BioNTech to Present Multiple Program Updates Across Modalities at ESMO Congress 2023

October 16, 2023

- *Program updates include new data for investigational CAR-T and ex-vivo T cell therapies, a novel ADC, a FixVac off-the-shelf mRNA cancer vaccine, and a bi-specific antibody*
- *New data from BioNTech's investigational autologous CAR-T therapy BNT211 demonstrate the potential of the Company's innovative approach of combining an autologous CAR-T cell therapy targeting Claudin-6 ("CLDN6") with a CLDN6-encoding CAR-T cell amplifying mRNA vaccine ("CARVac")*
- *First-in-human data from Phase 1/2 study with next-generation Trop-2 targeting ADC candidate BNT325 (DB-1305) in advanced/metastatic solid tumors show encouraging initial efficacy signals and a manageable safety profile*
- *BioNTech advances key clinical programs into late-stage development while strengthening its clinical-stage oncology pipeline with synergistic potential*

MAINZ, Germany, October 16, 2023 – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") will present data across its oncology pipeline, covering multiple solid tumor types and novel mechanisms of action, at the European Society for Molecular Oncology ("ESMO") Congress 2023 in Madrid, Spain from October 20-24, 2023. The updates will feature oral and poster presentations for five candidates of BioNTech's clinical pipeline across the Company's drug classes, which comprise mRNA-based immunotherapies, cell therapies, protein-based therapeutics, and small molecules.

"This year's ESMO presentations underline the potential of BioNTech's precision medicine toolkit for the treatment of solid tumor indications with high unmet medical need, where many patients still remain underserved," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "We aim to develop and combine innovative immunotherapies for patients at different disease stages, which we believe could increase the likelihood of therapeutic success, reduce the risk of emergence of secondary resistance mechanisms, and unlock a larger potential patient population."

Highlights of BioNTech's clinical stage programs to be presented at ESMO Congress 2023:

Cell therapies

- BioNTech will present new data of its investigational autologous Claudin-6 (CLDN6)-directed CAR-T cell therapy BNT211 (NCT04503278), including data showing the potential of combining these CAR-T cells with a CLDN6-encoding CAR-T cell amplifying mRNA vaccine ("CARVac").
- Initial data from BioNTech's first-in-human Phase 1 study with BNT221 (NCT04625205), a personalized, autologous neoantigen-specific T cell therapy, will be presented. The initial results show a manageable safety profile and tumor regression in several patients with anti-PD-1 and anti-CTLA4 pretreated advanced or metastatic melanoma.

Protein-based therapeutics

- The Company will present first-in-human data of BNT325 (DB-1305) (NCT05438329), a next-generation Trop-2-targeting antibody-drug conjugate ("ADC"), which is being jointly developed with Duality Biologics. Initial data with this candidate show encouraging preliminary efficacy and a manageable safety profile in patients with advanced/metastatic non-small cell lung cancer (NSCLC).

mRNA-based immunotherapies

- A trial in progress poster will inform on the ongoing EMPOWERVAX Lung 1 Phase 2 trial (NCT05557591), which is being conducted together with Regeneron, evaluating the efficacy and safety of BioNTech's fully-owned off-the-shelf mRNA cancer vaccine candidate BNT116 in combination with cemiplimab versus cemiplimab alone in the first-line treatment of patients with advanced NSCLC and PD-L1 expression ≥50%.

In addition, BioNTech will also present pre-clinical data from its BNT314 (GEN1059) program, which is being jointly developed with Genmab. BNT314 (GEN1059) is a novel bispecific antibody candidate aimed at boosting antitumor immune responses through EpCAM-dependent 4-1BB agonistic activity. In pre-clinical studies, BNT314 (GEN1059) enhanced T-cell activation, proliferation, and effector functions *in vitro* and *ex vivo* and promoted antitumor activity *in vivo*. A Phase 1/2 trial is planned to start by early 2024 and will assess the safety and preliminary antitumor activity of BNT314 (GEN1059) in patients with advanced or metastatic solid tumors.

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 ESMO Congress website. Click here for further information on BioNTech's pipeline candidates.

Full Presentation Details:

Late-breaking presentation
Candidate: BNT211
Session Title: Developmental Therapeutics
Abstract Title: "BNT211-01: Interim results from a repeat dose escalation study of CLDN6 CAR-T cells manufactured with an automated process ± a CLDN6-encoding CAR-T cell-Amplifying RNA Vaccine (CARVac)"
Abstract Number: LBA35
Date: Monday, October 23, 2023
Time: 4:30-6:00 PM CET

Proffered paper session
Candidate: BNT221
Session title: Investigational Immunotherapy
Abstract Title: "NTC-001: A phase I study to test safety and efficacy of BNT221, a non-engineered neoantigen-specific T cell product, in patients with advanced or metastatic melanoma"
Abstract Number: 1017O
Date: Monday, October 23, 2023
Time: 10:15-11:40 AM CET

Poster
Candidate: BNT325 (DB-1305)
Session Title: Developmental Therapeutics
Abstract Title: "DB-1305 (a Trop-2 targeted antibody-drug-conjugate [ADC]) in patients with advanced solid tumors: Preliminary clinical results from the Phase 1/2a study"
Poster Number: 689P
Date: Monday, October 23, 2023

Candidate: BNT116
Session Title: NSCLC. metastatic
Abstract Title: "A phase 2 study of cemiplimab plus BNT116 versus cemiplimab alone in first-line treatment of patients with advanced non-small cell lung cancer with PD-L1 expression ≥50%"
Poster Number: 1503TiP
Date: Monday, October 23, 2023

Candidate: BNT314 (GEN1059)
Session Title: Investigational Immunotherapy
Abstract Title: "DuoBody-EpCAMx4-1BB mediates conditional T cell co-stimulation and promotes antitumor activity in preclinical models"
Poster Number: 1072P
Date: Monday, October 23, 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 CAR-T cell therapy candidate BNT211, neoantigen-specific T cell therapy candidate BNT221, Trop-2-targeting ADC candidate BNT325 (DB-1305), bispecific antibody candidate BNT314 (GEN1059) and mRNA cancer vaccine candidate BNT116, 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.

CONTACTS

Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513
Media@biontech.de

Investor Relations
Victoria Meissner, M.D.
+1 617 528 8293
Investors@biontech.de