



P2.329: QL1706 Plus Pm-Pac and Platinum in the Treatment of Stage III Unresectable NSCLC: Preliminary Results from Dynamic-duo Study

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INTRODUCTION

- A series of studies including the phase II study led by Professor Wu's team demonstrated promising efficacy and acceptable safety profile in stage III unresectable non-small cell lung cancer (NSCLC). Based on this evidence, we designed this phase II trial to evaluate the feasibility and potential benefit of using neoadjuvant Iparomlimab and Tuvonralimab (QL1706) plus polymeric micelles paclitaxel (pm-Pac) and platinum as induction therapy for these patients.
- QL1706 is a novel PD-1/CTLA-4 dual inhibitor. The DUBHE-L-201 study demonstrated favorable efficacy and safety for NSCLC patients with the combination of QL1706 and chemotherapy.
- Pm-Pac is a novel Cremophor EL-free, nanoparticle micellar formulation of paclitaxel (20nm). It encapsulates paclitaxel within micelles to enhance the permeability and retention effect, thereby improving pharmacokinetics and tumor-targeted delivery. The studies incorporating pm-Pac have shown impressive results in patients with locally advanced or metastatic NSCLC.

METHODS

- This is a prospective, multicenter, single-arm, phase II study (NCT07082179) that recruited 33 participants with EGFR/ALK/ROS1-negative stage III unresectable NSCLC (ECOG PS≤1). Participants received induction therapy with three cycles (administered every 3 weeks) of QL1706 (5 mg/kg) plus pm-Pac (230 mg/m², followed by a dose escalation to 300 mg/m² from the second cycle if no predefined toxicities were observed) and a platinum agent (cisplatin 70 mg/m² or carboplatin AUC 5 mg/mL/min). Operable participants underwent surgery, while those deemed inoperable received definitive radiotherapy (radical or hypofractionated segmental). Following local treatment, consolidation therapy with QL1706 ± pm-Pac was administered up to 1 year or no more than 17 cycles (including 3 cycles with induction therapy).
- The primary endpoint was objective response rate (ORR). Secondary endpoints included disease control rate (DCR), surgical conversion rate (SCR), pathological complete response (pCR), major pathological response (MPR), R0 resection rate, 18-month event free survival rate (EFS), overall survival (OS), and safety.

RESULTS

Patients baseline characteristics and disposition

- Between September 4, 2025, and May 18, 2026, a total of 38 patients were screened. Of these, five failed to meet the inclusion criteria, resulting in an evaluable population of 33 patients. Among them, two patients completed only one cycle of induction therapy: One discontinued treatment because of active pulmonary tuberculosis, while the other was lost to follow-up due to grade 3 immune-mediated pneumonia. Baseline patient characteristics are summarized in Table 1.
- As of the data cutoff on August 15, 2026, the median follow-up duration was 8.3 months. Of the 33 patients, 31 (93.9%) completed the induction treatment period, and 29 (87.9%) subsequently underwent local therapy (surgery, n = 11; radiotherapy, n = 18). The remaining two patients (6.1%) declined local therapy due to adverse events. During the consolidation phase, four patients (12.1%) discontinued treatment, primarily due to disease progression (n = 3) and adverse events (n = 1). Patient disposition is summarized in Figure 1.

