BioNTech and DualityBio Announce Phase 3 Trial of ADC Candidate BNT323/DB-1303 Met Primary Endpoint of Progression Free Survival in HER2-Positive Metastatic or Unresectable Breast Cancer

September 5, 2025

- *Trastuzumab pamirtecan (BNT323/DB-1303), an investigational next-generation antibody drug-conjugate ("ADC") targeting HER-2, met its primary endpoint of progression free survival ("PFS") in interim analysis of a Phase 3 trial (NCT06265428) conducted in China*
- *Positive result in the NCT06265428 trial marks milestone in BioNTech and DualityBio's strategic collaboration initiated in April 2023*
- *Additional global Phase 3 DYNASTY-Breast02 trial (NCT06018337) evaluating trastuzumab pamirtecan in patients with metastatic HER2-low breast cancer is ongoing and on track*

MAINZ, Germany and SHANGHAI, China, September 05, 2025 – BioNTech SE (Nasdaq: BNTX, "BioNTech") and Duality Biologics (Suzhou) Co., Ltd. ("DualityBio") today announced that the pivotal Phase 3 trial (NCT06265428) which DualityBio is conducting in China to evaluate trastuzumab pamirtecan (BNT323/DB-1303) versus trastuzumab emtansine (T-DM1) in patients with HER2-positive unresectable or metastatic breast cancer who have previously received trastuzumab and a taxane-based chemotherapy met its primary endpoint of progression free survival at a pre-specified interim analysis.

Trastuzumab pamirtecan is a next-generation antibody-drug conjugate candidate targeting the cancer cell surface protein Human Epidermal Growth Factor Receptor 2 ("HER2"). The clinical trial compares the candidate to the approved ADC trastuzumab emtansine (T-DM1). Based on the results from the interim analysis which were shared by the Independent Data Monitoring Committee (IDMC) with DualityBio and evaluated by the Blinded Independent Central Review (BICR), DualityBio plans to discuss the next steps with the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China regarding the submission of a Biologics License Application (BLA) of trastuzumab pamirtecan.

"This is a milestone in the fruitful collaboration with our colleagues at DualityBio," said **Prof. Özlem Türeci, M.D., Chief Medical Officer and Co-Founder at BioNTech**. "We believe that trastuzumab pamirtecan is an ADC candidate with enormous potential which makes it an important asset in our global oncology strategy including combinational approaches. It is the first of our late-stage oncology programs to meet its primary endpoint in a pivotal Phase 3 trial and also highlights our commitment to bringing novel oncology treatments with distinct profiles to patients."

"With over 350,000 new cases annually, breast cancer has a high incidence rate in China, making it the second most common malignant tumor among Chinese women," said **Global Medical Officer of DualityBio, Dr. Hua Mu**. "The positive Phase 3 data and trastuzumab pamirtecan meeting the primary endpoint at the interim analysis indicate the potential of the BNT323/DB-1303 program to become a new treatment option for breast cancer patients. Together with our partner BioNTech, we plan the development of trastuzumab pamirtecan in further tumor types towards BLA application in other regions including the United States and the European Union to maximize its potential for patients around the world."

This is the first positive Phase 3 data readout achieved in BioNTech's and DualityBio's strategic collaboration initiated in April 2023. The collaboration aims to accelerate the development of differentiated ADC therapeutics for solid tumors. In January 2024, the partners initiated a global Phase 3 DYNASTY-Breast02 trial program for trastuzumab pamirtecan in HR-positive, HER2-low metastatic breast cancer (DYNASTY-Breast02, NCT06018337) following positive Phase 1/2 safety and efficacy data in patients with HER2-expressing advanced solid tumors. BioNTech holds global commercial rights (excluding Mainland China, Hong Kong Special Administrative Region, and Macau Special Administrative Region), while DualityBio has commercial rights for Mainland China, Hong Kong Special Administrative Region, and Macau Special Administrative Region.

Further information for media: Fact Sheet about BNT323/DB-1303

About Trastuzumab Pamirtecan (BNT323/DB-1303)
Trastuzumab pamirtecan (BNT323/DB-1303) is a third-generation topoisomerase-1 inhibitor-based ADC targeting HER2 which was built from DualityBio's proprietary Duality Immune Toxin Antibody Conjugates ("DITAC") platform. HER2 is a surface-expressed protein on solid tumors and has been linked to the aggressive growth and spread of cancer cells, making it a potential target for innovative cancer therapeutics. The candidate has exhibited antitumor activity in both HER2-positive and HER2-low tumor models as well as in several solid tumor indications, including patients with breast and endometrial cancers, as well as other advanced solid tumors. Preclinical data and preliminary clinical data for trastuzumab pamirtecan indicate its potential to target HER2 receptors on solid tumors irrespective of expression level with a manageable safety profile and a potentially expanded therapeutic window. Trastuzumab pamirtecan is currently being additionally evaluated in an ongoing Phase 1/2 trial (NCT05150691) in patients with advanced/metastatic solid tumors and in a pivotal Phase 3 trial (DYNASTY-Breast02; NCT06018337) in patients with Hormone Receptor-positive ("HR+") and Human Epidermal Growth Factor Receptor 2 ("HER2")-low, metastatic breast cancer that have progressed on hormone and/or cyclin-dependent kinase 4/6 ("CDK4/6") therapy. The BNT323/DB-1303 program received the Fast Track designation and Breakthrough Therapy designation from the U.S. Food and Drug Administration ("FDA") for the treatment of endometrial cancer in 2023.

About the Phase 3 trial NCT06265428
The Chinese, multi-center, randomized, controlled Phase 3 trial (NCT06265428) assesses the efficacy and safety of trastuzumab pamirtecan compared with trastuzumab emtansine in patients with HER2-positive unresectable or metastatic breast cancer who have been treated with trastuzumab and taxanes. A total of 228 patients were enrolled across 48 trial sites and were randomized 1:1 to receive trastuzumab pamirtecan or T-DM1, respectively. The trial's primary endpoint is progression-free survival (PFS) as per RECIST 1.1 criteria, evaluated by Blinded Independent Central Review (BICR). Secondary endpoints include overall survival, objective response rate, duration of response, and safety.

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 Bristol Myers Squibb, 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.

About DualityBio
DualityBio is a clinical-stage company focusing on the discovery and development of the next generation ADC therapeutics for patients with cancer and autoimmune diseases. DualityBio has successfully established a number of next generation Antibody-Drug Conjugate (ADC) technology platforms with global intellectual property rights. Building upon deep understanding of disease biology and translational capability, DualityBio has advanced 4 assets into global clinical trials, and developed more than 10 innovative product candidates which are currently in preclinical stage. Additionally, DualityBio is continuing evolving its novel protein engineering and ADC technology platforms for the next wave of "super ADC" molecules including diverse payload classes, bispecific ADCs and dual payload ADCs.

For more information, please visit www.dualitybiologics.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 collaboration between BioNTech and DualityBio to jointly clinical develop antibody-drug conjugates (ADCs) including trastuzumab pamirtecan (BNT323/DB-1303); timing of the pivotal Phase 3 trial as well as any subsequent data readouts; the registrational potential of any trial we may initiate for trastuzumab pamirtecan; 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 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; the potential safety and efficacy of BioNTech's other product candidates; and BioNTech's anticipated market opportunity and size for its product candidates. Any forward-looking statements in this press release are based on BioNTech's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include but are not limited to discussions with regulatory agencies regarding timing and requirements for additional clinical trials; and the ability to produce comparable clinical results in future clinical trials. 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; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; 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 June 30, 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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