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 DECEMBER 2025

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): ☐

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DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On December 6, 2025, BioNTech SE (Nasdaq: BNTX, "BioNTech") and OncoC4, Inc. ("OncoC4") presented data from the non-pivotal dose-confirmation stage of the global randomized Phase 3 trial PRESERVE-003 (NCT05671510) for gotistobart (also known as BNT316 or ONC-392), a tumor microenvironment-selective regulatory T cell ("Treg") depletion candidate, targeting CTLA-4 in patients with metastatic squamous non-small cell lung cancer (sqNSCLC). 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/ Ramon Zapata-Gomez	By: /s/ Dr. Sierk Poetting
Name: Ramon Zapata-Gomez	Name: Dr. Sierk Poetting
Title: Chief Financial Officer	Title: Chief Operating Officer

Date: December 8, 2025

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	BioNTech and OncoC4 Announce Clinically Meaningful Overall Survival Benefit for Selective Treg Modulator Gotistobart in Patients with Previously Treated Squamous Non-Small Cell Lung Cancer

BioNTech and OncoC4 Announce Clinically Meaningful Overall Survival Benefit for Selective Treg Modulator Gotistobart in Patients with Previously Treated Squamous Non-Small Cell Lung Cancer

- *Selective Treg modulator gotistobart (BNT316/ONC-392) showed a reduction in the risk of death by more than half compared to standard of care chemotherapy and a manageable safety profile in the first of two stages of the global Phase 3 trial PRESERVE-003 in patients with squamous non-small cell lung cancer ("sqNSCLC") who have progressed on prior immunotherapy plus chemotherapy*
- *Median OS with gotistobart has not been reached at almost 15 months of follow-up, compared to a median OS of 10 months observed with chemotherapy*
- *As a chemotherapy-free monotherapy, gotistobart has the potential to become an alternative to traditional cytotoxic treatment for a patient population with high unmet medical need*
- *Gotistobart was granted Fast Track Designation by the U.S. Food and Drug Administration ("FDA") for the treatment of patients with metastatic NSCLC whose disease progressed on prior anti-PD-(L)1 therapy*

MAINZ, Germany, and ROCKVILLE, USA, December 6, 2025 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech") and OncoC4, Inc. ("OncoC4") today presented data from the non-pivotal dose-confirmation stage of the global randomized Phase 3 trial PRESERVE-003 (NCT05671510) for gotistobart (also known as BNT316 or ONC-392), a tumor microenvironment-selective regulatory T cell ("Treg") depletion candidate, targeting CTLA-4 in patients with metastatic squamous non-small cell lung cancer (sqNSCLC). Gotistobart demonstrated a clinically meaningful overall survival ("OS") benefit compared to standard-of-care chemotherapy and a manageable safety profile in sqNSCLC patients whose disease had progressed following anti-PD-(L)1 therapy and platinum-based chemotherapy. Data from the non-pivotal stage of the trial are being presented today in an oral presentation at the IASLC ASCO 2025 North America Conference on Lung Cancer, hosted by the International Association for the Study of Lung Cancer in Chicago, Illinois, USA.

"With a median survival of less than a year, advanced squamous NSCLC remains an aggressive and difficult-to-treat lung cancer[1,2]. Survival outcomes have improved in recent years due to advances in immunotherapy and combination regimens. However, patients who progress on anti-PD-(L)1 inhibitor treatment face a poor prognosis, leaving them only with the option of chemotherapy or palliative care," said **Byoung Chul Cho, M.D., Ph.D., Lead Investigator and Professor at the Division of Medical Oncology, Yonsei Cancer Center, Seoul**. "We are encouraged by the median overall survival still not being reached for patients treated with gotistobart at almost 15 months of follow-up, and we are excited to continue to investigate the candidate's potential in the ongoing pivotal stage of the trial."

