



Rh-Endostatin + Sintilimab plus Chemotherapy as First-Line Therapy for EGFR/ALK-Negative Squamous NSCLC: A Single-Arm, Multicenter Phase II Clinical Study

Jianguo Zhou¹, Hu Ma¹, Junzhu Xu¹, Shiyun Xing¹, Gang Shen¹, Mi Meng¹, Shanshan Deng¹, Wenwen Zhang¹, Lei Zhou¹

¹Department of Oncology, The Second Affiliated Hospital of Zunyi Medical University, Zunyi/CN

Correspondence to: Jian-Guo Zhou MD, Dr. rer. biol. hum (PhD), jianguo.zhou@yahoo.com.



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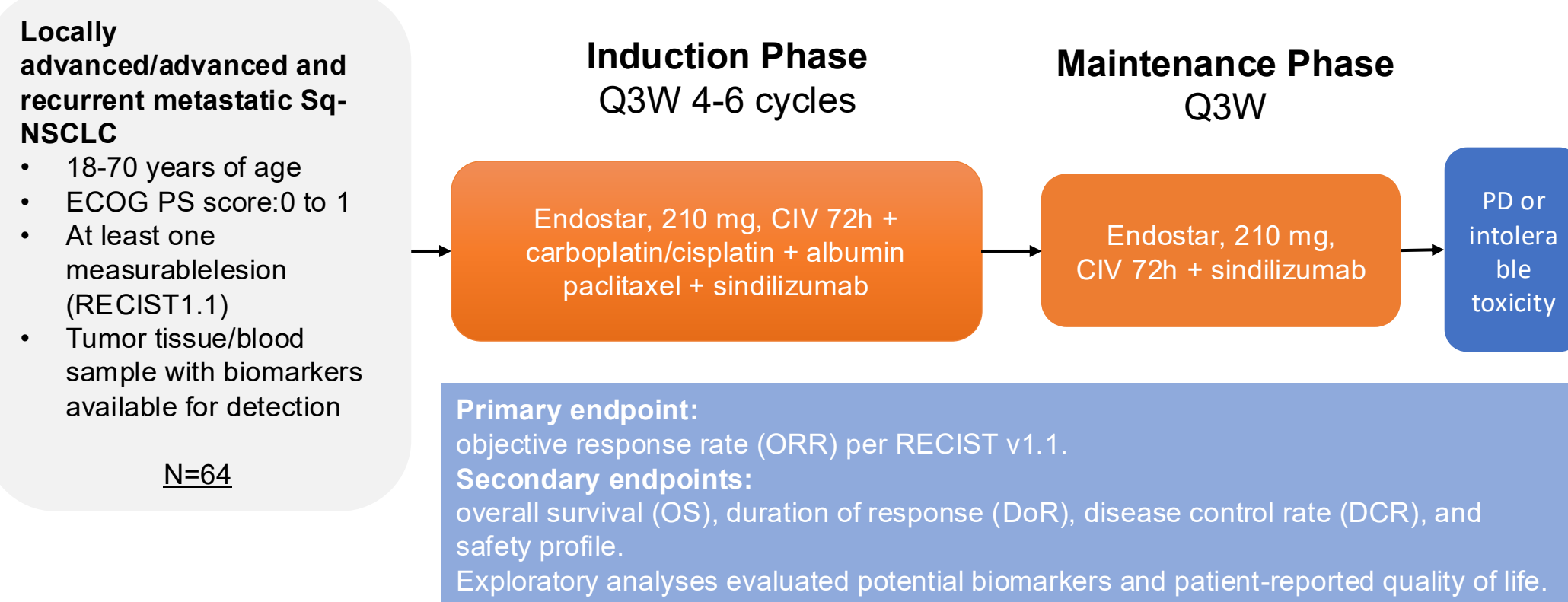
INTRODUCTION

- Squamous non-small cell lung cancer (sq-NSCLC) remains a leading cause of cancer-related mortality worldwide.
- Although immunotherapy combined with platinum-based chemotherapy has demonstrated improved clinical outcomes, response rates and survival benefits remain suboptimal.
- Anti-angiogenic agents, such as recombinant human endostatin (rh-endostatin, Endostar), may synergize with immune checkpoint inhibitors (ICIs) by modulating the tumor microenvironment and enhancing immune-mediated antitumor effects.
- This phase II trial investigates the efficacy and safety of rh-endostatin combined with sintilimab (an anti-PD-1 monoclonal antibody) and chemotherapy as first-line treatment for advanced sq-NSCLC.

