BioNTech and DualityBio Receive FDA Fast Track Designation for Antibody-Drug Conjugate Candidate BNT324/DB-1311 in Prostate Cancer

June 24, 2024

- *Designation is based on pre-clinical data and data from an ongoing Phase 1/2 trial for BNT324/DB-1311, with antitumor activity and a manageable safety profile demonstrated by preliminary Phase 1/2 clinical data from patients with advanced or metastatic solid tumors*[1,2]
- *With the Fast Track designation, the development of BNT324/DB-1311 can benefit from more frequent engagement with the U.S. Food and Drug Administration ("FDA") to support development and expedite regulatory review*
- *Prostate cancer is the second leading cause of cancer-related deaths among men worldwide*[3] *often diagnosed at advanced disease stages; patients with metastatic castration–resistant prostate cancer ("mCRPC"), an advanced form of prostate cancer, have a 5-year survival rate of around 36%*[4]
- *All three clinical stage antibody-drug conjugate ("ADC") candidates in BioNTech's and DualityBio's strategic collaboration have received FDA Fast Track designation supporting the potential of the companies' ADC technology*

MAINZ, Germany and SHANGHAI, China, June 24, 2024 – BioNTech SE (Nasdaq: BNTX, "BioNTech") and Duality Biologics (Suzhou) Co., Ltd. ("DualityBio") today announced that the U.S. Food and Drug Administration ("FDA") granted Fast Track designation for BNT324/DB-1311 for the treatment of patients with advanced/unresectable, or metastatic castration-resistant prostate cancer ("CRPC") who have progressed on or after standard systemic regimens. BNT324/DB-1311 is a next-generation antibody-drug conjugate ("ADC") candidate targeting the transmembrane glycoprotein B7-H3, an immune checkpoint protein which is overexpressed in a range of tumor types and has been associated with disease progression and poor prognosis for patients. The candidate is currently being evaluated in an ongoing Phase 1/2 study (NCT05914116) in patients with advanced solid tumors.

"The FDA's decision is a recognition of the potential of our B7-H3-targeting ADC candidate for the treatment of advanced CRPC. While patients with metastatic prostate cancer initially respond to hormone therapy, most patients progress after 18-24 months and develop CRPC, an advanced form of prostate cancer, leading to a poor prognosis for these patients. The 5-year survival rate for patients with metastatic CRPC is only around 36%," said **Prof. Özlem Türeci, M.D., Chief Medical Officer and Co-Founder at BioNTech**. "We are committed to further advancing BNT324/DB-1311 with our partner DualityBio and believe that a targeted ADC immunotherapy approach has the potential to improve outcomes for patients at advanced stages of the disease."

"BNT324/DB-1311 is the third asset in our strategic collaboration which has received FDA Fast Track designation, highlighting the potential of the candidate to fill an unmet medical need for novel treatment options for B7-H3 expressing cancers," said **Vivian Gu, M.D., Chief Medical Officer at DualityBio**. "Preliminary data from our ongoing Phase 1/2 trial has demonstrated antitumor activity and a manageable safety profile of BNT324/DB-1311 in patients with advanced solid tumors. With the designation and support by the FDA, we seek to expedite further development of BNT324/DB-1311."

Fast Track is a process designed to facilitate the development and expedite the review of new drugs and vaccines that are intended to treat or prevent serious conditions and have the potential to address an unmet medical need. The designation is based on preliminary safety and efficacy data from an ongoing Phase 1/2 trial with BNT324/DB-1311 in patients advanced or metastatic solid tumors. With the Fast Track designation, the development of BNT324/DB-1311 can benefit from more frequent engagement with the FDA, to support the development and expedite the regulatory review of BNT324/DB-1311.

All three clinical stage ADC candidates in BioNTech's and DualityBio's global strategic partnership have received FDA Fast Track designation. The lead candidate in the collaboration, BNT323/DB-1303, a next-ADC candidate targeting the Human Epidermal Growth Factor Receptor 2 ("HER2"), is being evaluated in a Phase 1/2 trial in patients with advanced solid tumors and a global Phase 3 clinical trial in patients with metastatic breast cancer. The BNT323/DB-1303 program received the Fast Track designation and Breakthrough Therapy designation from the FDA for the treatment of endometrial cancer in 2023. In January 2024, the companies' ADC candidate targeting the trophoblast cell-surface antigen 2 ("TROP2"), BNT325/DB-1305, received FDA Fast Track designation for the treatment of patients with platinum-resistant ovarian epithelial cancer.

About BNT324/DB-1311

BNT324/DB-1311 is a next-generation topoisomerase-I-inhibitor-based ADC candidate targeting the immune checkpoint protein B7-H3. The transmembrane glycoprotein B7-H3 plays a critical role in the anti-tumor immune response and the shaping of the tumor microenvironment. It is overexpressed in a range of solid tumors, with limited expression in healthy tissues, and has been associated with disease progression and very poor prognosis.[5] Preclinical studies have shown that BNT324/DB-1311 exhibits antitumor activity in various solid tumor models.[2] Preliminary data from the ongoing Phase 1/2 trial has demonstrated antitumor activity and a manageable safety profile for BNT324/DB-1311 in patients with advanced solid tumors.[1] BNT324/DB-1311 is currently being evaluated in a Phase 1/2 clinical trial (NCT05914116) in patients with advanced or metastatic solid tumors.

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 ("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 pharmaceutical collaborators, including Biotheus, 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 four assets into global clinical studies, and developed more than 10 innovative product candidates which are currently in preclinical stage. Additionally, DualityBio is continuing to evolve 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 clinically develop antibody-drug conjugates (ADCs), including BNT324/DB-1311; the registrational potential of any trial we may initiate for BNT324/DB-1311; 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 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 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.

CONTACTS

BioNTech
Investor Relations
Victoria Meissner, M.D.
+1 617 528 8293
Investors@biontech.de

Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513
Media@biontech.de

DualityBio
Business Development
bd@dualitybiologics.com

[1] Data on file.

[2] Li C, Yao J, et al. Cancer Res (2023) 83 (7_Supplement): 2967.

[3] Cancer TODAY. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. Available at: https://gco.iarc.who.int (last access: 20.06.2024).

[4] SEER*Explorer: An interactive website for SEER cancer statistics. Cancer Stat Facts: Prostate Cancer. 2024 Apr 17.Available at: https://seer.cancer.gov/statfacts/html/prost.html (last access: 20.06.2024).

[5] Ranjana K. Kanchan, et al. Biochim Biophys Acta Rev Cancer. 2022 Sep;1877(5):188783.