BioNTech to Present Progress Across Diversified Oncology Pipeline at the 2025 ASCO Annual Meeting

May 27, 2025

MAINZ, Germany, May 27, 2025 -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") will present clinical trial data from select pipeline candidates across the Company's diversified oncology portfolio at the American Society of Clinical Oncology ("ASCO") Annual Meeting, to be held in Chicago, IL, from May 30 to June 3, 2025. The data highlight continued progress of the Company's clinical programs consisting of complementary therapeutic modalities, including mRNA cancer immunotherapies, next-generation immunomodulators, and targeted therapies, including antibody-drug conjugates ("ADCs").

"We believe that the next era of cancer medicine will be defined by the interplay of complementary mechanisms and innovative molecules, unlocking their full potential through synergy. Our data presentations at this year's ASCO Annual Meeting show how we aim to help shape this era," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "We will present clinical progress with two of our therapeutic modalities: our next generation immunomodulators, most notably our investigational anti-PD-L1xVEGF-A antibody BNT327, and for one of our ADC programs, which are an important pillar of our combination strategy. These data underline the potential of our assets to improve outcomes for patients."

Highlights of BioNTech's oncology programs to be presented at ASCO 2025:

- Three presentations on **BNT327**[1], an investigational anti-PD-L1xVEGF-A antibody, will detail data from ongoing later-stage and potentially registrational clinical trials: An oral presentation will feature the first data from a Phase 2 clinical trial (NCT05918107) of BNT327 in combination with chemotherapy as first-line treatment for patients with unresectable malignant mesothelioma. Malignant mesothelioma is a type of cancer that develops in the tissue that covers the lung or the abdomen. The preliminary data indicated anti-tumor activity and a manageable safety profile. Two posters will detail the ongoing global Phase 3 and Phase 2/3 clinical trials, ROSETTA Lung-01 (NCT06712355) in extensive-stage small cell lung cancer ("ES-SCLC") and ROSETTA Lung-02 (NCT06712316) in non-small cell lung cancer ("NSCLC"). BNT327 combines the two complementary anti-tumor mechanisms of PD-L1 checkpoint and VEGF-A signaling blockade in the tumor microenvironment, thereby aiming to enhance anti-tumor activity.

- Data on **BNT324/DB-1311**, a B7H3-targeted ADC candidate, from an ongoing Phase 1/2 clinical trial (NCT05914116) in patients with heavily pre-treated castration-resistant prostate cancer ("CRPC") will be presented during an oral session. The data indicated early clinical activity and a manageable safety profile. BNT324/DB-1311 received Fast Track Designation by the U.S. Food & Drug Administration ("FDA") for this patient population in 2024 and is being developed in collaboration with Duality Biologics (Suzhou) Co. Ltd. ("DualityBio").

- Preliminary data on **BNT316/ONC-392 (gotistobart),** an investigational anti-CTLA-4 antibody, from two ongoing Phase 1/2 clinical trials evaluating the antibody candidate in combination with current standard of care treatments will be presented. Data from the PRESERVE-001 clinical trial (NCT04140526) in patients with advanced melanoma indicated a manageable safety profile and early signs of anti-tumor activity. The data included an analysis of overall survival ("OS") and an ad-hoc analysis of next-treatment free survival ("NTFS"), a measure for potential long-lasting benefit after initial treatment. Data from the PRESERVE-006 clinical trial (NCT05682443) in patients with metastatic CRPC indicated a manageable safety profile and preliminary efficacy. BNT316/ONC-392 is being developed in collaboration with OncoC4, Inc. ("OncoC4").

- Data on **BNT142** from an exploratory Phase 1/2 dose finding trial (NCT05262530) in patients with CLDN6-positive advanced solid tumors will be featured in an oral presentation. BNT142 is an investigational lipid nanoparticle-formulated mRNA immunotherapy that encodes a CD3xCDLN6 T cell engager antibody. Preliminary data indicated a manageable safety profile and early signs of clinical activity, supporting scientific proof-of-concept and underscoring the potential of mRNA-encoded bispecific antibodies.

BioNTech has established a diversified oncology portfolio to develop novel treatment approaches for patients living with cancer. The Company is advancing its oncology pipeline across multiple solid tumor indications, including more than 20 active Phase 2 and 3 clinical trials with a strategic focus on two pan-tumor priority programs: investigational mRNA cancer immunotherapies and the next-generation immunomodulator candidate BNT327. BioNTech expects multiple data readouts in 2025 and 2026 aimed at supporting its strategy and advancing the Company towards becoming a diversified multi-product oncology company.

