ROSETTA LUNG-02

149TiP

ROSETTA Lung-02: A Global Phase II/III, Randomized, Open-Label Trial of Pumitamig, a PD-L1 × VEGF-A Bispecific Antibody, in Combination With Chemotherapy in Patients With First-Line Non-Small Cell Lung Cancer (NSCLC)

Solange Peters,[1] Younjoo Lee,[2] Mustafa Erman,[3] Stephen V. Liu,[4] **Ben Solomon**,[5] Terufumi Kato,[6] Shun Lu,[7] Sanjay Popat,[8] Ilhan Celik,[9] Ulug Mutlu Gunaydin,[10] René Bartz,[9] Vikesh Patel,[11] Shraddha Patel,[10] Kevin Tsai,[10] Li Li,[10] Claudia-Nanette Gann,[9] Aurora O'Brate,[12] Ugur Sahin,[9] Özlem Türeci,[9] Byoung Chul Cho[13]

[1]Centre Hospitalier Universitaire Vaudois Lausanne (CHUV), Lausanne, Switzerland; [2]National Cancer Center, Goyang, Republic of Korea; [3]Hacettepe University Cancer Institute, Ankara, Türkiye; [4]Lombardi Comprehensive Cancer Center, Georgetown University, Washington, DC, USA; [5]Sir Peter MacCallum Department of Oncology, University of Melbourne, Melbourne, VIC, Australia; [6]Tokyo Metropolitan Komagome Hospital, Tokyo, Japan; [7]Shanghai Lung Cancer Center, Shanghai Chest Hospital, Shanghai Jiao Tong University, Shanghai, China; [8]Royal Marsden Hospital NHS Foundation Trust, London, UK; [9]BioNTech SE, Mainz, Germany; [10]BioNTech US Inc., Cambridge, MA, USA; [11]BioNTech UK Ltd, London, UK; [12]BioNTech Pharmaceuticals Spain, S.L., Barcelona, Spain; [13]Yonsei University College of Medicine, Seoul, Republic of Korea.

Four other pumitamig posters are available to view at ELCC (21P, 69P, 426P, 439TiP).
For more details, please see the table with additional information.

Scan the QR code to access the poster online.

Background

- Although the introduction of immune checkpoint inhibition for the treatment of 1L NSCLC has improved survival, long-term outcomes remain suboptimal, highlighting the need for more efficacious treatments[1]
- Pumitamig (BNT327/BMS986545) is an investigational anti–PD-L1 × VEGF-A bispecific antibody that has shown encouraging early efficacy and acceptable safety in patients with thoracic malignancies, including those with SCLC[2–5] and NSCLC[5–7]
  - In advanced NSQ NSCLC with PD-L1 ≥1%, pumitamig monotherapy showed a uORR of 47.1% and a DCR of 100%; mPFS was 13.6 months[5]
  - Similarly, in advanced SQ NSCLC, pumitamig monotherapy showed a uORR of 61.5% and a DCR of 92.3%; PFS was immature at the time of analysis[5]
- To date, more than 2000 patients have been treated with pumitamig across different indications, including lung cancer (**Table 1**)
- 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

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

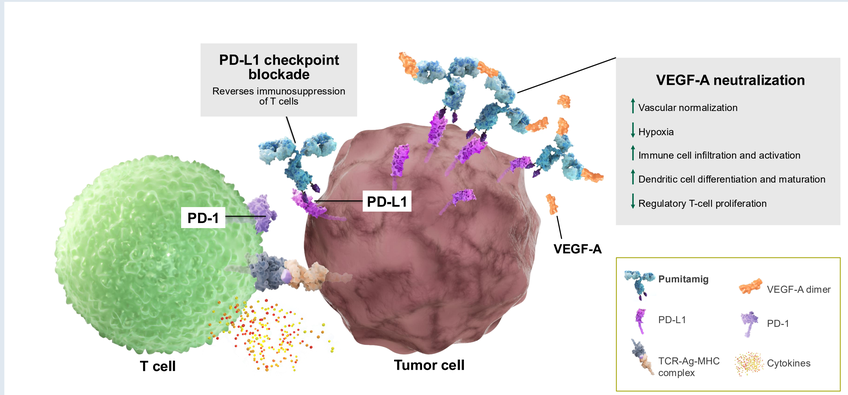


Table 1. Ongoing global pumitamig trials in patients with lung cancer

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

*Partnered with Duality Bio.