METHODS

Design:

- This single-arm, multicenter, phase II clinical trial (NCT06746179) enrolled 64 treatment-naïve patients with EGFR/ALK-negative, advanced sq-NSCLC (stage IIIB–IV) across five research centers in China.
- During the induction phase, patients received rh-endostatin (210 mg continuous intravenous infusion, days 1–3), sintilimab (200 mg), and chemotherapy (nab-paclitaxel + carboplatin/cisplatin) every 3 weeks for 4–6 cycles. Following induction, maintenance therapy with rh-endostatin and sintilimab was administered until disease progression or intolerable toxicity.
- The primary endpoint was objective response rate (ORR) per RECIST v1.1.
- Secondary endpoints included overall survival (OS), duration of response (DoR), disease control rate (DCR), and safety profile.
- Exploratory analyses evaluated potential biomarkers and patient-reported quality of life.



DISCUSSION AND CONCLUSION

Actionable Take Away Message

- In 9 evaluable patients, ORR reached 55.6% (5/9 PRs) and DCR was 88.9% (8/9), demonstrating promising antitumor activity.
- Median PFS was not yet reached at data cutoff, indicating durable disease control for responders.
- The combination showed a manageable safety profile, with most treatment-related AEs being grade 1-2 (no grade 4-5 events or treatment-related deaths).

Future Direction for Research

- These preliminary results support the potential of combining anti-angiogenic therapy with chemoimmunotherapy to improve outcomes in patients with advanced sq-NSCLC.

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Trial Registration

ClinicalTrials.gov Identifier: NCT06746179 | Abstract ID: 2026-CTP-3403-WCLC

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Disclosure

The authors declare no conflicts of interest relevant to this work.

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RESULTS

- Between June 13, 2024, and June 23, 2025, nine patients were enrolled, with a median age of 57 years (range: 46–76); all were male (100%).
- As of March 30, 2026, nine patients were evaluable for efficacy.
- The ORR was 55.6% (5/9 partial responses [PRs]), and the DCR was 88.9% (8/9).
- Most treatment-related adverse events (AEs) were grade 1–2 and clinically manageable.
- Two patient experienced grade 3 chemotherapy-induced myelosuppression (CIM).
- No grade 4-5 AEs or treatment-related deaths occurred.
- Median progression-free survival (mPFS) was not yet reached at data cutoff.

Table 1. Baseline demographics and disease characteristics

characteristics	Treatment group (n=9)
Median age(range), years <65 years, n (%) ≥65 years, n (%)	57 (46-76) 6 (66.7) 3 (33.3)
Sex, n(%) Male Female	9 (100) 0 (0)
ECOG PS, n (%) 0 1	4 (44.4) 5 (55.6)
Smoking status, n (%) never smokers	3 (33.3) 6 (66.7)
Disease stage at diagnosis,n(%) III IV	5 (55.6) 4 (44.4)

Table2. Summary of Objective Response

Response	Treatment group (n=9)
ORR, %	55.6
DCR, %	88.9
BOR, n (%)	
CR	0 (0)
PR	5 (55.6)
SD	3 (33.3)
PD	1 (11.1)

Table3. Summary of adverse events

AE	treatment group (n=9) , n (%)	
	All grades	Grade 3/4
Any AE	5 (55.6)	2 (22.2)
Haematological		
Neutropenia	2 (22.2)	1 (11.1)
Thrombocytopenia	1 (11.1)	1 (11.1)
Leukocytopenia	3 (33.3)	0 (0)
Anaemia	1	0 (0)
Nonhaematological		
Drug allergy	1 (11.1)	0(0)