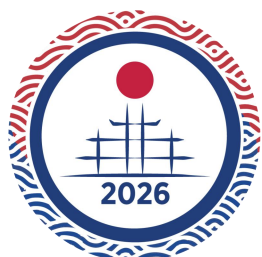




P2.100: Efficacy and Safety of Liposomal Irinotecan Combined with Cadonilimab as Second-Line Therapy for Extensive-Stage Small Cell Lung Cancer (ES-SCLC): A Prospective, Single Arm Phase II Clinical Study

Hui Zhu¹, Xuquan Jing², Chufeng Zhang³, Ning Tang⁴, Yaru Tian¹, Xiaoyang Zhai¹, Wenxiao Jia¹, Xiaoyong Tang³
¹Department of Radiation Oncology, Shandong Cancer Hospital and Institute, Shandong First Medical University and Shandong Academy of Medical Sciences, Jinan/CN, ²Shandong Cancer Hospital and Institute, Shandong First Medical University, Shandong Academy of Medical Sciences, Jinan/CN, ³Department of Respiratory Medical Oncology, Shandong Cancer Hospital and Institute, Shandong First Medical University and Shandong Academy of Medical Sciences, Jinan/CN, ⁴Department of Internal Medicine-Oncology, Shandong Cancer Hospital and Institute, Shandong First Medical University and Shandong Academy of Medical Sciences, Jinan/CN
Correspondence: drzhuh@126.com



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INTRODUCTION

- At present, the available treatment options for second-line treatment of ES-SCLC are relatively limited.
- Liposomal irinotecan, as a new drug delivery system, offers enhanced tumor targeting, prolonged drug release, reduced adverse events, and improved cellular affinity.
- This study aims to explore the efficacy and safety of liposomal irinotecan and cadonilimab in second-line ES-SCLC.

METHODS

- This is a prospective, single-center phase II clinical study that enrolled ES-SCLC pts who had previously received first-line treatment.
- Eligible pts received combination therapy with liposomal irinotecan and cadonilimab, followed by maintenance therapy with cadonilimab.
- The primary endpoint was objective response rate (ORR), while the secondary endpoints included disease control rate (DCR), progression free survival (PFS), 1-year overall survival rate (1y-OS rate), and safety.

DISCUSSION AND CONCLUSION

In our single-arm Phase II trial, liposomal irinotecan combined with cadonilimab achieved an ORR of 47.4% and a DCR of 100% in previously treated ES-SCLC patients. The treatment-related adverse events were mainly mild to moderate; only 15.8% of the patients experienced grade 3 adverse events. As of the current data cutoff time, the median progression-free survival (PFS) and overall survival (OS) have not been reached. The results indicate that the combination of liposomal irinotecan and cadonilimab has promising efficacy and acceptable safety in second-line ES-SCLC pts receiving prior treatment. This research is still ongoing and deserves further exploration in the future.

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RESULTS

Patients

Baseline characteristics	Total (n=19)
Age (years), Median (range), n (%)	63(53-76)
Sex,n(%)	
Male	15(78.9)
Female	4(21.1)
ECOG performance status,n(%)	
0	6(31.6)
1	13(68.4)
History of smoking,n(%)	
Yes	13(68.4)
No	6(31.6)
Metastasis status,n(%)	
Yes	19(100)
Metastatic sites,n(%)	
Lymph node	12(63.2)
Liver	7(36.8)
Brain	6(31.6)
Bone	2(10.5)
Adrenal	3(15.8)
Clinical stages,n(%)	
IV	18(94.7)

Efficacy

	n=19
PR,n(%)	9 (47.4%)
SD,n(%)	10 (52.6%)
ORR,n(%)	9 (47.4%)
DCR,n(%)	19 (100%)

Safety

AE, n=19	Anygrade	Grades3-4
Total,n(%)	14(73.7%)	3(15.8%)
Diarrhea	7(36.8%)	2(10.5%)
Decreased white blood cell count	8(42.1%)	0
Anemia	4(21.1%)	0
Decreased platelet count	3(15.8%)	0
Hypokalemia and hyponatremia	4(21.1%)	0
Decreased neutrophil count	3(15.8%)	1(5.3%)

- As of January 16, 2026, a total of 19 pts with previously treated ES-SCLC have been enrolled.
- There were 9 pts (47.4%) with the best therapeutic effect for PR and 10 pts (52.6%) with SD; the ORR and DCR were 47.4% and 100%, respectively. The median PFS and the median OS have not yet been reached.
- 73.7% (14/19) of pts observed adverse events (AEs). The incidence of grade 3 adverse events was 15.8% (3/19), including grade 3 diarrhea (2/19).