First Disclosure of Global Interim Phase 2 Data for BioNTech and Bristol Myers Squibb PD-L1xVEGF-A Bispecific Antibody Pumitamig (BNT327/BMS986545) in Patients with Extensive-Stage Small Cell Lung Cancer Shows Encouraging Antitumor Activity

September 8, 2025

- *PD-L1xVEGF-A bispecific antibody pumitamig (BNT327/BMS986545) plus chemotherapy continues to show encouraging antitumor activity in patients with extensive-stage small cell lung cancer ("ES-SCLC") , expanding evidence for its potential to set a new standard of care in first-line ES-SCLC and beyond*
- *Global interim Phase 2 data showed a 76.3% confirmed objective response rate (cORR), 100% disease control rate (DCR), a median progression free survival (mPFS) of 6.8 months and a manageable safety profile*
- *Data confirm dose selection for the ongoing global pivotal Phase 3 ROSETTA LUNG-01 trial*

MAINZ, Germany, and PRINCETON, USA, September 8, 2025 – BioNTech SE (Nasdaq: BNTX, "BioNTech") and Bristol Myers Squibb Company (NYSE: BMY, "BMS") today presented interim data from a global randomized Phase 2 trial (NCT06449209) evaluating pumitamig (also known as BNT327 or BMS986545), an investigational bispecific antibody targeting PD-L1 x VEGF-A, plus chemotherapy in patients with extensive-stage small cell lung cancer ("ES-SCLC"). The data, which are consistent with data presented at the European Lung Cancer Congress ("ELCC") 2025 from a Phase 2 trial conducted in China (NCT05844150), showed encouraging anti-tumor responses with a positive trend in the secondary endpoint progression free survival. Pumitamig plus chemotherapy demonstrated a manageable safety profile with no new safety signals and a low discontinuation rate. The data are being presented today as a late-breaker oral presentation at the IASLC 2025 World Conference on Lung Cancer ("WCLC") hosted by the International Association for the Study of Lung Cancer in Barcelona.

"Small cell lung cancer is the most aggressive type of lung cancer with rapid growth, a poor prognosis and 5-year relative survival rate of just 5% in advanced stages.[1,2,3] While approximately 60-70% of patients initially respond to current standard of care treatments, most progress within months after treatment signifying an urgent need for new treatment options which improve outcomes," said **John V. Heymach, M.D., Lead Investigator and Chair of Thoracic/Head and Neck Medical Oncology at The University of Texas MD Anderson Cancer Center**. "The response rate and early progression free survival we are seeing in this interim analysis are encouraging and merit further investigation in a larger trial to validate pumitamig's potential to offer patients more durable anti-tumor responses relative to current standard of care."

The interim analysis included 43 patients with untreated extensive-stage small cell lung cancer (Cohort 1) who received pumitamig in combination with standard of care chemotherapy in two dose levels. At the August 7, 2025 data cut-off, among 38 efficacy-evaluable patients, the confirmed overall response rate was 76.3% (85.0% at 20 mg/kg [dose level 1] and 66.7% at 30 mg/kg [dose level 2]) and the disease control rate (DCR) was 100%. The mean best percentage change in tumor size showed a tumor shrinkage of 56.7% with 89.5% of patients achieving early tumor shrinkage. Median progression-free survival (mPFS) was 6.8 months (6.3 months at 20 mg/kg and 7.0 months at 30 mg/kg), with mOS not being mature at the time of the analysis. Pumitamig plus chemotherapy showed a manageable safety profile, with no new safety signals beyond those typically described for chemotherapy agents and anti-PD-(L)1 and anti-VEGF monotherapies, and a discontinuation rate of 14%. Out of 43 patients, pumitamig-related treatment-emergent adverse events of Grade ≥3 were reported in 1 patient at dose level 1 and five patients at dose level 2.

"Every innovation we pursue starts with the needs of patients. These interim data for pumitamig presented today show encouraging signals for our science-driven approach to address two fundamental drivers of small cell lung cancer in one single molecule," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "Our ultimate goal is to translate science into meaningful survival benefits for many patients by overcoming some of the biggest treatment challenges, not only in small cell lung cancer but also across other difficult-to-treat solid tumors. These interim data for pumitamig represent an important step in the right direction."

"Today's data add to the growing body of evidence indicating the potential of pumitamig to improve outcomes across a wide range of solid tumors," said **Bryan Campbell, Senior Vice President, Head of Program Leadership, Hematology, Oncology, Cell Therapy at Bristol Myers Squibb**. "These are the first-ever data in a global population in advanced small cell lung cancer for a PD-(L)1 x VEGF bispecific antibody, supporting a possible new standard of care for patients with extensive-stage small cell lung cancer. We look forward to continuing to jointly advance research and development of pumitamig as a potential new treatment option with meaningful clinical benefit for patients in need."

A global randomized Phase 3 trial, ROSETTA-LUNG-01 (NCT06712355), evaluating pumitamig plus chemotherapy versus atezolizumab plus chemotherapy as a first-line treatment in patients with untreated ES-SCLC is ongoing. The pivotal trial is enrolling patients at clinical trial sites in the United States, the United Kingdom, Türkiye, China, the Republic of Korea, and Australia with additional sites planned to open globally. Pumitamig received Orphan Drug designation from the U.S. Food and Drug Administration ("FDA") for the treatment of patients with small cell lung cancer in 2025.

