

ROSETTA Lung-01: A Phase III, Two-Stage Trial of Punitamig, a PD-L1 × VEGF-A Bispecific Antibody, Plus Chemotherapy Versus Atezolizumab + Chemotherapy as First-Line Treatment in Patients With Extensive-Stage Small Cell Lung Cancer

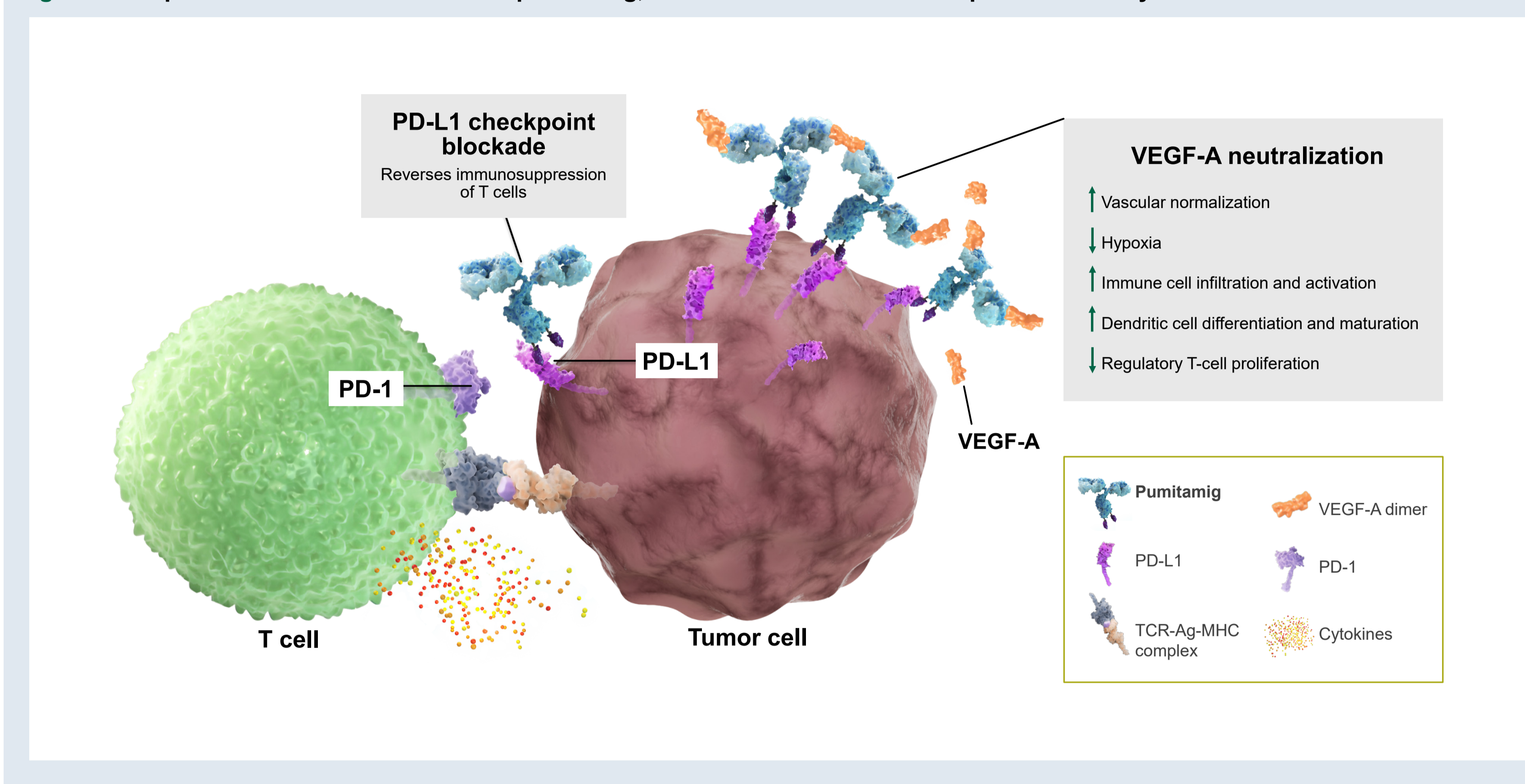
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Background

