UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF DECEMBER 2025

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

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Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On December 9, 2025, BioNTech SE (Nasdaq: BNTX, "BioNTech") and Bristol Myers Squibb Company (NYSE: BMY, "BMS") announced the first interim data from a global randomized Phase 2 trial (NCT06449222) evaluating pumitamig (BNT327/BMS986545), an investigational bispecific antibody targeting PD-L1 and VEGF-A, plus chemotherapy in patients with locally advanced/metastatic triple-negative breast cancer ("TNBC") irrespective of PD-L1 expression levels. The press release is attached hereto as Exhibit 99.1.

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By:	/s/ Ramon Zapata-Gomez	By:	/s/ Dr. Sierk Poetting
	Name: Ramon Zapata-Gomez		Name: Dr. Sierk Poetting
	Title: Chief Financial Officer		Title: Chief Operating Officer

Date: December 9, 2025

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	BioNTech and Bristol Myers Squibb Present First Global Phase 2 Data for PD-L1xVEGF-A Bispecific Antibody Pumitamig Showing Encouraging Efficacy in Advanced Triple-Negative Breast Cancer

BioNTech and Bristol Myers Squibb Present First Global Phase 2 Data for PD-L1xVEGF-A Bispecific Antibody Pumitamig Showing Encouraging Efficacy in Advanced Triple-Negative Breast Cancer

- *Global interim Phase 2 data in locally advanced/metastatic triple-negative breast cancer ("TNBC") show encouraging antitumor activity for investigational therapy pumitamig (BNT327/BMS986545) plus chemotherapy in first- and second-line patients*
- *Pumitamig plus chemotherapy achieved confirmed objective response rate (cORR) of 61.5%, unconfirmed ORR (uORR) of 71.8% and disease control rate (DCR) of 92.3% irrespective of PD-L1 expression levels*
- *Data highlight the potential of pumitamig for patients with TNBC, including PD-L1 low or negative (CPS<10) TNBC which has limited treatment options and high unmet need*
- *Data are consistent with the previously reported data from the 1L TNBC Phase 1b/2 trial conducted in China and confirm dose selection for the pivotal Phase 3 ROSETTA BREAST-01 trial*

MAINZ, Germany, and PRINCETON, USA, December 9, 2025 – BioNTech SE (Nasdaq: BNTX, "BioNTech") and Bristol Myers Squibb Company (NYSE: BMY, "BMS") today announced the first interim data from a global randomized Phase 2 trial (NCT06449222) evaluating pumitamig (BNT327/BMS986545), an investigational bispecific antibody targeting PD-L1 and VEGF-A, plus chemotherapy in patients with locally advanced/metastatic triple-negative breast cancer ("TNBC") irrespective of PD-L1 expression levels.

The data showed encouraging anti-tumor responses and a manageable safety profile for pumitamig plus chemotherapy in first-line and second-line treatment setting. The data will be presented at the 2025 San Antonio Breast Cancer Symposium ("SABCS").

"Triple-negative breast cancer is a highly aggressive disease with a poor prognosis and 5-year survival rate of just 15% in advanced stages. [1] There remains an urgent need for new treatment options – particularly for patients with PD-L1 low or negative tumors (CPS<10), a subgroup for whom the current standard of care is chemotherapy alone and existing PD-(L)1 inhibitors have historically shown limited benefit," said **Peter Schmid, M.D., Ph.D., Lead Investigator and Director of the Breast Cancer Centre at St. Bartholomew's Hospital**. "The anti-tumor efficacy observed in this interim analysis is encouraging and supports the ongoing investigation of pumitamig in the Phase 3 ROSETTA BREAST-01 trial."

The trial evaluated pumitamig in two dose levels and in combination with four different chemotherapeutic agents in the first- and second-line treatment of participants with locally advanced/metastatic TNBC. In Cohort 1, reported in this analysis, patients received pumitamig (15 or 20 mg/kg Q2W) plus nab-paclitaxel until disease progression or unacceptable toxicity. In Cohort 2, patients received the flat-dose equivalent of 20 mg/kg in combination with three different chemotherapy regimens (Arm 1: paclitaxel; Arm 2: gemcitabine + carboplatin; Arm 3: eribulin).

