BioNTech Outlines 2024 Strategic Priorities at the 42nd Annual J.P. Morgan Healthcare Conference

January 9, 2024

- *Plans to have ten or more potentially registrational trials by the end of 2024*
- *Preparing to be commercial-ready by the end of 2025*
- *Ended 2023 with approximately €17.5 billion (unaudited) in cash, cash equivalents and security investments*
- *Expects full year 2024 revenues of approximately €3 billion*
- *Presentation and webcast at the 42nd Annual J.P. Morgan Healthcare Conference on Tuesday, January 9, 2024, at 6:00 p.m. CET/ 12:00 p.m. ET*

Mainz, Germany, January 9, 2024 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") provided its full year 2024 revenue guidance as part of its outlined 2024 strategic priorities today at the 42nd Annual J.P. Morgan Healthcare Conference in San Francisco, California.

"At BioNTech, we are making important strides towards building a global immunotherapy company. In 2023, we continued our vaccine leadership in the fight against COVID-19 and significantly expanded our mid- and late-stage oncology pipeline. Currently, late-stage trials are ongoing in multiple oncology indications, and we plan to have ten or more potentially registrational trials in our pipeline by the end of 2024," **said Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. "This year will be a year of significant execution at BioNTech as we continue to expand and develop our innovative pipeline towards our first oncology launches expected from 2026 onwards."

Prof. Ugur Sahin, M.D., will present a corporate overview and update at the 42nd Annual J.P. Morgan Healthcare Conference on Tuesday, January 9, 2024, at 6:00 p.m. CET/ 12:00 p.m. ET. A live webcast of the presentation will be available on the "Events & Presentations" page in the Investor Relations section on the Company's website. The replay of the webcast will be archived on the Company's website for 30 days following the conference.

2024-2026 Financial Framework

BioNTech projects total company revenues of approximately €3 billion for the financial year 2024, mainly driven by the COVID-19 vaccine franchise which is expected to remain profitable given the Company's cost sharing structure with its partner Pfizer Inc. ("Pfizer"). The Company plans to provide detailed full year 2024 financial guidance during its Full Year and Fourth Quarter 2023 Financial Results call on Wednesday, March 20, 2024.

BioNTech ended 2023 with approximately €17.5 billion (unaudited) in cash, cash equivalents and security investments. The Company plans to maintain a strong financial position and generate significant interest income in 2024. BioNTech expects to grow its topline again in 2025. In the outer years, the Company projects revenues derived from both oncology and respiratory combination vaccine launches, which are subject to successful development and regulatory approval.

As a science and innovation driven company, BioNTech will continue to focus investments on R&D and scaling the business for commercial readiness in oncology in multiple countries by the end of 2025 while continuing to be cost disciplined.

Summary of Selected Pipeline Updates and Expected Milestones

COVID-19 & Other Infectious Diseases

BioNTech's infectious disease portfolio seeks to address four key areas of high medical need: respiratory viruses, latent viruses, global health pathogens, and antimicrobials. The Company has established a broad early-stage infectious disease vaccine candidate pipeline containing seven clinical programs leveraging its mRNA technology.

BNT162b2 + BNT161 is an mRNA-based combination vaccine program against COVID-19 and influenza being developed in collaboration with Pfizer. Topline data from the Phase 1/2 trial (NCT05596734) demonstrated robust immune responses to influenza A, influenza B, and SARS-CoV-2 strains and that the safety profile of the candidates was consistent with the companies' COVID-19 vaccine.

Oncology

In 2023, BioNTech made significant progress in demonstrating the potential of its oncology programs as part of its in-house discovery and development efforts and added six new clinical assets, including next generation antibody-drug conjugate (ADC) candidates and antibody programs, to the Company's oncology pipeline through internal and collaborative efforts. The Company's pipeline continued to mature in 2023 with various programs advancing towards later stages of development. BioNTech's pipeline currently contains 11 ongoing Phase 2 and 3 trials.

Selected later-stage programs:

BNT323/DB-1303 is an HER2-targeted antibody-drug conjugate candidate being developed in collaboration with Duality Biologics (Suzhou) Co. Ltd. ("DualityBio"). First-in-human data from an ongoing Phase 1/2 trial (NCT05150691) demonstrated anti-tumor activity in patients with heavily pretreated HER2-expressing solid tumors. In December 2023, the U.S. Food and Drug Administration ("FDA") granted Breakthrough Designation for BNT323/DB-1303 for the treatment of advanced endometrial cancer in patients who progressed on or after treatment with immune checkpoint inhibitors. A pivotal Phase 3 trial (NCT06018337) in patients with Hormone Receptor-positive ("HR+") and HER2-low metastatic breast cancer that have progressed on hormone and/or cyclin-dependent kinase 4/6 ("CDK4/6") therapy is planned. Additional potentially registrational trials are planned to be initiated in 2024.

BNT316/ONC-392 (gotistobart) is a next-generation anti-CTLA-4 monoclonal antibody candidate jointly developed by BioNTech and OncoC4, Inc.

("OncoC4"). A pivotal Phase 3 trial (NCT05671510) evaluating BNT316/ONC-392 (gotistobart) in patients with immunotherapy-experienced non-small cell lung cancer (NSCLC) is ongoing.

