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Four-Year Clinical Outcomes of Tislelizumab Plus Chemotherapy as Neoadjuvant/Adjuvant Therapy for Stage IIB-IIIC NSCLC (LungMark Study)

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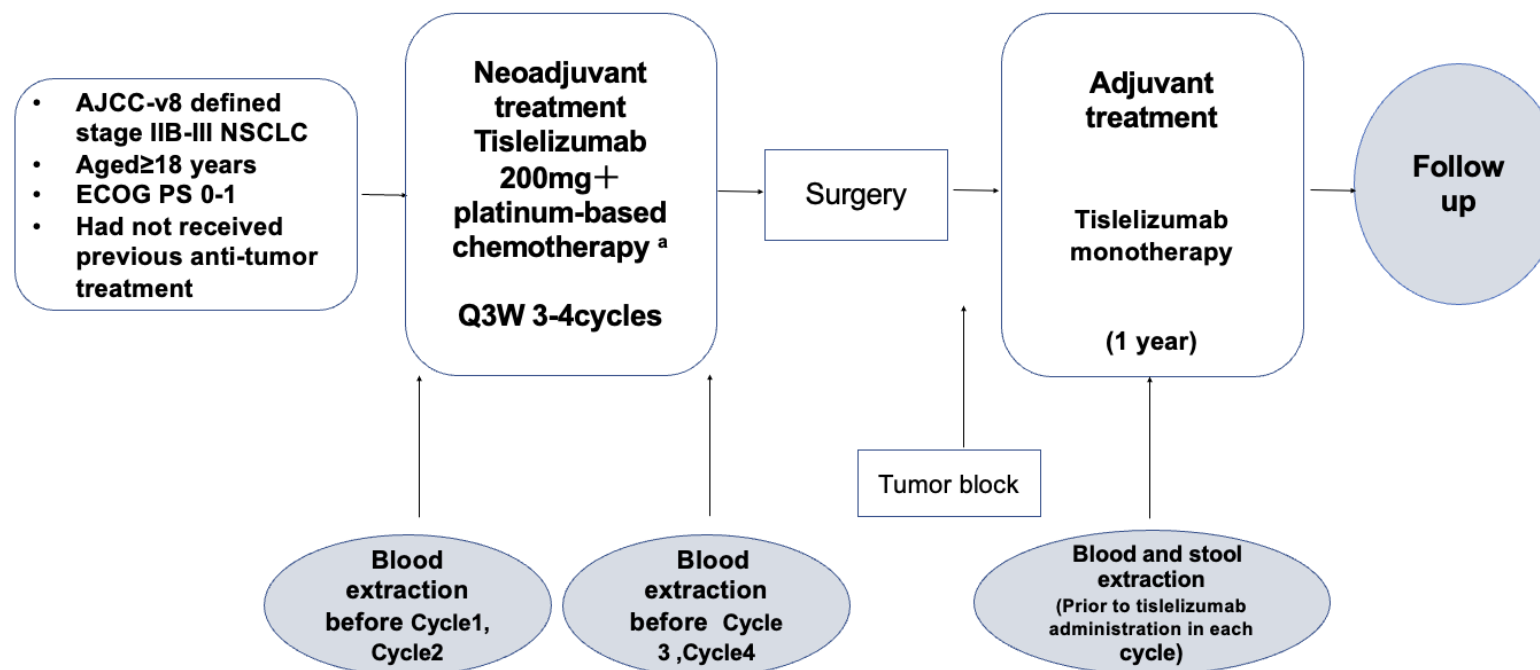
■ Background

- LungMark study is a phase II study investigating the feasibility of neoadjuvant PD-1 inhibitor tislelizumab with chemotherapy in patients with stage IIB-IIIC non-small-cell lung cancer (NSCLC).
- The preliminary results of this trial had been presented in 2023 ASCO abstract 8564, demonstrating a major pathological response (MPR) rate of 72.7% and a pathological complete response (pCR) rate of 47.7% in the surgical resection population.
- Forty-four patients (44/53, 83.0%) underwent resection, in which 36 (36/53, 67.9%) received adjuvant tislelizumab.
- Here we present the 4-year survival outcomes of the LungMark study.

