BioNTech Provides Update on Phase 2 Clinical Trial of Autogene Cevumeran in Resected Colorectal Cancer

MAINZ, Germany, August 28, 2026 – BioNTech SE (Nasdaq: BNTX, "BioNTech") today announced that it has decided to terminate the Phase 2 clinical trial (BNT122-01; NCT04486378) evaluating autogene cevumeran (BNT122/RO7198457), an investigational individualized mRNA cancer immunotherapy, as an adjuvant monotherapy in patients with circulating tumor DNA ("ctDNA")-positive, surgically resected Stage II (high risk) or Stage III colorectal cancer ("CRC"). Autogene cevumeran is being jointly developed by BioNTech and Genentech, a member of the Roche Group. The decision to terminate the clinical trial was made in consultation with Genentech.

The decision follows a new recommendation from the independent Data Safety Monitoring Board ("DSMB") which is responsible for overseeing the safety and integrity of the trial. As previously reported, the futility boundary was crossed in October 2025. At that time, the DSMB concluded that the data were not sufficiently mature to support reliable conclusions regarding efficacy, and that follow-up time was insufficient to evaluate the trial's primary endpoint. Therefore, in the absence of safety concerns and with no objection from the DSMB, BioNTech decided to continue the trial in accordance with the protocol.

In its most recent review of the available data of this trial, the DSMB identified a numerical imbalance in overall survival between treatment arms in this specific patient population and noted that further trial continuation was unlikely to change the efficacy outcome. Therefore, the DSMB recommended discontinuing treatment of patients in this trial and terminating the clinical trial. No new safety signals were identified by the DSMB regarding autogene cevumeran. BioNTech has informed investigators and relevant regulatory authorities accordingly.

The BNT122-01 clinical trial was designed to assess whether an investigational individualized mRNA cancer immunotherapy as monotherapy, i.e. without supportive checkpoint inhibitor treatment, could help prevent disease recurrence in this high-risk patient population, compared with watchful waiting, the current standard of care. CRC is a biologically complex disease and an immunologically "cold" tumor type, that is historically largely unresponsive to immunotherapy and associated with a high risk of metastatic relapse, marking an area of significant unmet medical need.

"Any decision concerning clinical trials is made with utmost care, keeping patients as our highest priority," **said Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "While this outcome is not what we had envisioned for mRNA as a monotherapy in colorectal cancer, it provides scientific insight into the challenges of treating immunotherapy-insensitive tumor types with immune-suppressive microenvironments and will help inform the further development of investigational mRNA cancer immunotherapies. We remain committed to mRNA as a key pillar in our oncology strategy and our novel-novel combination approaches. We are deeply grateful to the patients, families, investigators and site teams whose participation has made this important research possible."

As is standard procedure, BioNTech will be conducting a thorough analysis of the trial data aiming to provide insights into the patient population selection and informing the clinical development strategy for potential further investigational mRNA cancer immunotherapies. The results of the trial will be shared with the scientific and medical community at an appropriate time.

The Phase 2 clinical trial IMcode003 (NCT05968326) evaluating autogene cevumeran in combination with checkpoint inhibition and chemotherapy in adjuvant pancreatic ductal adenocarcinoma ("PDAC") is not affected and continues as planned.

About BioNTech

BioNTech is a global next generation biopharmaceutical company pioneering novel investigative therapies for cancer and other serious diseases. In oncology, BioNTech is committed to transforming how cancer is treated. Its ambition is to develop innovative medicines with pan-tumor or synergistic potential to address cancer from multiple angles and across the full continuum of the disease from early- to late-stage. Its growing late-stage oncology pipeline comprises complementary treatment approaches spanning immunomodulators, antibody drug conjugates, and mRNA cancer immunotherapies. BioNTech has partnered with multiple global and specialized pharmaceutical collaborators leveraging complementary expertise and resources to accelerate innovation and drive progress, including Bristol Myers Squibb, Duality Biologics, Genentech, a member of the Roche Group, Genmab, MediLink, OncoC4, and Pfizer.

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: the initiation, timing, progress and results of BioNTech's research and development programs in oncology, including the targeted timing and number of additional potentially registrational trials; BioNTech's and its collaborators' current and future preclinical and clinical trials in oncology; 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 and potential commercialization with respect to BioNTech's product candidates; and the potential safety and efficacy of BioNTech's product candidates; and BioNTech's plans with respect to the analysis and sharing of data from the BNT122-01 clinical trial. 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, projected data release timelines, 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 ability to produce comparable clinical results in future clinical trials; 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; the impact of tariffs and escalations in trade policy; 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; 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 June 30, 2026 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.

Media contact

Media Relations

Jasmina Alatovic

Senior Vice President Global Corporate Communications & External Affairs

media@biontech.de

Investor Relations

Douglas Maffei, PhD

Vice President, Strategy and Investor Relations

investors@biontech.de