BioNTech to Present Clinical Data Updates for Next-Generation Immunotherapy Candidates at the ASCO Annual Meeting 2024

May 21, 2024

MAINZ, Germany, May 21, 2024 – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") will present clinical trial data for selected programs from the Company's diversified immuno-oncology pipeline at the American Society of Clinical Oncology ("ASCO") Annual Meeting in Chicago, Illinois, from May 31 to June 4, 2024. Moreover, in support of the Company's ongoing CAR-T cell and individualized mRNA programs, BioNTech will also present epidemiological and real-world data from two observational studies in patient populations for which product candidates are being developed in the Company's respective clinical programs.

"Our aim is to develop innovative treatment options across the continuum of cancer disease and establish new treatment paradigms that have the potential to address the fundamental challenges of treating cancer to drive meaningful improvements in the long-term survival rates for patients," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "The data from the interventional and observational studies that we will present at this year's ASCO are of relevance for progress towards our goal as they will contribute to informing the direction of further development of several of our priority product candidates as well as the design of planned pivotal and later-stage clinical trials across all three key pillars of our diversified oncology pipeline, including novel immunomodulators, targeted therapies such as cell therapies and ADCs, and mRNA-based therapeutic cancer vaccines."

Highlights of BioNTech's updates to be presented at the ASCO Annual Meeting 2024:

- Updates on several Phase 1b/2a trials investigating BNT327/PM8002 as a monotherapy in patients with solid tumors will be presented. BNT327/PM8002 is a bispecific antibody candidate combining PD-L1 checkpoint inhibition with VEGF-A neutralization to create a cycle of vascular normalization and immunostimulation in the microenvironment of the tumor. Two posters will provide clinical data updates for cohorts with advanced cervical cancer, platinum-resistant recurrent ovarian cancer and advanced non-small cell lung cancer ("NSCLC"). The product candidate is being developed in collaboration with Biotheus Inc. ("Biotheus").

- Initial results from the randomized, open-label, Phase 2 trial (NCT05117242) with the bispecific antibody candidate BNT311/GEN1046 (acasunlimab) alone or in combination with pembrolizumab in patients with previously treated metastatic NSCLC ("mNSCLC") will be presented. BNT311/GEN1046 combines PD-L1 checkpoint inhibition with 4-1BB costimulatory activation. The product candidate is being developed in collaboration with Genmab S/A ("Genmab").

- BioNTech will present preliminary data of an epidemiological study (NCT04813627) that correlates post-operative circulating tumor DNA ("ctDNA"), a cancer biomarker for minimal residual disease, with disease-free survival in patients with colorectal cancer ("CRC"). This observational study provides supportive epidemiological and prognostic data for the ongoing interventional Phase 2 trial (NCT04486378) with the individualized neoantigen-specific immunotherapy ("iNeST") candidate autogene cevumeran (BNT122, RO7198457) in ctDNA-positive, high-risk stage II/stage III adjuvant CRC. Autogene cevumeran is jointly being developed by BioNTech and Genentech Inc. ("Genentech"), a member of the Roche Group.

- BioNTech will present an analysis of real-world data that investigated the overall survival, treatment patterns and prognostic variables of patients with testicular germ cell tumors receiving palliative chemotherapy. This analysis will inform the design of BioNTech's planned pivotal trial with the Company's CAR-T cell therapy candidate BNT211 in patients with germ cell tumors. BNT211 combines an autologous CAR-T cell therapy candidate targeting the oncofetal antigen Claudin-6 ("CLDN6") and an investigational CLDN6-encoding CAR-T cell amplifying RNA vaccine ("CARVac").