■ Method

- The study enrolled treatment-naïve patients with stage IIB-IIIC NSCLCs.
- Surgical resection was performed 4-6 weeks after 3~4 cycles of neoadjuvant PD-1 inhibitor tislelizumab (200mg), carboplatin (area under the curve 5), and pemetrexed (500 mg/m² for adenocarcinoma) or nab-paclitaxel (260 mg/m² for other subtypes) on day 1 of each 21-day cycle. Adjuvant tislelizumab monotherapy was followed for 1 year.

■ Study Design



Primary endpoint

- Safety

Secondary endpoints

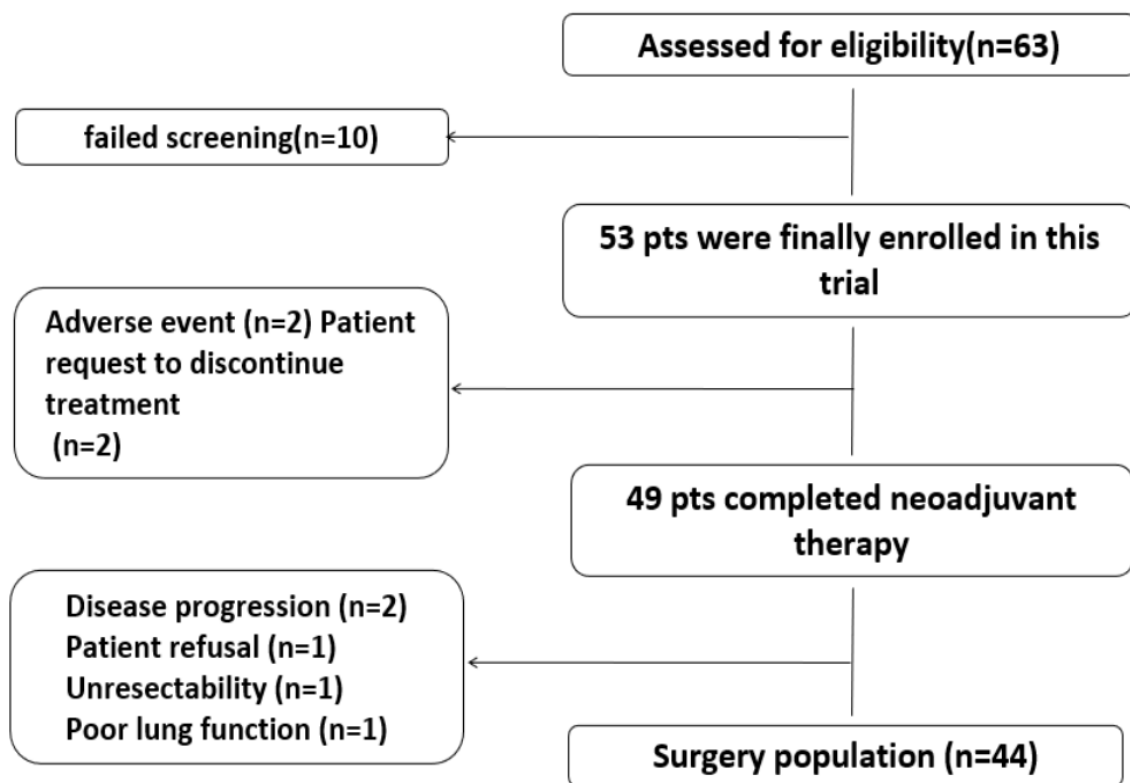
- MPR
- R0 resection rate
- pCR
- Event-free survival (EFS)

Exploratory endpoint

- Molecular markers on efficacy and safety

a: Carboplatin (AUC5) + Pemetrexed (500 mg/m² for adenocarcinoma) or Nab-paclitaxel (260mg/m² for squamous carcinoma)

