



BioNTech Receives FDA Fast Track Designation for its FixVac Candidate BNT111 in Advanced Melanoma

November 19, 2021

MAINZ, GERMANY, November 19, 2021 —[BioNTech SE](#) (Nasdaq: BNTX, “BioNTech” or “the Company”) today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation for BNT111, an investigational cancer immunotherapy for the potential treatment of advanced melanoma. BNT111 is the lead product candidate from BioNTech’s fully owned FixVac platform that utilizes a fixed combination of mRNA-encoded, tumor-associated antigens aiming to trigger a strong and precise immune response against cancer. The vaccine candidate is currently being investigated in a Phase 2 trial (EudraCT No.: [2020-002195-12](#); [NCT04526899](#)) in patients with anti-PD-1-refractory/relapsed unresectable Stage III or IV melanoma.

“The Fast Track Designation underlines the potential of our FixVac platform to address current treatment challenges of pre-treated and immune checkpoint blocker experienced melanoma with limited standard of care therapy options left. This is an important step to pave the way for this versatile new treatment approach in a high medical need setting,” said **Özlem Türeci, M.D., Co-founder and Chief Medical Officer of BioNTech**. “With the Fast Track status and support by the FDA, we aim to expedite the further development of the BNT111 program to provide a new therapeutic option for patients with life-threatening, hard-to-treat melanoma.”

Fast Track is a process designed to facilitate the development, and expedite the review, of new drugs and vaccines that are intended to treat or prevent serious conditions that have the potential to address an unmet medical need. The FDA’s decision is based on available preclinical and clinical data showing the potential of BNT111 to overcome current limitations in the treatment of inoperable therapy-resistant advanced-stage melanoma. With the Fast Track Designation, the development of BNT111 can benefit from more frequent engagement with the FDA, which will support the collection of appropriate data needed to accelerate BNT111’s development.

The ongoing randomized Phase 2 trial ([BNT111-01](#)) in patients with anti-PD1-refractory/relapsed unresectable Stage III or IV melanoma investigates BNT111 in combination with Libtayo® (cemiplimab), an anti-PD-1 monoclonal antibody being co-developed by Regeneron and Sanofi. The BNT111-01 trial which is conducted in collaboration with Regeneron is enrolling a total of 180 patients into three treatment arms in the United States, the United Kingdom, Australia, Spain, Germany, Italy and Poland. This trial seeks to support initial data reported from the ongoing Phase 1 Lipo-MERIT monotherapy dose escalation trial ([EudraCT No. 2013-001646-33](#); [NCT02410733](#); DOI: [10.1038/s41586-020-2537-9](#)) that demonstrated a favorable safety profile and anti-tumor responses of BNT111 alone and in combination with immune checkpoint inhibitor therapy in patients with advanced melanoma.

About BNT111

BNT111 is an intravenous therapeutic cancer immunotherapy candidate encoding a fixed set of four cancer-specific antigens optimized for immunogenicity and delivered as RNA-lipoplex formulation. Based on current data from an exploratory interim analysis of the ongoing Phase 1 Lipo-MERIT monotherapy dose escalation trial, published in [Nature](#), BNT111 induces novel antigen-specific anti-tumor immune responses and enhances pre-existing immune responses against the encoded melanoma-associated antigens (NY-ESO-1, MAGE-A3, tyrosinase, and TPTE), which are expressed in more than 90% of cutaneous melanomas. BNT111 is one of four clinical-stage FixVac product candidates within BioNTech’s development pipeline.

BNT111 is not yet authorized by any regulatory authority and the safety and efficacy has not yet been established.

About BioNTech

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company 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 T cells, bispecific checkpoint immuno-modulators, targeted cancer antibodies and 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 pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma and Pfizer.

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

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to statements concerning: BioNTech’s FixVac program candidate BNT111; timing for any data readouts of the Phase 2 trial; the registrational potential of any Phase 2 trial we may initiate for BNT111; 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 and specifically including, but not limited to, statements regarding timing or plans for initiation of clinical trials, enrollment or submission for and receipt of product approvals with respect to BioNTech’s product candidates; the ability of BioNTech’s mRNA technology to demonstrate clinical efficacy outside of BioNTech’s infectious disease platform; the potential safety and efficacy of our other product candidates; and BioNTech’s anticipated market opportunity and size for its product candidates, the rate and degree of market acceptance of BioNTech’s investigational medicines, if approved. Any forward-looking statements in this press release are based on BioNTech’s current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: discussions with regulatory agencies regarding timing and requirements for additional clinical trials; and the ability to produce comparable clinical results in future clinical trials.

For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, which is available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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