The interim analysis at the October 1, 2025 data cut-off included 74 patients with 1L/2L+ locally advanced/metastatic TNBC who received pumitamig in combination with standard of care chemotherapy. Key data highlights are provided below:

Efficacy:

- Among 39 efficacy-evaluable first-line and second-line patients, all in Cohort 1, the confirmed objective response rate ("cORR") was 61.5% (24/39), the unconfirmed objective response rate ("uORR") was 71.8% (28/39) and the disease control rate ("DCR") was 92.3% (36/39).
- Efficacy was encouraging across dose levels, PD-L1 expression levels and lines of treatment and higher doses correlated with higher response (dose levels: uORR: 63.2% at 15 mg/kg dose; 80.0% at 20 mg/kg dose; PD-L1 expression levels: uORR: 70.6% in CPS ≥10; 70.6% in CPS <10; lines of treatment: uORR: 76.5% in 1L and 68.2% in 2L).
- The progression-free survival ("PFS") rate at 9 months was 59.3%. Median PFS, median duration of response ("DOR") and median overall survival ("OS") were not mature at the time of analysis.

Safety:

- Pumitamig plus chemotherapy demonstrated a manageable safety profile in both Cohorts in combination with all four chemotherapy regimens.
- Grade ≥3 treatment-related adverse events (TRAEs) were reported in 17/40 (42.54%) and 13/34 (38.2%) patients in Cohorts 1 and 2, respectively, with no pumitamig-related deaths reported.

"We are encouraged by these first locally advanced/metastatic TNBC data from a global patient population that indicate the potential of pumitamig in patients with advanced TNBC irrespective of PD-L1 status," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech** . "The activity we see in TNBC is consistent with findings in other solid tumors and further supports the pan-tumor potential of pumitamig, which we are advancing together with BMS in a broad development program that also includes novel/novel combination regimens."

"These data add to the growing evidence from global pumitamig studies across multiple indications," said **Anne Kerber, Senior Vice President, Head of Development, Hematology, Oncology, Cell Therapy at Bristol Myers Squibb**. "The encouraging results are especially meaningful in patients with PD-L1 low or negative tumors (CPS<10), representing the potential of pumitamig to deliver meaningful benefit across PD-L1 expression levels, including patients who historically have had fewer effective treatments."

A global randomized Phase 3 trial, ROSETTA-BREAST-01 (NCT07173751), is evaluating pumitamig plus chemotherapy versus placebo plus chemotherapy in patients with previously untreated locally advanced/metastatic TNBC determined ineligible for PD-(L)1 therapy based on PD-L1 negative disease. Pumitamig is also being studied in more than 20 clinical trials as monotherapy, in combination with chemotherapy, or with other novel treatment modalities in more than 10 solid tumor indications.

About the BNT327-02 Phase 2 clinical trial

The global randomized, open-label Phase 2 clinical trial (BNT327-02; NCT06449222) evaluated pumitamig (BNT327/ BMS986545) in combination with chemotherapeutic agents in the first- and second-line treatment of participants with locally advanced/metastatic TNBC. In Cohort 1, patients received pumitamig Q2W (15 or 20 mg/kg) plus chemotherapy (nab-paclitaxel) until disease progression or unacceptable toxicity. In Cohort 2, patients received the flat dose equivalent of 20 mg/kg in combination with chemotherapy (Arm 1: paclitaxel Q2W; Arm 2: gemcitabine + carboplatin Q3W; Arm 3: eribulin Q3W). The primary endpoints of the trial were objective response rate (ORR) per investigator's assessment (RECIST 1.1), 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 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. The addition of PD-(L)1 immune checkpoint inhibitors to chemotherapy for the first-line treatment of TNBC has improved outcomes in patients with high levels of PD-L1 expression (CPS ≥ 10) on the surface of tumor cells, but many patients experience relapse. In addition, for patients with PD-L1 negative TNBC (CPS<10), the current standard of care is chemotherapy alone, as other PD-(L)1 inhibitors have historically demonstrated poor efficacy in this subgroup. The 5-year survival rate for patients with advanced TNBC is only 15%, emphasizing the need for new treatment options.[1]

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 1,400 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, including five 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), 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). 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, 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: 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 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 September 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) plus chemotherapy 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 plus 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, 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.

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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 November 10, 2025.