BioNTech and Bristol Myers Squibb Announce Global Strategic Partnership to Co-Develop and Co-Commercialize Next-generation Bispecific Antibody Candidate BNT327 Broadly for Multiple Solid Tumor Types

- *BNT327, BioNTech's PD-L1xVEGF-A bispecific antibody, is a clinically advanced investigational immunotherapy candidate with the potential to surpass current checkpoint inhibitor outcomes and set a new standard of care in multiple tumor types*
- *The co-development and co-commercialization collaboration with a 50/50 profit/loss split will leverage both partners' expertise, resources and global footprint to accelerate BNT327's path towards potential regulatory approvals and market launches*
- *BioNTech and Bristol Myers Squibb will jointly execute a broad clinical development program to evaluate and advance BNT327 across numerous solid tumor types*

MAINZ, Germany, and PRINCETON, USA, June 2, 2025 -- BioNTech SE (Nasdaq: BNTX, "BioNTech") and Bristol Myers Squibb (NYSE: BMY, "BMS") today announced that the companies have entered into an agreement for the global co-development and co-commercialization of BioNTech's investigational bispecific antibody BNT327 across numerous solid tumor types. Under the agreement, BioNTech and BMS will work jointly to broaden and accelerate the development of this clinical candidate.

BioNTech's BNT327, a next-generation bispecific antibody candidate targeting PD-L1 and VEGF-A, is currently being evaluated in multiple ongoing trials with more than 1,000 patients treated to date, including global Phase 3 trials with registrational potential evaluating BNT327 as first-line treatment in extensive stage small cell lung cancer ("ES-SCLC") and non-small cell lung cancer ("NSCLC"). A global Phase 3 trial evaluating the candidate in triple negative breast cancer ("TNBC") is planned to start by the end of 2025. Preliminary data from ongoing trials underscore the potential for combining anti-PD-L1 and anti-VEGF-A – two well-established therapeutic targets – into a single molecule to deliver synergistic clinical benefits for patients across multiple tumor types.

Under the terms of the agreement, the companies will jointly develop and commercialize BNT327, including the development of BNT327 as monotherapy and in combination with other products. Both companies have the right to independently develop BNT327 in further indications and combinations, including combinations of BNT327 with proprietary pipeline assets.

"We believe BNT327 has the potential to become a foundational immuno-oncology backbone, moving beyond single-mechanism checkpoint inhibitors and expanding into multiple solid-tumor indications. Our collaboration with BMS, a pioneering leader in immuno-oncology, aims to accelerate and broadly expand BNT327's development to fully realize its potential," said Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech. "Our focus remains on advancing high-impact, pan-tumor programs and combination strategies in oncology, with BNT327 complementing our antibody-drug conjugate programs and mRNA-based immunotherapies. We are dedicated to delivering truly transformative options for patients in need."

"Our deep experience and expertise in advancing and delivering groundbreaking immuno-oncology medicines positions BMS well to collaboratively realize the potential of BNT327, an asset with significant potential for transforming the standard of care for patients with solid tumors," said Christopher Boerner, Ph.D., Board Chair and CEO of Bristol Myers Squibb. "The science behind BNT327 and its leading clinical position in multiple hard-to-treat tumor types, further bolsters our pursuit of novel mechanisms and multiple modalities in oncology, and enhances our growth trajectory. We are impressed by the innovation that

BioNTech has achieved to date, and we look forward to partnering to accelerate existing clinical trials and time to market, while expanding the number of potential indications."

BMS will pay BioNTech $1.5 billion in an upfront payment and $2 billion total in non-contingent anniversary payments through 2028. These tax-deductible charges will be recorded as Acquired IPR&D Expense when incurred, with the $1.5 billion being incurred in Q2. In addition, BioNTech will be eligible to receive up to $7.6 billion in additional development, regulatory and commercial milestones. BioNTech and BMS will share joint development and manufacturing costs on a 50:50 basis, subject to certain exceptions. Global profits/losses will be equally shared between BioNTech and BMS.

