BioNTech Completes Acquisition of Biotheus

February 3, 2025

- *Acquisition to strengthen key pillar of BioNTech's oncology strategy aimed at establishing BNT327 as a pan-tumor technology platform for the treatment of advanced cancers*
- *With the closing of the transaction, BioNTech will expand its capabilities to develop, manufacture and commercialize novel BNT327 combinations and next-generation bispecific antibodies*
- *Biotheus will become a new indirect Chinese subsidiary of BioNTech, adding a local research and development hub and an advanced biologics manufacturing facility to the Company's network*

MAINZ, Germany, February 3, 2025 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") announced today the completion of the acquisition of Biotheus ("Biotheus"), a clinical-stage biotechnology company dedicated to the discovery and development of novel antibodies to address unmet medical needs of patients with oncological or inflammatory diseases. The acquisition was announced on November 2024 and builds on the successful collaboration on the late-stage clinical asset BNT327, an investigational bispecific antibody targeting PD-L1 and VEGF-A, and other bispecific antibody candidates.

The transaction is part of BioNTech's oncology strategy, aimed at expanding the Company's capabilities to research, develop and commercialize BNT327 as a pan-tumor technology platform for combination therapies. With this completion of the acquisition, BioNTech obtains full global rights to BNT327 and rights to all other candidates of Biotheus' pipeline as well as to its in-house antibody generation platform and bispecific antibody drug conjugate capability. Biotheus will operate as a new indirect Chinese subsidiary of BioNTech, adding a local research and development hub and an advanced biologics manufacturing facility to the Company's network.

The total consideration to acquire 100 percent of the issued share capital by Biotheus amounts to $800 million, predominantly in cash, with a small portion in BioNTech American Depositary Shares, plus additional performance-based payments of up to $150 million if certain milestones are met.

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 the tumor cells aimed at enriching BNT327 in the tumor microenvironment and promoting localized anti-cancer activity. The co-localized blockade of the PD-(L)1 pathway and the VEGF-A driven formation of an immuno-suppressive microenvironment has been shown to deliver synergistically enhanced anti-tumor immune responses in several solid tumor types.[1,2]

More than 750 patients have been treated with BNT327 in clinical trials to date. Multiple clinical trials are currently ongoing evaluating BNT327 either as a monotherapy or in combination with other treatment modalities targeting different oncogenic pathways in various 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"), non-small cell lung cancer ("NSCLC") and 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 drug platforms with the intent of 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 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 DualityBio, 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 this acquisition on BioNTech's business; the creation of long-term value for BioNTech and Biotheus shareholders; potential synergies between BioNTech and Biotheus and their businesses; BioNTech's ability to research, develop and potentially commercialize BNT327 and potentially other assets in Biotheus' pipeline; the expansion of BioNTech's operations in China; 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; and the impact of BioNTech's collaboration and licensing agreements. 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 reaction of BioNTech and Biotheus’ competitors and business partners to the proposed transaction; the retention of Biotheus employees; BioNTech’s plans for Biotheus; the future development of BioNTech’s business and the possibility that integration following the transaction may be more difficult than expected; the risk that Biotheus’ collaborations will not continue or will not be successful; risks related to Biotheus’ ability to protect and maintain its intellectual property position; risks related to Biotheus’ capital requirements, use of capital and unexpected expenditures, including Biotheus’ ability to manage operating expenses or obtain funding to support planned business activities or to explore and establish strategic alternative transactions; risks related to Biotheus’ ability to attract and retain personnel; the uncertainties inherent in research and development; competition from other product candidates Biotheus’ 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; BioNTech's ability to manage its development; 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 September 30, 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.

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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.