BioNTech and DualityBio Announce Topline Results of the DYNASTY-Breast02 Global Phase 3 Clinical Trial Evaluating Trastuzumab Pamirtecan in HR+/HER2-low Metastatic Breast Cancer

MAINZ, Germany and SHANGHAI, China, October 26, 2026 – BioNTech SE (Nasdaq: BNTX, "BioNTech") and DualityBiologics (Suzhou) Co., Ltd. ("DualityBio", HKEX: 9606.HK) announced today that the DYNASTY-Breast02 global Phase 3 clinical trial (NCT06018337) met its primary endpoint demonstrating a statistically significant, yet modest improvement in progression-free survival ("PFS") with trastuzumab pamirtecan (BNT323/DB-1303) compared to investigator's choice of chemotherapy in chemotherapy-naïve patients with HR+/HER2-low metastatic breast cancer who have progressed on endocrine therapy. At this interim analysis for the secondary endpoint of overall survival ("OS"), data were not mature.

A higher rate of interstitial lung disease ("ILD") was reported in this trial compared to prior trials with trastuzumab pamirtecan, with most cases being Grade 1 and 2. Severe and fatal events were reported in a small proportion of patients (Grade 3-5). Otherwise, the overall safety profile was consistent with prior clinical trials and no new safety signals were observed.

The available efficacy and safety data, as of this data cut-off date, suggest that the potential benefit to patients would be limited in the context of the HR+/HER2-low metastatic breast cancer treatment landscape. The companies will discuss the data and determine next steps.

BioNTech and DualityBio are developing trastuzumab pamirtecan in three ongoing clinical trials, including two global Phase 3 clinical trials, in HR+/HER2-low metastatic breast cancer (NCT06018337) and in HER2-expressing recurrent endometrial cancer (NCT06340568), as well as in a global Phase 1/2 clinical trial (NCT05150691) in patients with advanced/metastatic solid tumors.

About DYNASTY-Breast02

DYNASTY-Breast02 is a global Phase 3 randomized, multi-center, open-label clinical trial in patients living with HR+/HER2-low metastatic breast cancer whose disease has progressed on at least two lines of prior hormone therapy or within six months of first line hormone therapy plus cyclin-dependent kinase (CDK) 4/6 inhibitor in the metastatic setting. The primary endpoint of the clinical trial is PFS with a key secondary endpoint of OS. In the trial, 541 patients with HER2-low expression (IHC 2+/ISH- and IHC 1+) were randomized 1:1 to receive either trastuzumab pamirtecan or investigator's choice single-agent chemotherapy (capecitabine, paclitaxel or nab-paclitaxel).

About trastuzumab pamirtecan

Trastuzumab pamirtecan (BNT323/DB-1303) is a third-generation topoisomerase-1 inhibitor-based ADC targeting HER2 being developed by BioNTech and Duality Biologics. Trastuzumab pamirtecan 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.

Trastuzumab pamirtecan is being evaluated in an ongoing Phase 1/2 trial (NCT05150691) in patients with advanced/metastatic solid tumors, in Fern-EC-01, a randomized Phase 3 clinical trial (NCT06340568) evaluating trastuzumab pamirtecan compared with investigator's choice of single agent chemotherapy in previously treated patients with HER2-expressing advanced recurrent endometrial cancer, and in DYNASTY-Breast02, a randomized Phase 3 clinical trial (NCT06018337) in chemotherapy-naïve patients with HR+/HER2-low metastatic breast cancer who have progressed on endocrine therapy.

About BioNTech

BioNTech is a global next generation biopharmaceutical company pioneering novel investigative therapies for cancer and other serious diseases. In oncology, BioNTech is committed to transforming how cancer is treated. Its ambition is to develop innovative medicines with pan-tumor or synergistic potential to address cancer from multiple angles and across the full continuum of the disease from early- to late-stage. Its growing late-stage oncology pipeline comprises complementary treatment approaches spanning immunomodulators, antibody-drug conjugates, and mRNA cancer immunotherapies. BioNTech has partnered with multiple global and specialized pharmaceutical collaborators leveraging complementary expertise and resources to accelerate innovation and drive progress, including Bristol Myers Squibb, Duality Biologics, Genentech, a member of the Roche Group, Genmab, MediLink, OncoC4, and Pfizer.

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 collaboration between BioNTech and DualityBio to jointly clinically develop antibody-drug conjugates (ADCs) including trastuzumab pamirtecan (BNT323/DB-1303); the initiation, timing, progress, and results of BioNTech's research and development programs, including data from the DYNASTY-Breast02 Phase 3 clinical trial (NCT06018337) evaluating trastuzumab pamirtecan in HR+/HER2-low metastatic breast cancer; the expected timing of initiation, enrollment, and completion of trials and related preparatory work and the availability of results; and discussions with regulatory agencies. 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 clinical data, 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 impact of tariffs and escalations in trade policy; competition related to BioNTech's product candidates; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its product candidates; 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 its product candidates, if approved; BioNTech's ability to manage its development and related expenses; regulatory and political developments in the United States and other countries; BioNTech's ability to effectively scale its production capabilities and manufacture its products and product candidates; 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, 2026, 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.

About DualityBio

DualityBio is a clinical-stage innovative biopharmaceutical company dedicated to developing next-generation antibody-drug conjugates (ADCs) for patients with cancer and autoimmune diseases. The Company has successfully built multiple next-generation ADC technology platforms with global intellectual property rights. Grounded in a deep understanding of disease biology, DualityBio has established a robust clinical-stage ADC pipeline and is conducting multiple global, multicenter clinical trials across nearly 20 countries, with over 3,500 patients enrolled to date. Furthermore, DualityBio has entered into several out-licensing collaborations with global pharmaceutical companies and leading innovative biotech firms. Serving as a global engine for ADC innovation, DualityBio continues to develop next-generation novel ADCs, including bispecific ADCs, ADCs with novel payloads, and autoimmune ADCs.

For more information, please visit www.dualitybiologics.com.

Contacts

BioNTech:
Media Relations

Jasmina Alatovic
media@biontech.de

Investor Relations

Douglas Maffei, PhD
investors@biontech.de

DualityBio:
Media Relations

PR@dualitybiologics.com

Investor Relations

IR@dualitybiologics.com