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 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 June 5, 2022, BioNTech SE (the "Company") announced initial data from an ongoing investigator-initiated first-in-human Phase 1 study evaluating the safety and tolerability of the mRNA-based individualized neoantigen specific immunotherapy (iNeST) autogene cevumeran (also known as BNT122, RO7198457) in combination with anti-PD-L1 immune checkpoint inhibitor atezolizumab and chemotherapy in patients with resected pancreatic ductal adenocarcinoma (PDAC. 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: June 5, 2022

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Positive Phase 1 Data from mRNA-based Individualized Neoantigen Specific Immunotherapy in Patients with Resected Pancreatic Cancer presented at ASCO

Positive Phase 1 Data from mRNA-based Individualized Neoantigen Specific Immunotherapy in Patients with Resected Pancreatic Cancer presented at ASCO

- *Preliminary analysis of data from an ongoing investigator-initiated, single-center Phase 1 study supported by BioNTech and Genentech and conducted at Memorial Sloan Kettering Cancer Center, New York, United States*
- *Autogene Cevumeran, a fully individualized mRNA cancer immunotherapy (iNeST) demonstrated that vaccine-induced immunity significantly correlates with delayed tumor recurrence in patients with resected pancreatic ductal adenocarcinoma*
- *Initial results suggest sequential combination of anti-PD-L1 checkpoint inhibitor atezolizumab with individualized cancer therapy autogene cevumeran, and chemotherapy showed a favorable safety profile, while the product candidate was feasibly manufactured in a clinically relevant timeframe*
- *BioNTech and Genentech plan to jointly initiate a randomized study of autogene cevumeran in adjuvant pancreatic cancer*

MAINZ, Germany and CHICAGO, June 5, 2022 (GLOBE NEWSWIRE) – BioNTech SE (Nasdaq: BNTX, "BioNTech") today announced initial data from an ongoing investigator-initiated first-in-human Phase 1 study evaluating the safety and tolerability of the mRNA-based individualized neoantigen specific immunotherapy (iNeST) autogene cevumeran (also known as BNT122, RO7198457) in combination with anti-PD-L1 immune checkpoint inhibitor atezolizumab and chemotherapy in patients with resected pancreatic ductal adenocarcinoma (PDAC). Feasibility of the process of profiling each patient's tumor to inform individualized vaccine design and on-demand manufacturing of iNeST in a clinically relevant timeframe was confirmed. The preliminary results showed a favorable safety profile as well as encouraging signs of clinical activity. The data have been presented at the American Society of Clinical Oncology ("ASCO") Annual Meeting 2022 by Vinod Balachandran, M.D., at Memorial Sloan Kettering Cancer Center. Autogene cevumeran is the lead candidate from BioNTech's iNeST platform, which is jointly developed together with Genentech, a member of the Roche Group, in multiple solid tumor indications.

The data presented at the ASCO Annual Meeting include a total of 19 patients who underwent surgery and received atezolizumab. 16 out of these 19 patients (84%) received autogene cevumeran at 9.4 weeks (median; 95% CI 9–10) after surgery. The preliminary data readout from these 16 vaccinated patients revealed that autogene cevumeran in combination with atezolizumab was well-tolerated. Only 1 of 16 patients (6%) developed a vaccine-related Grade 3 fever and hypertension, no other Grade 3 or higher adverse events were observed. In addition, the treatment induced de-novo, neoantigen-specific T cell response in half (8/16) of these patients from undetectable levels to large fractions of all blood T cells (median 2.9%). At an early median follow-up of 18 months, patients with de-novo immune response (n=8) had a significantly longer recurrence-free survival (RFS) as compared to those without vaccine-induced immune responses (n=8) (median not reached vs. 13.4 months, HR 0.08, 95% CI 0.01-0.4, P = 0.003). Based on these data, BioNTech and Genentech are planning a randomized study to further evaluate the efficacy and safety of autogene cevumeran in combination with atezolizumab and chemotherapy in patients with resected PDAC.

"With only under 5 percent of patients responding to current treatment options, PDAC is one of the highest unmet medical need cancers. We are committed to take up this challenge by leveraging our long-standing research in cancer vaccinology and are trying to break new

ground in the treatment of such hard-to-treat tumors," said **Prof. Özlem T✔reci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "The results of this Phase 1 study are encouraging. We look forward to further evaluating these early results in a larger randomized study."

