BioNTech Publishes Data from mRNA-based BNT111 FixVac Melanoma Trial in Nature

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- *Preliminary Phase 1 results from Lipo-MERIT trial with data from 89 patients highlight favorable tolerability profile of BNT111 in advanced melanoma patients*
- *Efficacy analysis in a subset of 42 checkpoint-inhibitor (CPI)-experienced metastatic melanoma patients shows that BNT111 mediates durable responses both as a single agent and in combination with anti-PD-1 antibodies*
- *Durable objective responses by BNT111 are associated with activation and strong expansion of tumor-antigen-specific CD4+ and CD8+ T cells*
- *Phase 2 trial with registrational potential planned to commence in 2020*

MAINZ, Germany, July 30, 2020 (GLOBE NEWSWIRE) -- BioNTech SE (NASDAQ: BNTX, "BioNTech" or "the Company"), announced today the publication of interim Phase 1 data for the Company's FixVac cancer vaccine program BNT111 in the journal *Nature*. The Lipo-MERIT trial is a multicenter, open-label, dose-escalation Phase 1 trial (NCT02410733) to evaluate safety and tolerability of vaccinated patients with stage IIIB-C and stage IV melanoma. The publication titled "*An RNA vaccine drives immunity in checkpoint-inhibitor-treated melanoma*" summarizes the findings of an exploratory interim analysis (data extraction date July 29, 2019). Safety assessment was performed in 89 advanced melanoma patients treated with intravenously delivered repeated doses of mRNA-based cancer vaccine BNT111 ranging from 7.2µg to 400µg. Overall, BNT111 treatment was well tolerated with no dose limiting toxicity. Most common adverse events were mild to moderate, transient flu-like symptoms, such as pyrexia and chills. Assessment of blood cytokines showed transient upregulation of cytokines such as Interferon-alpha (IFNa), Interferon-gamma (IFNγ) and Interleukin-12 (IL12) in line with a toll-like-receptor (TLR)-mediated antiviral immune modulation critical for expansion of Th1 type antigen-specific T cells.

Efficacy was evaluated in a subset of 42 checkpoint-inhibitor (CPI)-experienced patients with radiologically evaluable melanoma assessed by imaging of metastatic lesions before and after vaccination. At the data extraction date, three patients out of 25 patients in the BNT111 monotherapy group experienced a partial response, seven patients showed stable disease and one patient showed a complete metabolic remission of metastatic lesions. Of the 17 patients treated with the combination of BNT111 with anti-PD-1, six patients developed a partial response. Treatment with BNT111 resulted in the expansion and activation of circulating tumor-antigen-specific T cells with memory-function that exhibited strong cytotoxic activity against tumor cells. Vaccine-induced T cells displayed a Th1 phenotype which is of importance for cell-mediated immune responses such as activation of antigen-specific cytotoxic T cells.

This interim data shows that BNT111 alone and in combination with PD-1 checkpoint blockade, while being well tolerated, mediates durable objective responses in melanoma patients that had progressed after prior checkpoint blockade. Vaccine-induced antigen-specific memory T cells persisted for more than one year under continuous monthly vaccination.

BNT111 is composed of four melanoma antigens (NY-ESO-1, MAGE-A3, tyrosinase, and TPTE) and is the most advanced of five clinical-stage FixVac product candidates within BioNTech's broader development pipeline. The FixVac platform is an off-the-shelf mRNA immunotherapy approach that targets a fixed combination of shared non-mutated tumor-associated antigens specific to each cancer type.

Further FixVac cancer vaccine candidates are currently investigated in Phase 1 clinical trials for prostate cancer (BNT112) (*Clinicaltrials.gov Identifier NCT04382898*), HPV16-positive cancers (BNT113) (*Clinicaltrials.gov Identifier NCT03418480*), triple negative breast cancer (BNT114) (*Clinicaltrials.gov Identifier NCT02316457*) and ovarian cancer (BNT115) (*Clinicaltrials.gov Identifier NCT04163094*).

About FixVac
BioNTech's FixVac platform candidates consist of a fixed combination of mRNA-encoded non-mutated antigens shared within specific cancer types. They feature the Company's proprietary RNA-lipoplex delivery formulation which is designed to enhance stability and translation of the mRNA cargo as well as specifically target dendritic cells to trigger a strong and precise innate and adaptive immune response against cancer cells overexpressing the respective antigen.

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, bi-specific 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, Genevant, Fosun Pharma, and Pfizer.

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

BioNTech Forward-looking Statements
This press release contains "forward-looking statements" of BioNTech 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 commencement of a Phase 2 trial; and the registrational potential of any Phase 2 trial we may initiate for BNT111. Any forward-looking statements in this press release are based on BioNTech 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 filed with the SEC on March 31, 2020, which has been filed with the SEC and 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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