BioNTech and Bristol Myers Squibb Report Encouraging Global Phase 2 Data for Pumitamig in Advanced NSCLC After Progression on Immunotherapy Plus Chemotherapy

- *Pumitamig plus docetaxel demonstrated encouraging responses in squamous and non-squamous non-small cell lung cancer across PD-L1 expression levels with a confirmed objective response rate of 36.7% following progression on or after immunotherapy plus chemotherapy*
- *An early median progression-free survival of 6.9 months was observed*
- *Significant unmet need remains for patients who have progressed on an immunotherapy-containing regimen, with the average progression-free survival below 4 months for standard of care docetaxel*
- *Data represent the third global Phase 2 dataset for pumitamig in lung cancer and reinforce its potential to improve outcomes over current standards of care*

MAINZ, Germany, and PRINCETON, USA, October 25, 2026 – BioNTech SE (Nasdaq: BNTX, "BioNTech") and Bristol Myers Squibb Company (NYSE: BMY, "BMS") today announced first data from the global Phase 2 ROSETTA Lung-107 clinical trial (NCT06841055) evaluating pumitamig, an investigational PD-L1xVEGF-A bispecific immunomodulator (BNT327/BMS986545), in combination with docetaxel in patients with metastatic non-small cell lung cancer ("NSCLC") whose disease progressed on or after first-line immunotherapy plus chemotherapy.

The data showed encouraging antitumor activity, with responses observed in both squamous and non-squamous NSCLC and across PD-L1 expression levels, together with a manageable safety profile consistent with prior global datasets for pumitamig. The data were presented today in a late-breaking rapid oral presentation (abstract #LBA76) at the European Society for Medical Oncology ("ESMO") Congress 2026 in Madrid, Spain.

"Despite meaningful advances in first-line treatment, outcomes remain poor for the many patients with non-small cell lung cancer whose disease progresses after immunotherapy plus chemotherapy, a setting where docetaxel has remained the standard of care for years,"[1] said **Byoung Chul Cho, M.D., Ph.D., Trial Investigator and Professor of Medical Oncology at Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, Republic of Korea.** "These first data from ROSETTA Lung-107 show encouraging response rates and progression-free survival across PD-L1 expression levels and histology, suggesting that pumitamig may help re-engage antitumor immunity in patients who have progressed on prior immunotherapy plus chemotherapy. These findings support continued investigation of pumitamig in this population with high unmet need."

ROSETTA Lung-107 is evaluating pumitamig 1400 mg in combination with docetaxel every three weeks. The July 10, 2026, data cut-off included 50 patients with a median follow-up of 12.2 weeks, and 33 patients remained on treatment. Among 30 efficacy-evaluable patients, pumitamig plus docetaxel showed a confirmed objective response rate ("cORR") of 36.7% with a disease control rate ("DCR") of 90.0%. Responses were observed across PD-L1 expression levels (cORR: 42.9% TPS # 1%; 33.3% TPS 1–49%; 40.0% TPS # 50%) and histologies (cORR: 57.1% squamous; 30.4% non-squamous), with DCRs above 80% in all subgroups. Median time to response was 1.4 months. In the overall treated population (n=50), median progression-free survival ("PFS") was 6.9 months (95% CI: 4.2 – not reached), with a six-month PFS rate of 63.3%. Historically, standard-of-care docetaxel has delivered a median PFS of approximately 3.6 or 3.9 months for non-squamous and squamous metastatic NSCLC patients, respectively, following prior immunotherapy plus chemotherapy.[1]

"Our ambition is to improve outcomes for patients across the full spectrum of lung cancer, spanning disease subtypes, stages and lines of therapy," **said Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "These encouraging results for pumitamig plus docetaxel extend the clinical evidence to patients whose disease has progressed after immunotherapy plus chemotherapy, a setting in which treatment options remain limited. Together with our findings in first-line NSCLC and extensive-stage small cell lung cancer, they support our strategy to develop pumitamig across a broad range of lung cancer settings, including those with particularly high unmet medical need."

"This is the third global Phase 2 dataset to show consistent activity for pumitamig in lung cancer across PD-L1 expression levels, and it extends our evidence into a second-line setting where current options fall short," said **Cristian Massacesi, Executive Vice President, Chief Medical Officer and Head of Development at Bristol Myers Squibb**. "Together with BioNTech, we are advancing one of the broadest development programs in the class as we continue to build the growing body of clinical evidence for pumitamig across multiple types and treatment lines of lung cancer, with four ongoing global Phase 3 trials, and we look forward to defining the path forward for pumitamig in second-line NSCLC."

