49%	6 (37.5)
$\geq 50\%$	5 (31.3)
unknown	2 (12.5)
KRAS mutation subtype, n (%)	
G12C	4 (25.0)
G12D	6 (44.0)
G12V	2 (12.5)
G13C	1 (5.3)
G13V	1 (5.3)
Q61H	1 (5.3)
unknown	1 (5.3)
Neoadjuvant treatment cycle, n (%)	
2 cycle	4 (30.7)
3 cycle	5 (38.4)
4 cycle	4 (30.7)

Pathological response

- Among 12 pts who underwent resection, 3 pts (25.0%) achieved pCR and 5 pts (41.6%) pts MPR (Figure 3). The study successfully into 2nd stage.
- EFS was immature, 1 pts developed recurrence, the others remain under follow-up.

Figure 3. Pathological response



Radiological response

- The ORR and DCR were 50.0% and 100.0%, respectively (Table 2).

Table 2. Radiological response

	Patients (n=16)
PR	8 (50.0)
SD	8 (50.0)

Surgical outcome

- All 12 pts undergoing surgery achieved R0 resection.
- 11 pts underwent VATS and only 1 required thoracotomy (Table 3).

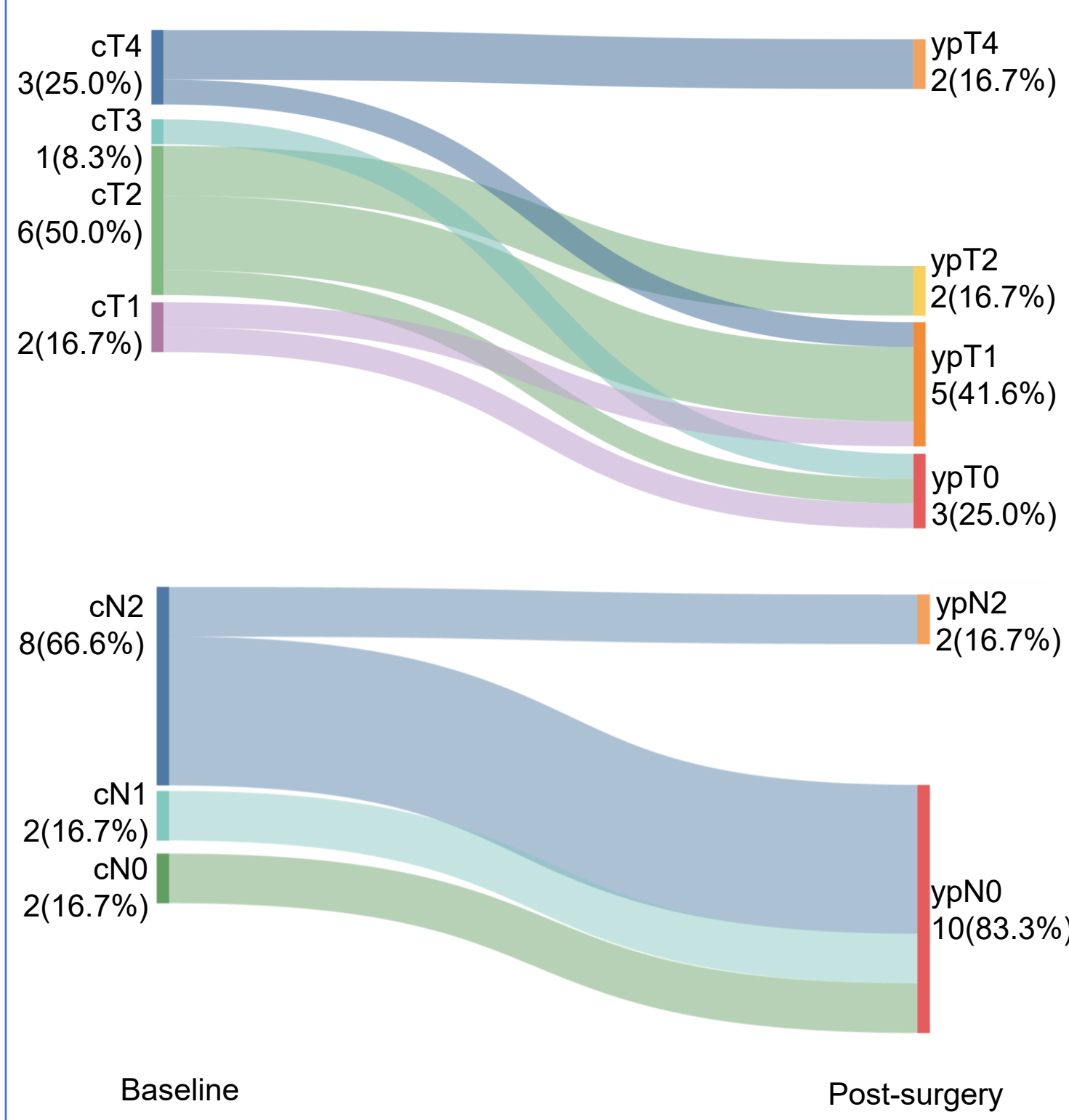
Table 3. Summary of surgical outcomes

	Patients (n=12)
R0 resection, n (%)	12 (100.0)
Surgical approach , n (%)	
Video-assisted thoracoscopic surgery	11 (91.7)
Thoracotomy	1 (8.3)
Resection type, n (%)	
lobectomy	10 (83.3)
Bilobectomy	1 (8.3)
Pneumonectomy	1 (8.3)

Downstaging

- Pathological downstaging occurred in 75.0% (9/12) of patients who underwent surgery (Figure 4).

Figure 4. Pathological downstaging



Safety

- The most common TRAEs were decreased red blood cell and lymphocyte counts (37.5% each).
- Most TRAEs were grade 1 or 2. Grade ≥ 3 TRAEs included neutrophil count decreased (25.0%) and lymphocyte count decreased (12.5%).
- No grade 4-5 AEs were reported (Table 4).

Table 4. Adverse events

	Any Grade (n=16)	$\geq$ Grade 3 (n=16)
