



BioNTech to Present Clinical and Preclinical Data Across mRNA and Next-Generation Immuno-Oncology Priority Programs at AACR 2025

April 24, 2025

MAINZ, Germany, April 24, 2025 -- [BioNTech SE](#) (Nasdaq: BNTX, "BioNTech" or "the Company") will present data for selected assets from its diversified oncology pipeline, including mRNA cancer immunotherapies, next-generation immunomodulators, and targeted therapies, at the American Association for Cancer Research ("AACR") Annual Meeting held in Chicago, Illinois from April 25-30, 2025. The oral and poster presentations underline both the progress of BioNTech's advanced priority oncology programs as well as the execution of the Company's combination strategy in oncology, with first data to be presented for the combination of the PD-L1xVEGF-A bispecific antibody candidate BNT327¹ plus antibody-drug conjugates ("ADCs").

"We believe that the future standard of care for the treatment of advanced cancers will be combinations with novel immuno-oncology backbones," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "Our data presentations at this year's AACR support our approach to combine complementary mechanisms of action with the aim of driving synergistic anti-tumor activity. The data we present indicate that we are well positioned to work towards our vision of improving outcomes for patients across the full continuum of cancer disease."

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

- BioNTech will present preclinical data characterizing the mode of action of **BNT327**. BNT327 is an investigational next-generation bispecific antibody combining PD-L1 checkpoint inhibition with VEGF-A neutralization. BNT327 showed a high binding affinity to PD-L1 and VEGF-A and efficient blocking of PD-1/PD-L1 and VEGF-A/VEGFR2 signaling. Anti-tumor activity superior to single PD-1/PD-L1 blockade or anti-VEGF-A treatment was observed in multiple tumor models.
- First data for the combination of **BNT327 with various ADC candidates**, which are being jointly developed by BioNTech and Duality Biologics (Suzhou) Co. Ltd. ("DualityBio"), will be presented. The presentation will include preclinical evaluation of BNT327 plus ADCs, showing inhibition of tumor growth that is superior to each candidate alone. Further, early clinical data of the ongoing global Phase 1/2 trial ([NCT05438329](#)) of BNT327 in combination with **BNT325/DB-1305**, a TROP2-targeting ADC candidate, including safety and early efficacy data, will be presented in the poster session.
- BioNTech will present data from the Phase 1 clinical trial LuCa-MERIT-1 ([NCT05142189](#)) for its mRNA cancer immunotherapy candidate **BNT116** in combination with the anti-PD1 cemiplimab in an oral presentation. The update includes safety and clinical activity data, along with biomarker data from a cohort of frail patients with advanced or metastatic non-small cell lung cancer ("NSCLC") who were not eligible for platinum-based chemotherapy as first-line treatment. The preliminary data showed anti-tumor activity, consistent immune response induction, and a manageable safety profile.
- Preclinical data for the EpCAMx4-1BB antibody candidate **BNT314/GEN1059**, which is being developed in collaboration with Genmab A/S ("Genmab"), will be presented in a poster session. BNT314/GEN1059 was evaluated in combination with PD-1 inhibition in a tumor model unresponsive to each single treatment. The data showed anti-tumor activity, delayed tumor outgrowth and prolonged survival for the combination treatment compared to both single treatments. The immunomodulatory activity of BNT314/GEN1059 was further potentiated in combination with PD-1 blockade.

BioNTech has established a diversified oncology portfolio including mRNA cancer immunotherapies, next-generation immunomodulators, and targeted therapies, comprising ADCs and cell therapies, to develop novel treatment approaches for patients living with cancer. The Company is further maturing its clinical oncology pipeline across multiple solid tumor indications, including more than 20 active Phase 2 and Phase 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 [AACR Annual Meeting website](#). Click [here](#) for further information on BioNTech's pipeline assets.

Full presentation details:

Oral presentation

Asset: BNT116

Session Title: "ADCs and Immunooncology-focused Biological Approaches"

Abstract Title: "Phase I trial evaluating BNT116, a TAA-encoding mRNA vaccine, in combination with cemiplimab in frail patients with advanced non-small cell lung cancer (NSCLC)"

Abstract Number: CT013

Location: Room S100 A (Grand Ballroom A)

Date: Sunday, April 27, 2025

Time: 4:20 PM - 4:30 PM CDT

Poster presentations

Asset: BNT327 + BNT325/DB-1305

Session Title: "Combination Immunotherapies"

Abstract Title: "Activity of BNT327/PM8002 (PD-L1 x VEGF-A bispecific antibody) in combination with BNT325/DB-1305 (TROP2 ADC) in solid tumors: Early preclinical and clinical evidence to support BNT327 + ADC combinations"

Poster Number: 648 / 14
Location: Section 28
Date: Sunday, April 27, 2025
Time: 2:00 PM - 5:00 PM CDT

Asset: BNT327

Session Title: "Antibodies 3: Multi-Target Checkpoint Inhibitors and Immune Activators"

Abstract Title: "Dual PD-L1 blockade and VEGF-A neutralization with the bispecific antibody BNT327/PM8002 shows potent antitumor activity in preclinical models"

Poster Number: 6061 / 2

Location: Section 37

Date: Tuesday, April 29, 2025

Time: 2:00 PM - 5:00 PM CDT

Asset: BNT314/ GEN1059

Session Title: "Antibodies 3: Multi-Target Checkpoint Inhibitors and Immune Activators"

Abstract Title: "The combination of an EpCAMx4-1BB bispecific antibody with PD-1 blockade exhibits antitumor activity in a murine tumor model unresponsive to each individual antibody"

Poster Number: 6075 / 16

Location: Section 37

Date: Tuesday, April 29, 2025

Time: 2:00 PM - 5:00 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 lipoplex-formulated uridine mRNA immunotherapy BNT116, the investigational bispecific antibodies BNT327 and BNT314/GEN1059, and the investigational ADC therapy BNT325/DB-1305; 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 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 20-F for the period ended December 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.

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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.