Across 50 patients in the safety evaluation, pumitamig plus chemotherapy showed a manageable safety profile, with no new safety signals. Pumitamig treatment-related adverse events ("TRAEs") of any grade were reported in 52.0% of patients and grade # 3 TRAEs in 18.0%, leading to treatment discontinuation in four (8.0%) patients. Immune- related AEs occurred in 11 (22.0%) patients and grade # 3 immune- related AEs in five (10.0%) patients. VEGF-related events were reported in 13 (26.0%) patients; grade 3 events were rare (two patients, 4.0%), with no grade 4 or 5 events. Bleeding events occurred in eight (16.0%) patients and were limited to grade 1 or 2 severity. There were no pumitamig-related deaths or dose-limiting toxicities ("DLTs").

BioNTech and BMS are advancing a broad development plan for pumitamig in multiple cancer types, including lung cancer across disease stages, subgroups and lines of therapy. ROSETTA Lung-107 extends the program into the second-line NSCLC setting, and these data will inform the further development of pumitamig in this underserved patient population.

1. Ahn MJ et al. J Clin Oncol. 2025;43(3):260–272.

About ROSETTA Lung-107

The global, open-label, single-arm Phase 2 ROSETTA Lung-107 trial (NCT06841055) is evaluating pumitamig (BNT327/BMS986545) in combination with docetaxel in patients with stage IV squamous or non-squamous NSCLC whose disease progressed following first-line immunotherapy plus chemotherapy, with any level of PD-L1 expression. Patients with prior exposure to anti-VEGF monoclonal antibodies or PD-(L)1xVEGF bispecific antibodies were excluded. In Part 1 (safety run-in), patients received pumitamig 1400 mg or 2000 mg plus docetaxel 75 mg/m² every three weeks (Q3W). In Part 2 (dose expansion), patients received pumitamig 1400 mg plus docetaxel 75 mg/m² Q3W, the dose recommended by the internal review committee based on the totality of evidence from Part 1 and the broader pumitamig lung cancer program. The primary endpoints are dose-limiting toxicities (Part 1 only), safety, and objective response rate ("ORR") per investigator's assessment (RECIST 1.1). Secondary endpoints include disease control rate ("DCR"), duration of response ("DOR"), depth of response, time to response, progression-free survival ("PFS"), overall survival ("OS"), pharmacokinetics, and antidrug antibody prevalence. The trial enrolled 59 patients at sites in Australia, the Republic of Korea, Spain, Türkiye, the United Kingdom, and the United States.

About Pumitamig

Pumitamig is an investigational bispecific immunomodulator, jointly developed by BioNTech and BMS, designed to cooperatively bind to PD-L1 and VEGF-A. It is aimed at restoring the immune system's ability to recognize and destroy tumor cells while simultaneously cutting off the blood and oxygen supply that feeds tumor cells (anti-angiogenesis effect), preventing them from growing and proliferating. By anchoring to PD-L1 receptors on tumor cells, we believe pumitamig localizes VEGF-A blockade within the tumor microenvironment, potentially enhancing antitumor activity while minimizing systemic exposure.

More than 4,000 patients have been treated with pumitamig in clinical trials to date. Seven global Phase 3 trials with registrational potential are currently ongoing, evaluating pumitamig plus chemotherapy compared to standard of care treatments, in first-line small cell lung cancer (ROSETTA Lung-01, NCT06712355); first-line non-small cell lung cancer (ROSETTA Lung-02, NCT06712316); unresectable stage III non-small cell lung cancer (ROSETTA Lung-201, NCT07361497); first-line advanced PD-L1 # 50% non-small cell lung cancer (ROSETTA Lung-202, NCT07361510); first-line triple-negative breast cancer (ROSETTA Breast-01, NCT07173751); first-line microsatellite stable colorectal cancer (ROSETTA CRC-203, NCT07221357); and first-line gastric cancer (ROSETTA Gastric-204, NCT07221149). Pumitamig is also being explored in 10+ novel-novel combination trials with ADCs and other novel modalities, with the aim of expanding its role across tumor types and identifying additional pivotal opportunities.

