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 OCTOBER 2023

COMMISSION FILE NUMBER 001-39081

BioNTech SE
(Translation of registrant's name into English)

An der Goldgrube 12
D-55131 Mainz
Germany
+49 6131-9084-0
(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 October 23, 2023, BioNTech SE (the "Company") announced follow-up data from its ongoing first-in-human Phase 1/2 trial (NCT04503278; 2019-004323-20) evaluating the safety and efficacy of the Company’s Claudin-6 (CLDN6)-directed CAR-T cell therapy candidate BNT211 in patients with CLDN6-positive refractory/relapsed solid tumors. 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: October 23, 2023

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	BioNTech Presents Positive Phase 1/2 Data Update for CAR-T Cell Therapy Candidate BNT211 in Advanced Solid Tumors at ESMO Congress 2023

BioNTech Presents Positive Phase 1/2 Data Update for CAR-T Cell Therapy Candidate BNT211 in Advanced Solid Tumors at ESMO Congress 2023

- *BNT211 combines two innovative approaches in one regimen with first-in-class potential: an autologous CAR-T cell therapy targeting the oncofetal antigen Claudin-6 (CLDN6) and a CLDN6-encoding CAR-T cell amplifying RNA vaccine ("CARVac")*
- *Data presented at ESMO Congress 2023 demonstrates that the application of CARVac increases the persistence of the adoptively transferred autologous CAR-T cells*
- *BNT211 continues to show encouraging antitumor activity in patients with CLDN6-positive relapsed or refractory advanced solid tumors*
- *Follow-up of efficacy data at 1x10^8 CAR-T cells with or without CARVac shows an overall response rate ("ORR") of 59% and a disease control rate ("DCR") of 95%, with the CARVac cohort demonstrating a prolonged persistence of CAR-T cells*

MAINZ, Germany, October 23, 2023 (GLOBE NEWSWIRE) – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") today announced follow-up data from its ongoing first-in-human Phase 1/2 trial (NCT04503278; 2019-004323-20) evaluating the safety and efficacy of the Company's Claudin-6 (CLDN6)-directed CAR-T cell therapy candidate BNT211 in patients with CLDN6-positive refractory/relapsed solid tumors. The data show encouraging signs of clinical activity and an increased persistence of cancer-specific CAR-T cells when combined with CARVac. At the ESMO Congress 2023 in Madrid, Prof. John Haanen, M.D., Ph.D., Netherlands Cancer Institute (NKI), Amsterdam, Netherlands presented the data in an oral late-breaking data session which confirms the positive interim data presented at this year's American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, USA.

"Our goal is to unlock the potential of CAR-T for solid tumors and to help improve the outcomes for a broad range of hard-to-treat tumors," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "BNT211 aims to address two of the key limitations of CAR-T cell approaches in solid tumors, namely the lack of suitable cancer-specific cell surface targets and the limited persistence of CAR-T cells. To address this challenge, we have designed a CLDN6-specific autologous CAR-T cell therapy that we combine with our mRNA-based vaccine CARVac."

The data update included 44 patients who received CLDN6 CAR-T cells at four dose levels alone or in combination with CARVac. Patients with germ cell tumors (n=16), ovarian cancer (n=17) and other solid tumor types (n=11) were treated. In course of the dose escalation, a dose-dependent increase in adverse events was observed, with cytokine release syndromes occurring in 23 of 44 safety evaluable patients. In most cases, these were of grade 1 and 2, with one patient with a grade 3 and one with a grade 4 event. Neurotoxicity was mild and self-limiting in two patients. Of the total 44 patients, 38 were efficacy evaluable. The overall response rate ("ORR") for these 38 patients was 45% and the disease control rate ("DCR") 74%. Further, 27 patients were treated with CLDN6 CAR-T cells at dose level 2 (1x10^8 CAR-T cells) with or without CARVac. At this dose level, 13 patients showed partial responses resulting in an ORR of 59% and a DCR of 95%. Additionally, in the same cohort, patients who received CARVac showed a prolonged persistence of CAR-T cells.

These results further underline the potential of BioNTech's BNT211 program. One objective of the ongoing Phase 1/2 trial is to determine the recommended dose for the initiation of a potential pivotal Phase 2 trial in patients with germ cell tumors which is expected to be initiated in 2024.

About BNT211
To harness the power of cell therapies for solid cancers, BioNTech has combined their CAR-T and FixVac platform technologies to develop a tumor-specific CAR-T cell therapy which is enhanced by a **C**AR-T Cell **A**mplifying **R**NA **Vac**cine (CARVac) that is based on BioNTech's mRNA-lipoplex technology and encodes for the CAR-T target antigen. The mRNA vaccine is designed to boost CAR-T persistence and functionality. BNT211 is a CAR-T cell therapy directed against the novel oncofetal antigen Claudin-6 (CLDN6), a target expressed on multiple solid tumors such as ovarian cancer, sarcoma, testicular cancer, endometrial cancer and gastric cancer. The program is currently being evaluated in a first-in-human Phase 1/2 trial as a monotherapy and in combination with a CLDN6-encoding CARVac in patients with CLDN6-positive relapsed or refractory advanced solid tumors.

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.

Forward-Looking Statements
This press release may contain 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 initiation, timing, progress and results of BioNTech's research and development programs in oncology; BioNTech's current and future preclinical studies and clinical trials in oncology, including CAR-T cell therapy candidate BNT211, including statements regarding the timing of initiation and completion of studies or trials, such as the expected initiation of a pivotal Phase 2 trial of BNT211 in germ cell tumors, related preparatory work and the availability of results; timing for any data readouts; the registrational potential of any trial we may initiate for our product candidates; the potential safety and efficacy of our product candidates, including qualitative assessments of available data and expectations of potential benefits (including Phase 1/2 data for BNT211 in advanced solid tumors); and BioNTech's anticipated market opportunity and size for its product candidates. 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 neither promises nor guarantees, and 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 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 preclinical and clinical data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; future commercial demand and medical need; the availability of raw materials; competition from other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis

of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; 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; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its 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, 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.

CONTACTS

Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513
Media@biontech.de
Investor Relations
Victoria Meissner, M.D.
+1 617 528 8293
Investors@biontech.de