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 2024

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 1, 2024, BioNTech SE and Genmab A/S (Nasdaq: GMAB, "Genmab") announced initial data from the ongoing Phase 2 trial (NCT05117242) evaluating acasunlimab (DuoBody-PD-L1x4-1BB), an investigational bispecific antibody also known as GEN1046/BNT311, as monotherapy and in combination with pembrolizumab in patients with PD-L(1)-positive metastatic non-small cell lung cancer ("mNSCLC") who had disease progression following one or more prior lines of anti-PD(L)1-containing treatment. 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/ Jens Holstein	By: /s/ Dr. Sierk Poetting
Name: Jens Holstein	Name: Dr. Sierk Poetting
Title: Chief Financial Officer	Title: Chief Operating Officer

Date: June 3, 2024

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Investigational Acasunlimab (DuoBody® -PD-L1x4-1BB) in Combination with Pembrolizumab Demonstrates Meaningful Clinical Activity in Phase 2 Trial in Patients with Previously Treated Metastatic Non-small Cell Lung Cancer (mNSCLC)

Investigational Acasunlimab (DuoBody® -PD-L1x4-1BB) in Combination with Pembrolizumab Demonstrates Meaningful Clinical Activity in Phase 2 Trial in Patients with Previously Treated Metastatic Non-small Cell Lung Cancer (mNSCLC)

- *Initial data from the ongoing Phase 2 trial showed a 12-month overall survival rate of 69% and a median overall survival of 17.5 months in patients with previously treated PD-L1-positive metastatic non-small cell lung cancer treated with a combination of acasunlimab and pembrolizumab every six weeks*
- *Data from this ongoing Phase 2 study to inform the planned pivotal Phase 3 trial, which is expected to start before the end of 2024*

COPENHAGEN, Denmark, and MAINZ, Germany, June 1, 2024 — Genmab A/S (Nasdaq: GMAB, "Genmab") and BioNTech SE (Nasdaq: BNTX, "BioNTech") today announced initial data from the ongoing Phase 2 trial (NCT05117242) evaluating acasunlimab (DuoBody-PD-L1x4-1BB), an investigational bispecific antibody also known as GEN1046/BNT311, as monotherapy and in combination with pembrolizumab in patients with PD-L(1)-positive metastatic non-small cell lung cancer ("mNSCLC") who had disease progression following one or more prior lines of anti-PD(L)1-containing treatment. The results showed a 12-month overall survival ("OS") rate of 69%, a median overall survival ("mOS") of 17.5 months, and a 30% overall response rate ("ORR") (confirmed ORR 17%) at the time of data cut-off in patients treated with the combination of acasunlimab and pembrolizumab every six weeks. The findings were presented at the 2024 American Society of Clinical Oncology ("ASCO") Annual Meeting held in Chicago, IL from May 31-June 4, 2024.

The Phase 2 study randomized a total of 113 patients in three arms, evaluating acasunlimab alone (Arm A) and in combination with pembrolizumab (Arms B and C). The objective response analysis was conducted for 62 centrally confirmed PD-L1-positive efficacy-evaluable patients. The OS was evaluated in all centrally confirmed PD-L1-positive patients (n=80). Arm A showed a mOS rate of 5.5 months, a 50% disease control rate (DCR) and a 31% ORR (confirmed ORR 13%) in patients treated with acasunlimab alone. An 8.6 months mOS, a 59% DCR and a 21% ORR (confirmed ORR 18%) for treatment of acasunlimab in combination with pembrolizumab every three weeks (Arm B) and a 17.5 months mOS, a 75% DCR and a 30% ORR (confirmed ORR 17%) when the combination was administered every six weeks (Arm C). Anti-tumor activity was observed in patients with a tumor proportion score ("TPS") of 1–49% and ≥50%, in patients with <6 months and ≥6 months of previous immune checkpoint inhibitor ("CPI") treatment, and in patients with squamous and non-squamous histology.

