Global Data for BioNTech and Bristol Myers Squibb's PD-L1xVEGF-A Bispecific Pumitamig Shows Encouraging Efficacy in Patients with Non-Small Cell Lung Cancer in ROSETTA Lung-02 Trial

May 30, 2026

- *First investigational PD-(L)1xVEGF bispecific immunomodulator to present global data showing encouraging efficacy in combination with chemotherapy in first-line non-small cell lung cancer across PD-L1 expression levels and subtypes, highlighting its potential to set a new standard of care*
- *Pumitamig plus chemotherapy showed robust and consistent antitumor activity in first-line non-small cell lung cancer at both evaluated dose levels, with higher confirmed objective response rates at the lower dose of 63.6% in the non-squamous and 72.7% in the squamous subtypes*
- *Pumitamig is advancing through a comprehensive global Phase 3 development program in non-small cell lung cancer, including the actively enrolling pivotal Phase 3 part of the ROSETTA Lung-02 trial, along with two additional global Phase 3 trials*

MAINZ, Germany, and PRINCETON, USA, May 30, 2026 – BioNTech SE (Nasdaq: BNTX, "BioNTech") and Bristol Myers Squibb Company (NYSE: BMY, "BMS") today announced interim Phase 2 data from the global Phase 2/3 ROSETTA Lung-02 clinical trial (NCT06712316) evaluating the investigational PD-L1xVEGF-A bispecific immunomodulator pumitamig (also known as BNT327 or BMS-986545) plus chemotherapy in patients with previously untreated advanced non-small cell lung cancer ("NSCLC").

The data showed encouraging anti-tumor activity, with high response rates observed in both non-squamous and squamous NSCLC and at each PD-L1 expression level (TPS < 1%, TPS 1 – 49%, and TPS ≥ 50%). The data are being presented today as a rapid oral presentation (abstract #8513) at the 2026 American Society of Clinical Oncology ("ASCO") Annual Meeting in Chicago.

"Despite significant immuno-oncology advances in the treatment of non-small cell lung cancer, most advanced diseases relapse on or after a PD-(L)1 checkpoint inhibitor treatment,[1] indicating that targeting this immunologic pathway alone is insufficient to achieve durable responses," said **Solange Peters, M.D., Ph.D., Lead Investigator and Director of Oncology at the University Hospital of Lausanne, Switzerland.** "I am encouraged by the efficacy signal with this bispecific approach, showing robust responses across subtypes and PD-L1 levels, supporting the continued investigation of pumitamig and its potential to deliver improved outcomes for a broad range of patients with NSCLC."

The Phase 2 part of the ROSETTA Lung-02 trial evaluated pumitamig in two dose levels, in combination with chemotherapy. At this interim analysis at the April 13, 2026 data cut-off, among 40 response-evaluable patients with a median follow-up of 9.0 months, pumitamig plus chemotherapy showed a confirmed objective response rate ("cORR") of 57.1% in patients with non-squamous NSCLC and 68.4% with squamous NSCLC with a disease control rate ("DCR") of 100%. Encouraging anti-tumor activity was observed at both dose levels, with higher response rates at the lower dose showing a cORR of 63.6% for non-squamous and 72.7% for squamous NSCLC. Results were high at each PD-L1 expression level (cORR: 47.6% TPS < 1%; 77.8% TPS 1 – 49 %; 100% TPS ≥ 50%).

Pumitamig plus chemotherapy demonstrated a manageable safety profile with a low discontinuation rate. Grade ≥ 3 treatment-related adverse events ("TRAEs") were reported in 48.8% of patients and were considered pumitamig-related in 23.3%, leading to treatment discontinuation in four (9.3%) patients. Immune-related AEs ("irAEs") occurred in 16 (37.2%) patients and grade ≥ 3 irAEs in two (4.7%) patients. Bleeding events were reported in nine (20.9%) patients, with only one event being grade 3.

"The data we are presenting today provide further evidence of the potential of pumitamig to enhance anti-tumor responses in advanced lung cancer, one of the most challenging indications, by simultaneously targeting PD-L1 and VEGF-A with a single molecule," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "Pumitamig has consistently shown efficacy in three global Phase 2 trials across PD-L1 expression levels. Together with our partner BMS, we are continuing to advance pumitamig in ongoing pivotal and novel-novel combination trials with the goal of delivering better outcomes for more patients."

"We are committed to advancing the science of lung cancer with pumitamig and improving on the standard of care for people with this challenging disease," said **Anne Kerber, Senior Vice President, Head of Development, Hematology, Oncology, Cell Therapy at Bristol Myers Squibb**. "With one of the broadest registrational programs in the class, we are focused on accelerating the development of pumitamig together with BioNTech, with the goal of delivering meaningful benefit to patients, including those who have been left behind by current therapies."

BioNTech and BMS are advancing a broad development plan for pumitamig in non-small cell lung cancer across disease stages and subgroups. In addition to the ongoing global ROSETTA Lung-02 trial, which is currently recruiting for the Phase 3 part of the trial, there are two additional global Phase 3 clinical trials in NSCLC currently enrolling. These include ROSETTA Lung-201 (NCT07361497), evaluating pumitamig compared to durvalumab following concurrent chemoradiation therapy in patients with unresectable stage III NSCLC; and ROSETTA Lung-202 (NCT07361510), evaluating pumitamig compared to pembrolizumab as a first-line treatment for patients with advanced PD-L1 ≥ 50% NSCLC. Pumitamig is also being investigated in combination with other novel investigative treatments for NSCLC, including in combination with investigational antibody-drug conjugates ("ADCs") and other modalities.

About ROSETTA Lung-02

The global Phase 2/3 ROSETTA Lung-02 trial (NCT06712316) is evaluating pumitamig (BNT327/ BMS986545) in combination with chemotherapy in patients with first-line treatment of non-squamous and squamous non-small cell lung cancer without actionable genomic alterations and with any level of PD-L1 expression. In the Phase 2 dose-optimization part of the trial, patients were randomized 1:1 to 1400 mg or 2000 mg pumitamig plus histology-specific chemotherapy Q3W (non-squamous: carboplatin + pemetrexed; squamous: carboplatin + paclitaxel). The primary endpoints of the Phase 2 part of the trial are objective response rate (ORR) per investigator's assessment (RECIST 1.1), best percentage change in tumor size from

baseline, and safety. Key secondary endpoints include duration of response (DOR) and disease control rate (DCR). The Phase 3 part of the trial will evaluate pumitamig plus chemotherapy versus pembrolizumab plus chemotherapy. Based on the totality of the data, a pumitamig 1500 mg flat dose Q3W plus chemotherapy was selected for further evaluation in the Phase 3 part. The primary endpoint of the Phase 3 part of the trial is progression free survival (PFS) assessed by blinded independent central review (BICR). Key secondary endpoints include overall survival (OS), ORR, DOR.

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 2,000 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.

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 March 31, 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: Transforming Patients' Lives Through Science
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 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.

CONTACTS

BioNTech
Media Relations
Jasmina Alatovic
Media@biontech.de

Investor Relations
Douglas Maffei, PhD
Investors@biontech.de

Bristol Myers Squibb
Media Relations
media@bms.com

Investor Relations
investor.relations@bms.com

1. Mariniello A et al. BioDrugs, 2025 Feb 15;39(2):215–235.
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.