BioNTech has established a diversified clinical oncology pipeline based on its modular multi-platform approach. The Company is advancing more than 20 clinical programs in unmet medical need solid tumor indications, including mRNA-based immunotherapies, targeted therapies entailing cell therapies and antibody-drug conjugates (ADCs), and novel immunomodulators. These candidates are currently being evaluated in more than 30 clinical studies, including nine programs in advanced Phase 2 trials and two candidates in pivotal Phase 3 trials. BioNTech is advancing key programs into late-stage development with the aim to have ten or more potentially registrational trials in its oncology pipeline by the end of 2024. The Company aims to launch its first cancer immunotherapy in 2026. By 2030, BioNTech plans to obtain approvals for a total of ten cancer indications across various drug classes.

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

Full poster details:

Candidate: BNT327/PM8002
Session title: Lung Cancer—Non-Small Cell Metastatic
Abstract Title: A Phase Ib/IIa Trial to Evaluate the Safety and Efficacy of PM8002, a Bispecific Antibody Targeting PD-L1 and VEGF-A, as a Monotherapy in Patients with advanced NSCLC
Location: Hall A, Poster Board 397

Abstract Number: 8533
Date: Monday, June 3, 2024
Time: 1.30 PM-4.30 PM CDT

Candidate: BNT327/PM8002
Session title: Gynecologic Cancer
Abstract Title: Efficacy and Safety of PM8002, a Bispecific Antibody Targeting PD-L1 and VEGF-A, as a Monotherapy in Patients with Solid Tumors: Clinical Data from Advanced Cervical Cancer and Platinum-resistant Recurrent Ovarian Cancer Cohorts
Location: Hall A, Poster Board 395
Abstract Number: 5524
Date: Monday, June 3, 2024
Time: 9.00 AM-12.00 PM CDT

Candidate: BNT326/YL202
Session title: Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology
Abstract Title: YL202/BNT326, a HER3-targeted ADC, in patients with locally advanced or metastatic non-small cell lung cancer and breast cancer: Preliminary results from a first-in human phase I trial
Location: Hall A, Poster Board 179
Abstract Number: 3034
Date: Saturday, June 1, 2024
Time: 09:00 AM – 12:00 PM CDT

Candidate: BNT311/GEN1046 (acasunlimab)
Session Title: Developmental Therapeutics—Immunotherapy
Abstract Title: Acasunlimab (DuoBody-PD-L1x4-1BB) alone or in combination with pembrolizumab (pembro) in patients (pts) with previously treated metastatic non-small cell lung cancer (mNSCLC): initial results of a randomized, open-label, phase 2 trial
Location: Hall A, Poster Board 12
Abstract Number: 2533
Date: Saturday, June 1, 2024
Time: 9.00 AM-12.00 PM CDT

Candidate: Autogene cevumeran (BNT122, RO7198457)
Session Title: Gastrointestinal Cancer—Colorectal and Anal
Abstract Title: Preliminary results correlating post-operative ctDNA status with disease-free survival in Stage II (high risk) / III Colorectal Cancer Patients in the BNT000-001 epidemiology study
Location: Hall A, Poster board 189
Abstract Number: 3526
Date: Saturday, June 1, 2024
Time: 1.30 PM-4.30 PM CDT

Candidate: BNT211
Session Title: Genitourinary Cancer—Prostate, Testicular, and Penile
Abstract Title: Real-world evidence of overall survival (OS) and treatment patterns of patients (pts) with testicular germ cell tumors (DCT) receiving palliative chemotherapy in the United States
Location: Poster board 356
Abstract Number: 5038
Date: Sunday, June 2, 2024
Time: 9.00 AM – 12.00 PM CDT

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 be 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 current and future preclinical studies and clinical trials in oncology, including the bispecific antibody candidates BNT311/GEN1046 (acasunlimab) in patients with mNSCLC and BNT327/PM8002 in patients with advanced cervical cancer, platinum-resistant recurrent ovarian cancer and advanced NSCLC, iNeST candidate autogene cevumeran (BNT122, RO7198457) in patients with colorectal cancer, the CAR-T cell candidate BNT211 in multiple solid tumor types, and the ADC candidate BNT326/YL202 in patients with locally advanced or metastatic NSCLC and breast cancer; 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; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products 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 March 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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