



P2.354: Surufatinib Plus Chemotherapy Versus Surufatinib in Patients With Thoracic Neuroendocrine Tumor: A Randomized, Phase II Study

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INTRODUCTION

- Treatment options for advanced neuroendocrine tumors (NETs) of pulmonary, thymic, or mediastinal origin remain limited.
- For these tumors (typical or atypical carcinoid), NCCN guidelines (Version 3.2025) recommend etoposide combined with platinum, or temozolomide plus capecitabine¹.
- Surufatinib is a novel tyrosine kinase inhibitor that selectively targets VEGFR-1/2/3, FGFR-1, and CSF-1R, and is approved by the NMPA (China) for pulmonary, thymic, or mediastinal NETs based on the phase III SANET-ep study².
- This study explores whether combining surufatinib with chemotherapy can further enhance survival benefit compared with surufatinib monotherapy.

STUDY DESIGN

Multicenter, randomized, controlled, open-label, phase II trial (NCT07357623), ongoing at 5 centers in China.

Key inclusion criteria (N=96)

- Histologically/cytologically confirmed stage IIIb–IV pulmonary, thymic, or mediastinal NETs (typical or atypical carcinoid)
- Age ≥ 18 years; any sex
- ECOG performance status 0–1 (amputees 0–2)
- No prior anti-angiogenic targeted therapy*
- Adequate organ function

*including but not limited to surufatinib, sunitinib, cabozantinib, axitinib, anlotinib, apatinib, bevacizumab, and recombinant human endostatin

Randomization 1:1

Combination arm (N=48)

Surufatinib 250 mg once daily (po)
+ chemotherapy (CAPTEM or EC)

Treatment continues until disease progression, death, unacceptable toxicity, or withdrawal of consent.

Monotherapy arm (N=48)

Surufatinib 300 mg once daily (po)

Endpoints

Primary:

- ORR

Secondary:

- DCR
- PFS
- OS
- 4-month PFS rate
- Safety

- Up to August 20, 2026, 8 of the planned 96 patients had been enrolled: 4 in the surufatinib plus chemotherapy group and 4 in the surufatinib monotherapy group.

SAMPLE SIZE

- Sample size calculation was performed using PASS 15 software (version 15.0.5.0) via the Two Proportions Test, with a one-sided α of 0.05 and a target power of 80%. The null hypothesis for ORR was 10% (derived from ORR data of the SANET-ep study), and the alternative hypothesis was 35%. Accounting for a 10% dropout rate, a total sample size of 96 patients was determined, with 48 patients to be enrolled in each group.

REFERENCES & ACKNOWLEDGEMENTS

References

1. NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors, Version 3.2025.
2. Xu J, et al. Surufatinib in advanced extrapancreatic neuroendocrine tumours (SANET-ep): a randomised, double-blind, placebo-controlled, phase 3 study. Lancet Oncol. 2020 Nov;21(11):1500-1512. doi: 10.1016/S1470-2045(20)30496-4.

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Trial registration: NCT07357623.

AI use disclosure: No artificial intelligence (AI) tools were used in the data analysis or in the preparation of this poster.

PRELIMINARY RESULTS

- Among the 3 efficacy-evaluable patients, all achieved stable disease (best change –0.79% to –7.69%), consistent with the generally indolent course of these tumors.

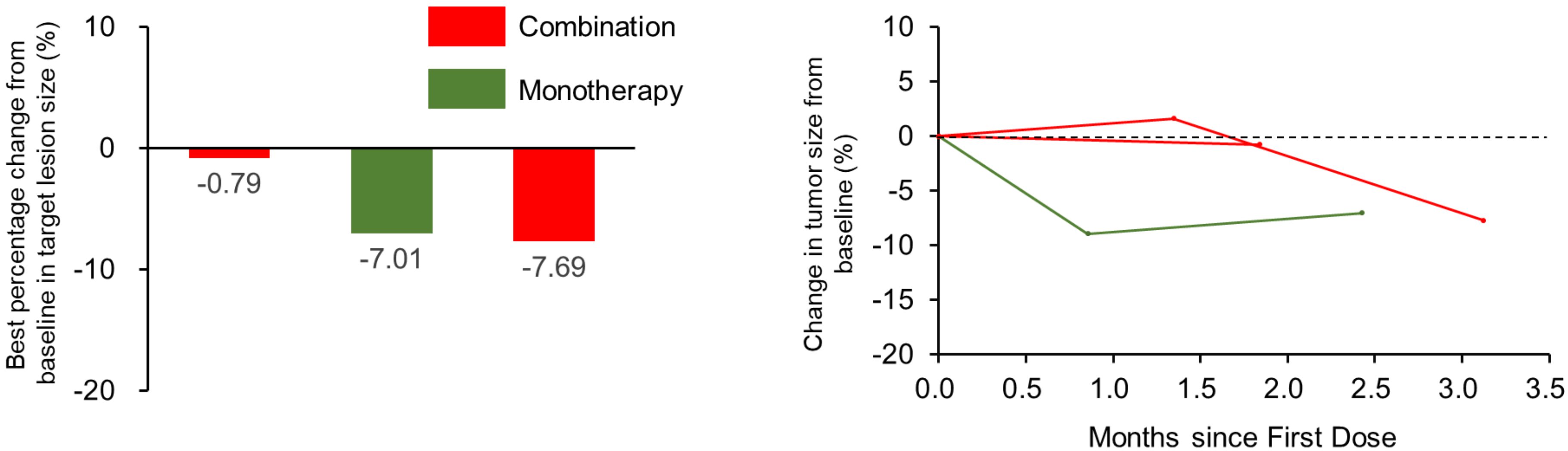


Figure. Best percentage changes from baseline in target lesions and Change of tumor size overall time of 3 efficacy evaluable patients.