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 2023

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

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(Address of principal executive offices)

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 21, 2023, BioNTech SE and Duality Biologics (Suzhou) Co. Ltd. announced that the U.S. Food and Drug Administration granted Breakthrough Therapy designation for BNT323/DB-1303 for the treatment of advanced endometrial cancer in patients who progressed on or after treatment with immune checkpoint inhibitors. 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/ Dr. Sierk Poetting

Name: Dr. Sierk Poetting

Title: Chief Operating Officer

Date: December 21, 2023

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	BioNTech and DualityBio Receive FDA Breakthrough Therapy Designation for Antibody-Drug Conjugate Candidate BNT323/DB-1303 in Endometrial Cancer

BioNTech and DualityBio Receive FDA Breakthrough Therapy Designation for Antibody-Drug Conjugate Candidate BNT323/DB-1303 in Endometrial Cancer

- *Designation is based on Phase 1/2 safety and efficacy data in patients with Human Epidermal Growth Factor Receptor 2 ("HER2")-expressing advanced endometrial cancer with encouraging early signs of anti-tumor activity*
- *Breakthrough Therapy designation will allow for an expedited development and regulatory review of BNT323/DB-1303*
- *Endometrial or uterine cancer is the second most common gynecologic cancer globally with over 400,000 cases occurring each year*

MAINZ, Germany and SHANGHAI, China, December 21, 2023 – BioNTech SE (Nasdaq: BNTX, "BioNTech") and Duality Biologics (Suzhou) Co. Ltd. ("DualityBio") today announced that the U.S. Food and Drug Administration ("FDA") granted Breakthrough Therapy designation for BNT323/DB-1303 for the treatment of advanced endometrial cancer in patients who progressed on or after treatment with immune checkpoint inhibitors. BNT323/DB-1303 is a next-generation antibody-drug conjugate ("ADC") candidate targeting the Human Epidermal Growth Factor Receptor 2 ("HER2"), a cell surface protein which is expressed in a range of tumor types. The designation is based on encouraging topline data from a Phase 1/2 study (NCT05150691) with BNT323/DB-1303 in patients with HER2-expressing advanced endometrial cancer.

Endometrial or uterine cancer is the second most common gynecologic cancer globally, with over 400,000 cases occurring each year[1,2] and both incidence and mortality are increasing[3,4]. While localized, early disease stages can be cured via surgery, the five-year survival rate for patients with advanced, metastatic or recurrent disease is only 18.4%[5].

"The Breakthrough Therapy designation for BNT323/DB-1303 shows the potential of our ADC candidate to address current treatment challenges for patients with advanced HER2-expressing endometrial cancer who progressed under several lines of systemic therapy. For these patients the survival rates are still low and the medical need for new and more effective treatments remains high," said **Prof. Özlem Türeci, M.D., Chief Medical Officer and Co-Founder at BioNTech**. "With the designation and support by the FDA, we seek to expedite further development of BNT323/DB-1303."

"The FDA's decision is an important milestone in the development of our novel differentiated ADC candidate directed at HER2. The HER2 protein overexpression and/or gene amplification is present in approximately 17% to 38%[6] of patients with endometrial cancer and more than 50%[7] of patients in late disease stage exhibit HER2 overexpression. We believe BNT323/DB-1303 has the potential to serve as a new therapeutic option for patients with HER2 expressing advanced endometrial carcinoma including both patients with high and low expression levels of HER2," said **Vivian Gu, M.D., Chief Medical Officer at DualityBio**. "We are committed to advancing BNT323/DB-1303 with the aim to improve outcomes for patients in late disease stages."

Breakthrough Therapy designation is an FDA program designed to expedite the development and regulatory review of investigational therapies that are designed to address serious or life-threatening conditions. To receive the designation, the candidate needs to demonstrate preliminary clinical evidence that indicates that it may offer substantial improvement over existing therapies on one or more clinically significant endpoints. With the Breakthrough Therapy designation, the development of BNT323/DB-1303 may benefit from more frequent engagement with the FDA, which will support the collection of appropriate data needed to accelerate development and may also allow for priority review if the relevant criteria are met.

