



BioNTech to Acquire Biotheus to Boost Oncology Strategy

November 13, 2024

- Acquisition to support the global execution of BioNTech's oncology strategy and provide full global rights to BNT327/PM8002, an investigational PD-L1 x VEGF-A bispecific antibody, with potential to replace current checkpoint inhibitor standard of care treatments for solid tumors
- With the acquisition of Biotheus, BioNTech aims to further strengthen its capabilities to develop, manufacture and commercialize next-generation bispecific antibodies and novel treatment combinations
- BioNTech and Biotheus plan to initiate multiple registrational trials with BNT327/PM8002 in late 2024 and 2025; further clinical trials evaluating BNT327/PM8002 as combination therapies are planned to start in 2024 and 2025
- BioNTech to pay \$800 million to acquire 100 percent of the issued share capital and up to \$150 million in potential milestone payments
- Additional details will be shared at BioNTech's Innovation Series R&D Day event on 14 November 2024

MAINZ, Germany, November 13, 2024 (GLOBE NEWSWIRE) -- [BioNTech SE](#) (Nasdaq: BNTX, "BioNTech") and [Biotheus](#) ("Biotheus") today announced the signing of a definitive agreement for the acquisition of 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.

With the acquisition, BioNTech will obtain full global rights to the late-stage clinical asset BNT327/PM8002, an investigational bispecific antibody targeting PD-L1 and VEGF-A. The transaction is part of BioNTech's oncology strategy, aimed at enhancing the company's capabilities to research, develop and commercialize combination therapies using BNT327/PM8002. Clinical trials with BNT327/PM8002 and the PD-(L)1 x VEGF bispecific class of drugs have demonstrated encouraging clinical activity in various tumor types including in patients with PD-L1-low and -negative tumors who have typically been less responsive to current checkpoint inhibitor treatments.

"The acquisition of Biotheus builds on our successful ongoing collaboration on BNT327/PM8002 and other investigational bispecific antibodies," said **Prof. Ugur Sahin, M.D., Ph.D., CEO and co-founder of BioNTech**. "We believe that BNT327/PM8002 has the potential to set a new standard of care in multiple oncology indications, surpassing traditional checkpoint inhibitors. We are committed to advancing its research and development in combination with our investigational mRNA vaccines, targeted therapies, and immunomodulators with the aim of enhancing outcomes for patients with solid tumors."

"We are thrilled to deepen our bond with BioNTech. We share the goal of advancing the development of BNT327/PM8002 for future combination therapies in the fight against cancer," said **Xiaolin Liu, President, CEO, and Co-Founder of Biotheus**. "We believe that BNT327/PM8002 holds significant potential across various tumor indications, and we have an exciting pipeline of innovative investigational assets under development including an antibody discovery and development platform. As we move forward, we are committed to leveraging our strengths with the aim of advancing transformative cancer treatments and enhance our ability to develop treatments for patients in need."

BNT327/PM8002 has shown encouraging efficacy and tolerability in patients across various tumor types, with more than 700 patients treated in clinical trials to date. Multiple registrational trials are planned to start in 2024 and 2025, evaluating BNT327/PM8002 plus chemotherapy in various solid tumor indications including in patients with small cell lung cancer, non-small cell lung cancer and triple-negative breast cancer. Additional trials will explore combining BNT327/PM8002 and BioNTech's proprietary antibody-drug conjugates ("ADCs"). In June 2024, the evaluation of BNT327/PM8002 in combination with BNT325/DB-1305, a Trophoblast Cell-Surface Antigen 2 ("TROP2")-targeted ADC candidate developed by BioNTech in collaboration with Duality Biologics (Suzhou) Co., Ltd. ("DualityBio"), was initiated as part of an ongoing Phase 1/2 clinical trial ([NCT05438329](#)).

Under the terms of the agreement, BioNTech will pay Biotheus shareholders an upfront consideration of \$800 million, predominantly in cash, with a small portion in American depositary shares ("ADS"), to acquire 100 percent of the issued share capital, subject to customary purchase price adjustments, plus additional performance-based contingent payments of up to \$150 million if certain milestones are met. The transaction is expected to close in the first quarter of 2025, subject to the satisfaction of customary closing conditions, including regulatory approvals. The acquisition follows an initial exclusive global license and collaboration agreement between BioNTech and Biotheus, which closed in November 2023, granting BioNTech the rights to develop, manufacture and commercialize BNT327/PM8002 globally ex-Greater China.

Upon closing, BioNTech will gain full rights to Biotheus' pipeline candidates and its in-house bispecific antibody drug conjugate capability. The acquisition will expand BioNTech's footprint in China, adding a local research and development hub to conduct clinical trials. In addition, BioNTech will gain a state-of-the-art biologics manufacturing facility to contribute to its future global manufacturing and supply, and more than 300 Biotheus employees in R&D, manufacturing and enabling functions are expected to join the BioNTech workforce.

BioNTech's Innovation Series R&D Day

BioNTech leadership will present additional details on the Biotheus transaction, as well as updates on the corporate strategy, commercial strategy and clinical progress across its pipeline during an edition of the company's Innovation Series R&D Day on 14 November. The live webcast of the event will be available via this [link](#) and will begin at 4:30 pm CET (3:30 pm GMT, 10:30 am EST). A replay of the webcast will be available shortly after the event's conclusion and archived on BioNTech's website for one year.

About BNT327/PM8002

BNT327/PM8002 is an investigational bispecific antibody combining PD-L1 checkpoint inhibition with VEGF-A neutralization. The checkpoint inhibition is aimed at restoring T cells' ability to recognize and destroy tumor cells while targeting VEGF-A is aimed at inhibiting tumor angiogenesis, which cuts off the blood and oxygen supply that feeds tumor cells and thus prevents the tumor from growing and proliferating. The combined blockade of the PD-(L)1 pathway and the VEGF-A driven angiogenesis has been shown to deliver synergistically enhanced anti-tumor immune responses in several

solid tumor types.^{i,ii} If successfully developed and approved, BioNTech aims to use this bispecific antibody candidate as a new therapeutic backbone in combination with other treatment modalities targeting different oncogenic pathways.

About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a global next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. BioNTech 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 and specialized pharmaceutical collaborators, including Biotheus, 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 proposed acquisition on BioNTech's and Biotheus' business; the timing of the closing of the proposed acquisition; 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/PM8002 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 possibility that the proposed transaction may not close; 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 and Biotheus' business and the possibility that integration following the proposed 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.

About Biotheus

Biotheus is a clinical-stage biotech company dedicated to the discovery, development, and delivery of novel antibodies to address the unmet medical needs of patients with oncology or inflammatory diseases worldwide. Since its inception, Biotheus has established several innovative platforms for antibody discovery. With an experienced development team, Biotheus has built a robust pipeline of ten programs at various stages of clinical development.

For more information about Biotheus, please visit www.biotheus.com.

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ⁱ Tzuri N, et al. Sci Rep. 2023;13(1):11923.

ⁱⁱ Kim HJ, et al. Arch Pharm Res. 2022;45(6):401-416.