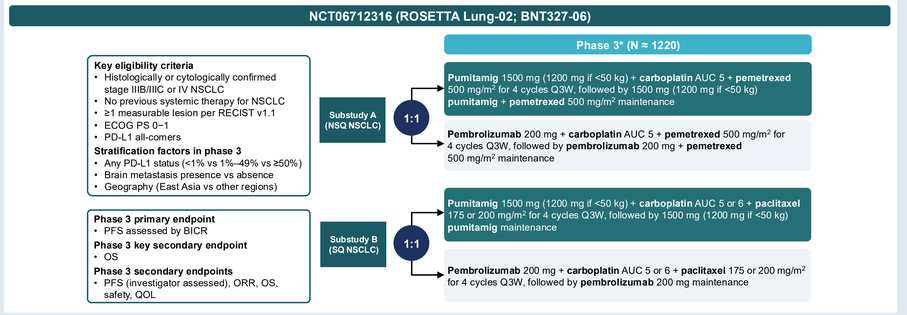
Objective

- This phase 3 trial will assess the safety and efficacy of pumitamig plus chemotherapy vs pembrolizumab plus chemotherapy in previously untreated patients with advanced NSCLC (in NSQ and SQ substudies)

Trial design

- Global, randomized, open-label, phase 2/3 trial recruiting patients with previously untreated NSQ NSCLC without actionable *EGFR* mutations or *ALK* rearrangements (substudy A) and SQ NSCLC (substudy B) (**Figures 2 and 3**)
- Each substudy consists of a phase 2 and a phase 3 part. Phase 2 has been fully enrolled
- In the ongoing phase 3 part, ~1220 patients will be randomized 1:1 to receive the treatment regimens summarized in **Figure 2**
- Patients will be stratified by tumor PD-L1 expression status (<1% vs 1%–49% vs ≥50%), brain metastasis (presence vs absence), and geography (East Asia vs other regions). In the ongoing phase 3 part, treatment will continue until disease progression, intolerable toxicity, withdrawal, trial termination, or up to a maximum of 2 years, whichever comes first

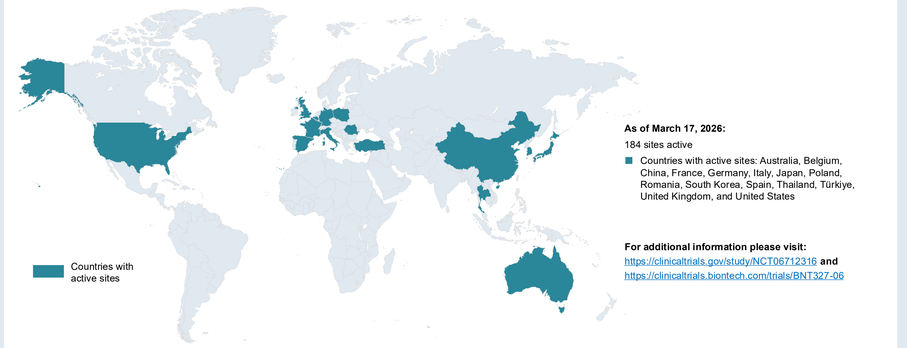
Figure 2. Trial design



*Platinum-based chemotherapy will be given for four cycles.

Recruitment status

Figure 3. ROSETTA Lung-02 trial locations[8]



Additional information

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

Poster number	Title	Presenter	Date
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	Yi-Long Wu	Friday, March 27, 13:00–14:00 CET
69P	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	Liang Zhang	Friday, March 27, 13:00–14:00 CET
439TiP	ROSETTA Lung-01: A Phase III, Two-Stage Trial of Pumitamig, 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	Martin Reck	Thursday, March 26, 13:00–14:00 CET
426P	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	Ying Liu	Thursday, March 26, 13:00–14:00 CET

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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; AUC, area under the curve; BICR, blinded independent central review; bsAb, bispecific antibody; DCR, disease control rate; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; ES-SCLC, extensive-stage small cell lung cancer; IV, intravenous; MHC, major histocompatibility complex; mPFS, median progression-free survival; NA, not applicable; 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; RECIST, Response Evaluation Criteria in Solid Tumors; SCLC, small cell lung cancer; SQ, squamous; TCR, T-cell receptor complex; TKI, tyrosine kinase inhibitor; TME, tumor microenvironment; uORR, unconfirmed objective response rate; VEGF, vascular endothelial growth factor; VEGF-A, vascular endothelial growth factor A.

References: 1. Paik PK, et al. *Clin Lung Cancer.* 2025;S1525-7304(25)00241–4. 2. Cheng Y, et al. Presented at: European Society for Medical Oncology (ESMO) Congress 2023; October 20–24, 2023; Madrid, Spain. Poster 1992P. 3. Cheng Y, et al. Presented at: European Lung Cancer Congress (ELCC) 2025; March 26–29, 2025; Paris, France. Poster 302P. 4. Cheng Y, et al. Presented at: European Lung Cancer Congress (ELCC) 2025; March 26–29, 2025; Paris, France. Poster 332P. 5. Zhang L, et al. Presented at: European Lung Cancer Congress (ELCC) 2026; March 25–28, 2026; Copenhagen, Denmark. Abstract 1129. 6. Wu C, et al. Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting 2024; May 31–June 4, 2024; Chicago, IL. Poster 8533. 7. Wu YL, et al. Presented at: European Society for Medical Oncology (ESMO) Congress 2024; September 13–17, 2024; Barcelona, Spain. Poster 1255MO. 8. U.S. National Library of Medicine. ClinicalTrials.gov NCT06712316. Updated February 13, 2026. https://clinicaltrials.gov/study/NCT06712316.

Corresponding author email address: solange.peters@chuv.ch

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