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 JUNE 2021

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 June 18, 2021, BioNTech SE (the "Company") announced that the first patient has been treated in its BNT111 Phase 2 cancer vaccine trial (2020-002195-12; NCT04526899). The publications are 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 Financial Officer

Date: June 18, 2021

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	BioNTech Announces First Patient Dosed in Phase 2 Clinical Trial of mRNA-based BNT111 in Patients with Advanced Melanoma.

BioNTech Announces First Patient Dosed in Phase 2 Clinical Trial of mRNA-based BNT111 in Patients with Advanced Melanoma

- *First program from BioNTech's fully-owned mRNA cancer vaccine platform FixVac treats patients in a randomized clinical Phase 2 clinical trial*
- *Phase 2 trial is based on positive results from Phase 1 Lipo-MERIT trial that demonstrated a favorable safety profile for BNT111 as well as durable objective responses observed in patients with melanoma who had progressed following prior checkpoint blockade*
- *Trial is enrolling a total of 120 patients at clinical trial sites in the European Union, the United Kingdom, the United States and Australia*

MAINZ, Germany, June 18, 2021 (GLOBE NEWSWIRE) – BioNTech SE (NASDAQ: BNTX, "BioNTech" or "the Company"), announced today that the first patient has been treated in its BNT111 Phase 2 cancer vaccine trial (2020-002195-12; NCT04526899). The study is evaluating the Company's therapeutic cancer vaccine candidate BNT111 in combination with Libtayo® (cemiplimab) in patients with anti-PD1-refractory/relapsed unresectable Stage III or IV melanoma. BNT111 is the lead product candidate from BioNTech's FixVac platform that targets a fixed combination of mRNA-encoded, tumor-associated antigens with the objective of triggering a strong and precise immune response against cancer and is fully owned by BioNTech.

The BNT111-01 trial which is being conducted in collaboration with Regeneron was reviewed and approved by the regulatory authorities in Spain, Germany, Italy and Poland as well as in the United Kingdom, the United States and Australia. The open-label randomized trial evaluates the efficacy, tolerability, and safety of BNT111 in combination with Libtayo, an anti-PD-1 monoclonal antibody, being co-developed by Regeneron and Sanofi. The trial is enrolling a total of 120 patients and will evaluate the effects of the combination as well as single agents alone. The primary endpoint is the overall response rate of BNT111 in combination with Libtayo. Secondary endpoints include overall response rate in the single agent arms, duration of response, and safety. The first patient has been dosed in the European Union. BioNTech retains global commercial rights to BNT111.

"Our vision is to harness the power of the immune system against cancer and infectious diseases. We were able to demonstrate the potential of mRNA vaccines in addressing COVID-19. We must not forget that cancer is also a global health threat, even worse than the current pandemic," said **Özlem Türeci, M.D., Co-founder and Chief Medical Officer of BioNTech**. "BNT111 has already shown a favorable safety profile and encouraging preliminary results in early clinical evaluation. With the start of patient treatment in our Phase 2 trial, we are encouraged to continue on our initial path to realize the potential of mRNA vaccines for cancer patients."

BNT111 is an intravenous therapeutic cancer vaccine candidate encoding for a fixed set of four cancer-specific antigens optimized for immunogenicity and delivered as RNA-lipoplex formulation. More than 90% of melanomas in patients express at least one of the four tumor-associated antigens encoded in BNT111 (NY-ESO-1, MAGE-A3, tyrosinase, and TPTE). BNT111 is one of the most advanced of five clinical-stage FixVac product candidates within BioNTech's development pipeline.

This Phase 2 clinical trial is based on previous results from the Phase 1 Lipo-MERIT dose escalation trial (NCT02410733) that demonstrated a favorable safety profile in 89 patients with advanced melanoma. In addition, efficacy analysis of the Lipo-MERIT study in a subset of 42 metastatic melanoma patients previously treated with a checkpoint-inhibitor showed that BNT111 mediated durable responses both as a single agent and in combination with anti-PD-1 antibodies and that durable objective responses by BNT111 were associated with activation and strong expansion of tumor-antigen-specific CD4+ and CD8+ T cells. These results were published in *Nature* in July 2020.

The Company also plans to start randomized Phase 2 trials with mRNA vaccine product candidates in two additional programs in 2021 (FixVac: BNT113 and iNeST: BNT122). As part of its development strategy, BioNTech aims to rapidly advance its broad oncology pipeline and expects to bring additional candidates into late-stage clinical development and towards market entry within the next five years.

About FixVac

BioNTech's FixVac platform candidates consist of a fixed combination of mRNA-encoded non-mutated antigens shared within specific cancer types. They feature the Company's proprietary RNA-lipoplex delivery formulation which is designed to enhance stability and translation of the mRNA cargo as well as specifically target dendritic cells. Thus, the vaccine candidate aims to trigger a strong and precise innate and adaptive immune response against cancer cells overexpressing the respective antigen.

About BioNTech
Biopharmaceutical New Technologies 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 T cells, bispecific checkpoint immuno-modulators, targeted cancer antibodies and 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 Genmab, Sanofi, Bayer Animal Health, 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 FixVac program candidate BNT111; timing for commencement of a Phase 2 trial as well as any data readouts; the registrational potential of any Phase 2 trial we may initiate for BNT111; 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; BioNTech's anticipated market opportunity and size for its product candidates the rate and degree of market acceptance of BioNTech and Pfizer's COVID-19 vaccine and BioNTech's investigational medicines, if approved; and BioNTech's efforts to combat COVID-19. Any forward-looking statements in this press release are based on BioNTech 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 BioNTech's Annual Report on Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, 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.

Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513
Media@biontech.de

Investor Relations
Sylke Maas, Ph.D.
+49 (0)6131 9084 1074
Investors@biontech.de