



P2.384: Perioperative Tislelizumab Combined with Chemotherapy and Bevacizumab for Resectable Lung Adenocarcinoma: A Phase II Study

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INTRODUCTION

- Immune checkpoint inhibition (ICI) combined with chemotherapy has transformed the treatment paradigm for patients with resectable NSCLC. However, patients with lung adenocarcinoma (LUAD) typically exhibit lower pathological complete response (pCR) rates than those with squamous cell carcinoma, and increasing pCR is considered a key strategy to improve long-term outcomes.
- Bevacizumab, an anti-VEGF monoclonal antibody, has the potential to enhance the efficacy of ICIs by normalizing tumor vasculature, increasing immune cell recruitment, and reversing the immunosuppressive tumor microenvironment.
- This study aims to evaluate the efficacy and safety of perioperative tislelizumab combined with chemotherapy and bevacizumab in patients with resectable stage IIA-IIIB LUAD, followed by surgery and biomarker-stratified adjuvant therapy.

STUDY DESIGN

Key Eligibility Criteria: N=30

- Age 18-75 years
- Resectable Stage IIA-IIIB LUAD (AJCC 9th Edition)
- ECOG PS 0-1

Neoadjuvant Phase: Quadruplet regimen

- Tislelizumab 200mg
- Bevacizumab 15mg/kg
- Pemetrexed plus Platinum Q3W, 2-3 cycles

Surgery

EGFR & ALK
Negative

Intensive Adjuvant:

- Tislelizumab
- Bevacizumab
- Pemetrexed plus Platinum Q3W, 1-2 cycles (for a total of 4 cycles)

EGFR or ALK
Positive

Intensive Adjuvant:

- Bevacizumab
- Pemetrexed plus Platinum Q3W, 1-2 cycles (for a total of 4 cycles)

Maintenance:

- Tislelizumab 200 mg (up to 15 cycles, total 1 year)

Maintenance:

- Targeted TKI Therapy (≥12 weeks IO washout)

Primary endpoint: The pathological complete response (pCR) rate

Secondary endpoints: Major pathological response (MPR) rate, objective response rate (ORR) during the induction phase, event-free survival (EFS), overall survival (OS), and incidence of adverse events

METHODS

Key Inclusion Criteria

- Aged 18 to 75 years at the time of informed consent.
- ECOG performance status of 0 or 1.
- Histologically confirmed stage IIA-IIIB (stage IIIB limited to T2-4N2, AJCC 9th Edition) lung adenocarcinoma.
- Assessed by a thoracic surgeon as eligible for curative-intent R0 resection.
- Adequate hematologic and organ function within 7 days prior to enrollment.

Key Exclusion Criteria

- Known history of central nervous system (CNS) metastases.
- Tumor invasion of major blood vessels or high risk of fatal bleeding.
- Prior treatment with immune checkpoint inhibitors or systemic antiangiogenic therapy.
- Active hemoptysis, bleeding diathesis, or unhealed wounds/ulcers.
- Severe cardiovascular disease, uncontrolled hypertension, or active autoimmune disease.

Treatment

Neoadjuvant Treatment Period: Eligible patients receive 2-3 cycles of Tislelizumab (200 mg) + Bevacizumab (15 mg/kg) + Pemetrexed + Platinum (Cisplatin or Carboplatin) every 3 weeks.

Surgery Period: Surgery performed 4-6 weeks after the last neoadjuvant dose. Bevacizumab must be discontinued ≥28 days prior to surgery.

Adjuvant Treatment Period: Adjuvant therapy is stratified based on postoperative EGFR and ALK testing results. Bevacizumab cannot be used until at least 28 days post-surgery and complete wound healing.

EGFR/ALK Negative Cohort: Patients will receive 1-2 cycles of intensive adjuvant therapy (Tislelizumab + Pemetrexed + Platinum + Bevacizumab) to complete a total of 4 perioperative chemotherapy cycles, followed by Tislelizumab monotherapy maintenance for up to 15 cycles or until disease recurrence.

EGFR/ALK Positive Cohort: Patients will receive 1-2 cycles of intensive adjuvant therapy (Pemetrexed + Platinum + Bevacizumab), followed by adjuvant TKI therapy.

REFERENCES

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