Data presented from the ongoing Phase 1/2 study at ASCO 2023 and ESGO 2023 demonstrated encouraging anti-tumor activity in heavily pretreated patients with advanced endometrial cancer with an unconfirmed objective response rate of 58.8% and an unconfirmed disease control rate of 94.1%. BNT323/DB-1303 was well tolerated with a manageable safety profile across all evaluated patients with advanced/metastatic solid tumors.

The BNT323/DB-1303 program received FDA Fast Track designation for the treatment of endometrial cancer in January 2023.

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About BNT323/DB-1303
BNT323/DB-1303 is a third-generation topoisomerase-1 inhibitor-based ADC targeting HER2 which was built from DualityBio's proprietary Duality Immune Toxin Antibody Conjugates ("DITAC") platform. HER2 is a surface-expressed protein on solid tumors and has been linked to the aggressive growth and spread of cancer cells, making it a potential target for innovative cancer therapeutics. The candidate has exhibited antitumor activity in both HER2-positive and HER2-low tumor models as well as in several solid tumor indications, including patients with breast, gastric, endometrial, biliary tract cancers, and other advanced solid tumors. Preclinical data and preliminary clinical data for BNT323/DB-1303 indicate its potential to target HER2 on solid tumors irrespective of expression level with a manageable safety profile and a potentially expanded therapeutic window. BNT323/DB-1303 is currently being evaluated in an ongoing Phase 1/2 study (NCT05150691) in patients with advanced/metastatic solid tumors and in a pivotal Phase 3 study (NCT06018337) in patients with Hormone Receptor-positive ("HR+") and HER2-low metastatic breast cancer that have progressed on hormone and/or cyclin-dependent kinase 4/6 ("CDK4/6") therapy.

About BioNTech
Biopharmaceutical New Technologies (BioNTech) is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor ("CAR") T cells, several protein-based therapeutics, including bispecific immune checkpoint modulators, targeted cancer antibodies and antibody-drug conjugate ("ADC") therapeutics, as well as small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are 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 pharmaceutical collaborators, including Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron, Sanofi and Pfizer.

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

About DualityBio
DualityBio is a clinical-stage company focusing on the discovery and development of the next generation ADC therapeutics for patients with cancer and autoimmune diseases. DualityBio has successfully established a number of next generation Antibody-Drug Conjugate (ADC) technology platforms with global intellectual property rights. Building upon deep understanding of disease biology and translational capability, DualityBio has advanced 4 assets into global clinical studies, and developed more than 10 innovative product candidates which are currently in preclinical stage. Additionally, DualityBio is continuing to evolve its novel protein engineering and ADC technology platforms for the next wave of "super ADC" molecules including diverse payload classes, bispecific ADCs and dual payload ADCs.

For more information, please visit www.dualitybiologics.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 be limited to, statements concerning: the collaboration between BioNTech and DualityBio to jointly clinical develop the antibody-drug conjugate (ADC) candidate BNT323/DB-1303; the registrational potential of any trial we may initiate for BNT323/DB-1303; the nature and characterization of and timing for release of clinical data for BNT323/DB-1303, which is subject to peer review, regulatory review and market interpretation; planned next steps in BioNTech's pipeline programs, including, but not limited to, statements regarding timing or plans for initiation of clinical trials, enrolment or submission for and receipt of product approvals with respect to BioNTech's product candidates; the ability of BioNTech's mRNA technology to demonstrate clinical efficacy outside of BioNTech's infectious disease platform; the potential safety and efficacy of our product candidates; and BioNTech's anticipated market opportunity and size for its product candidates. Any forward-looking statements in this press release are based on BioNTech's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such 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 preclinical and clinical data, including the data discussed in this release, 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 the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; discussions with regulatory agencies regarding timing and requirements for additional clinical trials; the ability to produce comparable clinical results in future clinical trials; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; BioNTech's and its counterparties' ability to manage and source necessary energy resources; 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, if approved, its product candidates; BioNTech's ability to manage its development and expansion; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products and BioNTech's product candidates; risks relating to the global financial system and markets; 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, 2023, and in subsequent filings made by BioNTech with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at www.sec.gov. 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. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

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