



P2.387: STELLAR: Phase II Study of Tislelizumab Plus Docetaxel in Metastatic Non-Small Cell Lung Cancer Progressing on First-Line Chemoimmunotherapy

Bin Xu¹, Junju He¹, Jie Wu¹, Zhiqiang Cai², Ming Luo³

¹Cancer Center, Renmin Hospital of Wuhan University, Wuhan, China; ²Department of Oncology, Jingzhou First People's Hospital, Jingzhou, China;

³Department of Oncology, Shiyan Taihe Hospital, Affiliated Hospital of Hubei University of Medicine, Shiyan, China.

Correspondence: Xubin_oncology@whu.edu.cn



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INTRODUCTION

- The combination of anti-PD-(L)1 antibodies with platinum-doublet chemotherapy is the standard first-line (1L) treatment for metastatic non-small cell lung cancer (NSCLC) lacking actionable driver mutations.
- Despite initial efficacy, most patients eventually experience disease progression, and second-line (2L) options remain limited, with docetaxel being a standard but modestly effective choice.
- Emerging rationale suggests that continuing PD-1 blockade beyond progression, combined with taxane-based chemotherapy, may overcome acquired immune resistance and restore anti-tumor immunity.
- The STELLAR (Second-line Tislelizumab Efficacy in Lung cancer: Longitudinal Assessment of Response) study evaluates the efficacy, safety, and longitudinal multi-omics biomarker profiles of tislelizumab combined with docetaxel as a 2L therapy for metastatic NSCLC patients failing 1L chemoimmunotherapy.

STUDY DESIGN

Key Eligibility Criteria: N=42

- Metastatic NSCLC (AJCC 9th Edition)
- EGFR, ALK, and ROS1 negative
- Progressed on 1L PD-(L)1 + chemotherapy (IL PFS $\geq$ 84 days)
- At least one measurable lesion per RECIST v1.1
- ECOG PS 0-1
- No prior treatment with docetaxel

Treatment:

- Tislelizumab (200 mg, IV, Q3W), up to 2 years
- Docetaxel (60 mg/m², IV, Q3W), up to 4 cycles

Treatment Duration:

- Disease progression
- Unacceptable toxicity
- Death
- Withdrawal of informed consent

Primary endpoint: Investigator-assessed 6-month progression-free survival (PFS) rate per RECIST v1.1

Secondary endpoints: PFS, overall survival (OS), objective response rate (ORR), disease control rate (DCR), duration of response (DoR), and safety (per NCI-CTCAE v5.0)

METHODS

Key Inclusion Criteria

- Aged 18-75 years with an ECOG performance status of 0 or 1.
- Histologically or cytologically confirmed metastatic NSCLC (AJCC 9th Edition) without known EGFR, ALK, or ROS1 rearrangements.
- Documented disease progression during or after 1L treatment with an anti-PD-(L)1 antibody plus platinum-doublet chemotherapy and first-line PFS of $\geq$ 84 days.
- At least one measurable lesion according to RECIST v1.1.
- Adequate hematologic and organ function.

Key Exclusion Criteria

- Prior treatment with docetaxel, anti-angiogenic therapy, or immunotherapies other than anti-PD-(L)1 antibodies.
- Unacceptable toxicity from prior anti-PD-(L)1 therapy.
- Active brain or meningeal metastasis.
- Active autoimmune diseases or conditions requiring systemic immunosuppressive therapy within 14 days pre-enrollment.

Treatment

- Patients will receive tislelizumab (200 mg, IV, Q3W, up to 2 years) combined with docetaxel (60 mg/m², IV, Q3W, up to 4 cycles) until disease progression, unacceptable toxicity, death, withdrawal of consent, or reaching the 2-year maximum.
- Patients experiencing radiological progression per RECIST v1.1 may continue study treatment if the investigator determines ongoing clinical benefit, provided they have stable ECOG PS and no rapid disease progression requiring urgent intervention.

Translational Research (Exploratory): A longitudinal sampling strategy is implemented to identify predictive biomarkers and resistance mechanisms, including baseline whole blood and plasma for single-cell RNA sequencing (scRNA-seq) and deep proteomics, optional baseline tumor tissue collection, and dynamic monitoring via paired blood samples collected at first partial response (PR) or stable disease (SD) at Cycle 4 (if no prior PR), and at progressive disease (PD).

REFERENCES

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