21P

Progression-Free Survival and Overall Survival With Pumitamig (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

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CONCLUSIONS

- Pumitamig plus chemotherapy showed encouraging antitumor activity in patients with EGFR-mutated locally advanced or metastatic NSQ NSCLC who progressed on or after at least one prior EGFR-TKI treatment
- Encouraging efficacy of pumitamig plus chemotherapy was observed across PD-L1 expression levels, with highest ORR, PFS, OS observed in patients with high (≥50%) PD-L1 expression
- Pumitamig demonstrated manageable safety and tolerability, with a low rate of treatment discontinuation

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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; ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; AUC, area under the curve; BOR, best overall response; bsAb, bispecific antibody; CI, confidence interval; CPK, creatine phosphokinase; cDRR, confirmed objective response rate; CR, complete response; 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; LOT, line of therapy; MHC, major histocompatibility complex; NA, not available; 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; TEAE, treatment-emergent adverse event; TKI, tyrosine kinase inhibitor; TME, tumor microenvironment; TPS, tumor proportion score; TRAE, treatment-related adverse event; TSH, thyroid-stimulating hormone; TTR, time to response; VEGF, vascular endothelial growth factor; VEGF-A, vascular endothelial growth factor A; WBC, white blood cell.

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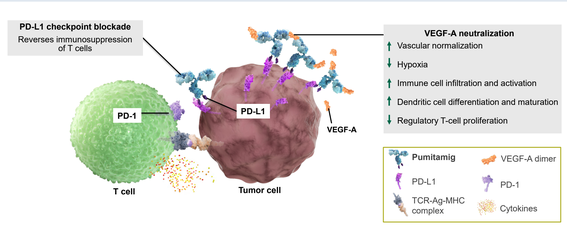
Background

- 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 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
- The majority of patients with EGFR-mutated metastatic NSQ NSCLC respond to initial EGFR-TKI treatment[6]
- Many patients develop acquired resistance and disease progression after ~1 year,[6] highlighting an urgent need for improved treatment options for patients with EGFR-mutated metastatic NSCLC progressing after first-line EGFR-TKI therapy[6]
- We present PFS and OS data from an ongoing single-arm phase 2 study of pumitamig + chemotherapy in patients with EGFR-mutated advanced NSCLC who progressed on or after standard EGFR-TKI treatment

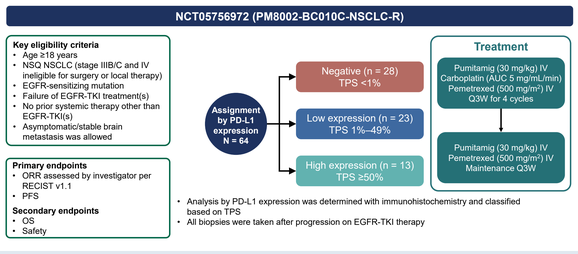
Figure 1. Proposed mechanism of action of pumitamig, an anti–PD-L1 × VEGF-A bispecific antibody



Methods

- Multicenter, single-arm, phase 2 open-label trial (NCT05756972) conducted in China to investigate the efficacy and safety of pumitamig combined with chemotherapy in patients with EGFR-mutated metastatic NSCLC after standard EGFR-TKI treatment (**Figure 2**)
- The correlation between tumor PD-L1 expression and efficacy outcomes was investigated

Figure 2. Trial design



Results

Baseline Characteristics

- As of October 18, 2025, the median follow-up was 20.4 months in the 64 patients enrolled (**Table 1**)
  - Median age was 59.0 years, 89.1% had ECOG PS 1, and 23.4% had brain metastasis at baseline
  - At time of database lock, median duration of treatment was 39.6 months and 8 (12.5%) patients remained on treatment