Efficacy

- Among the 33 patients, two achieved complete responses (CR) and 27 had partial responses (PR), two had stable disease (SD), and two were not evaluated (NE) assessed by the investigator according to RECIST 1.1. The ORR was 87.9% (95% CI: 71.8-96.6), and DCR was 93.9% (95% CI: 79.8-99.3) after induction treatment (Table 2). A ≥50% reduction in target lesion size from baseline to the induction treatment period was observed in 20 of the 31 evaluable patients with a median best reduction of -59.3% (interquartile range [IQR], -67.5% to -47.6%) (Figure 2A).
- 33.3% (11/33) of patients successfully underwent surgical conversion, with an R0 resection rate of 100.0% (11/11). Among the 11 resected patients, three had stage IIIA, four had stage IIIB, and four had stage IIIC disease at baseline. The pCR rate was 54.5% (6/11), MPR rate was 72.7% (8/11). Similarly, a ≥50% reduction in target lesion size from baseline to the induction treatment period was observed in 7 of 11 resected patients with a median best reduction of -53.1% (interquartile range [IQR], -62.9% to -47.3%) (Figure 2B).
- In examining the pathological outcomes of 11 resected patients, seven (63.6%) had a complete response in the primary tumor (ypT0), one (9.1%) had ypT1, and three (27.3%) had ypT2. Significantly, all patients with N1-N3-positive lymph nodes achieved ypN0 status. A Sankey diagram showing detailed changes in stage, including T classification and N classification, before induction therapy versus after surgery is shown in Figure 2C-E.
- The median EFS was not reached, and the six-month EFS rate was 84.2% (95% CI: 65.9-93.1) (Table 2 and Figure 2F).

Safety

- All patients (33/33, 100%; Table 3) reported at least one treatment-related adverse event (TRAE) of any grade. TRAEs of grade 3 or higher were observed in 24 of 33 patients (72.7%), with neutrophil count decreased (16/33, 48.5%), lymphocyte count decreased (12/33, 36.4%), and white blood cell decreased (7/33, 21.2%) being the most common.
- The overall incidence of irAEs of any grade was 93.9% (31/33), with events of grade 3 or higher occurring in 21.2% of patients (7/33; Table 3).

Table 1. Baseline characteristics

Total (n=33)	
Age, years	
Median (range)	67 (50-74)
≥65, n (%)	18 (54.5)
≤65, n (%)	15 (45.5)
Sex, n (%)	
Male	33 (100.0)
Smoking status, n (%)	
Current or former smoker	31 (94.0)
Non-smoker	2 (6.0)
ECOG performance status, n (%)	
0	3 (9.1)
1	30 (90.9)
Histological type, n (%)	
Adenocarcinoma	13 (39.4)
Squamous carcinoma	19 (57.6)
Others*	1 (3.0)
Disease stage, n (%)	
IIIA	9 (27.3)
IIIB	13 (39.4)
IIIC	11 (33.3)
PD-L1 TPS, n (%)	
<1%	16 (48.5)
1-49%	9 (27.3)
≥50%	8 (24.2)
Platinum choice, n (%)	
Carboplatin	33 (100.0)

*adenocarcinoma, partially with possible neuroendocrine differentiation

Table 2. Efficacy data of the efficacy analysis set

Variables	QL1706 Plus Pm-Pac and Platinum (n = 33)
Best objective response, n (%)	
Complete response	2 (6.1)
Partial response	27 (81.8)
Stable disease	2 (6.1)
Not evaluable*	2 (6.1)
ORR, % (95% CI)	87.9 (71.8-96.6)
DCR, % (95% CI)	93.9 (79.8-99.3)
Surgical Conversion, n (%)	11 (33.3)
EFS	not reached
Six months EFS rate, % (95% CI)	84.2 (65.9-93.1)

ORR, Objective Response Rate; DCR, Disease Control Rate; pCR, Pathological Complete Response; MPR, Major Pathological Response; EFS, Event-free Survival. *After only one cycle of induction therapy, one died of active pulmonary tuberculosis, and the other was lost to follow-up due to grade 3 immune-mediated pneumonia.

