BioNTech Receives FDA Fast Track Designation for mRNA Cancer Immunotherapy Candidate BNT113 in HPV16+ Head and Neck Cancer

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- *BNT113 is an investigational mRNA cancer immunotherapy that induces anti-tumor immune responses against human papilloma virus type 16 positive ("HPV16+") solid tumors, currently being evaluated in a pivotal clinical trial as a first-line treatment in patients with unresectable recurrent or metastatic HPV16+ head and neck squamous cell carcinoma ("HNSCC") expressing PD-L1*
- *HNSCC is the seventh most common cancer type worldwide, with about one third of cases being HPV-positive and of which the majority is driven by HPV16[1,2]; there are currently no HPV-targeted treatments approved for patients with HPV16+ HNSCC[3], leaving them with limited treatment options and poor prognosis*
- *With the Fast Track designation, the development of BNT113 can benefit from more frequent engagement with the U.S. Food and Drug Administration to support development and expedite regulatory review*

MAINZ, Germany, January 21, 2026 – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") today announced that the U.S. Food and Drug Administration ("FDA") has granted Fast Track designation to BNT113, an investigational mRNA cancer immunotherapy, for the treatment of patients with human papillomavirus type 16 positive ("HPV16+") head and neck squamous cell carcinoma ("HNSCC") expressing PD-L1, a distinct cancer type associated by infection with high-risk human papillomavirus.

The FDA Fast Track process is designed to facilitate the development and expedite the review of new drugs and vaccines that are intended to treat or prevent serious conditions and have the potential to address an unmet medical need. The designation has been granted based on preliminary safety and efficacy data from the ongoing pivotal Phase 2/3 AHEAD-MERIT clinical trial (NCT04534205) evaluating BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first-line treatment in patients with unresectable recurrent or metastatic HPV16+ HNSCC expressing PD-L1.

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.[2,4] About one third of HNSCC cases are HPV-positive following a HPV infection, with a rising trend, of which about 90% of oropharyngeal cancers are driven by the subtype HPV16.[1,5] Despite the distinct characteristics of HPV-positive tumors, there are currently no HPV-targeted treatments approved.[3] Many patients with HPV16+ HNSCC experience disease progression under current standard of care treatments with a median overall survival of 20.7 months[6], underlining the unmet medical need for novel HPV-targeted chemotherapy-free treatment options that improve long-term survival. HNSCC is among BioNTech's key tumor areas.

BNT113 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.

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 immunomodulators, targeted therapies such as antibody-drug conjugates (ADCs) and innovative chimeric antigen receptor (CAR) T cell therapies, and mRNA cancer immunotherapies. 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, Genmab, MediLink, OncoC4, Pfizer and Regeneron.

For more information, please visit www.BioNTech.com.

BioNTech Forward-Looking Statements
This statement 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 ability to successfully develop and commercialize BNT113, 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 the ongoing Phase 2/3 AHEAD-MERIT clinical trial; expectations regarding the potential indications in which BNT113 may be approved, if at all; 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 statement 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. 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, 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 statement in the event of new information, future developments or otherwise.

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