■ Baseline characteristics



Characteristics	Total (n = 44)	MPR (n = 32)	non-MPR (n = 12)
Age, years (median, [IQR])	61 [56–66]	63 [58–67]	56 [48–64]
Sex (n [%])			
Male	37 [84.1]	29 [90.6]	8 [66.7]
Female	7 [15.9]	3 [9.4]	4 [33.3]
Stage (n [%])			
II	7 [15.9]	7 [21.9]	0 [0]
III	37 [84.1]	25 [78.1]	12 [100.0]
Histology (n [%])			
Adenocarcinoma	10 [22.7]	3 [9.4]	7 [58.3]
Squamous carcinoma	30 [68.2]	27 [84.4]	3 [25.0]
Others	4 [9.1]	2 [6.2]	2 [16.7]
Pathological assessment (n [%])			
pCR	21 [47.7]	21 [65.6]	0 [0]
non-pCR	23 [52.3]	11 [34.4]	12 [100]

■ EFS and OS of the ITT population

- On Jan 2026, the median follow-up duration was 48.6 months (95% CI: 43.0-51.7). Recurrence occurred in 18 pts (18/44, 40.9%) of who had surgery.
- EFS and OS at 48 months was 53.4% (95% CI:38.5-66.1) and 71.8% (95% CI:56.9-82.3), respectively.