The full abstract is available on the WCLC website. Click here for further information on BioNTech's pipeline assets.

About the BNT327-01 Phase 2 clinical trial
The global randomized, open-label, parallel group Phase 2 clinical trial (BNT327-01; NCT06449209) evaluated pumitamig (BNT327/BMS986545) in patients with untreated extended-stage small-cell lung cancer (ES-SCLC) (Cohort 1) or small-cell lung cancer (SCLC) who progressed on first- or second-line treatment (Cohort 2 and Cohort 3). In Cohort 1, patients received pumitamig in two dose levels + chemotherapy (etoposide+carboplatin) for four cycles, followed by pumitamig maintenance for up to 2 years or until disease progression or unacceptable toxicity to identify an optimized dose for future clinical investigation. Cohort 2 and Cohort 3 explored the combination of two dose levels of pumitamig plus paclitaxel, or topotecan in the second- or third-line setting. The co-primary endpoints of the trial were per RECIST 1.1 objective response rate (ORR), change in tumor size and early tumor shrinkage, and safety per NCI CTCAE v5.0. Secondary endpoints include duration of response (DoR), disease control rate (DCR), progression free survival (PFS) and overall survival (OS).

About Small Cell Lung Cancer

Small cell lung cancer (SCLC) accounts for 15% of all lung cancer cases, with an estimated 250,000 new cases globally per year.[1] It is the most aggressive type of lung cancer often spreading early to other parts of the body and developing resistance mechanisms which makes it more challenging to treat.[1,2] Platinum-based chemotherapy combined with etoposide chemotherapy has been the standard first-line treatment for decades. While the addition of immune checkpoint inhibitors to chemotherapy has shown improved survival outcomes for patients with advanced or extensive-stage disease, most patients progress within months after treatment, and the prognosis remains poor. The 5-year survival rate for patients with extensive-stage SCLC is only 5%, emphasizing the need for new treatment options that extend progression-free survival.[2, 3]

About pumitamig (also known as BNT327 or BMS986545)

Pumitamig is a novel investigational bispecific antibody, jointly developed by BioNTech and BMS, combining two complementary, validated mechanisms in oncology into one single molecule. Pumitamig combines PD-L1 checkpoint inhibition aimed at restoring T cells' ability to recognize and destroy tumor cells with the neutralization of VEGF-A. The blocking of VEGF-A is aimed at reversing the tumor's immuno-suppressive effect in its microenvironment and cutting off the blood and oxygen supply that feeds tumor cells (anti-angiogenesis effect), with the intention of preventing the tumor from growing and proliferating. Pumitamig may be differentiated via its mechanism of action of targeting PD-L1 on tumor cells to localize anti-VEGF activity within the tumor microenvironment, aiming to enhance therapeutic precision and minimize systemic exposure.

More than 1,200 patients have been treated with pumitamig in clinical trials to date. More than 20 clinical trials are currently ongoing or planned to evaluate pumitamig either as a monotherapy or in combination with other treatment modalities targeting different oncogenic pathways in more than 10 solid tumor indications. Multiple global trials are ongoing or planned to start in 2025, including three global clinical trials with registrational potential 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) and first-line triple-negative breast cancer (ROSETTA BREAST-01). Additional trials are ongoing exploring novel treatment combinations of pumitamig, including combinations with BioNTech's proprietary antibody-drug conjugate candidates ("ADCs") or immunomodulator candidates.

About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a global next generation immunotherapy company pioneering novel investigative therapies for cancer and other serious diseases. BioNTech exploits a wide array of computational discovery and therapeutic modalities with the intent of rapid development of novel biopharmaceuticals. Its diversified portfolio of oncology product candidates aiming to address the full continuum of cancer includes mRNA cancer immunotherapies, next-generation immunomodulators and targeted therapies such as antibody-drug conjugates (ADCs) and innovative chimeric antigen receptor (CAR) T cell therapies. Based on its deep expertise in mRNA development and in-house manufacturing capabilities, BioNTech and its collaborators are researching and developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global and specialized pharmaceutical collaborators, including Bristol Myers Squibb, Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, MediLink, OncoC4, Pfizer and Regeneron.

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: the collaboration with Bristol Myers Squibb (BMS); the ability of BioNTech and BMS 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 development 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, 2025 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

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol Myers Squibb, visit us at BMS.com or 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 pumitamig (also known as BNT327 or BMS986545) may not 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 and, if approved, whether such product candidates 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, 2024, 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] Rudin CM, Brambilla E, Faivre-Finn C, Sage J. Small-cell lung cancer. Nat Rev Dis Primers. 2021 Jan 14;7(1):3. doi: 10.1038/s41572-020-00235-0. PMID: 33446664; PMCID: PMC8177722.

[2] Yılmaz, F., Yaşar, S., Tatar, Ö.D. et al. Prognostic value of the StAN score in elderly small cell lung cancer. Sci Rep 15, 23495 (2025). https://doi.org/10.1038/s41598-025-08115-x

[3] Byers LA, Rudin CM. Cancer. 2014 Oct 21;121(5):664–672.