The full abstracts are available on the ASCO Annual Meeting website. Click here for further information on BioNTech's pipeline assets.

Full presentation details:

Oral presentations

Asset: BNT327
Session Title: Clinical Science Symposium | Two Targets, One Goal: The Potential for Bispecific Antibodies in Thoracic Malignancies

Abstract Title: First report of efficacy and safety results from a phase 2 trial evaluating BNT327/PM8002 plus chemotherapy (chemo) as first-line (1L) treatment in unresectable malignant mesothelioma
Location: E451
Abstract Number: 8511
Date: June 3, 2025
Time: 9:45 AM – 11:15 AM CDT

Asset: BNT324/DB-1311
Session Title: Rapid Oral Abstract Session | Genitourinary Cancer—Prostate, Testicular, and Penile
Abstract Title: DB-1311/BNT324 (a novel B7H3 ADC) in patients with castrate-resistant prostate cancer (CRPC)
Location: Hall D2
Abstract Number: 5015
Date: June 1, 2025
Time: 4:30 PM – 6:00 PM CDT

Asset: BNT142
Session Title: Oral Abstract Session | Developmental Therapeutics—Immunotherapy
Abstract Title: First-in-human phase I/II trial evaluating BNT142, a first-in-class mRNA encoded, bispecific antibody targeting Claudin 6 (CLDN6) and CD3, in patients (pts) with CLDN6-positive advanced solid tumors.
Location: Hall D2
Abstract Number: 2501
Date: May 31, 2025
Time: 3:00 PM - 6:00 PM CDT

Poster Presentations

Asset: BNT327
Session Title: Lung Cancer—Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers
Abstract Title: A global Phase 3 double-blind, randomized trial of BNT327/PM8002 plus chemotherapy (chemo) compared to atezolizumab plus chemo in patients (pts) with first-line (1L) extensive-stage small cell lung cancer (ES-SCLC)
Poster Board: #242a
Abstract Number: TPS8129
Date: May 31, 2025
Time: 1:30 PM – 4:30 PM CDT

Asset: BNT327
Session Title: Lung Cancer—Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers
Abstract Title: Phase 2/3, global, multisite, randomized, open-label trial of BNT327/PM8002 in combination with chemotherapy (chemo) in first-line (1L) non-small cell lung cancer (NSCLC)
Poster Board: #138b
Abstract Number: TPS8670
Date: May 31, 2025
Time: 1:30 PM – 4:30 PM CDT

Asset: BNT316/ONC-392 (gotistobart)
Session Title: Melanoma/Skin Cancers
Abstract Title: Gotistobart in combination with pembrolizumab in patients with advanced melanoma who have progressed on PD-1 inhibitors with or without CTLA-4 inhibitors
Poster Board: #34
Abstract Number: 9551
Date: June 1, 2025
Time: 9:00 AM – 12:00 PM CDT

Asset: BNT316/ONC-392 (gotistobart)
Session Title: Genitourinary Cancer—Prostate, Testicular, and Penile
Abstract Title: Phase 1 study of gotistobart (BNT316/ONC-392) in combination with lutetium Lu 177 vipivotide tetraxetan (Lu 177) in patients with metastatic castration-resistant prostate cancer (mCRPC)
Poster Board: #266
Abstract Number: 5067
Date: June 2, 2025
Time: 9:00 AM – 12:00 PM CDT

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 Duality Biologics, 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 limited to, statements concerning: the initiation, timing, progress and results of BioNTech's research and development programs in oncology, including the targeted timing and number of additional potentially registrational trials; BioNTech's and its collaborators' current and future preclinical studies and clinical trials in oncology, including the investigational bispecific antibody BNT327 in various indications, the B7H3-targeted ADC candidate BNT324/DB-1311 in advanced solid tumors, the anti-CTLA-4 antibody candidate BNT316/ONC-392 in advanced melanoma, and the mRNA-based RiboMab candidate BNT142 in CLDN6-positive advanced solid tumors; 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, 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; the impact of tariffs and escalations in trade policy; 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 and regions; 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, 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.

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[1] BNT327, formerly also known as PM8002, was initially jointly developed by BioNTech and Biotheus Inc ("Biotheus"). Since February 2025, Biotheus is a member of the BioNTech Group.