BioNTech to Present Clinical Data Updates for Personalized mRNA-based and Targeted Oncology Candidates at AACR 2024

March 11, 2024

MAINZ, Germany, March 11, 2024 – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") will present clinical trial data for selected candidates from its oncology pipeline at the American Association for Cancer Research ("AACR") Annual Meeting 2024 in San Diego, California, from April 5-10, 2024. The oral and poster presentations will feature BioNTech's investigational mRNA-based cancer vaccine and novel investigational antibody-drug conjugate ("ADC") approaches.

"This year's AACR presentations feature candidates from our individualized and off-the-shelf mRNA cancer vaccine platforms, including a late-breaking presentation of longer-term follow-up data with our individualized mRNA-based candidate autogene cevumeran in patients with pancreatic cancer," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "Our investigational mRNA cancer vaccine approaches are an important pillar in our oncology portfolio, aimed at eliminating residual tumor foci and reducing the tumor burden by targeting multiple antigens at once. The data we will be sharing at AACR show how we're delivering on our commitment to patients through investigating novel treatment approaches."

Highlights of BioNTech's clinical stage programs to be presented at AACR Annual Meeting 2024:

- Longer-term follow-up data of activity and immune responses of the investigator-initiated first-in-human Phase 1 trial (NCT04161755) with the mRNA-based individualized neoantigen-specific immunotherapy ("iNeST") candidate autogene cevumeran (BNT122, RO7198457) in patients with resected pancreatic ductal adenocarcinoma ("PDAC") will be presented. The results of the Phase 1 trial were published in Nature. The candidate is currently being evaluated in an ongoing randomized Phase 2 trial (NCT05968326) in PDAC and is jointly being developed by BioNTech and Genentech, a member of the Roche Group.
- BioNTech will present preliminary results on the LuCa-MERIT-1 Phase 1 trial (NCT05142189) with its off-the-shelf, shared tumor-associated-antigen-based mRNA therapeutic cancer vaccine candidate BNT116 in combination with docetaxel in patients with advanced unresectable or metastatic non-small cell lung cancer ("NSCLC"). The data show antitumor activity, consistent induction of immune responses in heavily pre-treated patients with advanced NSCLC, and a manageable safety profile.
- A trial in progress poster will inform on the global Phase 1/2a trial (NCT05914116) of the topoisomerase-1 inhibitor-based ADC candidate BNT324/DB-1311 targeting the immune checkpoint protein B7H3 in patients with pretreated advanced or metastatic solid tumors. The candidate is being jointly developed by BioNTech and Duality Biologics.

BioNTech has established a diversified clinical oncology pipeline of more than 20 clinical programs along mRNA-based therapeutic cancer vaccines, targeted therapies comprising cell therapies and ADCs, and novel immunomodulators in unmet medical need solid tumor indications. These candidates are currently being evaluated in more than 30 clinical studies, including nine programs in advanced Phase 2 trials and two candidates in pivotal Phase 3 trials. BioNTech is advancing the Company's key programs into late-stage development with the aim to have ten or more potentially registrational trials in its oncology pipeline by the end of 2024.

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

Full presentation details:

Late-breaking presentation
Candidate: Autogene cevumeran (BNT122, RO7198457)
Session Title: "Cancer Vaccines: Ready for Prime Time?"
Abstract Title: "Personalized RNA neoantigen vaccines induce long-lived CD8+ T effector cells in pancreatic cancer"
Abstract Number: CT025
Date: Sunday, April 7, 2024
Time: 3:00 PM - 5:00 PM PST

Posters
Candidate: BNT116
Session Title: Phase I Clinical Trials
Abstract Title: "Preliminary results from LuCa-MERIT-1, a first-in-human Phase I trial evaluating the hexavalent TAA-encoding mRNA vaccine BNT116 + docetaxel in patients with advanced non-small cell lung cancer"
Location: Poster Section 48
Poster Number: CT051
Date: Monday, April 8, 2024

Candidate: BNT324/DB-1311
Session Title: Phase I Clinical Trials in Progress 2
Abstract Title: "A phase 1/2a, multicenter, open-label, first-in-human study to assess the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of DB-1311 (a B7-H3-targeting ADC) in patients with advanced/metastatic solid tumors"
Location: Poster Section 50
Poster Number: CT165

Date: Monday, April 8, 2024

About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a 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 pharmaceutical collaborators, including Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron and Pfizer.

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 be 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 current and future preclinical studies and clinical trials in oncology, including individualized neoantigen specific immunotherapy ("iNeST") autogene cevumeran (BNT122, RO7198457) in patients with resected PDAC, mRNA cancer vaccine candidate BNT116 in combination with docetaxel in advanced unresectable or metastatic NSCLC, and ADC candidate BNT324/DB-1311 in advanced or metastatic solid tumors, 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 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. 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. 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, 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 the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; 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 BioNTech's production capabilities and manufacture BioNTech's products and BioNTech's 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 September 30, 2023, and in subsequent filings made by BioNTech with the 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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