About BNT327

BNT327 is a novel investigational bispecific antibody combining two complementary, validated mechanisms in oncology into one single molecule. BNT327 combines PD-L1 checkpoint inhibition aimed at restoring T cells' ability to recognize and destroy tumor cells with the neutralization of VEGF-A. The blocking of VEGF-A is aimed at reversing the tumor's immuno-suppressive effect in its microenvironment and cutting off the blood and oxygen supply that feeds tumor cells (anti-angiogenesis effect), with the intention of preventing the tumor from growing and proliferating. BNT327 may be differentiated via its mechanism of action of targeting PD-L1 on tumor cells to localize anti-VEGF activity within the tumor microenvironment, aiming to enhance therapeutic precision and minimize systemic exposure. A treatment with BNT327 is intended to help normalize blood vessels at the tumor site, improving delivery and potential effectiveness of combination therapies. This targeted vascular remodeling positions BNT327 as a potential backbone therapy across a wide range of solid tumors.[1,2]

More than 1,000 patients have been treated with BNT327 in clinical trials to date. More than 20 clinical trials are currently ongoing or planned to evaluate BNT327 either as a monotherapy or in combination with other treatment modalities targeting different oncogenic pathways in more than 10 solid tumor indications. Multiple global trials are ongoing or planned to start in 2025, including three global clinical trials with registrational potential in first-line small cell lung cancer ("SCLC"), first-line non-small cell lung cancer ("NSCLC") and first-line triple-negative breast cancer ("TNBC"). Additional trials will explore combining BNT327 and BioNTech's proprietary antibody-drug conjugate candidates ("ADCs"). If successfully developed and approved, BioNTech aims to use this bispecific antibody candidate as a next-generation immuno-oncology ("IO") backbone in combination with other treatment modalities targeting a broad range of cancer indications.

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.

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: expectations regarding the impact of the collaboration with Bristol Myers Squibb (BMS) on BioNTech's business; the creation of long-term value for BioNTech; the ability of BioNTech and BMS to successfully co-develop and co-commercialize BNT327, if approved; BioNTech's eligibility to receive development, regulatory, and commercial milestone payments; the rate and degree of market acceptance of BioNTech's investigational medicines, if approved; the initiation, timing, progress, results, and cost of BioNTech's research and development programs, including BioNTech's current and future preclinical studies and clinical trials, including statements regarding the expected timing of initiation, enrollment, and completion of studies or trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations; BioNTech's expectations regarding potential future commercialization in oncology, including goals regarding timing and indications; the targeted timing and number of additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; discussions with regulatory agencies; BioNTech's expectations with respect to intellectual property; the impact of BioNTech's collaboration and licensing agreements; the development, nature and feasibility of sustainable drug production and supply solutions; and BioNTech's estimates of revenues, research and development expenses, selling, general and administrative expenses, and capital expenditures for operating activities. 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, 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; pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors; the impact of tariffs and escalations in trade policy; competition related to BioNTech's product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; 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 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; 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, 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.

About Bristol Myers Squibb
Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol Myers Squibb, visit us at BMS.com or follow us on LinkedIn, X, YouTube, Facebook and Instagram.

Bristol Myers Squibb Cautionary Statement Regarding Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of pharmaceutical products and the collaboration with BioNTech. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on current expectations and projections about Bristol Myers Squibb's future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond Bristol Myers Squibb's control and could cause its future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. These risks, assumptions, uncertainties and other factors include, among others, that the expected benefits of, and opportunities related to the collaboration with BioNTech may not be consistent with the realized by Bristol Myers Squibb or may take longer to realize than anticipated, that the therapeutic potential of BNT327 may change, that Bristol Myers Squibb may fail to discover and develop any commercially successful product candidates through the collaboration with BioNTech, that such product candidates may not receive regulatory approval for the indications described in this release and, if approved, whether such product candidates will be commercially successful. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Bristol Myers Squibb's business and market, particularly those identified in the cautionary statement and risk factors discussion in Bristol Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2024, as updated by Bristol Myers Squibb's subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by applicable law, Bristol Myers Squibb undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

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[1] Tzuri N, et al. Sci Rep. 2023;13(1):11923.
[2] Kim HJ, et al. Arch Pharm Res. 2022;45(6):401-416.