BNT327/PM8002 is an anti-VEGF-A antibody candidate fused to a humanized anti-PD-L1 VHH being developed in collaboration with Biotheus Inc. ("Biotheus"). BNT327/PM8002 is currently being evaluated in several Phase 2/3 studies in China to assess the efficacy and safety of the candidate as a monotherapy or in combination with chemotherapy in various indications. Trial data are planned to be presented this year at a medical conference, and an Investigational New Drug application has been accepted by the FDA for further studies in the U.S. A potentially registrational trial is planned in 2024.

BNT311/GEN1046 (acasunlimab) is a potential first-in-class bispecific antibody candidate combining PD-L1 checkpoint inhibition with 4-1BB costimulatory activation being developed in collaboration with Genmab S/A ("Genmab"). Based on emerging clinical data, the companies have planned engagement with health authorities on the design of a Phase 3 trial for BNT311/GEN1046 (acasunlimab) in second line NSCLC. The companies intend to share the data on which this decision was based at a medical conference in 2024.

BNT312/GEN1042 is a potential first-in-class bispecific antibody candidate designed to induce conditional immune activation by crosslinking CD40 and 4-1BB positive cells, also being developed in collaboration with Genmab. Data required to determine next steps for this program are planned to be shared at a medical conference in 2024.

BNT122 (autogene cevumeran) is an mRNA cancer vaccine candidate based on an individualized neoantigen-specific immunotherapy (iNeST) approach being developed in collaboration with Genentech Inc. ("Genentech"), a member of the Roche Group. In October 2023, BioNTech announced the initiation of IMCODE003, a Phase 2 trial (NCT05968326) evaluating the efficacy and safety of autogene cevumeran in combination with the anti-PD-L1 immune checkpoint inhibitor atezolizumab and standard of care chemotherapy in patients with resected pancreatic ductal adenocarcinoma. This is the third indication for which autogene cevumeran is being evaluated in a Phase 2 trial, alongside other ongoing studies in first-line melanoma and adjuvant colorectal cancer. An additional Phase 2 trial is planned to be initiated as early as late 2024.

BNT211 consists of two investigational medicinal products: a CAR-T cell product candidate targeting Claudin-6 (CLDN6)-positive solid tumors, in combination with a CAR-T cell-amplifying RNA vaccine (CARVac) encoding CLDN6. BioNTech plans to initiate a pivotal Phase 2 trial in relapsed/refractory germ cell tumors in 2024.

In 2024, BioNTech intends to accelerate the development of its portfolio of next-generation investigational medicines both as monotherapies and in combination with immunotherapy agents and other targeted therapies across a wide range of tumor types. BioNTech believes it is well positioned to have ten or more potentially registrational trials in areas of unmet medical need by the end of 2024 in advance of launching its first oncology products from 2026 onwards.

Upcoming Investor and Analyst Events

- Full Year and Fourth Quarter 2023 Financial Results: March 20, 2024
- Annual General Meeting: May 17, 2024

About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company 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 T cells, bispecific immune checkpoint modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech is developing multiple mRNA vaccine candidates for evaluation for a range of infectious diseases alongside its diverse oncology pipeline, either on its own or together with collaborators. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including DualityBio, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron and Pfizer.

For more information, please visit www.BioNTech.com

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: planned next steps in BioNTech's pipeline programs, including, but not limited to, statements regarding timing or plans for initiation of clinical trials, enrollment or submission for, and receipt of product approvals with respect to BioNTech's product candidates; BioNTech's estimates of certain financial information, including financial guidance for full year 2024 revenue, which includes expected revenues related to sales of BioNTech's COVID-19 vaccine (referred to as COMIRNATY where approved for use under full or conditional marketing authorization) in territories controlled by BioNTech's collaboration partners, particularly for those figures that are derived from preliminary estimates provided by BioNTech's partners; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment and expected regulatory recommendations to adapt vaccines to address new variants or sublineages; the registrational potential of any trials BioNTech may initiate; the initiation, timing, progress, results, and cost of BioNTech's research and development programs, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the availability of results, and characterization and timing of clinical data; BioNTech's targeted timing for a potential oncology product launch, subject to approval, including expectations regarding the timing of commercial readiness activities; the potential safety and efficacy of BioNTech's product candidates; BioNTech's expectations with respect to its intellectual property; and BioNTech's ongoing relationships with Pfizer, Inc.; Duality Biologics (Suzhou) Co. Ltd.; OncoC4, Inc.; Biotheus Inc.; Genmab S/A; Genentech Inc., a member of the Roche Group; and others. 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 neither promises nor guarantees, and 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 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 the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; discussions with regulatory agencies regarding timing and requirements for additional clinical trials; 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 BioNTech's product candidates; the ability of BioNTech's mRNA technology to demonstrate clinical efficacy outside of BioNTech's infectious disease platform; BioNTech's pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after BioNTech's initial sales to national governments; 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 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 BioNTech's COVID-19 vaccine and other 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 expansion; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products, including BioNTech's target COVID-19 vaccine production levels, and BioNTech's 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, 2023, and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at www.sec.gov. 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. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

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