BioNTech to Present Clinical Data Updates Across mRNA and Immunomodulatory Oncology Portfolio at ESMO Congress 2024

September 5, 2024

MAINZ, Germany, September 05, 2024 – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") will present clinical trial data for selected assets from its multi-platform oncology pipeline at the European Society for Molecular Oncology ("ESMO") Congress 2024 in Barcelona, Spain from September 13-17, 2024. The oral and poster presentations will feature programs across BioNTech's clinical pipeline, including mRNA-based cancer vaccines, next-generation immunomodulators and targeted therapy approaches.

"We believe that the future of cancer treatment will be driven by the combination of modalities, including immunomodulators, targeted and mRNA-based therapies," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "At this year's ESMO, we will present data from three clinical trials with BNT327/PM8002, one of the key backbones for our combination treatment strategy. This bispecific antibody will be an element in multiple novel combination treatment approaches that may open up new synergistic mechanisms of action. Our mRNA platforms are another important component of our combination strategy. At ESMO, we will present clinical data that further support the proof of concept of our mRNA-based FixVac approach, which targets non-mutated tumor-associated antigens, showing early clinical activity across various indications."

Highlights of BioNTech's clinical stage programs to be presented at ESMO Congress 2024:

- Updates on several Phase 2 and Phase 1/2 clinical trials evaluating **BNT327/PM8002** in various indications as monotherapy and in combination with chemotherapy will be presented. BNT327/PM8002 is an investigational bispecific antibody combining PD-L1 checkpoint inhibition with VEGF-A neutralization for vascular normalization and immunostimulation in the microenvironment of the tumor. Two oral presentations and one poster will provide clinical data updates for cohorts with advanced non-small cell lung cancer ("NSCLC"), locally advanced/metastatic triple-negative breast cancer ("TNBC") and advanced renal cell carcinoma. BNT327/PM8002 is being developed in collaboration with Biotheus Inc. ("Biotheus").
- Preliminary data from an ongoing clinical Phase 2 trial (NCT04534205) evaluating **BNT113** in combination with PD-1 blockade and data from an investigator-initiated Phase 1/2 clinical trial (NCT03418480) evaluating BNT113 as monotherapy in HPV16-driven cancers will be presented. The data show immunogenicity and antitumor activity in heavily pre-treated patients in several HPV16-positive indications, including head and neck cancer, and a manageable safety profile. BNT113 is an investigational lipoplex-formulated uridine mRNA immunotherapy encoding E6 and E7 antigens of HPV16.
- Preliminary data of the randomized Phase 2 clinical trial (NCT05446298) with **BNT316/ONC-392 (gotistobart),** an investigational anti-CTLA-4 antibody, in combination with pembrolizumab in patients with platinum-resistant recurrent ovarian cancer ("PROC") will be presented in a late-breaking session. BNT316/ONC-392 is being developed in collaboration with OncoC4, Inc. ("OncoC4").
- Follow-up data of activity and immune responses from the ongoing first-in-human Phase 1 clinical trial (NCT04503278) with **BNT211** in patients with relapsed/refractory CLDN6+ solid tumors will be presented. BNT211 combines autologous CAR-T cells directed against the oncofetal antigen Claudin-6 ("CLDN6") and an CLDN6-encoding CAR-T cell amplifying mRNA vaccine ("CARVac"). The data update shows signs of antitumor activity across all indications and an increased persistence of cancer-specific CAR-T cells when combined with CARVac, for example in patients with testicular and ovarian cancers. The safety profile is consistent with the previously published data of CAR-T therapies.

BioNTech has established a diversified clinical oncology pipeline including mRNA-based therapeutic cancer vaccines, targeted therapies comprising cell therapies and ADCs, and novel immunomodulators in unmet medical need solid tumor indications. These investigational treatments are currently being evaluated in more than 32 clinical trials, including eight programs in advanced Phase 2 trials and two assets in pivotal Phase 3 trials globally. BioNTech is advancing the Company's key programs into late-stage development with the aim of having ten or more potentially registrational trials in its oncology pipeline by the end of 2024.

The full abstracts are available on the ESMO Congress website. Click here for further information on BioNTech's pipeline assets.

Full presentation details:

Late-breaking presentation
Asset: BNT316/ONC-392 (gotistobart)
Session title: Mini oral session 1: Gynaecological cancers (ID 166)
Room: Burgos Auditorium - Hall 5
Presentation title: "A randomized, Phase 2, dose optimization of gotistobart, a pH-sensitive anti-CTLA-4, in combination with standard dose pembrolizumab in platinum-resistant recurrent ovarian cancer: safety, efficacy and dose optimization (PRESERVE-004/GOG-3081)"
Presentation number: LBA32
Date: Sunday, September 15, 2024
Lecture time: 09:10 AM – 09:15 AM CEST

Mini oral presentations
Asset: BNT113
Session title: Mini oral session: Investigational immunotherapy

