BioNTech Advances Phase 3 Clinical Trial of Pumitamig in Combination with Gilead's TROP2-Directed ADC Sacituzumab Govitecan in Triple-Negative Breast Cancer

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- *BioNTech enters a clinical trial collaboration with Gilead Sciences with the aim of improving outcomes in patients with PD-L1 low or negative triple-negative breast cancer*
- *The global Phase 3 ROSETTA Breast-01 trial will evolve to evaluate pumitamig in combination with sacituzumab govitecan, a TROP2-directed antibody-drug conjugate, reflecting the new standard of care in first-line treatment of metastatic triple-negative breast cancer*
- *This will be the first global Phase 3 trial of pumitamig in combination with an antibody-drug conjugate*

MAINZ, Germany, October 22, 2026 – BioNTech SE (Nasdaq: BNTX, "BioNTech") today announced a clinical trial collaboration and supply agreement with Gilead Sciences Inc. ("Gilead") to evaluate pumitamig in combination with the TROP2-directed antibody-drug conjugate ("ADC") sacituzumab govitecan (Trodelvy®) as first-line treatment for patients with locally advanced or metastatic PD-L1 low or negative triple-negative breast cancer ("TNBC"). Pumitamig is an investigational bispecific immunomodulator designed to cooperatively bind to PD-L1 and VEGF-A that is being jointly developed by BioNTech and Bristol Myers Squibb ("BMS").

ROSETTA Breast-01 is a global, double-blinded Phase 3 clinical trial (NCT07173751) currently evaluating pumitamig in combination with chemotherapy versus chemotherapy in patients with locally advanced or metastatic PD-L1 low or negative TNBC (CPS < 10), initiated based on positive results from a global Phase 2 trial. In line with the evolving treatment landscape in this indication, BioNTech and BMS plan to adapt ROSETTA Breast-01 replacing chemotherapy with sacituzumab govitecan, pending regulatory authority approval, to ensure that patients are receiving the latest standard of care treatment.

Under the terms of the agreement, BioNTech will continue to sponsor and lead the ROSETTA Breast-01 trial. Gilead will supply sacituzumab govitecan for the combination trial.

"When the ROSETTA Breast-01 trial was initiated, chemotherapy was the only option for patients with PD-L1 negative advanced TNBC. While chemotherapy remains a standard first-line option, TROP2-directed ADCs like sacituzumab govitecan are quickly becoming the new global standard of care. I am excited to evaluate the combination of pumitamig and sacituzumab govitecan in the ROSETTA Breast-01 trial to potentially further amplify the already meaningful improvement in patient outcomes that sacituzumab govitecan has demonstrated over chemotherapy," said **Peter Schmid, M.D., Ph.D., Lead Investigator and Director of the Breast Cancer Centre at St. Bartholomew's Hospital** .

Pumitamig is currently being investigated in seven ongoing global Phase 3 trials and 10+ Phase 2 novel-novel combination trials. ROSETTA Breast-01 will be the first global Phase 3 trial of pumitamig in combination with an ADC. BioNTech and Bristol Myers Squibb plan to evaluate the full potential of pumitamig in additional Phase 3 novel combination trials in multiple solid tumors, leveraging their broad oncology pipelines and exploring other potential additional collaborations.

"We aim to maximize potential benefit for patients with triple-negative breast cancer. Adapting ROSETTA Breast-01 to reflect the evolving standard of care gives the trial the best chance to inform clinical practice and, ultimately, treatment decisions for patients," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "Combining pumitamig as a potential backbone with complementary modalities such as ADCs is central to our therapeutic approach. Sacituzumab govitecan has advanced first-line treatment of triple-negative breast cancer. By combining pumitamig and sacituzumab govitecan, we aim to determine whether this approach can further improve outcomes of patients."

The use of pumitamig and sacituzumab govitecan in patients with first-line PD-L1 negative metastatic TNBC is investigational, and the safety and efficacy of this combination has not been established.

About Triple-Negative Breast Cancer
Triple-negative breast cancer (TNBC), which is defined by a lack of hormone receptors (estrogen or progesterone) and HER2 protein, accounts for about 10-15% of all invasive breast cancer cases.[1] It is an aggressive type of breast cancer that tends to grow and spread faster and has a worse prognosis compared to other breast cancer types. TNBC disproportionally impacts younger, premenopausal, and Black and Hispanic women. The 5-year survival rate for patients with metastatic TNBC is only 15%, emphasizing the need for new treatment options.[1]

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 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's collaboration with Gilead; 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.

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1 American Cancer Society. Triple-Negative Breast Cancer. https://www.cancer.org/cancer/types/breast-cancer/about/types-of-breast-cancer/triple-negative.html. Accessed October 15, 2026.