BioNTech and DualityBio Receive FDA Fast Track Designation for Next-Generation Antibody-Drug Conjugate Candidate BNT325/DB-1305

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- *Designation is based on preliminary safety and efficacy data from an ongoing Phase 1/2 trial in patients with platinum-resistant ovarian epithelial cancer, fallopian tube, or primary peritoneal cancer*[1]
- *Fast Track designation can facilitate the development and expedite the regulatory review of BNT325/DB-1305*
- *Ovarian cancer is the fourth most common gynecological tumor type*[2] *with over 300,000 cases diagnosed globally each year*[3]*; over 90% of ovarian tumors arise from epithelial cells, including the epithelial tissue of the ovary, the lining of a fallopian tube or the peritoneum*[4]

MAINZ, Germany and SHANGHAI, China, January 31, 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 BNT325/DB-1305 for the treatment of patients with platinum-resistant ovarian epithelial cancer, fallopian tube cancer, or primary peritoneal cancer who have received one to three prior systemic treatment regimens. BNT325/DB-1305 is a next-generation antibody-drug conjugate ("ADC") candidate targeting the trophoblast cell-surface antigen 2 ("TROP2"), a protein which is overexpressed on a range of tumor types. The candidate is currently being evaluated in an ongoing Phase 1/2 study (NCT05438329) in patients with TROP2-expressing advanced solid tumors.

Ovarian cancer is the fourth most common gynecological tumor type, with over 300,000 cases diagnosed globally each year.[3] Over 90% of ovarian tumors arise from epithelial cells including the epithelial tissue of the ovary, the lining of a fallopian tube or the peritoneum.[4] Ovarian epithelial cancer is often diagnosed at advanced disease stages, leading to a poor prognosis for patients. This makes it one of the most frequent causes of cancer death in women.[3] The 5-year survival rate ranges from 26% to 42%, depending on the initial disease stage.[3]

"The FDA's decision is an important recognition of the potential of our TROP2-targeting ADC candidate. Platinum-based chemotherapy is the backbone of treatment for ovarian epithelial cancer and related subtypes that form in the epithelial tissue. Patients with platinum resistance who relapse within under six months have a poor prognosis, and effective and well-tolerated treatment options remain a substantial unmet medical need," said **Prof. Özlem Türeci, M.D., Chief Medical Officer and Co-Founder at BioNTech**. "Recent studies have indicated the role of TROP2 in aggressive tumor growth and progression in patients with chemotherapy-resistant ovarian tumors. We are committed to further advancing BNT325/DB-1305 and believe that a TROP2-targeted treatment approach has the potential to overcome current limitations in the treatment of advanced ovarian cancers."

"BNT325/DB-1305 is the second investigational asset in our strategic collaboration which has received FDA Fast Track designation highlighting the potential of the candidate to fill an unmet medical need," said **Vivian Gu, M.D., Chief Medical Officer at DualityBio**. "Data from the Phase 1/2 clinical trial with BNT325/DB-1305 have demonstrated encouraging anti-tumor signals in heavily pretreated patients with TROP2-expressing solid tumors who had failed standard therapy with an objective response rate of 30.4% and a disease control rate of 87.0%.[5] We look forward to progressing the further development of BNT325/DB-1305 within the fast track framework, and hope to be one step closer to potentially improving outcomes for a range of patients."

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 that have the potential to address an unmet medical need. The designation is based on preliminary data from an ongoing Phase 1/2 study with BNT325/DB-1305 in patients with platinum-resistant ovarian epithelial cancer, fallopian tube, or primary peritoneal cancer patients.[1] With the Fast Track designation, the development of BNT325/DB-1305 can benefit from more frequent engagement with the FDA, to support the development and expedite the review of BNT325/DB-1305.

About BNT325/DB-1305
BNT325/DB-1305 is a third-generation topoisomerase-1 inhibitor-based ADC targeting TROP2 which was built from DualityBio's proprietary Duality Immune Toxin Antibody Conjugates ("DITAC") platform. TROP2 is a cell surface protein which is expressed in many normal tissues but is overexpressed in a variety of tumors. TROP2 plays an important role in tumor cell proliferation, apoptosis, and invasion, thereby impacting the prognosis and treatment of cancer patients.[6,7] BNT325/DB-1305 has exhibited antitumor activity in tumor models as well as in several advanced solid tumor indications, including non-small cell lung cancer ("NSCLC") and ovarian epithelial cancer. [8] Preclinical data and preliminary clinical data for BNT325/DB-1305 indicate its potential to target TROP2 receptors on solid tumors irrespective of expression level with a manageable safety profile and a potentially expanded therapeutic window.[5]

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 Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron and Pfizer.

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 studies, 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 BNT325/DB-1305; the registrational potential of any trial we may initiate for BNT325/DB-1305; 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 September 30, 2023, and in subsequent filings made by BioNTech with the U.S. Securities and Exchange Commission ("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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[1] Data on file. Based on October 30, 2023, data cut-off from the Phase 1/2 trial.

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[5] Marathe O. et al. Annals of Oncology (2023) 34 (suppl_2): S458-S497. 10.1016/annonc/annonc1324
[6] Wen Y, Ouyang D et al. Ann Transl Med. 2022 Dec; 10(24): 1403.
[7] Wu B, Yu C et al. Exp Ther Med. 2017 Sep;14(3):1947-1952.
[8] Data on file: https://investors.biontech.de/static-files/bf304f1c-3c61-47bf-b3b3-2efb5373a3b9