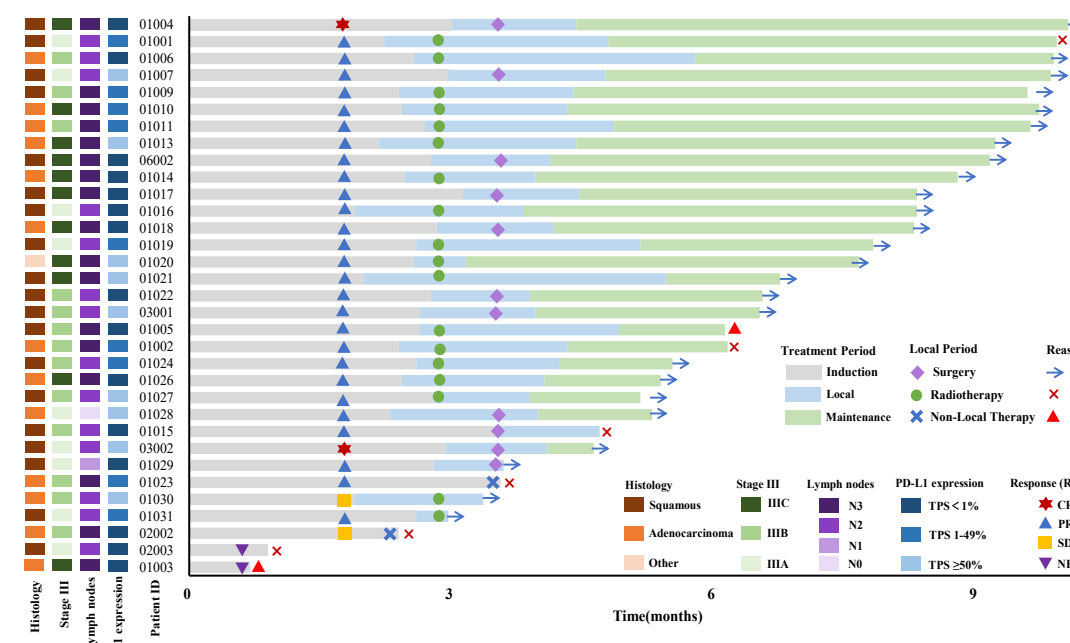


Figure 1. Patients Disposition PD-L1, Programmed death-ligand 1; TPS, tumor proportion score; CR, complete response; PR, partial response; SD, stable disease; NE, not evaluated. Lymph nodal status was assessed at study entry by contrast-enhanced CT or PET-CT.

