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First-Line Pumitamig (PD-L1 × VEGF-A bsAb) Monotherapy in PD-L1+ Non-Squamous and Squamous Non-Small Cell Lung Cancer: Data From a Phase Ib/IIa Trial in China

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CONCLUSIONS

- Pumitamig showed encouraging antitumor activity in patients with previously untreated advanced NSCLC PD-L1 ≥1%, including those with SQ cell carcinoma
- Pumitamig demonstrated manageable safety and tolerability, with a low rate of treatment discontinuation
- Pumitamig monotherapy and in combination with chemotherapy as treatment for NSCLC is being further investigated in ongoing global studies, including ROSETTA Lung-02 (NCT06712316), ROSETTA Lung-201 (NCT07361497), ROSETTA Lung-202 (NCT07361510), and BNT327-07 (NCT06841055)

Four other pumitamig posters are available to view at ELCC (21P, 426P, 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; Ag, antigen; AGA, actionable genomic alteration; ALK, anaplastic lymphoma kinase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; BOR, best overall response; bsAb, bispecific antibody; CI, confidence interval; cORR, confirmed objective response rate; DCR, disease control rate; DOR, duration of response; ECG, electrocardiogram; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; GGT, gamma-glutamyl transferase; irAE, immune-related adverse event; IV, intravenous; LDH, lactate dehydrogenase; LOT, line of therapy; MHC, major histocompatibility complex; NA, not applicable; 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; Q2W, every 2 weeks; QT, QT interval; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; SQ, squamous; TCR, T-cell receptor; TEAE, treatment-emergent adverse event; TKI, tyrosine kinase inhibitor; TME, tumor microenvironment; TPS, tumor proportion score; TRAE, treatment-related adverse event; TTR, time to response; uORR, unconfirmed objective response rate; VEGF, vascular endothelial growth factor; VEGF-A, vascular endothelial growth factor A; WT, wild-type.

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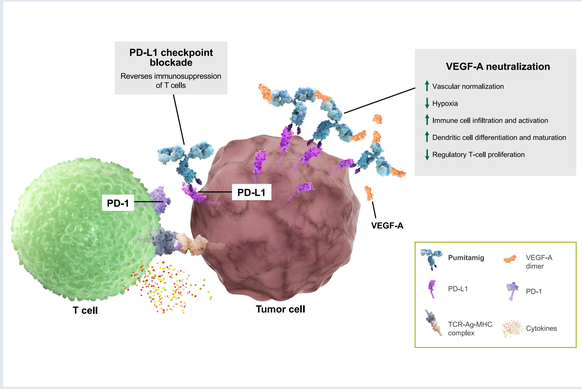
Background

- Pumitamig (BNT327/BMS986545) is an investigational anti-PD-L1 × VEGF-A bispecific antibody that has shown encouraging efficacy, with a manageable safety profile, in thoracic malignancies, including advanced NSCLC[1–5]
- Pumitamig 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 to localize VEGF-A neutralization within the TME. Neutralizing local VEGF can normalize tumor vasculature and reverse VEGF-induced immune suppression
- Although substantial progress has been made in the 1L treatment of patients with advanced NSCLC, additional therapeutic options are needed[6]
  - Despite an improvement in outcomes with checkpoint inhibitor-based therapy, outcomes remain particularly suboptimal in SQ NSCLC, with patients still experiencing comparatively poorer survival outcomes than those with NSQ disease[6]
- We report updated data from an ongoing phase 1b/2a trial of pumitamig monotherapy in patients with treatment-naïve advanced NSCLC

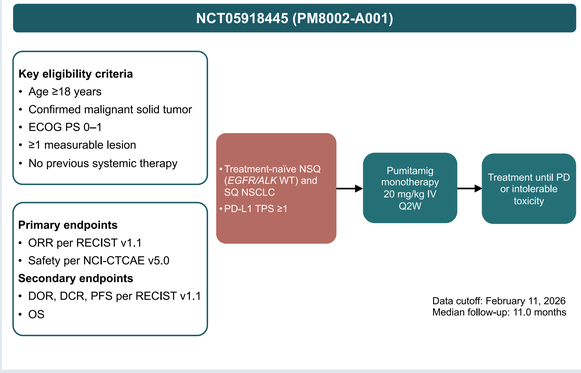
Figure 1. Proposed mechanism of action of pumitamig, an anti–PD-L1 × VEGF-A bispecific antibody