Adverse events were consistent with the safety profiles of the individual drugs and treatment related adverse events ("TRAEs") were primarily grade 1 and 2. The most common TRAEs (all grades) in Arm A were asthenia (22.7%), diarrhea (18.2%), nausea (18.2%), anemia (13.6%), and liver-related events (13.6%). In the combination arms (Arms B and C), the most common TRAEs were liver-related events (28.6%, 18.4%), fatigue (21.4%, 8.2%), asthenia (12%, 12.2%), and diarrhea (12%, 10.2%). Overall, a lower incidence of grade ≥3 TRAEs, treatment-related liver-related events and lower discontinuation rates were observed with the combination regimen therapy administered every six weeks. Transaminase elevations, were generally asymptomatic and manageable with the administration of steroids and/or treatment delay and resolved more rapidly in patients treated with the combination therapy administered every six weeks.

"We are encouraged by the findings of this ongoing Phase 2 study. The initial results of acasunlimab in combination with pembrolizumab administered every 6 weeks suggest a potential meaningful impact on

patients with metastatic non-small cell lung cancer," said **Judith Klimovsky, Executive Vice President & Chief Development Officer at Genmab**. "We will continue to evaluate these data to inform further development of acasunlimab including a planned Phase 3 trial as we remain committed to investigate acasunlimab as a potential treatment option."

"Most patients with mNSCLC have limited treatment options following progression on first-line checkpoint inhibitor therapy. For these patients, chemotherapy remains the main treatment despite limited efficacy and considerable toxicity," said **Prof. Özlem Türeci, M.D., Chief Medical Officer and Co-Founder at BioNTech**. "The data of our Phase 2 trial show that the combination of acasunlimab with PDL1-blockade may be a suitable approach in this heavily pretreated patient population."

About the GCT1046-04 Clinical Trial
The GCT1046-04 trial (NCT05117242) is a randomized, open-label trial evaluating the safety and efficacy of acasunlimab in patients with relapsed/refractory metastatic non-small cell lung cancer ("mNSCLC") after treatment with standard of care therapy containing immune checkpoint inhibitor therapy. Patients with stage IV NSCLC with at least one prior line of systemic therapy containing an anti-PD-1/PD-L1 and a tumor PD-L1 expression in ≥1% of the tumor cells are included in the study. The primary endpoint of the trial is the overall response rate ("ORR"). Key secondary endpoints include overall survival ("OS"), progression free survival ("PFS"), time to response ("TTR"), duration of response ("DOR"), and safety. More information on this trial can be found at clinicaltrials.gov.

About Non-small Cell Lung Cancer (NSCLC)
Non-small cell lung cancer ("NSCLC") is the most common type of lung cancer, accounting for about 85% of all reported cases. NSCLC starts in cells that line the airways and can grow into nearby tissues or spread to other parts of the body. NSCLC is often diagnosed at an advanced stage, when it is hard to treat and has a poor prognosis. The survival rate of patients with NSCLC varies depending on the stage at diagnosis.[i,ii,iii,]The treatment of NSCLC depends on the stage, subtype, and biomarker status of the disease, and may include surgery, radiation therapy, chemotherapy, targeted therapy, immunotherapy, or a combination of these modalities.

About Acasunlimab (GEN1046/BNT311)
Acasunlimab (GEN1046/BNT311) is an investigational PD-L1x4-1BB bispecific antibody fusing Genmab's proprietary DuoBody® technology platform and BioNTech's proprietary immunomodulatory antibodies. Acasunlimab is designed to elicit an antitumor response via conditional activation of 4-1BB on T cells and natural killer cells, which is strictly dependent on simultaneous binding of the PD-L1 arm. Acasunlimab is being developed in collaboration by BioNTech and Genmab under a license and collaboration agreement. The candidate is currently being investigated in three clinical trials: (1) a Phase 1/2 safety trial in patients with multiple solid tumors, (2) a Phase 1 dose escalation trial in patients with advanced solid tumors in Japan, and (3) a randomized Phase 2 safety and efficacy trial with acasunlimab as a monotherapy and in combination with pembrolizumab in patients with NSCLC who have failed previous standard of care treatments with immune checkpoint inhibitors. Please visit www.clinicaltrials.gov for more information.