The analysis from the non-pivotal stage of the global Phase 3 trial included 45 metastatic sqNSCLC patients who received gotistobart as monotherapy, compared with 42 metastatic sqNSCLC patients who received chemotherapy (docetaxel) as second or later line of systemic therapy. At the data cut-off on

August 8, 2025, 87 patients with sqNSCLC had been randomized to either gotistobart 6 mg/kg with two 10 mg/kg loading doses (N=45) or docetaxel 75 mg/m^2 (N=42). The OS rate at 12 months was 63.1% for gotistobart compared to 30.3% for docetaxel. At a median follow-up of 14.5 months, patients in the gotistobart treatment arm had not yet reached the median OS, while the docetaxel treatment arm achieved a median OS of 10 months. The data showed that the gotistobart arm reduced the risk of death by 54% compared to the docetaxel treatment arm (HR=0.46, 95% CI: 0.25–0.84; nominal p-value 0.0102). The safety profile of gotistobart was consistent with previously established data and remained manageable. Grade ≥3 treatment-related adverse events ("AEs") were reported in 19/45 (42.2%) patients in the gotistobart treatment arm versus 20/41 (48.8%) patients in docetaxel treatment arm. The pivotal stage of the Phase 3 trial is ongoing in more than 160 sites globally.

"Gotistobart is designed to selectively deplete tumor-infiltrating regulatory T cells within the tumor microenvironment. The data presented today showed encouraging signals for our approach to translating our deep understanding of the immune system into meaningful survival benefits for patients with squamous NSCLC," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "With its unique mode of action, we are investigating gotistobart both as a monotherapy and in synergistic combinations with other modalities. Our goal is to deliver transformative treatment options that provide meaningful and durable benefits for patients."

"Gotistobart represents a step forward in our goal of offering a chemotherapy-free treatment option for patients with advanced squamous NSCLC, a population with limited therapeutic choices and a lack of actionable biomarkers to guide treatment," said **Pan Zheng, M.D., Ph.D., Chief Medical Officer and Co-Founder at OncoC4**. "The encouraging data presented today underscore the potential of gotistobart to address the unmet medical needs. We look forward to continuing to jointly explore the potential of the novel mechanism of action and advance clinical development for patients who have not benefited from currently approved immunotherapy."

About the PRESERVE-003 trial

PRESERVE-003 (NCT05671510) is a two-stage, open-label Phase 3 trial evaluating the efficacy and safety of gotistobart as monotherapy compared to the standard-of-care chemotherapy (docetaxel) in sqNSCLC patients, who have progressed on PD-(L)1 inhibitors and platinum-based chemotherapy. The non-pivotal stage of the trial originally included all NSCLC patients. The ongoing pivotal stage is currently enrolling patients with sqNSCLC. During the ongoing pivotal stage, approximately 500 patients are planned to be enrolled at clinical sites in various countries and regions, including Australia, Belgium, Canada, China, Germany, Italy, the Netherlands, Spain, South Korea, Türkiye, the United Kingdom and the United States. The primary endpoint is overall survival. Secondary endpoints include overall response rate, progression-free survival and safety profile.

About gotistobart (BNT316/ONC-392)

Gotistobart (BNT316/ONC-392) is a tumor microenvironment-selective Treg depletion candidate developed jointly by BioNTech and OncoC4. As a pH-sensitive monoclonal antibody, gotistobart is designed to enable CTLA-4 protein recycling. After binding to the CTLA-4 receptor on the cell surface, the complex is internalized, and the pH change causes the antibody to unbind, allowing CTLA-4 to return to the surface to preserve the immune checkpoint function at peripheral organs and to enhance anti-tumor

immunity in the tumor microenvironment[3]. Gotistobart is currently in late-stage clinical development as monotherapy and as a component of combination therapy in various cancer indications. Gotistobart has received Fast Track Designation from the U.S. Food and Drug Administration ("FDA") in 2022 for the treatment of patients with metastatic NSCLC whose disease progressed on prior anti-PD-(L)1 therapy and Breakthrough Therapy Designation from China's National Medical Products Administration ("NMPA") in 2025.

Multiple trials are ongoing, including a pivotal Phase 3 trial (PRESERVE-003; NCT05671510) in patients with metastatic squamous NSCLC, a Phase 2 trial (PRESERVE-004; NCT05446298) in patients with platinum-resistant ovarian cancer, a Phase 2 trial (PRESERVE-006; NCT05682443) in patients with metastatic castration-resistant prostate cancer, and a Phase 1/2 open-label dose escalation trial (PRESERVE-001; NCT04140526) in patients with advanced solid tumors. BioNTech also evaluates gotistobart in combination with its mRNA cancer immunotherapy candidate BNT116 in a signal seeking cohort of the ongoing Phase 1 trial (LuCa-MERIT-1; NCT05142189).