Methods

- Open-label, phase 1b/2a, multiple-cohort, dose-expansion monotherapy study (NCT05918445) enrolling patients in China with advanced solid tumors, including those with NSCLC
- We report data from patients with previously untreated PD-L1+ advanced *EGFR*/*ALK* WT NSQ and SQ NSCLC (**Figure 2**)

Figure 2. Trial design



Results

Baseline characteristics

- Median age was 64.5 years, and most patients were male (73.3%) and had ECOG PS 1 (76.7%) (**Table 1**)
- At time of database lock, 2 (11.8%) patients with NSQ disease and 8 (61.5%) with SQ disease remained on treatment

Table 1. Baseline characteristics (as of February 11, 2026)

	Overall (N = 30)	NSQ NSCLC (n = 17)	SQ NSCLC (n = 13)
Median age, years (range)	64.5 (53–79)	65.0 (53–75)	64.0 (53–79)
Female, n (%)	8 (26.7)	5 (29.4)	3 (23.1)
ECOG PS 0, n (%)	7 (23.3)	5 (29.4)	2 (15.4)
Never smoker, n (%)	14 (46.7)	9 (52.9)	5 (38.5)
Brain metastasis, n (%)	4 (13.3)	4 (23.5)	0 (0.0)
PD-L1 1%–49%, n (%)	15 (50.0)	9 (52.9)	6 (46.2)
PD-L1 ≥50%, n (%)	15 (50.0)	8 (47.1)	7 (53.8)

Efficacy

Tumor response

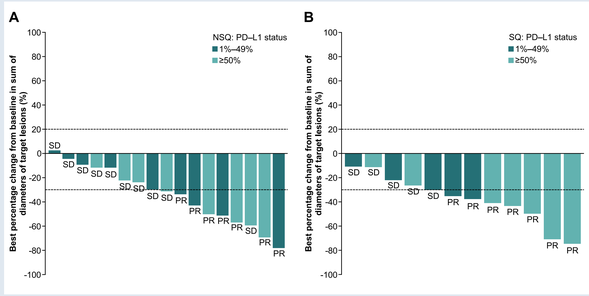
- uORR was 53.3% in the overall population, 47.1% in patients with NSQ NSCLC and 61.5% in patients with SQ NSCLC (**Table 2 and Figure 3**)
- Responses were observed regardless of tumor histology or PD-L1 status (**Table 2 and Figure 3**)

Table 2. Summary of tumor responses overall and by PD-L1 expression

	Overall (N = 30)	NSQ NSCLC			SQ NSCLC		
		Overall (n = 17)	PD-L1 1%–49% (n = 9)	PD-L1 ≥50% (n = 8)	Overall (n = 13)	PD-L1 1%–49% (n = 6)	PD-L1 ≥50% (n = 7)
uORR, % (95% CI)	53.3 (34.3–71.7)	47.1 (23.0–72.2)	44.4 (13.7–78.8)	50.0 (15.7–84.3)	61.5 (31.6–86.1)	50.0 (11.8–88.2)	71.4 (29.0–96.3)
cORR, % (95% CI)	46.7 (28.3–65.7)	41.2 (18.4–67.1)	44.4 (13.7–78.8)	37.5 (8.5–75.5)	53.8 (25.1–80.8)	33.3 (4.3–77.7)	71.4 (29.0–96.3)
BOR, n (%)							
PR	14 (46.7)	7 (41.2)	4 (44.4)	3 (37.5)	7 (53.8)	2 (33.3)	5 (71.4)
SD	15 (50.0)	10 (58.8)	5 (55.6)	5 (62.5)	5 (38.5)	3 (50.0)	2 (28.6)
DCR, % (95% CI)	96.7 (82.8–99.9)	100 (80.5–100)	100 (66.4–100)	100 (63.1–100)	92.3 (64.0–99.8)	83.3 (35.9–99.6)	100 (59.0–100)
TTR, median, months (95% CI)	2.7 (1.3–8.3)	2.7 (1.3–4.1)	2.1 (1.3–4.1)	2.8 (2.7–3.0)	2.7 (1.4–8.3)	5.6 (3.0–8.3)	1.5 (1.4–5.6)

DOR data were not mature–tumor responses still ongoing.