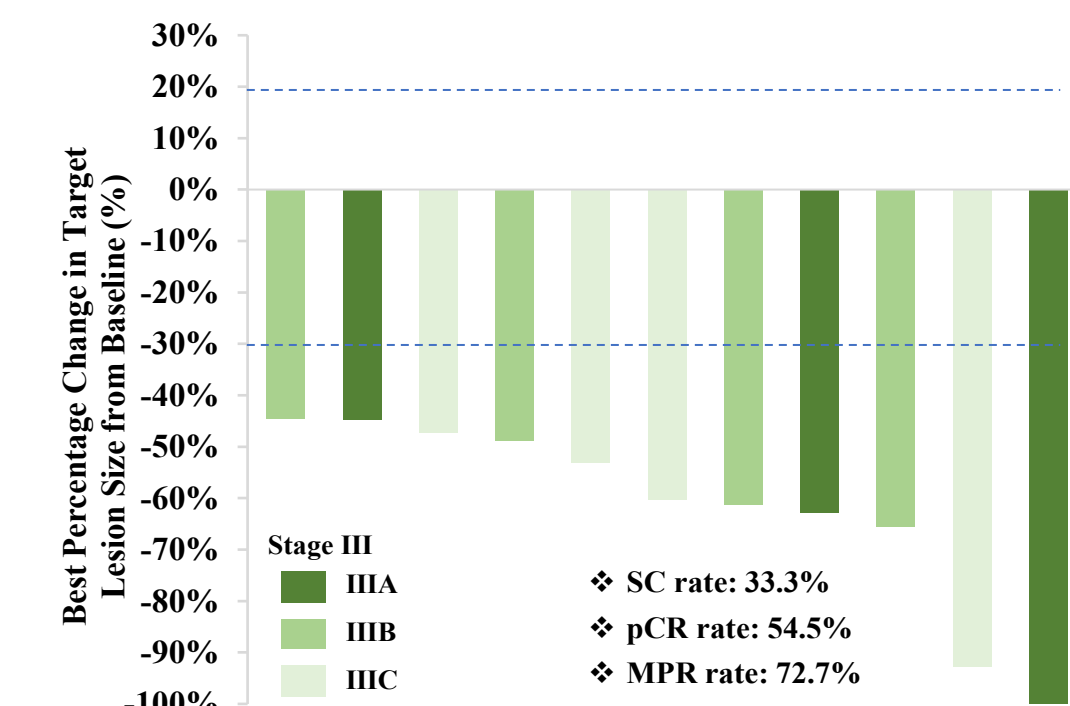


Figure 2B. Waterfall Plot of Tumor Response and Remission of 11 resected Patients

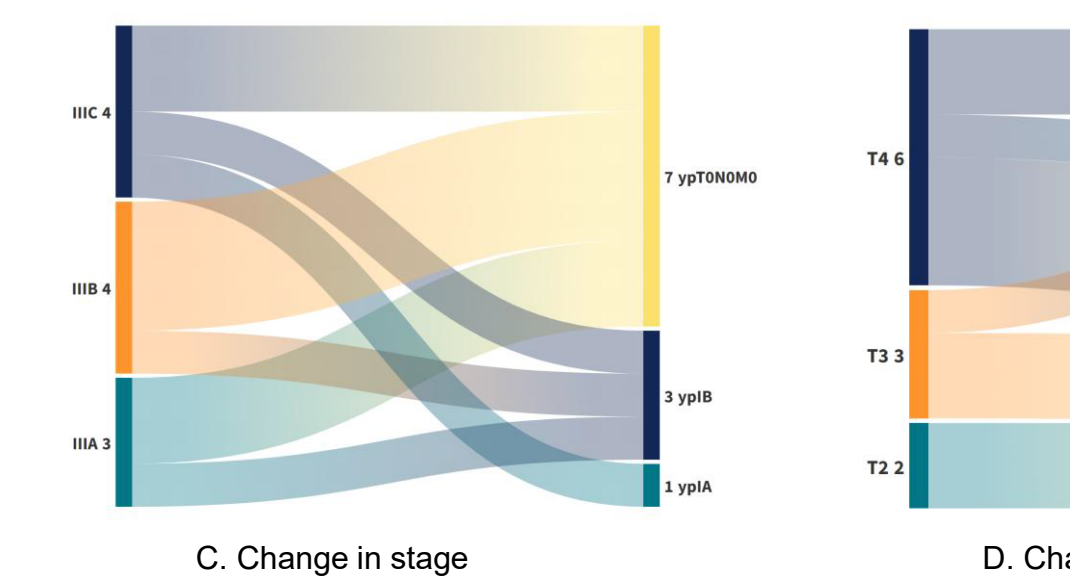


Figure 2C-E. Sankey diagrams visualizing shifts in stage (C), primary tumor (D), and lymph node involvement (E) from pre-induction therapy to post-surgery.

Table 3. Summary of treatment-related adverse events and irAE

Total (n=33)	
Table 3. Summary of treatment-related adverse events and irAE	
	All grade
Any TRAE, n(%)	33(100.0)
Any irAE, n(%)	31(93.9)
TRAE led to interruptions	16(48.5)
TRAE led to discontinuation	1(3.0)
TRAE led to death	1(3.0)
TRAE occurring in ≥20% patients, n(%)	
Anemia	26(78.8)
Lymphocyte count decreased	25(75.8)
Neutrophil count decreased	23(69.7)
White blood cell decreased	22(66.7)
Pain	22(66.7)
Malaise	18(54.5)
Platelet count decreased	18(54.5)
Alanine aminotransferase increased	18(54.5)
Elevated lactate dehydrogenase	17(51.5)
Hypercholesterolemia	16(48.5)
Hypertriglyceridemia	16(48.5)
Alopecia	16(48.5)
Hypoalbuminemia	15(45.5)
Neuropathy peripheral	15(45.5)
Hyperglycemia	15(45.5)
Aspartate aminotransferase increased	15(45.5)
Anorexia	13(39.4)
Pruritus	11(33.3)
Infusion related reaction	11(33.3)
Elevated gamma-glutamyl transferase	11(33.3)
Hyperuricemia	9(27.3)
Rash	9(27.3)
Elevated alkaline phosphatase	8(24.2)
Elevated troponin T	8(24.2)
Decreased blood corticotropin	7(21.2)
irAE occurring in ≥10% patients, n(%)	
Malaise	18(54.5)
Pruritus	9(27.3)
Elevated troponin T	8(24.2)
Rash	8(24.2)
Infusion related reaction	8(24.2)
Blood corticotropin decreased	7(21.2)
Thyroid stimulating hormone increased	6(18.2)
Hypothyroidism	4(12.1)