The investigator-initiated, single-center, Phase 1 trial (NCT04161755) was designed to evaluate the treatment of the companies' individualized immunotherapy candidate autogene cevumeran in combination with the anti-PDL-1 immune checkpoint inhibitor atezolizumab as an add-on to the standard-of-care regimen with adjuvant chemotherapy mFOLFIRINOX in patients with resected PDACs. The primary objective of the study is to assess the safety. Secondary objectives include the efficacy of the treatment measured as the 18-month RFS, the immunogenicity as well as the feasibility of the treatment regimen.

"Pancreatic cancer remains one of the deadliest cancers as it is resistant to all treatments, including immunotherapies. Conventional thinking has been that, as pancreatic cancers have few mutations, the immune system is unlikely to recognize mutation-derived neoantigens," said **Vinod Balachandran, M.D., surgeon-scientist at Memorial Sloan Kettering Cancer Center and Principal Investigator of the study.** "Our research, and now the results from this study show that the immune system can recognize neoantigens in pancreatic cancer, and that we can use mRNA vaccines to stimulate T cells to recognize neoantigens in pancreatic cancer patients. We now look forward to further investigating these results in a larger randomized trial."

BioNTech's iNeST platform previously demonstrated encouraging results with a tolerable safety profile of autogene cevumeran as single agent and in combination with atezolizumab in a heterogenous patient population with advanced and heavily pretreated solid tumors. In a Phase1a/b trial autogene cevumeran revealed robust $CD8^+$ and $CD4^+$ T cell responses and a manageable safety profile (NCT03289962). In October 2021, BioNTech announced that the first patient was dosed in a randomized Phase 2 trial (NCT04813627) of autogene cevumeran in the adjuvant treatment of post-operative circulating tumor DNA (ctDNA) positive, surgically resected colorectal cancer. BioNTech and Genentech are also conducting a Phase II proof-of-concept study, which is designed to evaluate autogene cevumeran plus pembrolizumab in the first-line treatment of advanced melanoma (NCT03815058).

The abstract is available under the following link:
Title: Phase I Trial of adjuvant autogene cevumeran, an Individualized mRNA Neoantigen Vaccine, for Pancreatic Ductal Adenocarcinoma

a. Poster: 172
b. Abstract: 2516

About resected pancreatic ductal adenocarcinoma (PDAC)
PDAC is amongst the leading causes of cancer-related deaths in the United States with ~90% of patients dying within two years of their diagnosis. A combination of surgical removal and systemic cytotoxic chemotherapy has shown to improve clinical outcomes, however, even with surgical resection, the relapse rate remains high, and the 5-year overall survival is only approximately 20% in patients who undergo surgery followed by adjuvant chemotherapy (ACT) and only 10% in those who do not receive ACT. Thus, there is a high unmet medical need for novel therapies for patients with resected PDAC. The individualized Neoantigen Specific immunoTherapy (iNeST) candidate autogene cevumeran (also known as BNT122, RO7198457) provides a novel treatment strategy aimed to induce de-novo immune responses against cancer-specific neoantigens, recognize residual cancer cells and to prevent relapse.

About iNeST (individualized Neoantigen Specific immunoTherapy)
iNeST immunotherapies are individualized cancer therapies tailored to a specific patient's tumor. They contain unmodified, pharmacologically optimized mRNA encoding up to 20 patient-specific

neoantigens, identified using real-time next generation sequencing and bioinformatic neoantigen discovery. Neoantigens are proteins that are produced by cancer cells that differ from the proteins produced by healthy cells and are recognized by immune cells. The mRNA is encapsuled in BioNTech's proprietary intravenous RNA-lipoplex delivery formulation which is designed to enhance stability as well as enable targeted delivery to dendritic cells. By analyzing each patient's tumor, BioNTech is able to identify the cancer mutations that may act as neoantigens. Each individual cancer vaccine encodes for neoantigen candidates with the highest likelihood to help the immune system to recognize the cancer. For this purpose, BioNTech has developed a first of its kind, on-demand manufacturing process, following Good Manufacturing Practice (GMP) conditions.

An iNeST Fact Sheet and images from the iNeST manufacturing process are available in the media materials section on BioNTech's website at this link.

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 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, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma and Pfizer.

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. These forward-looking statements may include, but may not be limited to, statements concerning: The collaboration between BioNTech and Genentech to jointly clinical develop the iNeST program candidate autogene cevumeran (BNT122); timing for commencement of a Phase 2 trial as well as any subsequent data readouts; the registrational potential of any trial we may initiate for BNT122; 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, 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 other product candidates; 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 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 as 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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