BioNTech Provides Update on Phase 2/3 Clinical Trial for mRNA Cancer Immunotherapy Candidate BNT113 in Metastatic HPV16-positive Head and Neck Cancer

- *AHEAD-MERIT Phase 2/3 clinical trial did not meet its first dual primary endpoint of progression-free survival for the mRNA cancer immunotherapy candidate BNT113 plus pembrolizumab compared with pembrolizumab alone*
- *The trial will continue to evaluate the second dual primary endpoint of overall survival completing the assessment with the potential of this treatment approach to help patients live longer*
- *Under the trial's pre-specified statistical design, a statistically significant improvement in overall survival would establish a positive trial outcome, even if the progression-free survival dual primary endpoint was not met*
- *mRNA cancer immunotherapies are a key pillar of BioNTech's oncology strategy, which includes novel treatment combinations to maximize the potential of its diversified oncology pipeline and elevate treatment outcomes for patients*

MAINZ, Germany, October 13, 2026 – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") today announced the first topline results from the AHEAD-MERIT Phase 2/3 clinical trial (NCT04534205) for its investigational mRNA cancer immunotherapy BNT113 (tenumomeran /raplemomeran or "tenu-ra").

The clinical trial is evaluating BNT113 in combination with pembrolizumab compared to pembrolizumab monotherapy as a first-line treatment for patients with unresectable recurrent or metastatic human papillomavirus 16-positive ("HPV16+") head and neck squamous cell carcinoma ("HNSCC") expressing PD-L1. Approximately one third of HNSCC cases are associated with HPV infection. The majority are linked to HPV16, one of the most common, high-risk HPV types associated with cancer.

The Phase 3 part of AHEAD-MERIT has dual primary endpoints, progression-free survival ("PFS") and overall survival ("OS"), providing complementary measures of clinical benefit. At the analysis for PFS, BNT113 in combination with pembrolizumab did not demonstrate a statistically significant improvement in PFS versus pembrolizumab alone. The Independent Data Monitoring Committee ("IDMC") has recommended that the clinical trial continues as planned to evaluate the second primary endpoint of OS to complete the assessment of the potential of this approach to help patients live longer. Under the trial's pre-specified statistical design, a statistically significant improvement in overall survival would establish a positive trial outcome, even if the PFS dual primary endpoint was not met. BioNTech remains blinded to ongoing trial data in accordance with the trial's governance procedures.

"The potential of mRNA cancer immunotherapies in combination regimen lies in their ability to induce immune responses that may translate into durable clinical benefit and, ultimately, prolonged survival of patients. While the PFS result was not statistically significant at this first analysis, the data support continued evaluation of BNT113 plus pembrolizumab in this trial and show that it is engaging its intended therapeutic mechanism," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "As immune-mediated anti-tumor effects build and deepen over time, the analysis of the second dual primary endpoint, overall survival, will be critical to fully assess the potential of this approach to deliver durable benefit for patients with HPV-driven head and neck cancer."

Despite the distinct characteristics of HPV-positive tumors, there are currently no HPV-targeted treatments approved. Many patients with HPV16+ HNSCC experience disease progression with current standard-of-care treatments, underscoring the continued need for novel HPV-targeted options that improve long-term survival. The investigational mRNA cancer immunotherapy BNT113 encodes a fixed set of antigens to specifically target two HPV16-derived antigens that are frequently expressed on HPV16+ tumor cells.

BioNTech's mRNA-based cancer immunotherapies are a key pillar of its oncology strategy, which includes novel treatment combinations to maximize the potential of its diversified oncology pipeline and elevate treatment outcomes for patients.

About AHEAD-MERIT

AHEAD-MERIT is an open-label, controlled, multi-site, interventional, 2-arm, Phase 2/3 trial of BNT113 in combination with pembrolizumab compared to pembrolizumab monotherapy as first line treatment in patients with unresectable recurrent or metastatic human papillomavirus 16-positive ("HPV16+") head and neck squamous cell carcinoma ("HNSCC") expressing programmed cell death ligand-1 (PD-L1) with combined positive score (CPS) #1. The trial has multiple parts: Part A, is an initial non-randomized Safety Run-In Phase to confirm the safety and tolerability at the selected dose range level of BNT113 in combination with pembrolizumab; Part B, is a randomized part to generate pivotal efficacy and safety data of BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy in the first line setting in patients with unresectable recurrent or metastatic HPV16+ HNSCC expressing PD-L1 with CPS #1. Patients are treated with BNT113 in combination with pembrolizumab or with pembrolizumab monotherapy for up to approximately 24 months. Part B has two dual primary endpoints, progression-free survival ("PFS") and overall survival ("OS"), providing complementary measures of clinical benefit. Secondary endpoints include safety, objective response rate ("ORR") and duration of response ("DoR").

About BNT113

BNT113 (also known as tenumomeran/raplemomeran or "tenu-ra") is an investigational mRNA cancer immunotherapy encoding the E6 and E7 proteins of HPV16, that are frequently found in HPV16+ solid tumors. This mRNA cancer immunotherapy approach is designed to induce HPV16-specific anti-tumor immune responses, thereby aiming to enhance clinical responses in patients being treated with checkpoint inhibitor standard of care treatment. BNT113 received Fast Track Designation by the U.S. Food and Drug Administration ("FDA") in January 2026.

About head and neck squamous cell carcinoma (HNSCC)

HNSCC is the seventh most common cancer type worldwide with increasing global incidence, mainly driven by a rise in HPV16-related oropharyngeal tumors, the most common subtype of HNSCC.[1,2] About one third of HNSCC cases are HPV-positive following HPV infection, with a rising trend, of which about 90% of oropharyngeal cancers are driven by the subtype HPV16.[3,4]

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: BioNTech's ability to successfully develop and commercialize BNT113 (also known as tenumomeran/raplemomeran or "tenu-ra"), if approved; the rate and degree of market acceptance of BNT113, if approved; the initiation, timing, progress, and results of BioNTech's research and development programs, including data from the AHEAD-MERIT Phase 2/3 clinical trial and statements regarding the expected timing of initiation, enrollment, and completion of trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations, including expectations regarding the potential indications in which BNT113 may be approved, if at all; the targeted timing and number of additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; and discussions with regulatory agencies. 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 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; the impact of tariffs and escalations in trade policy; competition related to BioNTech's product candidates; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its product candidates; 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; 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.

Footnotes

[1] Sun H et al. Front Oncol. 2025 Sep 25;15:1665019.

[2] Barsouk A et al. Med Sci (Basel). 2023;11(2):42.

[3] Satapathy P et al. BMC Infect Dis. 2024 May 23;24(1):516.

[4] Ndiaye C et al. Lancet Oncol. 2014;15:1319–31.

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