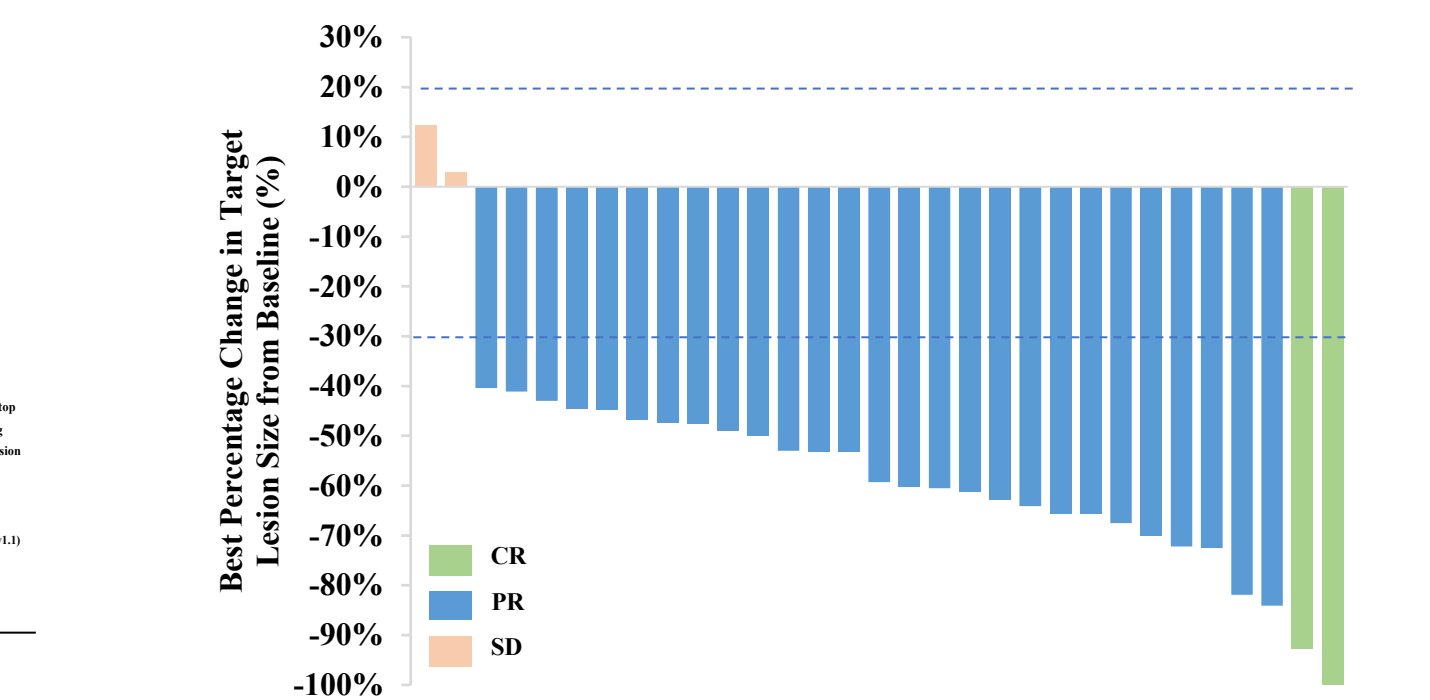


Figure 2A. Waterfall Plot of Tumor Response and Remission of 31 evaluated patients

