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Phase II Study of First-Line Pumitamig (PD-L1 × VEGF-A bsAb) Plus Chemotherapy for Extensive-Stage Small Cell Lung Cancer (ES-SCLC): Updated Efficacy and Safety Results

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CONCLUSIONS

- Pumitamig plus platinum-based chemotherapy as a 1L treatment for ES-SCLC showed encouraging durable efficacy in this long-term follow-up
- The safety profile was manageable, with a low rate of treatment discontinuation
- These phase 2 trial results support the ROSETTA Lung-01 global phase 3 trial (NCT06712355), underway in 1L ES-SCLC, as part of an extensive pumitamig lung cancer clinical development program

Four other pumitamig posters are available to view at ELCC (21P, 69P, 149TiP, 439TiP). For more details, scan the QR code below.

Scan the QR code to access the ePoster, details of the pumitamig Global Clinical Development Program, and a list of other pumitamig posters at ELCC.

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Abbreviations: 1L, first-line; 2L, second-line; 3L, third-line; ADC, antibody-drug conjugate; AE, adverse event; Ag, antigen; AGA, actionable genomic alteration; ALT, alanine aminotransferase; AST, aspartate aminotransferase; AUC, area under the curve; BOR, best overall response; bsAb, bispecific antibody; CI, confidence interval; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; ES-SCLC, extensive-stage small cell lung cancer; GGT, gamma-glutamyl transferase; irAE, immune-related adverse event; IV, intravenous; LDH, lactate dehydrogenase; MHC, major histocompatibility complex; NA, not available; NCI-CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events; NR, not reached; NSCLC, non-small-cell lung cancer; NSQ, nonsquamous; ORR, objective response rate; OS, overall survival; PD, progressive disease; PD-1, programmed cell death protein 1; PD-L1, programmed death ligand 1; PFS, progression-free survival; PR, partial response; Q3W, every 3 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; SCLC, small cell lung cancer; SD, stable disease; SQ, squamous; TCR, T-cell receptor complex; TEAE, treatment-emergent adverse event; TKI, tyrosine kinase inhibitor; TRAE, treatment-related adverse event; TROP2, trophoblast cell surface antigen 2; TSH, thyroid-stimulating hormone; TTR, time to response; VEGF-A, vascular endothelial growth factor A; VEGFR, vascular endothelial growth factor receptor; WBC, white blood cell.

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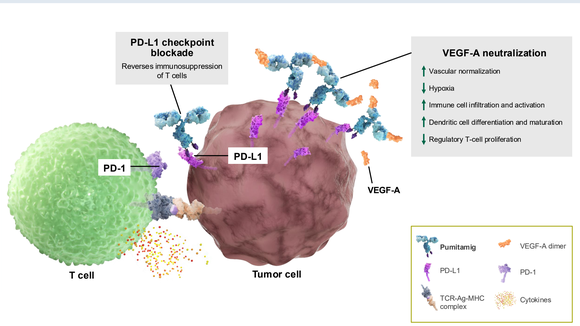
Background

- Pumitamig (BNT327/BMS986545) is an investigational anti–PD-L1 × VEGF-A bispecific antibody designed to restore effector T-cell function and localize VEGF-A neutralization by targeting PD-L1 and VEGF-A in the tumor and tumor microenvironment (**Figure 1**)
  - This dual mechanism is intended to enhance antitumor immunity and inhibit angiogenesis
- SCLC accounts for ~15% of lung cancer cases, with around 250,000 new cases worldwide each year.[1] Despite recent advances, prognosis remains poor, and there is a high unmet need for therapies that provide durable clinical benefit[2–5]
- Two phase 2 trials (1 Chinese; 1 global) of pumitamig plus chemotherapy in patients with 1L ES-SCLC have reported encouraging efficacy and manageable safety[6,7]
- Here, we report updated efficacy results, including mature OS, from the Chinese Phase 2 trial of pumitamig combined with chemotherapy in 1L ES-SCLC

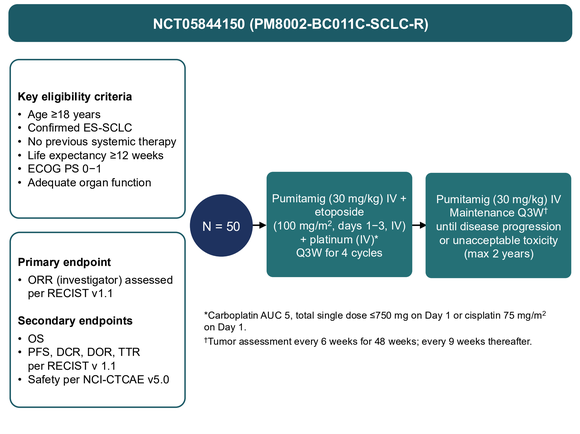
Figure 1. Proposed mechanism of action of pumitamig, an anti–PD-L1 × VEGF-A bispecific antibody



Methods

- Open-label, single-arm, multicenter, phase 2 trial (NCT05844150) to investigate the efficacy and safety of pumitamig plus platinum-etoposide (4 cycles), followed by pumitamig maintenance, in previously untreated patients with ES-SCLC. Mature OS is reported (**Figure 2**)

Figure 2. Trial design



Results

Baseline characteristics

- 50 patients were enrolled (median age 59 years, range 55–65; 80% ECOG PS 1; 20% current and 46% former smokers) (**Table 1**)
- At data cutoff (October 18, 2025), median follow-up time was 16.8 months (95% CI: 11.3–20.8) and median treatment duration was 26.5 weeks (95% CI: 18.1–37.1), with 2 patients still on treatment