Table 1. Baseline demographic and disease characteristics

	Overall (N = 64)	PD-L1 <1% (n = 28)	PD-L1 1%–49% (n = 23)	PD-L1 ≥50% (n = 13)
Median age, years (range)	59.0 (32–77)	59.0 (36–77)	60.0 (44–75)	60.0 (32–74)
Female, n (%)	29 (45.3)	11 (39.3)	11 (47.8)	7 (53.8)
ECOG PS, n (%)				
0	7 (10.9)	4 (14.3)	2 (8.7)	1 (7.7)
1	57 (89.1)	24 (85.7)	21 (91.3)	12 (92.3)
Brain metastasis, n (%)				
Yes	15 (23.4)	7 (25.0)	5 (21.7)	3 (23.1)
No	49 (76.6)	21 (75.0)	18 (78.3)	10 (76.9)
EGFR mutation, n (%)				
19Del	32 (50.0)	11 (39.3)	14 (60.9)	7 (53.8)
L858R	29 (45.3)	17 (60.7)	7 (30.4)	5 (38.5)
Other*	3 (4.7)	0 (0.0)	2 (8.7)	1 (7.7)

*S768I, L861Q, or G719X.

Results

Efficacy

Tumor response

- Responses were observed across PD-L1 expression levels (overall ORR: 59.4%), with the highest ORR in patients with PD-L1 ≥50% (92.3%) (**Table 2**)
- In patients with 19Del, 21L858, or other EGFR mutations, cORR was 65.6% (21/32), 55.2% (16/29) and 33.3% (1/3), and DCR was 96.9%, 93.1%, and 100%, respectively
- In patients with brain metastasis, cORR was 60.0% with a DCR of 100%

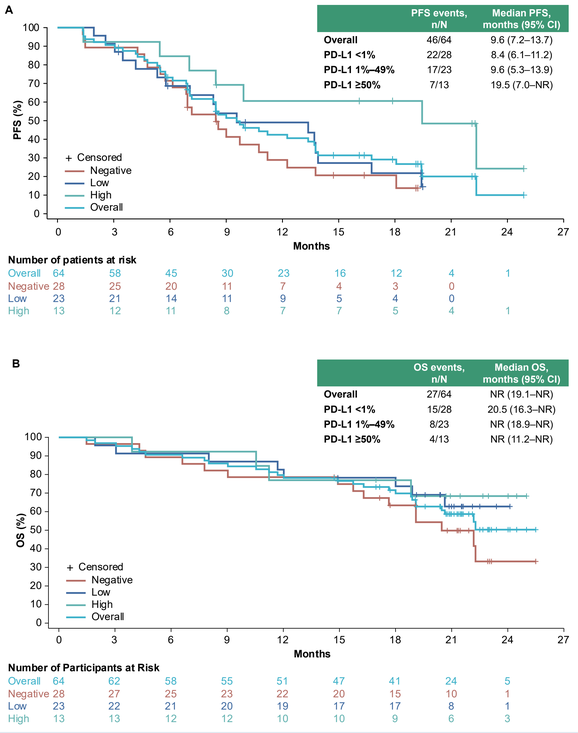
Table 2. Tumor response overall and by PD-L1 expression status

	Overall (N = 64)	PD-L1 <1% (n = 28)	PD-L1 1%–49% (n = 23)	PD-L1 ≥50% (n = 13)
Confirmed ORR, % (95% CI)	59.4 (46.4–71.5)	42.9 (24.5–62.8)	60.9 (38.5–80.3)	92.3 (64.0–99.8)
BOR, n (%)				
PR	38 (59.4)	12 (42.9)	14 (60.9)	12 (92.3)
SD	23 (35.9)	14 (50.0)	9 (39.1)	0 (0.0)
PD	3 (4.7)	2 (7.1)	0 (0.0)	1 (7.7)
DCR, % (95% CI)	95.3 (86.9–99.0)	92.9 (76.5–99.1)	100.0 (85.2–100.0)	92.3 (64.0–99.8)
DOR, median, months (95% CI)	8.3 (7.0–18.1)	7.6 (4.3–NR)	8.8 (4.2–17.9)	20.9 (5.7–NR)
TTR, median, months (95% CI)	1.5 (1.2–8.5)	2.1 (1.2–8.5)	1.4 (1.2–4.1)	1.6 (1.3–4.0)

