BioNTech Provides Business and Pipeline Updates at 43rd Annual J.P. Morgan Healthcare Conference

January 14, 2025

- *Executing in oncology with investigational BNT327/PM8002 combinations and mRNA cancer immunotherapy candidates as pan-tumor treatment approaches*
- *BioNTech aims to develop BNT327/PM8002 as a next-generation immuno-oncology ("IO") backbone for the Company's combination strategy targeting a broad range of indications*
- *Progressing development of BNT327/PM8002 with initiation of global clinical trials with registrational potential in first-line small cell lung cancer ("SCLC") and non-small cell lung cancer ("NSCLC")*
- *Advancing BNT327/PM8002 combination strategy with initiation of a second antibody drug conjugate ("ADC") combination trial; additional ADC-combination trials planned to be initiated in 2025*
- *Progress in mRNA cancer immunotherapy portfolio with multiple randomized trial read-outs of personalized and off-the-shelf candidates expected in 2025 and 2026*

MAINZ, Germany, January 14, 2025 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") today will present its 2025 strategic priorities and progress on the Company's pipeline of mRNA therapeutics, immunomodulators, and targeted therapies at the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco, California.

"We aim to develop BioNTech into a global immunotherapy powerhouse with the potential to improve the standard of care with innovative oncology products and prophylactic vaccines against infectious diseases. In oncology, we are focused on addressing the full spectrum of solid tumors with investigational combination therapies in two pan-tumor technology pillars: our mRNA-based cancer immunotherapies for the early, adjuvant setting, and our differentiated anti-PD-L1/-VEGF-A bispecific antibody candidate BNT327/PM8002 for the treatment of advanced cancers. With our capabilities, we believe BioNTech is uniquely positioned to develop personalized, yet scalable cancer treatments based on mRNA," said **Prof. Ugur Sahin, M.D., Co-Founder and Chief Executive Officer of BioNTech**. "2025 is an important year, with data updates expected across both pillars and additional global clinical trial starts planned to generate evidence on our combination treatment concepts."

Prof. Ugur Sahin, M.D., will present strategic priorities and a pipeline update at the conference on Tuesday, January 14, 2025, at 6:00 p.m. CET/ 12:00 p.m. EST. A live webcast of the presentation will be available on the "Events & Presentations" page in the investor relations section on the Company's website. A replay of the webcast will be archived on the Company's website for 30 days following the conference.

Summary of selected pipeline updates

BNT327/ PM8002, an investigational bispecific antibody combining PD-L1 checkpoint inhibition with VEGF-A neutralization being developed in collaboration with Biotheus:

- In December 2024, BioNTech initiated a global randomized Phase 3 clinical trial (NCT06712355) evaluating BNT327/PM8002 plus chemotherapy compared to atezolizumab plus chemotherapy in first line extensive-stage small cell lung cancer ("ES-SCLC").
- In December 2024, BioNTech initiated a global randomized Phase 2/3 clinical trial (NCT06712316) evaluating BNT327/PM8002 plus chemotherapy compared to pembrolizumab and chemotherapy in first line NSCLC.
- A global randomized Phase 3 clinical trial evaluating BNT327/PM8002 in first line triple-negative breast cancer ("TNBC") is on track to start in 2025.
- Plan to initiate additional clinical trials exploring novel combinations of BNT327/PM8002 with ADCs BNT323/DB-1303 (trastuzumab pamirtecan), BNT324/DB-1311 and BNT326/YL202 in 2025.
- Plan to present first clinical data from the ongoing global Phase 1/2 expansion cohorts (NCT05438329) evaluating BNT327/PM8002 plus BNT325/DB-1305 in multiple solid tumors in 2025.
- Plan to present clinical data from the ongoing global Phase 2 dose optimization trials evaluating BNT327/PM8002 plus chemotherapy in advanced TNBC (NCT06449222) and first line SCLC (NCT06449209) in 2025.

Autogene cevumeran (BNT122/RO7198457), an investigational mRNA cancer immunotherapy based on an individualized neoantigen-specific immunotherapy ("iNeST") approach being developed in collaboration with Genentech Inc. ("Genentech"), a member of the Roche Group:

- In December 2024, the first patient was treated in a global randomized Phase 2 clinical trial (IMCODE004) (NCT06534983) evaluating autogene cevumeran in combination with nivolumab compared to nivolumab alone in high-risk muscle-invasive urothelial carcinoma ("MIUC").
- Interim data from an ongoing global randomized Phase 2 clinical trial (NCT04486378) evaluating autogene cevumeran compared to watchful waiting in adjuvant ctDNA+ stage II (high risk) / stage III colorectal cancer ("CRC") are anticipated in late 2025 or 2026.

BNT323/DB-1303 (trastuzumab pamirtecan), an investigational HER2-targeted ADC being developed in collaboration with Duality Biologics (Suzhou) Co. Ltd. ("DualityBio"):

- Plan to present clinical data from an ongoing Phase 1/2a trial (NCT05150691) evaluating BNT323/DB-1303 in HER2-expressing advanced endometrial cancer in 2025.
- Preparation of a potential Biologics License Application ("BLA") submission for BNT323/DB-1303 as a second line or subsequent therapy in HER2-expressing advanced endometrial cancer in 2025.
- Plan to initiate a global Phase 3 confirmatory clinical trial (NCT06340568) evaluating BNT323/DB-1303 in advanced endometrial cancer in 2025.

COVID-19 vaccine and other candidates

- For 2025, BioNTech and Pfizer Inc. ("Pfizer") expect largely stable vaccination rates and market share in the U.S. and revenue phasing similar to 2024, primarily concentrated in the back half of the year, with the distribution between Q3 and Q4 dependent on the timing of strain recommendation and approvals by regulatory agencies. Advanced purchase agreements remain in place outside of the U.S., including in the European Union.
- BioNTech and Pfizer continue to invest in the research and development of next-generation and combination COVID-19 vaccine candidates.

Upcoming Investor and Analyst Events

- Full Year and Fourth Quarter 2024 Financial Results: March 10, 2025
- Annual General Meeting: May 16, 2025

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 limited to, statements concerning: BioNTech's expected revenues related to sales of BioNTech's COVID-19 vaccine; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; expectations regarding regulatory recommendations to adapt vaccines to address new variants or sublineages; the initiation, timing, progress, results, and cost of BioNTech's research and development programs, including BioNTech's current and future preclinical studies and clinical trials, including statements regarding the expected timing of initiation, enrollment, and completion of studies or trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations; BioNTech's expectations regarding potential future commercialization in oncology, including goals regarding timing and indications, potential combination approaches, and estimated addressable patient populations; the targeted timing and number of additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; discussions with regulatory agencies; BioNTech's expectations with respect to intellectual property; the impact of BioNTech's collaboration and licensing agreements; and BioNTech's ongoing activities with Biotheus. 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, projected data release timelines, 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 the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; BioNTech's pricing and coverage negotiations regarding its COVID-19 vaccine with governmental authorities, private health insurers and other third-party payors; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its product candidates; the ability of BioNTech's COVID-19 vaccines to prevent COVID-19 caused by emerging virus variants; 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 BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its development and related expenses; 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 September 30, 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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