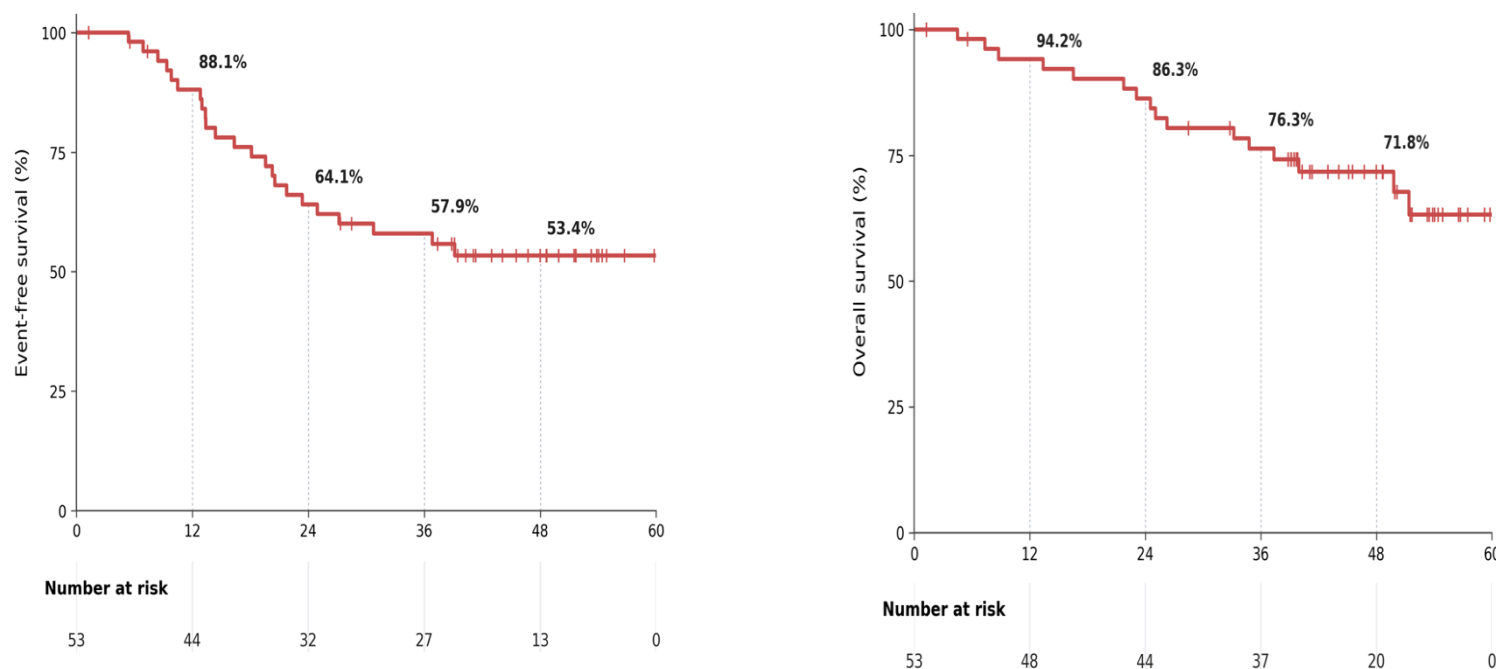


Figure 1. Survival Outcomes in the Evaluable Population

■ Molecular markers on efficacy

- Patients who achieved MPR showed a significantly higher gut-microbial alpha diversity, an enrichment of *Ruminococcaceae*, *Lachnospiraceae* and *Clostridiales* species, and an increased plasma level of tryptophan metabolites at baseline.
- On the contrary, non-MPR patients were characterized by enrichment of *Prevotella* species in faecal samples and higher plasma levels of linoleic acid metabolites. A high predictive accuracy was achieved using a small panel of differential microbial (*Clostridium* sp. M62/1 and *Eisenbergiella tayi*) or metabolomic features (linoleic acid, oxindole-3-acetic acid and quinolinic acid) with AUCs > 0.85.

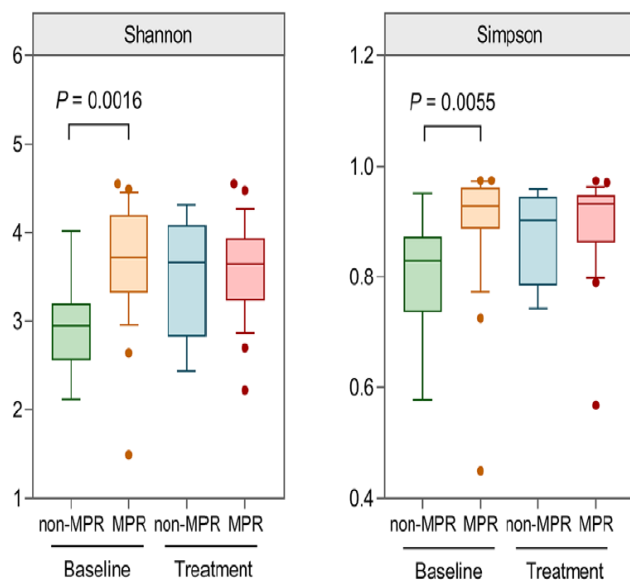


Figure 2. The indices of alpha-diversity in each group.

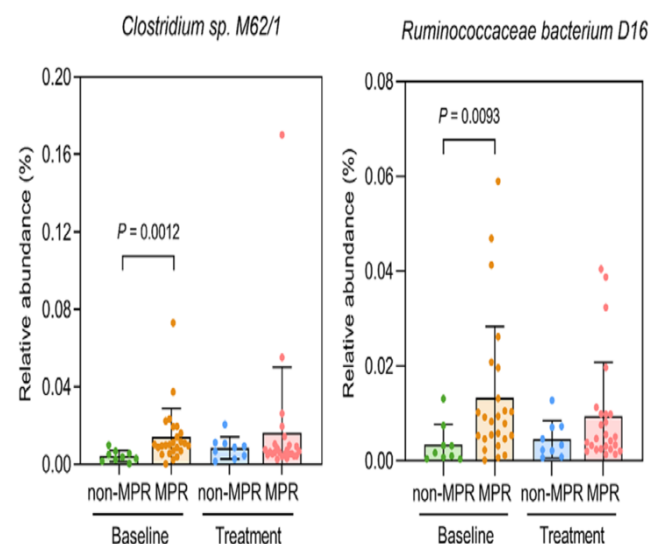


Figure 3. Examples of important differential species.

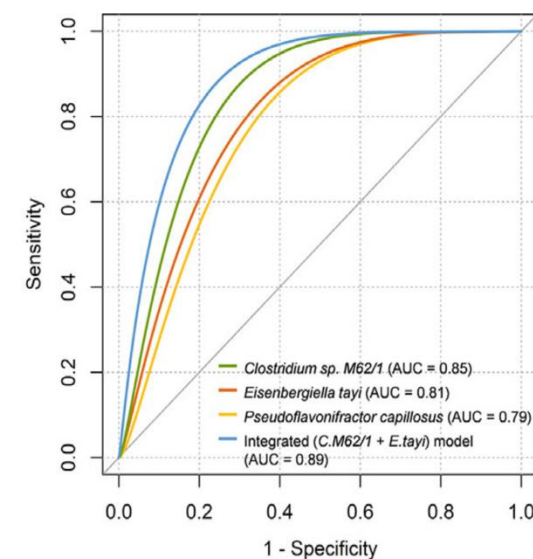


Figure 4. ROC curve of logistic regression model based on the selected differential species

