BioNTech SE Provides Update on Corporate Progress and Third Quarter 2019 Financial Results

November 14, 2019

- *Successfully transferred IND for BNT321 to BioNTech. All necessary safety and other reports and an updated protocol filed with the FDA. Phase 1/2 trial of BNT321 expected to be re-initiated in the fourth quarter of 2019.*
- *Initiated a first-in-human global Phase 1/2a trial in collaboration with Genmab for GEN1042 (BNT312), a bispecific antibody targeting CD40 and 4-1BB for the treatment of multiple solid tumors.*
- *Entered into a clinical trial supply agreement with Regeneron to supply cemiplimab for use in combination with BioNTech's BNT112 in a first-in-human Phase 1/2 trial of FixVac in advanced prostate cancer and received approval of clinical trial applications (CTAs) in various European countries to support the initiation of this trial.*
- *Filed IND for BNT411. Phase 1/2a clinical trial of BNT411 expected to be initiated as a mono- or combination therapy in solid tumors in the first half of 2020. The selective toll-like receptor 7 agonist has shown activity in numerous mouse tumor models, such as reduced tumor growth and tumor clearance.*
- *Ended the third quarter of 2019 with cash equivalents of $505m (€463.3m[1]).*
- *Raised additional $149m (approx. €135m) in net proceeds (after underwriting discounts and commissions) in Nasdaq IPO in October/November 2019.*

Conference call and webcast (in English) scheduled for November 14, 2019 at 08:00 a.m. ET
(2:00 p.m. CET)

MAINZ, Germany, Nov. 14, 2019 (GLOBE NEWSWIRE) -- BioNTech SE (NASDAQ: BNTX, "BioNTech" or "the Company"), a clinical-stage biotechnology company focused on patient-specific immunotherapies for the treatment of cancer and other serious diseases, today provided an update on its corporate progress and reported financial results for the quarter ended September 30, 2019.

"In the third quarter, we achieved important milestones in our ambition to become the leading global biotechnology company for individualized cancer medicine," said **Prof. Ugur Sahin**, BioNTech's CEO. "In addition to our successful IPO, we are also pleased with the advancement of our programs. We initiated the second first-in-human clinical trial in our 50:50 collaboration program with Genmab and successfully transferred the IND for BNT321 from MabVax to BioNTech. Our balance sheet remains strong and we are looking forward to advancing the development of our planned clinical development program and growth plans. We plan to initiate up to six first-in-human clinical trials by the end of 2020."

[1] ECB exchange rate on September 30th was 1.0889.

Key Pipeline Updates

Below is a summary of our clinical product candidates, organized by platform.

Oncology

FixVac: Our FixVac product candidates contain selected combinations of pharmacologically optimized uridine mRNA encoding known cancer-specific shared antigens.

- *BNT111 (advanced melanoma)*: We expect to initiate both a Phase 2 trial and a registrational, randomized Phase 3 trial for BNT111 in 2020.
- *BNT112 (prostate cancer)*: We plan to initiate a Phase 1/2 trial for BNT112 targeting prostate cancer in the second half of 2019. In the third quarter of 2019, CTAs were approved in various European countries to support the initiation of this trial.
- *BNT113 (HPV+ head and neck cancers)*: We are planning to initiate a Phase 2 trial for BNT113 in HPV+ head and neck cancers by the second half of 2020.
- *BNT114 (triple negative breast cancer)*: We are conducting a Phase 1 trial of BNT114 in triple negative breast cancer and expect to report a data update in the first half of 2020.

Individualized neoantigen specific immunotherapy (iNeST): Our iNeST immunotherapies contain unmodified, pharmacologically-optimized mRNA encoding up to 20 patient-specific neoantigens and also feature our proprietary RNA-LPX formulation. We are conducting, in collaboration with Genentech, clinical trials of our iNeST product candidate, RO7198457 (BNT122). We and Genentech expect to provide a data update from our RO7198457 (BNT122) Phase 1 trial in multiple solid tumors in 2020 and expect to report topline interim data from our RO7198457 (BNT122) Phase 2 trial in first-line melanoma in the second half of 2020.

mRNA intratumoral immunotherapy: In collaboration with Sanofi, we are conducting a Phase 1/2 trial of SAR441000 (BNT131), our first mRNA-based intratumoral immunotherapy, as a monotherapy or in combination with cemiplimab in patients with solid tumors. We plan to provide an update on this trial in the second half of 2020.

CLDN6 CAR-T cell immunotherapy: We are developing a proprietary chimeric antigen receptor T cell, or CAR T, product candidate, BNT211, targeting Claudin-6, or CLDN6, a novel solid tumor-specific antigen. We expect to initiate a Phase 1/2 clinical trial for BNT211 in patients with advanced CLDN6 + solid tumors in the first half of 2020.

Next-generation checkpoint immunomodulators: We are developing, in collaboration with Genmab, novel bispecific antibodies that are designed for conditional activation of immunostimulatory checkpoint molecules. Our first bispecific candidates are GEN1046 (BNT311), which targets PD-L1 in conjunction with 4-1BB, and GEN1042 (BNT312), which targets CD40 in conjunction with 4-1BB. Genmab has initiated a Phase 1/2a trial for each of GEN1046 (BNT311) and GEN1042 (BNT312) in solid tumors.