Survival

- Median PFS was 9.6 months in the overall population, with a 12-month PFS rate of 42.4% (**Figure 3A**)
  - Median PFS was 8.4 months in the PD-L1 <1% subgroup, 9.6 months in the PD-L1 1%–49% subgroup, and 19.5 months in the PD-L1 ≥50% subgroup
- Median OS was not reached in the overall population (**Figure 3B**)
  - 12-month OS rates were 79.7% overall, 78.6% in the PD-L1 <1% subgroup, 82.6% in the PD-L1 1%–49% subgroup, and 76.9% in the PD-L1 ≥50% subgroup
- Median PFS in patients with 19del, 21L858, or other EGFR mutations was 10.7 months, 9.0 months, and NR, respectively
  - OS was not mature
- In patients with brain metastasis, median PFS was 8.3 months and median OS was 22.2 months

Figure 3. Kaplan-Meier curves of (A) PFS and (B) OS overall and by PD-L1 expression status



Results

Safety

- TRAEs related to any drug were reported in all patients, and were grade ≥3 in 68.8% (**Table 3**)
- The most frequent TRAEs included hematologic AEs, elevated aminotransferases, and proteinuria (**Figure 4**)
- TRAEs led to treatment discontinuation in 12 patients and to death in 1 patient due to pneumonia
- Grade ≥3 irAEs occurred in 7.8% of patients
- Grade ≥3 hemorrhage/bleeding events occurred in 3.1% of patients (**Table 4**)

Table 3. Safety summary*

	Overall (N = 64)
Any TEAE, n (%)	64 (100)
Grade ≥3	49 (76.6)
Any TRAE, n (%)	64 (100)
Grade ≥3	44 (68.8)
TRAE leading to dose interruption, n (%)	31 (48.4)
TRAE leading to permanent discontinuation, n (%)	12 (18.8)
TRAE leading to death, n (%)†	1 (1.6)
Grade ≥3 irAEs, n (%)	5 (7.8)

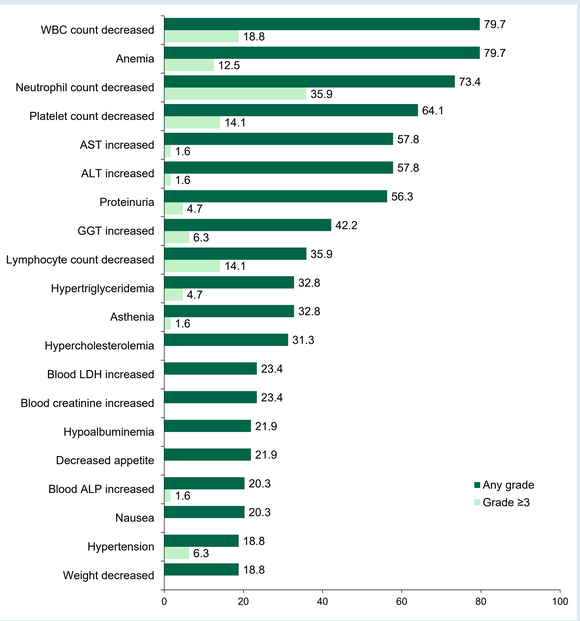
*TRAEs are pumitamig and/or chemotherapy related; †Pneumonia.

Table 4. Hemorrhage/bleeding TEAEs

	Patients (N = 64)
Any-grade, n (%)	12 (18.8)
Epistaxis	5 (7.8)
Hematochezia	3 (4.7)
Hematuria	2 (3.1)
Hemoptysis	2 (3.1)
Hemorrhage	1 (1.6)
Pulmonary hemorrhage	1 (1.6)
Grade ≥3, n (%)	2 (3.1)
Leading to interruption of pumitamig, n (%)	2 (3.1)
Leading to discontinuation of pumitamig, n (%)	2 (3.1)
Leading to death, n (%)*	1 (1.6)

*Hemorrhage. Death was not considered treatment related.

Figure 4. TRAEs related to any study drug occurring in ≥15% of patients (N = 64)



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