About Genmab
Genmab is an international biotechnology company with a core purpose of guiding its unstoppable team to strive toward improving the lives of patients with innovative and differentiated antibody therapeutics. For 25 years, its passionate, innovative and collaborative team has invented next-generation antibody technology platforms and leveraged translational, quantitative and data sciences, resulting in a proprietary pipeline including bispecific T-cell engagers, antibody-drug conjugates, next-generation immune checkpoint modulators and effector function-enhanced antibodies. By 2030, Genmab's vision is to

transform the lives of people with cancer and other serious diseases with knock-your-socks-off (KYSO®) antibody medicines.

Established in 1999, Genmab is headquartered in Copenhagen, Denmark, with international presence across North America, Europe and Asia Pacific. For more information, please visit Genmab.com and follow us on LinkedIn and X.

Genmab Forward-Looking Statements

This Media Release contains forward-looking statements. The words "believe," "expect," "anticipate," "intend" and "plan" and similar expressions identify forward-looking statements. Actual results or performance may differ materially from any future results or performance expressed or implied by such statements. The important factors that could cause our actual results or performance to differ materially include, among others, risks associated with preclinical and clinical development of products, uncertainties related to the outcome and conduct of clinical trials including unforeseen safety issues, uncertainties related to product manufacturing, the lack of market acceptance of our products, our inability to manage growth, the competitive environment in relation to our business area and markets, our inability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products or technologies obsolete, and other factors. For a further discussion of these risks, please refer to the risk management sections in Genmab's most recent financial reports, which are available on www.genmab.com and the risk factors included in Genmab's most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at www.sec.gov. Genmab does not undertake any obligation to update or revise forward-looking statements in this Media Release nor to confirm such statements to reflect subsequent events or circumstances after the date made or in relation to actual results, unless required by law.

About BioNTech
Biopharmaceutical New Technologies (BioNTech) is a global next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. BioNTech 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 and specialized pharmaceutical collaborators, including Biotheus, DualityBio, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, MediLink, OncoC4, Pfizer and Regeneron.
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, as amended, including, but not be limited to, statements concerning: the collaboration between BioNTech and Genmab to jointly clinical develop antibody candidates, including

GEN1046/BNT311 (acasunlimab); the timing of a pivotal Phase 3 trial with GEN1046/BNT311 as well as any subsequent data readouts; the registrational potential of any trial we may initiate for GEN1046/BNT311; BioNTech's current and future preclinical studies and clinical trials in oncology, including GEN1046/BNT311 in patients with mNSCLC; 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, including, but not limited to, statements regarding timing or plans for initiation or enrollment of clinical trials, or submission for and receipt of product approvals and potential commercialization 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; and the potential safety and efficacy of BioNTech's 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 based on BioNTech's current expectations and beliefs of future events, and are neither promises nor guarantees. 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 and adversely 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, 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 clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; 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 its product candidates; discussions with regulatory agencies regarding timing and requirements for additional clinical trials; 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 its production capabilities and manufacture its products and 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 March 31, 2024 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at www.sec.gov. These forward-looking statements speak only as of the date hereof. 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.

CONTACTS

Genmab
Media Contact
David Freundel
+1 609 430 2481
dafr@genmab.com

Investor Relations
Andrew Carlsen
+45 3377 9558
acn@genmab.com

BioNTech
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

[i] American Cancer Society. What is Non-Small Cell Lung Cancer? https://www.cancer.org/cancer/types/lung-cancer.html. Accessed May 14, 2024
[ii] Mayo Clinic. Non-Small Cell Lung Cancer. https://www.mayoclinic.org/diseases-conditions/lung-cancer/symptoms-causes/syc-20374620. Accessed May 14, 2024
[iii] CancerNet. Lung Cancer – Non-Small Cell: Introduction. https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/introduction. Accessed May 14, 2024