- Although incorporating immunotherapy into the frontline setting has improved outcomes, there is still an urgent need for efficacious treatments that can further extend the DOR and improve survival in ES-SCLC¹⁻⁴
- Punitamig (BNT327/BMS986545) is an investigational anti-PD-L1 × VEGF-A bispecific antibody that has shown encouraging early efficacy and acceptable safety in thoracic malignancies, including SCLC⁵⁻⁸ and NSCLC⁸⁻¹⁰
- Two phase 2 studies of punitamig + chemotherapy in patients with 1L ES-SCLC have reported confirmed ORR of ≈85% and median PFS of ≈6.8 months with a manageable safety profile in Chinese and global populations^{7,11}
- To date, more than 2000 patients have been treated with punitamig across different indications, including lung cancer (Table 1)
- Punitamig is designed to target both PD-L1 and VEGF-A in the tumor and TME (Figure 1)
 - Binding to PD-L1 on tumor cells aims to restore effector T-cell function and localize VEGF-A neutralization within the TME. Neutralizing local VEGF can normalize tumor vasculature and reverse VEGF-induced immune suppression

Figure 1. Proposed mechanism of action of punitamig, an anti-PD-L1 × VEGF-A bispecific antibody



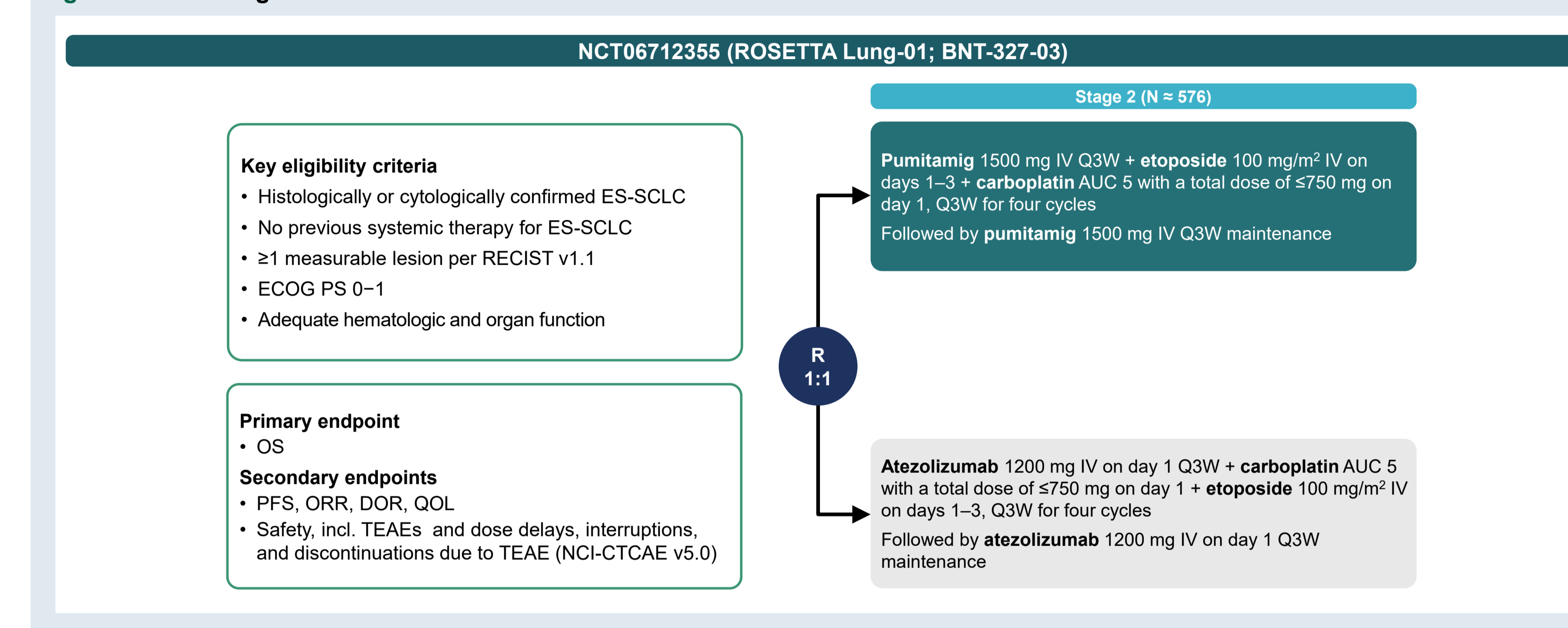
Objective

- This phase 3 trial will assess the safety and efficacy of punitamig plus chemotherapy vs atezolizumab plus chemotherapy in previously untreated patients with ES-SCLC