About NSCLC

Non-small cell lung cancer (NSCLC) covers all epithelial lung cancers other than small cell lung cancer and includes squamous cell carcinoma, large cell carcinoma, and adenocarcinoma of the lung. It is the most common type of lung cancer, accounting for approximately 85% of cases, and is the leading cause of cancer-related deaths worldwide.[2] Scientific advances have transformed the treatment of NSCLC, improving outcomes for many patients. However, NSCLC remains an aggressive disease with a poor prognosis and a 5-year survival rate of 18 to 22% in advanced stages.[3] Patients with low levels of PD-L1 expression typically do not respond well to checkpoint inhibitor-based regimens creating a significant unmet need for new treatment options that provide durable responses to a broad range of patients.

2. Lin Z et al. Medicine (Baltimore). 2025 Jul 25;104(30):e43300.

3. Liu SV et al. Immunotherapy. 2025 Oct;17(14):1005-1013.

About BioNTech

BioNTech is a global next generation biopharmaceutical company pioneering novel investigative therapies for cancer and other serious diseases. In oncology, BioNTech is committed to transforming how cancer is treated. Its ambition is to develop innovative medicines with pan-tumor or synergistic potential to address cancer from multiple angles and across the full continuum of the disease from early- to late-stage. Its growing late-stage oncology pipeline comprises complementary treatment approaches spanning immunomodulators, antibody-drug conjugates, and mRNA cancer immunotherapies. BioNTech has partnered with multiple global and specialized pharmaceutical collaborators leveraging complementary expertise and resources to accelerate innovation and drive progress, including Bristol Myers Squibb, Duality Biologics, Genentech, a member of the Roche Group, Genmab, MediLink, OncoC4, and Pfizer.

For more information, please visit www.BioNTech.com.

BioNTech Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: BioNTech's collaboration with Bristol Myers Squibb (BMS); BioNTech and BMS's ability to successfully co-develop and co-commercialize pumitamig (also known as BNT327 or BMS986545), if approved; the rate and degree of market acceptance of pumitamig, if approved; the initiation, timing, progress, and results of BioNTech's research and development programs, including BioNTech's current and future clinical trials, including statements regarding the expected timing of initiation, enrollment, and completion of trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations, including expectations regarding the potential indications in which pumitamig may be approved, if at all; the targeted timing and number of additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; and discussions with regulatory

agencies. In some cases, forward-looking statements can be identified by terminology such as “will,” “may,” “should,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

The forward-looking statements in this press release are based on BioNTech’s current expectations and beliefs of future events and are neither promises nor guarantees. You should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech’s control and which could cause actual results to differ materially and adversely from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with clinical data, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the impact of tariffs and escalations in trade policy; competition related to BioNTech’s product candidates; the timing of and BioNTech’s ability to obtain and maintain regulatory approval for its product candidates; BioNTech’s ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech’s third-party collaborators to continue research and development activities relating to BioNTech’s product candidates and investigational medicines; unforeseen safety issues and potential claims that are alleged to arise from the use of products and product candidates developed or manufactured by BioNTech; BioNTech’s and its collaborators’ ability to commercialize and market its product candidates, if approved; BioNTech’s ability to manage its development and related expenses; regulatory and political developments in the United States and other countries; BioNTech’s ability to effectively scale its production capabilities and manufacture its products and product candidates; and other factors not known to BioNTech at this time.

You should review the risks and uncertainties described under the heading “Risk Factors” in BioNTech’s Report on Form 6-K for the period ended June 30, 2026 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC’s website at www.sec.gov. These forward-looking statements speak only as of the date hereof. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise.

About Bristol Myers Squibb

At Bristol Myers Squibb, our mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. We are pursuing bold science to define what’s possible for the future of medicine and the patients we serve. For more information, visit us at BMS.com and follow us on LinkedIn, X, YouTube, Facebook and Instagram.

Bristol Myers Squibb Cautionary Statement Regarding Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of pharmaceutical products. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on current expectations and projections about Bristol Myers Squibb’s future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. These risks, assumptions, uncertainties and other factors include, among others, that the expected benefits of, and opportunities related to the collaboration with BioNTech may not be realized by Bristol Myers Squibb or may take longer to realize than anticipated, that future study results may not be consistent with the results to date, that pumitamig (also known as BNT327 or BMS986545) alone or in combination with chemotherapy (such as docetaxel) may not achieve its primary study endpoint or receive regulatory approval for the indications described in this release in the currently anticipated timeline or at all, any marketing approvals, if granted, may have significant limitations on their use, and, if approved, whether pumitamig alone or in combination with chemotherapy will be commercially successful. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Bristol Myers Squibb’s business and market, particularly those identified in the cautionary statement and risk factors discussion in Bristol Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2025, as updated by Bristol Myers Squibb’s subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by applicable law, Bristol Myers Squibb undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

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