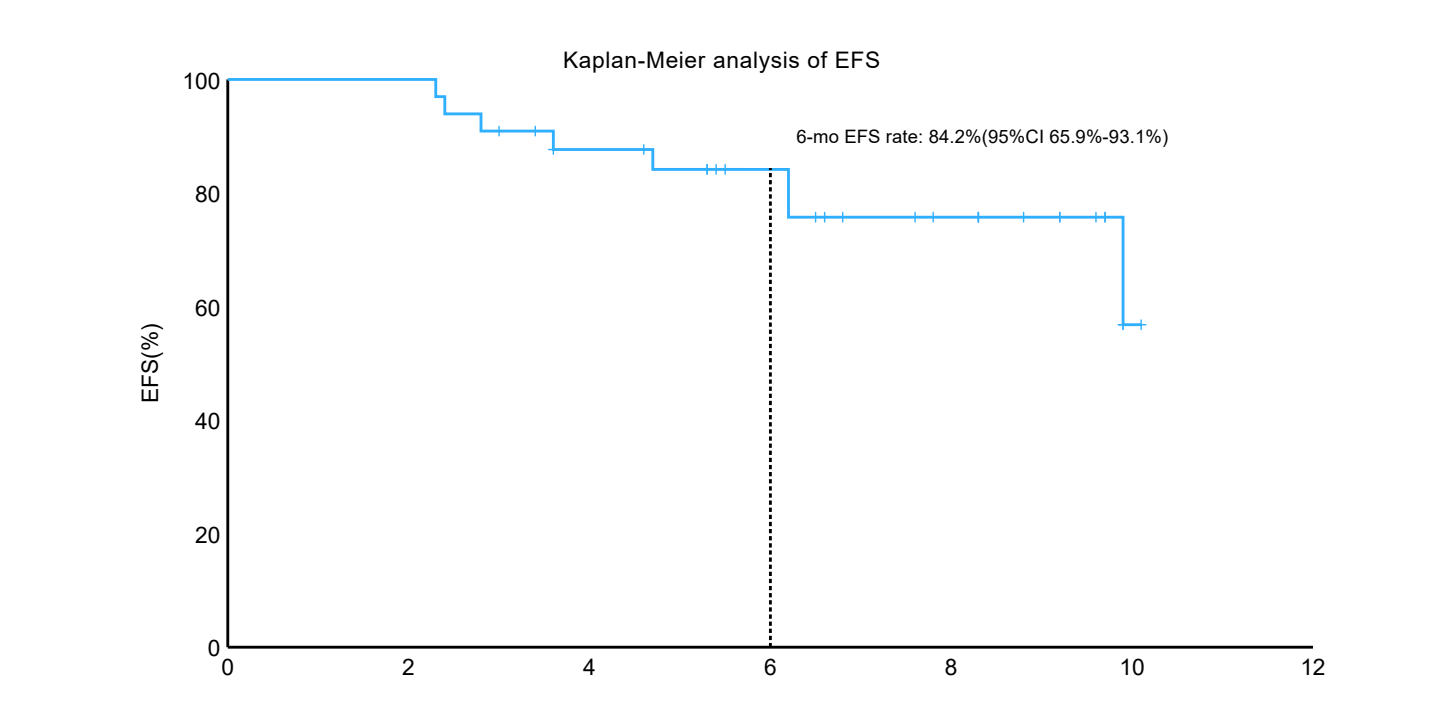


Figure 2F. Kaplan-Meier analysis of EFS

CONCLUSION

This is the first report on a novel PD-1/CTLA-4 dual inhibitor combined with the novel nanoscale chemotherapeutic agent pm-Pac for EGFR/ALK/ROS1-negative unresectable stage III NSCLC, demonstrating promising efficacy and manageable safety, warranting further investigation.

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Conflict of interest

The authors declare that there is no conflict of interest.