Table 1. Baseline patient and disease characteristics

	N = 50
Median age, years (range)	59.0 (55.0–65.0)
Age >65 years, n (%)	11 (22.0)
Female, n (%)	16 (32.0)
ECOG PS, n (%)	
0	10 (20.0)
1	40 (80.0)
Smoker, n (%)	
Never	17 (34.0)
Former	23 (46.0)
Current	10 (20.0)

Efficacy

Tumor response

- DOR was 5.52 months (**Table 2**)

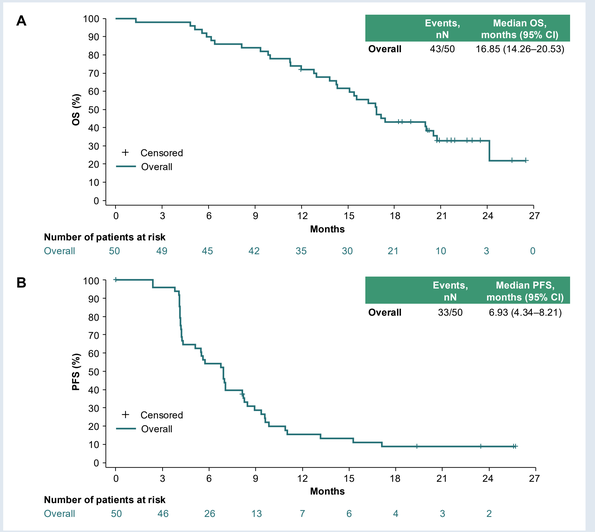
Table 2. Tumor responses, PFS, and OS

	Overall (N = 50)
BOR, n (%)	
PR	41 (82.0)
SD	6 (12.0)
PD	1 (2.0)
No postbaseline assessment	2 (4.0)
Confirmed ORR, % (95% CI)	82.0 (68.6–91.4)
DCR, % (95% CI)	94.0 (83.5–98.7)
DOR, median, months (95% CI)	5.52 (3.75–6.93)
TTR, median, months (95% CI)	1.38 (1.35–1.41)
OS, median, months (95% CI)	16.85 (14.26–20.53)
12-month OS rate, %	72.0
PFS, median, months (95% CI)	6.93 (4.34–8.21)
12-month PFS rate, %	15.4

Survival

- 12-month OS rate was 72.0% and median OS was 16.9 months (95% CI: 14.3–20.5) (**Figure 3**)
- 12-month PFS rate was 15.4% and median PFS was 6.9 months (95% CI: 4.3–8.2) (**Figure 3**)

Figure 3. Kaplan-Meier curves of (A) OS and (B) PFS



Results

Safety

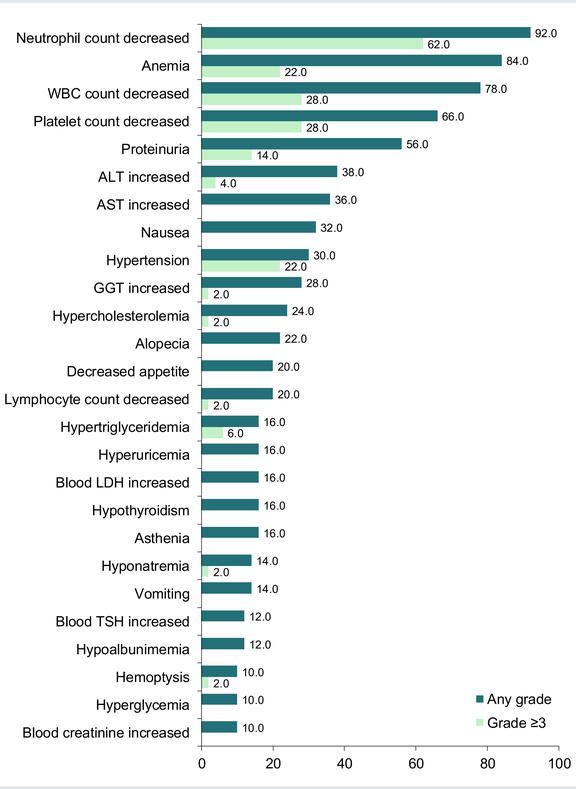
- All patients experienced at least 1 TRAE related to pumitamig and/or chemotherapy
  - Treatment-related discontinuation rate was low (n = 4, 8%) and related to myocarditis (n = 1), gastric hemorrhage (n = 1), autoimmune encephalitis (n = 1), and proteinuria (n = 1)
  - There were no TRAEs deaths (**Table 3**)
- The most commonly observed TRAE was neutrophil count decreased (**Figure 4**)

Table 3. Safety summary (October 18, 2025 data cutoff)

	Overall (N = 50)
Any TEAE, n (%)	50 (100.0)
Grade ≥3	45 (90.0)
Any TRAE,* n (%)	50 (100.0)
Grade ≥3	43 (86.0)
Any TRAE leading to dose interruption,* n (%)	29 (58.0)
Any TRAE leading to discontinuation,* n (%)	4 (8.0)
Any TRAE leading to death,* n (%)	0 (0.0)
Any irAE grade ≥3, n (%)	4 (8.0)
Any hemorrhage/bleeding of grade ≥3,† n (%)	3 (6.0)

*AEs related to pumitamig and/or chemotherapy. †Any hemorrhage/bleeding of grade ≥3 included gastric hemorrhage, hemoptysis, and hemorrhage intracranial.

Figure 4. TRAEs* in at least 10% of patients



*AEs related to pumitamig and/or chemotherapy.

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