■ Conclusions

- **Neoadjuvant and adjuvant tislelizumab combined with chemotherapy showed long-term benefit for patients with stage IIB-IIIC NSCLC.**
- **The baseline characteristics of the gut microbiota and plasma metabolites could provide early predictions of the response to neoadjuvant anti-PD-1 immunochemotherapy.**

■ Disclosure

- Conflict of Interest Disclosure: none
- AI Use Disclosure: none

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Conclusions

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- The baseline characteristics of the gut microbiota and plasma metabolites could provide early predictions of the response to neoadjuvant anti-PD-1 immunochemotherapy.

References

- References:
- 1. 2023 ASCO Abs8564. 2. 2024 WCLC P1.08C.03.
- 3. Clin Transl Med. 2026 Jan;16(1):e70579.

Results

- On Jan 2026, the median follow-up duration was 48.6 months (95% CI: 43.0-51.7). EFS and OS at 48 months was 53.4% (95% CI: 38.5-66.1) and 71.8% (95% CI: 56.9-82.3), respectively (Figure 2).
- Patients who achieved MPR showed a significantly higher gut-microbial alpha diversity, an enrichment of *Ruminococcaceae*, *Lachnospiraceae* and *Clostridiales* species, and an increased plasma level of tryptophan metabolites at baseline (Figure 3,4).
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Method

- Study design: Phase II, open-label study (NCT05244837)
- Eligible patients: histologically confirmed AJCC v8-defined stage IIB-III NSCLC deemed surgically resectable or potentially resectable.
- The primary endpoint was safety.
- The secondary endpoints included MPR, pCR, R0 resection rate and event-free survival (EFS), OS, potential predictive biomarkers.
- Shotgun metagenomic and plasma/faecal metabolomic studies were performed in 44 NSCLC patients, who underwent neoadjuvant tislelizumab plus platinum-based doublet chemotherapy.
- Samples were collected at baseline and before surgical resection, and the major pathologic response (MPR) was evaluated.

Figure 1. Study design

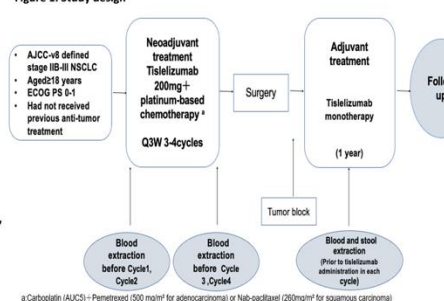


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IIB	7 [15.9]	7 [21.9]	0 [0]
IIIC	37 [84.1]	25 [78.1]	12 [100.0]
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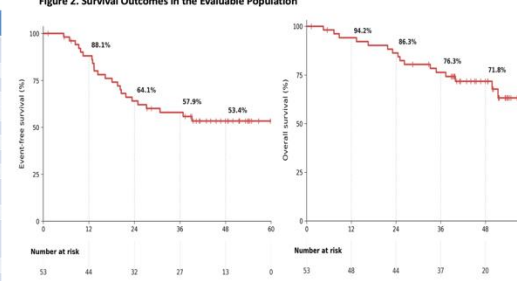


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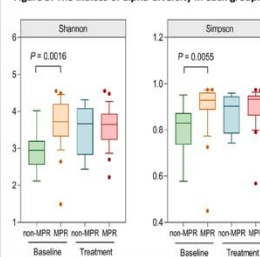


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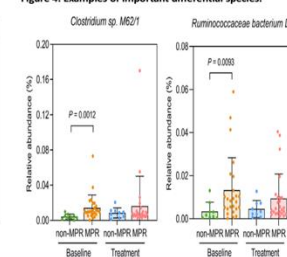


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