Red blood cell count decreased	6 (37.5)	1 (6.3)
Lymphocyte count decreased	6 (37.5)	2 (12.5)
Platelet count decreased	5 (31.2)	1 (6.3)
Alanine aminotransferase increased	5 (31.2)	1 (6.3)
Neutrophil count decreased	4 (25.0)	4 (25.0)
Aspartate aminotransferase increased	4 (25.0)	1 (6.3)
White blood cell count decreased	2 (12.5)	1 (6.3)
Creatine kinase increased	2 (12.5)	0
Vomiting	2 (12.5)	0
Hypothyroidism	2 (12.5)	0
QT interval prolonged	1 (6.3)	0
T3/T4 increased	1 (6.3)	0
Monocyte count decreased	1 (6.3)	0
Proteinuria	1 (6.3)	0
Immune-related pneumonitis	1 (6.3)	0
Anemia	1 (6.3)	1 (6.3)
Rash	1 (6.3)	0
Decreased appetite	1 (6.3)	0
Lung infection	1 (6.3)	0

CONCLUSIONS

- Tislelizumab combined platinum-based chemotherapy demonstrated promising pathological response, feasible surgical resection and manageable toxicity in resectable stage II-IIIB (N2) KRAS-mutant NSCLC. The preliminary results support the continued enrollment and further follow-up.

Abbreviations: ALK, anaplastic lymphoma kinase; AE, adverse event; cN, clinical N; cT, clinical T; DCR, disease control rate; ECOG PS, eastern cooperative oncology group performance status; EFS, event-free survival; EGFR, epidermal growth factor receptor; KRAS, kirsten rat sarcoma viral oncogene homolog; MPR, major pathological response; NSCLC, non-small cell lung cancer; ORR, Objective Response Rate; OS, overall survival; pCR, pathological complete response; PR, partial response; SD, stable disease; TRAEs, treatment-related adverse events; ypN, post-treatment pathological N; ypT, post-treatment pathological T.

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