Room: Granada Auditorium - Hall 6
Presentation title: “HARE-40: A phase I/II trial of therapeutic HPV vaccine (BNT113) in patients with HPV16 driven carcinoma”
Presentation number: 999MO
Date: Monday, September 16, 2024
Lecture time: 11:15 AM – 11:20 AM CEST

Asset: BNT211
Session title: Proffered paper session 2: Developmental therapeutics
Room: Salamanca Auditorium - Hall 5
Presentation title: “Updated results from BNT211-01 (NCT04503278), an ongoing, first-in-human, Phase 1 study evaluating safety and efficacy of CLDN6 CAR T cells and a CLDN6-encoding mRNA vaccine in patients with relapsed/refractory CLDN6+ solid tumors”
Presentation number: 611O
Date: Sunday, September 15, 2024
Lecture time: 03:45 PM – 03:55 PM CEST

Asset: BNT327/PM8002
Session title: Mini oral session: NSCLC metastatic
Room: Santander Auditorium - Hall 5
Presentation title: “A Phase II Safety and Efficacy Study of PM8002/BNT327 in Combination with Chemotherapy in Patients with EGFR-mutated Non-Small Cell Lung Cancer (NSCLC)”
Presentation number: 1255MO
Date: Saturday, September 14, 2024
Lecture time: 10:20 AM – 10:25 AM CEST

Asset: BNT327/PM8002
Session title: Mini oral session 2: Breast cancer, metastatic
Room: Barcelona Auditorium - Hall 2
Presentation title: “A Phase Ib/II Study to Assess the Safety and Efficacy of PM8002/BNT327 in Combination with Nab-Paclitaxel for First Line Treatment of Locally Advanced or Metastatic Triple-Negative Breast Cancer”
Presentation number: 348MO
Date: Monday, September 16, 2024
Lecture time: 08:35 AM – 08:40 AM CEST

Posters
Asset: BNT113
Poster title: " Exploratory efficacy and translational results from the safety run in of AHEAD-MERIT, a phase II trial of first line pembrolizumab plus the fixed-antigen cancer vaccine BNT113 in advanced HPV16+ HNSCC "
Room: Hall 6
Poster number: 877P
Date: Saturday, September 14, 2024

Asset: BNT314/GEN1059
Poster title: “Phase 1/2 dose escalation/expansion trial to evaluate safety and preliminary efficacy of DuoBody-EpCAMx4-1BB (BNT314/GEN1059) alone or in combination with an immune checkpoint inhibitor in patients with malignant solid tumors”
Room: Hall 6
Poster number: 1072TiP
Date: Saturday, September 14, 2024

Asset: BNT323/DB-1303
Poster title: “DYNASTY-Breast02: A Phase 3 trial of BNT323/DB-1303 vs Investigator's Choice Chemotherapy in HER2-low, Hormone Receptor Positive, Metastatic Breast Cancer”
Room: Hall 6
Poster number: 436TiP
Abstract number: 7363
Date: Monday, September 16, 2024

Asset: BNT327/PM8002
Poster title: “A Phase Ib/IIa Trial to Evaluate the Safety and Efficacy of PM8002/ BNT327, a Bispecific Antibody Targeting PD-L1 and VEGF-A, as a Monotherapy in Patients with advanced renal cell carcinoma”
Room: Hall 6
Poster number: 1692P
Date: Sunday, September 15, 2024

About BioNTech
Biopharmaceutical New Technologies (BioNTech) is a global next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. BioNTech 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 and specialized pharmaceutical collaborators, including Biotheus, DualityBio, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, MediLink, OncoC4, Pfizer and Regeneron.

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

BioNTech Forward-Looking Statements
This press release 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: the initiation, timing, progress and results of BioNTech's research and development programs in oncology, including the targeted timing and number of additional potentially registrational trials; BioNTech's and its collaborators' current and future preclinical studies and clinical trials in oncology, including the investigational lipoplex-formulated uridine mRNA immunotherapy BNT113, the investigational bispecific antibodies BNT327/PM8002 and BNT314/GEN1059, the investigational anti-CTLA-4 antibody BNT316/ONC-392 (gotistobart) in combination with pembrolizumab, the investigational CAR-T cell therapy BNT211, and the investigational ADC therapy BNT323/DB-1303; 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, including, but not limited to, statements regarding timing or plans for initiation or enrollment of clinical trials, or submission for and receipt of product approvals and potential commercialization 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; and the potential safety and efficacy of BioNTech's 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 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. 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, including the data discussed in this release, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the ability to produce comparable clinical results in future clinical trials; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its product candidates; discussions with regulatory agencies regarding timing and requirements for additional clinical trials; BioNTech's and its counterparties' ability to manage and source necessary energy resources; 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 development candidates and investigational medicines; unforeseen safety issues and potential claims that are alleged to arise from the use of products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market, if approved, its product candidates; BioNTech's ability to manage its development and expansion; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale its production capabilities and manufacture its products and product candidates; risks relating to the global financial system and markets; 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, 2024, 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 press release in the event of new information, future developments or otherwise.

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