Trial design

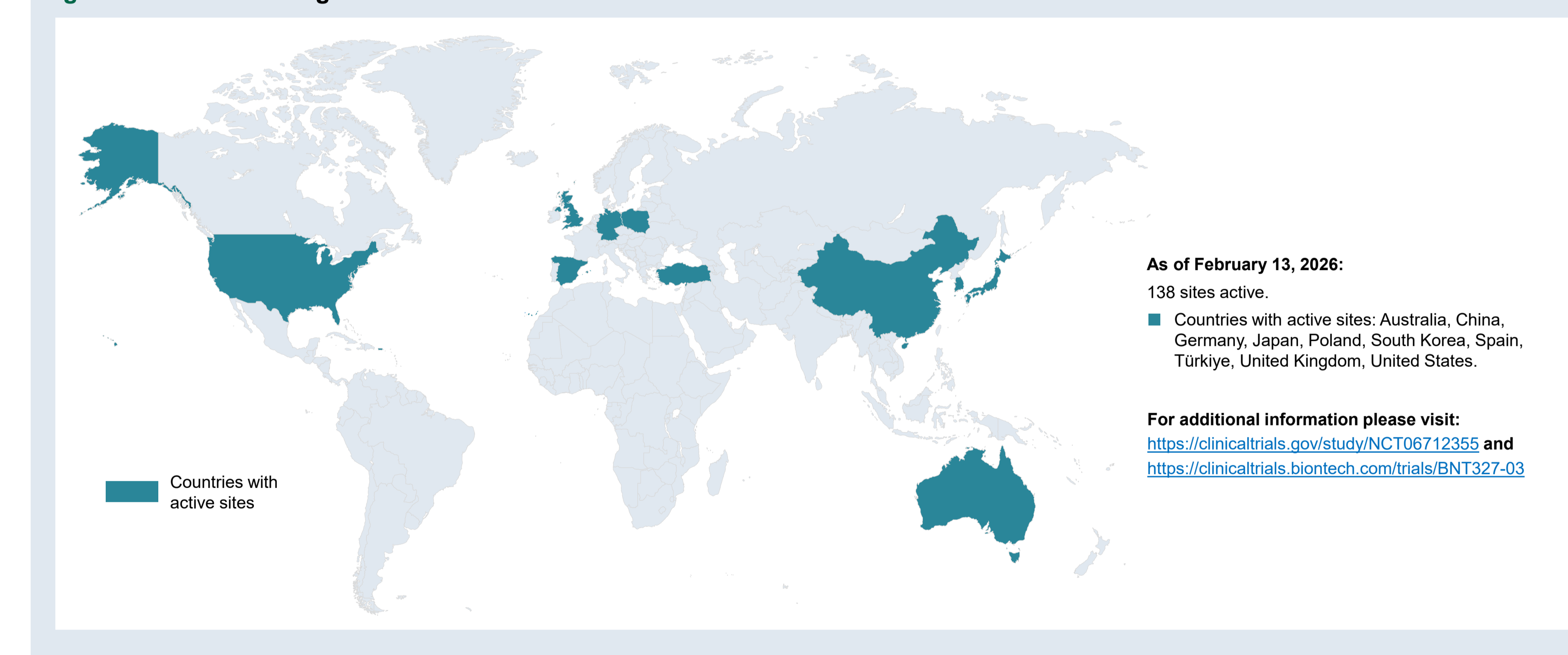
- Global, randomized, double-blind, phase 3 trial, recruiting patients with 1L ES-SCLC (Figures 2 and 3)
- Stratification includes presence of brain or liver metastasis per investigator assessment, smoking status, and geography
- Enrollment for stage 1 (dose optimization) has been completed. At stage 2, patients will be randomized 1:1 to the selected arm (punitamig-plus-chemotherapy or atezolizumab-plus-chemotherapy). Treatment in each arm is followed by maintenance therapy

Figure 2. Trial design



Recruitment status

Figure 3. ROSETTA Lung-01 trial locations¹²



Additional information

For more information on punitamig, please find the following posters on NSCLC and SCLC also presented at ELCC 2026

Poster number	Title	Presenter	Date
426P	Phase II Study of First-Line Punitamig (PD-L1 × VEGF-A bsAb) Plus Chemotherapy for Extensive-Stage Small Cell Lung Cancer (ES-SCLC): Updated Efficacy and Safety Results	Ying Liu	Thursday, March 26, 13:00–14:00 CET
69P	First-Line Punitamig (PD-L1 × VEGF-A bsAb) Monotherapy in PD-L1+ Non-Squamous and Squamous Non-Small Cell Lung Cancer: Data From a Phase Ib/Ia Trial in China	Liang Zhang	Friday, March 27, 13:00–14:00 CET
149TiP	ROSETTA Lung-02: A Global Phase II/III, Randomized, Open-Label Trial of Punitamig, a PD-L1 × VEGF-A Bispecific Antibody, in Combination With Chemotherapy in Patients (pts) With First-Line Non-Small Cell Lung Cancer	Ben Solomon	Friday, March 27, 13:00–14:00 CET
21P	Progression-Free Survival and Overall Survival With Punitamig (PD-L1 × VEGF-A bsAb) Plus Chemotherapy in Patients With EGFR-Mutated Advanced Non-Small Cell Lung Cancer Following Progression With EGFR TKI in China: Phase II Study Results	Yi-Long Wu	Friday, March 27, 13:00–14:00 CET