Figure 3. Waterfall plots of best change from baseline in tumor size in patients with (A) NSQ and (B) SQ NSCLC

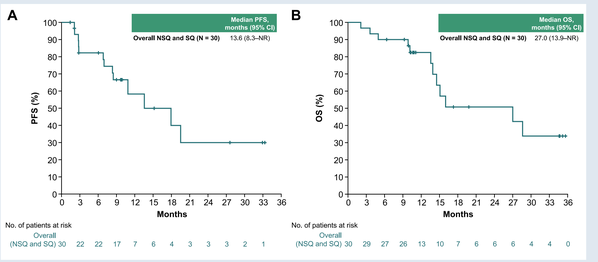


Survival

- In the overall population, median PFS was 13.6 months with a 24-month PFS rate of 30.0% (**Figure 4**)
  - Median PFS was 13.6 months (24-month PFS rate of 27.0%) in patients with PD-L1 1%–49% and 17.9 months (24-month PFS rate of 33.0%) in patients with PD-L1 ≥50%
  - In patients with NSQ NSCLC, median PFS was 13.6 months with a 24-month PFS rate of 27.8%
  - In patients with SQ NSCLC, PFS data were not mature
- In the overall population, median OS was 27.0 months with a 24-month OS rate of 50.8% (**Figure 4**)
  - Median OS was 16.0 months (24-month OS rate of 43.1%) in patients with PD-L1 1%–49% and NR (24-month OS rate of 63.0%) in patients with PD-L1 ≥50%

Results

Figure 4. Kaplan-Meier curves of (A) PFS and (B) OS in patients with NSQ and SQ NSCLC overall



Safety

- TRAEs were reported in 86.7% of patients, and were grade ≥3 in 40.0% (**Table 3**)
- The most frequent TRAEs were proteinuria, hypothyroidism, hypertension, and increased ALT (**Figure 5**)
  - TRAEs led to permanent treatment discontinuation in 4 patients
  - No TEAEs resulted in death
- Any-grade hemorrhage/bleeding events occurred in 10 (33.3%) patients that was grade 3 in 1 (3.3%) patient and led to treatment discontinuation in 2 patients (**Table 4**)
- The safety profile was comparable between patients with NSQ and SQ NSCLC

Table 3. Safety summary

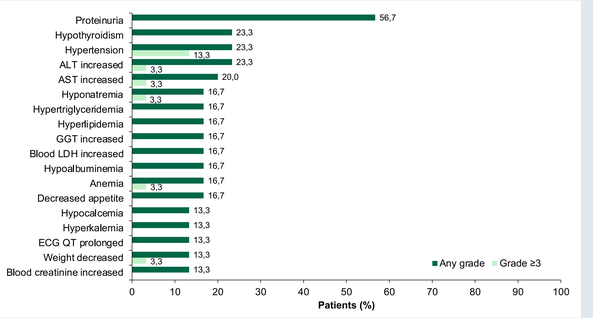
	Overall (N = 30)	NSQ NSCLC (n = 17)	SQ NSCLC (n = 13)
Any TRAE, n (%)	26 (86.7)	15 (88.2)	11 (84.6)
Grade ≥3	12 (40.0)	7 (41.2)	5 (38.5)
TRAE leading to dose interruption, n (%)	11 (36.7)	7 (41.2)	4 (30.8)
TRAE leading to permanent discontinuation, n (%)	4 (13.3)	2 (11.8)	2 (15.4)
Grade ≥3 irAEs, n (%)	3 (10.0)	1 (5.9)	2 (15.4)
Grade ≥3 VEGF-related event, n (%)	7 (23.3)	3 (17.6)	4 (30.8)
Any hemorrhage/bleeding, n (%)	10 (33.3)	7 (41.2)	3 (23.1)

Table 4. Hemorrhage/bleeding events

	Overall (N = 30)	NSQ NSCLC (n = 17)	SQ NSCLC (n = 13)
Any-grade, n (%)*	10 (33.3)	7 (41.2)	3 (23.1)
Hemoptysis	4 (13.3)	1 (5.9)	3 (23.1)
Grade ≥3, n (%)	1 (3.3)	0 (0.0)	1 (7.7)
Hematuria	3 (10.0)	3 (17.6)	0 (0.0)
Gingival bleeding	2 (6.7)	2 (11.8)	0 (0.0)
Ecchymosis	1 (3.3)	1 (5.9)	0 (0.0)
Epistaxis	1 (3.3)	1 (5.9)	0 (0.0)
Hematochezia	1 (3.3)	1 (5.9)	0 (0.0)
Mouth hemorrhage	1 (3.3)	1 (5.9)	0 (0.0)

*Nine bleeding events were grade 1–2; 1 event was grade ≥3 (hemoptysis, which was treatment-related).

Figure 5. TRAEs occurring in >10% of patients (N = 30)



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