# BioNTech to Present Clinical and Preclinical Data Updates Across Multiple Immuno-Oncology Programs at 2023 SITC Annual Meeting

October 31, 2023

**MAINZ, Germany, October 31, 2023** – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") will present data updates across multiple immuno-oncology programs at the Society for Immunotherapy of Cancer's ("SITC") 38 th Annual Meeting in San Diego, USA, from November 1-5, 2023. The updates will feature one oral and four poster presentations for the investigational anti-CTLA-4 monoclonal antibody candidate BNT316/ONC-392 (gotistobart), the FixVac off-the-shelf mRNA cancer vaccine BNT116, the ex-vivo T cell therapy BNT221, and the two bi-specific antibodies BNT312/GEN1042 and BNT313/GEN1053.

**Highlights of BioNTech's clinical stage programs to be presented at SITC Annual Meeting 2023:**

- BioNTech will share new Phase 1/2 (NCT04140526) data of its next-generation anti-CTLA-4 monoclonal antibody candidate BNT316/ONC-392 (gotistobart) in non-small cell lung cancer ("NSCLC") patients that progressed on anti-PD-1/PD-L1 therapy. The candidate is being jointly developed with OncoC4, Inc. ("OncoC4"). The results show encouraging anti-tumor activity for BNT316/ONC-392 as monotherapy in patients with immuno-oncologic (IO)-resistant NSCLC, as well as a manageable safety profile.
- First clinical data will be presented on the LuCa-MERIT-1 Phase 1 study (NCT05142189) with BioNTech's off-the-shelf mRNA therapeutic cancer vaccine candidate BNT116 alone and in combination with cemiplimab in patients with advanced, unresectable, or metastatic NSCLC. The data show encouraging initial clinical activity in heavily pre-treated patients with advanced NSCLC and a tolerable safety profile.
- As a follow-up to the data recently presented at ESMO, BioNTech will give an update on the first-in-human Phase 1 study with BNT221 (NCT04625205), a personalized, autologous neoantigen-specific T cell therapy, which is being evaluated in patients with anti-PD-1- and anti-CTLA-4-pretreated advanced or metastatic melanoma. The data update includes nine patients. Seven of these patients have stable disease with shrinkage of tumor lesions in four of these patients. The initial results show a manageable safety profile with no dose limiting toxicities. In addition, preliminary translational data show multiple functional neoantigen-specific T cell responses in all evaluable patients.

BioNTech has established a diversified clinical oncology pipeline of more than 25 programs in high unmet medical need solid tumor indications in more than 30 clinical studies, including seven programs in advanced Phase 2 studies and one candidate in a pivotal Phase 3 study. BioNTech is advancing the Company's key programs into late-stage development while strengthening its clinical-stage oncology pipeline with synergistic potential, with the aim to deliver the next generation of oncology breakthroughs.

The full abstracts are available on the SITC Annual Meeting website. Click here for further information on BioNTech's pipeline candidates.

**Full Presentation Details:**

**Oral Presentation**
*Candidate*: BNT316/ONC-392 (gotistobart)
*Session Title:* Promising Novel Biotechnologies for the Next Wave of IO Innovation
*Abstract Title*: "Single-agent safety and activities of target-preserving anti-CTLA-4 antibody gotistobart (ONC-392/BNT316) in PD-(L)1 resistant metastatic NSCLC and population PK analysis in patients with solid tumors"
*Abstract Number:* 599
*Date:* Friday, November 3, 2023
*Time:* 3:30-5:10 PM PDT

**Poster Presentations**
*Candidate*: BNT116
*Abstract Title*: "Preliminary results from LuCa-MERIT-1, a first-in-human Phase I trial evaluating the fixed antigen RNA vaccine BNT116 in patients with advanced non-small cell lung cancer"
*Abstract Number:* 597
*Date:* Friday, November 3, 2023, and Saturday, November 4, 2023

*Candidate*: BNT221
*Abstract Title*: "Interim clinical and translational data from NTC-001, a phase I study to evaluate the non-engineered neoantigen-specific T cell product BNT221 in patients with advanced or metastatic" melanoma
*Abstract Number:* 769
*Date:* Saturday, November 4, 2023

*Candidate*: BNT312/GEN1042
*Abstract Title*: "GEN1042-mIgG2a, an Fc-inert mouse-human chimeric variant of GEN1042 (DuoBody®-CD40x4-1BB), exhibits in vivo antitumor activity and peripheral immune modulation"
*Abstract Number:* 1181
*Date:* Friday, November 3, 2023

*Candidate*: BNT313/GEN1053
*Abstract Title*: “Combination of HexaBody-CD27 with PD-(L)1 blockade potentiates single-agent activity leading to enhanced human T-cell effector functions in vitro”
*Abstract Number:* 813
*Date:* Friday, November 3, 2023

**About BioNTech**
Biopharmaceutical New Technologies (BioNTech) 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 (CAR) T cells, several protein-based therapeutics, including bispecific immune checkpoint modulators, targeted cancer antibodies and antibody-drug conjugate (ADC) therapeutics, as well as 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 Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron, Sanofi and Pfizer.

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

**BioNTech Forward-Looking Statements**
This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not be limited to, statements concerning: the initiation, timing, progress and results of BioNTech’s research and development programs in oncology; BioNTech’s current and future preclinical studies and clinical trials in oncology, including next-generation anti-CTLA-4 monoclonal antibody candidate BNT316/ONC-392 (gotistobart), mRNA cancer vaccine candidate BNT116, neoantigen-specific T cell therapy candidate BNT221 and antibody candidates BNT312/GEN1042 and BNT313/GEN1053, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work and the availability of results; timing for any data readouts; the registrational potential of any trial we may initiate for our product candidates; the potential safety and efficacy of our product candidates; and BioNTech’s anticipated market opportunity and size for its product candidates. 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 neither promises nor guarantees, and 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 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 preclinical and clinical data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; future commercial demand and medical need; the availability of raw materials; competition from other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; 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 product candidates; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its 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, 2023, and in subsequent filings made by BioNTech with the U.S. Securities and Exchange Commission (“SEC”), which are available on the SEC’s website at www.sec.gov. 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. These forward-looking statements are based on BioNTech’s current expectations and speak only as of the date hereof.

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