About NSCLC

Non-small cell lung cancer ("NSCLC") covers all epithelial lung cancers other than small cell lung cancer and includes squamous cell carcinoma, large cell carcinoma, and adenocarcinoma of the lung. It is the most common type of lung cancer, accounting for up to 85% of cases[4], with risk factors ranging from smoking to asbestos exposure and pulmonary fibrosis[5]. Around 25% of all lung cancer cases are attributed to the subtype squamous cell carcinoma (SCC)[6]. With a 5-year relative survival rate of 15% and a median overall survival of 11 months in the United States (2000-2017), sqNSCLC is a devastating disease with limited treatment options[7]. Current standard-of-care includes surgery and radiotherapy in combination with chemotherapy[8]. Treatment options for second-line therapy after first-line immunotherapy and chemotherapy are limited to chemotherapy or palliative therapy in advanced/metastatic sqNSCLC, and remain more limited than for non-squamous NSCLC[5].

About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a global next generation immunotherapy company pioneering novel investigative therapies for cancer and other serious diseases. BioNTech exploits a wide array of computational discovery and therapeutic modalities with the intent of rapid development of novel biopharmaceuticals. Its diversified portfolio of oncology product candidates aiming to address the full continuum of cancer includes mRNA cancer immunotherapies, next-generation immunomodulators and targeted therapies such as antibody-drug conjugates (ADCs) and innovative chimeric antigen receptor (CAR) T cell therapies. Based on its deep expertise in mRNA development and in-house manufacturing capabilities, BioNTech and its collaborators are researching and 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 Bristol Myers Squibb, Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, 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 limited to, statements concerning: the collaboration with OncoC4; BioNTech and OncoC4's ability to successfully co-develop and co-commercialize gotistobart (also known as BNT316 or ONC-392), if approved; the rate and degree of market acceptance of gotistobart, if approved; the initiation, timing, progress, and results of BioNTech's research and development programs, including data from the non-pivotal dose-confirmation stage of the global randomized Phase 3 trial PRESERVE-003 and statements regarding the expected timing of initiation, enrollment, and completion of trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations, including expectations regarding the potential indications in which gotistobart may be approved, if at all; the targeted timing and number of additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; and discussions with regulatory agencies. 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 clinical data, 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 impact of tariffs and escalations in trade policy; competition related to BioNTech's product candidates; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its product candidates; 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 its product candidates, if approved; BioNTech's ability to manage its development and related expenses; regulatory and political developments in the United States and other countries; BioNTech's ability to effectively scale its production capabilities and manufacture its products and 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 September 30, 2025 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.

About OncoC4
Based in Rockville, Maryland, OncoC4 is a privately held, late clinical-stage biopharmaceutical company that is actively engaged in the discovery and development of novel biologicals for the treatment of cancer and immunological diseases. OncoC4's pipeline features assets with first-in-class and best-in-class potential targeting both novel and well validated targets across oncology and immunological diseases. Among them, AI-081 is a fully owned bispecific antibody candidate targeting PD-1 and VEGF. ONC-841 is a first-in-class anti-SIGLEC10 antibody currently in a Phase 2 trial for oncology indications and being explored for neurodegenerative diseases. OncoC4 has a strategic collaboration with BioNTech to co-develop gotistobart (BNT316/ONC-392), a tumor microenvironment-selective Treg depletion candidate targeting CTLA-4, in multiple solid tumor indications, including an ongoing pivotal clinical trial in squamous non-small cell lung cancer.

More information: www.oncoc4.com.

CONTACTS

BioNTech:

Investor Relations
Douglas Maffei, Ph.D.
Investors@BioNTech.de

Media Relations
Jasmina Alatovic
Media@BioNTech.de

OncoC4:

Investor Relations
Ryan Cui
ir@oncoc4.com

Media Relations
Helen Schiltz
hschiltz@oncoc4.com

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