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A global phase 2, open-label trial of pumitamig (PD-L1 × VEGF-A bsAb) + docetaxel post-chemoimmunotherapy in mNSCLC: First data from ROSETTA Lung-107

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Background

Pumitamig (BNT327/BMS986545) is an investigational bsAb designed to target both PD-L1 and VEGF-A within the tumor and TME with a single molecule. This dual blockade is hypothesized to boost antitumor immunity and improve clinical outcomes. We report initial efficacy and safety of pumitamig + docetaxel post-chemoimmunotherapy (CIT) in patients with mNSCLC.

Methods

ROSETTA Lung-107 is a global, open-label, single-arm phase 2 trial in patients with stage IV NSCLC who received 1L CIT, had measurable disease (RECIST v1.1), and ECOG PS ≤1. In Part 1 (safety run-in/dose escalation), patients received pumitamig 1400 (n=3) or 2000 mg (n=3; not shown) + docetaxel Q3W. In Part 2 (dose expansion), patients received pumitamig 1400 mg + docetaxel Q3W. Primary endpoints were DLTs (Part 1 only), safety, and ORR. Secondary endpoints included DCR and PFS.

Results

At data cutoff (July 10, 2026), 50 patients had received pumitamig 1400 mg + docetaxel in Part 1 and 2, and 33 remained on treatment. Median follow-up was 12.2 wk (0.1–41.3). Median age was 67.0 y (34–83), 70.0% were male, 26.0% had squamous histology, and 66.0% had ECOG PS 1. Encouraging responses were observed in response-evaluable patients (n=30) across PD-L1 levels (Table); median TTR was 1.4 mo (1.2–6.1). Median PFS was 6.9 mo (4.2–NR). In the safety analysis set (n=50), any-grade pumitamig-related TRAEs occurred in 52.0% of patients (Gr ≥3 18.0%). Pumitamig-related TRAEs led to discontinuation in 8.0%. Immune-mediated AEs occurred in 30.0% (Gr ≥3 14.0%) and VEGF-related events in 26.0% (Gr ≥3 4.0%). Hemorrhage/bleeding events occurred in 16.0% (all Gr 1/2). No DLTs were reported.Table: LBA76

	Overall (N=30) PD-L1 TPS <1% (n=7) PD-L1 TPS 1–49% (n=18) PD-L1 TPS ≥50% (n=5)			
Confirmed				
ORR, n (%)	11 (36.7)	3 (42.9)	6 (33.3)	2 (40.0)
DCR, n (%)	27 (90.0)	6 (85.7)	17 (94.4)	4 (80.0)
BOR, n (%)	11 (36.7)	3 (42.9)	6 (33.3)	
PR	16 (53.3)	3 (42.9)	11 (61.1)	2 (40.0)
SD	2 (6.7)	1 (14.3)	0	2 (40.0)
PD	1 (3.3)	0	1 (5.6)	1 (20.0)
NE				0
Unconfirmed				
ORR, n (%)	13 (43.3)	3 (42.9)	8 (44.4)	2 (40.0)

	Overall (N=30)	PD-L1 TPS <1% (n=7)	PD-L1 TPS 1–49% (n=18)	PD-L1 TPS ≥50% (n=5)
BOR, n (%)		3 (42.9)	8 (44.4)	2 (40.0)
PR	13 (43.3)	3 (42.9)	9 (50.0)	2 (40.0)
SD	14 (46.7)	1 (14.3)	0	1 (20.0)
PD	2 (6.7)	0	1 (5.6)	0
NE	1 (3.3)			

Patients received pumitamig 1400 mg + docetaxel 75 mg/m² Q3W. Response-evaluable patients had ≥2 post-baseline tumor assessments or 1 assessment followed by PD, death, or study discontinuation.

Conclusions

Pumitamig + docetaxel showed encouraging antitumor activity with a manageable safety profile in patients with mNSCLC post-CIT. These data support further development of pumitamig in this setting and will inform pivotal study design.

Clinical trial identification

NCT06841055.

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Legal entity responsible for the study

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Disclosure

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