



BioNTech and DualityBio Form Global Strategic Partnership to Accelerate Development of Differentiated Antibody-Drug Conjugate Therapeutics for Solid Tumors

April 3, 2023

- *BioNTech receives exclusive licenses from DualityBio for two investigational antibody-drug conjugate assets (DB-1303 and DB-1311) directed against targets expressed in a broad range of human cancers*
- *Collaboration will add a new class of precision medicine therapeutics to BioNTech's clinical-stage oncology portfolio, expanding the breadth of its immunotherapy toolkit with synergistic potential*
- *DualityBio receives upfront payments totaling \$170 million, and will be eligible to receive development, regulatory and commercial milestone payments potentially totaling over \$1.5 billion as well as single-digit to double-digit tiered royalties on potential future product sales*

MAINZ, Germany and SHANGHAI, China, April 3, 2023 – [BioNTech SE](#) (Nasdaq: BNTX, "BioNTech") and Duality Biologics (Suzhou) Co. Ltd. ("DualityBio"), a clinical-stage biotech company focusing on the discovery and development of next generation antibody-drug conjugate ("ADC") therapeutics to treat patients with cancer and autoimmune diseases, today announced that the companies have entered into exclusive license and collaboration agreements for two ADC assets to develop, manufacture and commercialize the two assets globally, excluding Mainland China, Hong Kong Special Administrative Region and Macau Special Administrative Region. With this collaboration, ADCs will become an additional drug class in BioNTech's oncology portfolio with the aim to further support BioNTech's mission of developing highly efficacious therapies for cancer patients at every stage of disease.

ADCs are a class of potent cancer therapies combining the selectivity of antibodies with the potent cell-killing properties of chemotherapy or other anti-cancer agents.

As part of the collaboration, BioNTech will gain access to DualityBio's lead candidate, DB-1303, which is a topoisomerase-1 inhibitor-based ADC directed against Human Epidermal Growth Factor Receptor 2 (HER2), a target that is overexpressed in a variety of cancers, which contributes to the aggressive growth and spread of cancer cells. Antibody therapy targeting HER2 has been shown to be an effective treatment strategy for HER2-expressing cancers. The DB-1303 program received the Fast Track designation from the U.S. Food and Drug Administration ("FDA") and is currently in a Phase 2 clinical trial ([NCT05150691](#)) for HER2-expressing advanced solid tumors.

BioNTech will also gain access to a second topoisomerase-1 inhibitor-based ADC candidate, DB-1311.

"Over the last years, the ADC field has made significant progress, overcoming several limitations and demonstrating its potential as a broadly applicable precision medicine drug class that might be an alternative to standard chemotherapy," said **Prof. Ugur Sahin, M.D., Chief Executive Officer and Co-Founder of BioNTech**. "The addition of these two ADCs to our portfolio strengthens our pipeline of immunotherapies and expands our capabilities with the aim to provide therapeutic benefits for patients with a range of solid tumors, along the entire patient journey."

"We are delighted to partner with BioNTech, a leading company which brings transformational medicine to patients through innovation," said **John Zhu, Ph.D., Founder and CEO of DualityBio**. "This is a recognition of not only DualityBio's next-generation ADC platform, but also its internal discovery and development capabilities. With this strategic partnership, we are committed to working together to advance the development of innovative therapies for the benefit of patients worldwide."

Under the terms of the agreements, DualityBio will receive upfront payments for both asset licenses totaling \$170 million, and additional development, regulatory and commercial milestone payments for both assets, potentially totaling over \$1.5 billion. DualityBio will be eligible to receive single-digit to double-digit tiered royalties on net sales for both ADC assets. BioNTech will hold commercial rights globally (excluding Mainland China, Hong Kong Special Administrative Region and Macau Special Administrative Region), while DualityBio will retain commercial rights for Mainland China, Hong Kong Special Administrative Region and Macau Special Administrative Region. As part of the agreement for DB-1311, DualityBio has the right to exercise a co-development cost and profit/loss sharing option for DB-1311 for the U.S. market, as well as a co-promotion option for the U.S. market.

About DB-1303

DB-1303, a third generation HER2 ADC molecule built from DualityBio's proprietary Duality Immune Toxin Antibody Conjugates (DITAC) platform, exhibited potent antitumor activity in both HER2 positive and HER2 low tumor models with a favorable safety profile and a potentially expanded therapeutic window. Both preclinical data and preliminary clinical data from DB-1303 suggest the potential of DB-1303 to address unmet medical needs in various HER2 expressing cancers.

About DB-1311

DB-1311 is an ADC comprised of a humanized antibody and DualityBio's proprietary DITAC linker-payload. It has exhibited potent antitumor activity in a range of tumor models representing multiple cancer types and has been well tolerated in preclinical studies, with a good pharmacokinetics profile. The wide therapeutic window demonstrated by preclinical antitumor activity and its safety profile support the potential of DB-1311 to address unmet medical needs across a broad range of cancers.

About BioNTech

Biopharmaceutical New Technologies 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 T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and 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 Genmab, Sanofi, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer.

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

BioNTech Forward-Looking Statements

This press release contains “forward-looking statements” of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech’s collaboration with Duality Biologics (Suzhou) Co. Ltd.; the ability of DualityBio’s antibody-drug conjugates (ADCs) to widen the therapeutic window of conjugated drugs and enhance anti-tumor activity in various cancer indications; DualityBio’s eligibility to receive development, regulatory and commercial milestone payments as well as tiered royalties; and the ability of BioNTech to develop and commercialize these immunotherapies, if successfully developed and approved. 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.

For a discussion of these and other risks and uncertainties, see BioNTech’s Annual Report on Form 20-F for the year ended December 31, 2022, filed with the SEC on March 27, 2023, which is available on the SEC’s website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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.

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