Table 1. Ongoing global punitamig trials in patients with lung cancer

	Line	Combination regimen	Comparator	Phase	NCT ID/Study name
SCLC	1L and 2L	Punitamig + carboplatin/etoposide (1L), paclitaxel, or topotecan (2L/3L)	NA	2	NCT06449209
	1L	Punitamig + carboplatin/etoposide	Atezolizumab + carboplatin/etoposide	3	NCT06712355 ROSETTA LUNG-01
	1L and 2L	Punitamig + B7H3 ADC BNT324/DB-1311*	NA	1/2	NCT06892548
NSCLC	1L	Punitamig + carboplatin/pemetrexed (NSQ) or carboplatin/paclitaxel (SQ)	Pembrolizumab + carboplatin/pemetrexed (NSQ) or + carboplatin/paclitaxel (SQ)	2/3	NCT06712316 ROSETTA LUNG-02
	Consolidation therapy	Punitamig	Durvalumab	3	NCT07361497 ROSETTA LUNG-201
	1L in PD-L1 ≥50%	Punitamig	Pembrolizumab	3	NCT07361510 ROSETTA LUNG-202
	2L	Punitamig + docetaxel	NA	2	NCT06841055 ROSETTA LUNG-107
	2L + (±AGA)	Punitamig + TROP2 ADC BNT325/DB-1305*	NA	1/2a	NCT05438329
	1L and 2L (±AGA)	Punitamig + B7H3 ADC BNT324/DB-1311*	NA	1/2	NCT06892548

*Partnered with Duality Bio.

Four other punitamig posters are available to view at ELCC (21P, 69P, 426P, 149TiP). For more details, please see the table with additional information.



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Abbreviations: 1L, first-line; 2L, second-line; 3L, third-line; ADC, antibody-drug conjugate; Ag, antigen; AGA, actionable genomic alteration; AUC, area under the curve; bsAb, bispecific antibody; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; ELCC, European Lung Cancer Congress; ES-SCLC, extensive-stage small cell lung cancer; IV, intravenous; MHC, major histocompatibility complex; NA, not available; NCI-CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events; NSCLC, non-small cell lung cancer; NSQ, nonsquamous; ORR, objective response rate; OS, overall survival; PD-1, programmed cell death protein 1; PD-L1, programmed death ligand 1; PFS, progression-free survival; Q3W, every 3 weeks; QOL, quality of life; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumors; SCLC, small cell lung cancer; SQ, squamous; TCR, T-cell receptor complex; TEAE, treatment-emergent adverse event; TKI, tyrosine kinase inhibitor; TME, tumor microenvironment; VEGF, vascular endothelial growth factor; VEGF-A, vascular endothelial growth factor A.

References: 1. Horn L, et al. *N Engl J Med*. 2018;379(23):2220–2229. 2. Liu SV, et al. *J Clin Oncol*. 2021;39(6):619–630. 3. Mansfield AS, et al. *Ann Oncol*. 2020;31(2):310–317. 4. Paz-Ares L, et al. *Lancet*. 2019;394(10212):1929–1939. 5. Zhang L, et al. Presented at: European Lung Cancer Congress (ELCC) 2026; March 25–28, 2026; Copenhagen, Denmark. Abstract 1129. 6. Cheng Y, et al. Presented at: European Society for Medical Oncology (ESMO) Congress 2023; October 20–24, 2023; Madrid, Spain. Poster 1992P. 7. Cheng Y, et al. Presented at: European Lung Cancer Congress (ELCC) 2025; March 26–29, 2025; Paris, France. Poster 302P. 8. Cheng Y, et al. Presented at: European Lung Cancer Congress (ELCC) 2025; March 26–29, 2025; Paris, France. Poster 332P. 9. Wu C, et al. Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting 2024; May 31–June 4, 2024; Chicago, IL. Poster 8533P. 10. Wu YL, et al. Presented at: European Society for Medical Oncology (ESMO) Congress 2024; September 13–17, 2024; Barcelona, Spain. Poster 1255MO. 11. Heymach J, et al. Presented at: World Conference on Lung Cancer (WCLC) 2025; September 6–9, 2025; Barcelona, Spain. Oral OA13.02. 12. U.S. National Library of Medicine. ClinicalTrials.gov NCT06712355. Updated February 13, 2026. <https://clinicaltrials.gov/study/NCT06712355>.