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 APRIL 2022

COMMISSION FILE NUMBER 001-39081

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

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Germany
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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 April 11, 2022, BioNTech SE (the "Company") presented data from its ongoing first-in-human Phase 1/2 trial evaluating the safety and preliminary efficacy of the Company's novel CAR-T cell therapy candidate, BNT211, in patients with advanced 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: April 11, 2022

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	BioNTech Presents Positive Preliminary Phase 1/2 Data for First-in-Class CAR-T Program BNT211 at AACR

BioNTech Presents Positive Preliminary Phase 1/2 Data for First-in-Class CAR-T Program BNT211 at AACR

- *BNT211 combines two innovative approaches in one regimen, an autologous CAR-T cell therapy targeting the oncofetal antigen Claudin-6 (CLDN6) and a CLDN6-encoding CAR-T cell amplifying RNA vaccine (CARVac) to improve persistence and functionality of the adoptively transferred cells*
- *Treatment with BNT211 alone or in combination with CARVac, currently being tested in a Phase 1/2 Trial in patients with advanced solid tumors, was well tolerated across multiple tumor indications in preliminary data from 16 patients*
- *Preliminary efficacy data showed encouraging signs of clinical activity with a disease control rate of 86% and an overall response rate of 43%*

Mainz, Germany, April 11, 2022 — BioNTech SE (Nasdaq: BNTX, "BioNTech") presented data from its ongoing first-in-human Phase 1/2 trial evaluating the safety and preliminary efficacy of the Company's novel CAR-T cell therapy candidate, BNT211, in patients with advanced solid tumors. The preliminary results demonstrated an encouraging safety profile and anti-tumor activity in testicular cancer patients at the first evaluated dose levels of BNT211. The data were presented in the Clinical Trials Plenary Session at the AACR Annual Meeting 2022 by Prof. John Haanen, M.D., Ph.D., Netherlands Cancer Institute (NKI), Amsterdam, Netherlands.

BNT211 is a potential first-in-class therapeutic approach which comprises two drug products, an autologous CAR-T cell therapy targeting the oncofetal antigen Claudin-6 (CLDN6) and a CLDN6-encoding CAR-T cell amplifying RNA vaccine (CARVac), which is based on BioNTech's mRNA-lipoplex technology to improve persistence and functionality of the adoptively transferred cells.

The presentation included data from 16 patients who received CLDN6 CAR-T cells at dose levels 1 ($1x10^7$ CAR-T cells) and 2 ($1x10^8$ CAR-T cells) alone or combined with CARVac. Tumor indications included testicular cancer (n=8) ovarian cancer (n=4), endometrial cancer, fallopian tube cancer, sarcoma, and gastric cancer (1 patient each). Treatment with CLDN6 CAR-T alone or in combination with CARVac up to dose level 2 was well tolerated and showed encouraging signs of clinical activity. All 16 patients showed robust CAR-T cell expansion 10-17 days after infusion with cell frequencies close to 10^9 total counts in dose level 2. Adverse events and dose limiting toxicities were manageable; cytokine release syndromes of grade 1 and 2 and one transient occurrence of neurotoxicity grade 1 were observed.

At the first efficacy assessment 6 weeks post infusion, 6 of 14 evaluable patients showed a partial response, and 5 patients had stable disease with shrinkage of target lesions. One patient showed no change from baseline and two patients were progressing. Responses were seen in testicular (n=4) and ovarian cancer (n=2) patients. At 12 weeks, 4 of the 6 patients with a partial response showed deepening and durability of responses with one patient reaching a complete response 18 weeks after infusion. All 4 testicular cancer patients in the higher dose level had disease control and 3 of these patients showed objective responses. In addition, 1 testicular cancer patient showed partial response after infusion of the lowest CAR-T dose level in combination with CARVac. Antitumor activity tended to be higher at the higher CAR-T dose and when combined with the vaccine, with 4 of 5 patients in the CARVac combination group showing a partial response.

"Seeing first anti-tumor effects even at the lowest CAR-T cell dose in this heavily pre-treated patient population is truly remarkable and points to the potential of our CAR design and our CARVac approach," said **Özlem T✔reci, M.D., Co-Founder and Chief Medical Officer at**

BioNTech. “The results support our assumption that Claudin-6 is a well-suited new tumor target. Bringing these innovations together in one regimen may benefit patients with hard-to-treat solid tumors with an otherwise poor prognosis, such as advanced testicular cancer. Our preliminary data indicate that the successes of CAR-T in hematological cancers may indeed be transferred to solid tumors.”

“Claudin-6 was never targeted with cellular therapy before, but in this study, the approach is already showing an efficacy that may be better than the data from other CAR-T trials in solid tumors,” said **John Haanen, M.D., Ph.D. a medical oncologist at the Netherlands Cancer Institute (NKI), Amsterdam, Netherlands, and principal investigator of the study**. “While the data are very early, it is remarkable that all patients with testicular cancer showed clinical benefits at dose level 2, and the responses we have observed can be deep, including one ongoing complete remission. I look forward to further evaluating this exciting new modality for solid tumor patients.”

The ongoing Phase 1/2 study (NCT04503278; 2019-004323-20) aims to evaluate the safety and preliminary efficacy of the CLDN6 CAR-T therapy alone and in combination with CARVac in heavily pretreated patients with CLDN6-positive relapsed or refractory advanced solid tumors and is conducted at multiple sites across Germany and the Netherlands. The next data update is expected later this year.

About BNT211
To harness the power of cell therapies for solid cancers and overcoming hurdles to date, BioNTech has combined their CAR-T and FixVac platform technologies to develop a highly tumor-specific CAR-T cell therapy product which is consecutively 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 respective CAR-T target antigen. The vaccine has the potential to boost CAR-T activity, thus enabling and maintaining a therapeutic effect even at low CAR-T doses. 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, aiming to boost persistence and functionality of the CLDN6-CAR-T cells, in patients with CLDN6-positiv relapsed or refractory advanced solid tumors.

About BioNTech
Biopharmaceutical New Technologies (BioNTech) is a next generation immunotherapy company pioneering novel therapies for cancer, infectious diseases and other serious conditions. 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 T cells, bispecific checkpoint immuno-modulators, targeted cancer antibodies and small molecules immunomodulators. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech is 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 Genmab, Sanofi, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma and Pfizer.

For more information, please visit www.BioNTech.de

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to statements concerning: BioNTech's CAR-T program candidate BNT211; timing for any data readouts of the Phase 1/2 trial; the registrational potential of any trial we may initiate for BNT211; the nature and characterization of and timing for release of clinical data across BioNTech's platforms, which is subject to peer review, regulatory review and market interpretation; the planned next steps in BioNTech's pipeline programs and specifically including, but not limited to, statements regarding timing or plans for initiation of clinical trials, enrollment 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 other product candidates; and BioNTech's anticipated market opportunity and size for its product candidates, the rate and degree of market acceptance of BioNTech's investigational medicines, if approved. 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: discussions with regulatory agencies regarding timing and requirements for additional clinical trials; and the ability to produce comparable clinical results in future clinical trials.

For a discussion of these and other risks and uncertainties, see the section entitled "Risk Factors" in BioNTech's Annual Report on Form 20-F for the Year Ended December 31, 2021, filed with the SEC on March 30, 2022, which is available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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