GEN1042 (BNT312) is a bispecific antibody designed to enhance an anti-tumor immune response through conditional CD40-mediated stimulation of antigen presenting cells crosslinked with conditional stimulation of 4-1BB+ T cells. We and Genmab began enrollment in August 2019 for a Phase 1/2a trial of BNT312 for the treatment of malignant solid tumors, including non-small cell lung cancer, colorectal cancer and melanoma. The first patient in this study was dosed in September 2019.

In the preclinical setting, GEN1042 (BNT312) activated antigen presenting cells and enhanced T cell activation, and also resulted in the conditional activation and expansion of previously activated CD8+ T cells and cytokines. The ongoing Phase 1/2a trial has an estimated enrollment of 126 participants and is an open-label, multi-center safety trial of GEN1042 (BNT312) administered intravenously every 21 days. The trial consists of a dose escalation phase and an expansion phase which will be initiated once the recommended Phase 2 dose has been determined. GEN1042 (BNT312) is one of two bispecific antibodies currently in clinical trials by Genmab and BioNTech as part of a 50:50 strategic collaboration in which development costs and future profit are shared. BioNTech and Genmab shall jointly commercialize GEN1042 (BNT312) as to be further defined in a commercialization agreement between the parties.

Targeted cancer antibodies: BNT321 (MVT-5873) is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLe^a), a novel epitope expressed specifically in pancreatic and other solid tumors. BNT321 (MVT-5873) is currently in Phase 1 clinical development in pancreatic cancer. We have filed the updated protocol and supporting regulatory documentation with the FDA to transfer the IND for MVT-5873 to BioNTech and resume the clinical trial following the acquisition of the assets of MabVax Therapeutics Holdings, Inc. and MabVax Therapeutics, Inc. in May 2019. The IND transfer of MVT-5873 to BioNTech was successfully achieved in August 2019. We expect the trial to be re-initiated in the fourth quarter of 2019 and anticipate resuming patient enrollment in the fourth quarter. This will be the first BioNTech-sponsored study conducted in the US under an IND.

BNT321 is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A or CA19-9, an epitope expressed in pancreatic and other gastrointestinal cancers that plays a role in tumor adhesion and metastasis formation and is a marker of an aggressive cancer phenotype.

In a Phase 1 dose-escalating study, 12 pancreatic cancer patients with CA19-9 positive metastatic malignancies were injected with MVT-2163, a radiolabelled PET imaging version of BNT321. A significant portion of patients demonstrated high uptake of BNT321 in tumor tissue, suggesting that the PET imaging high-affinity antibody version of BNT321 may be used as a theranostic tool for the sensitive detection of primary tumors and metastatic disease. BNT321 may also have potential to deliver therapeutic doses of radiation to cancer cells.

BNT321 has also been investigated as a naked antibody in an open-label, multi-center, non-randomized dose escalation Phase 1/2 trial evaluating the safety and recommended Phase 2 dose both as a monotherapy or in combination with a standard of care chemotherapy. In this cohort, BNT321 was given in combination with nab-paclitaxel and gemcitabine to six patients newly diagnosed with CA19-9+ pancreatic cancer. At a dose of 0.125mg/kg, BNT321 was generally well tolerated by all patients when added to first line chemotherapy. All six patients evaluated had measurable tumor reductions by RECIST criteria, with four patients meeting the criteria for partial response and two patients meeting the criteria for stable disease.

BioNTech intends to further evaluate BNT321 in CA19-9+ tumors, including in advanced pancreatic cancer and expects to resume the Phase 1/2 trial in the fourth quarter of 2019.

Small molecule immunomodulators: BNT411 is our novel small molecule TLR7 agonist product candidate. BNT411 is engineered for high potency and high selectivity for the TLR7 receptor to activate both the adaptive and innate immune system. BNT411 will be given as a monotherapy or in combination with chemotherapy and/or checkpoint inhibitors in multiple solid tumors, including colorectal cancer, bladder cancer and small cell lung cancer. We filed an IND with the FDA in early November 2019 and expect to initiate a Phase 1/2a clinical trial of BNT411 in the first half of 2020.

In preclinical studies, BNT411 induced a strong type-1 Interferon-dominated release of cytokines and a potent stimulation of antigen-specific CD8+ T cells, B cells, and innate immune cells such as NK cells and macrophages, resulting in potent anti-tumor activity in various mouse models.

Recent Corporate Developments

Clinical trial supply agreement with Regeneron:
In November 2019, BioNTech signed a clinical trial supply agreement with Regeneron to supply cemiplimab for use in combination with BioNTech's BNT112 in a first-in-human Phase 1/2 trial in advanced prostate cancer. Under the terms of the agreement, BioNTech and Regeneron will agree to a joint clinical development plan in prostate cancer and Regeneron will agree to supply their PD-1 checkpoint inhibitor Libtayo® (cemiplimab) at no cost to BioNTech for use in combination with BNT112 in BioNTech's planned Phase 1/2 trial. BioNTech and Regeneron will each retain full commercial rights to BNT112 and Libtayo respectively. BioNTech will be the sponsor of the trial. The CTA in various European countries was accepted on November 5, 2019. BioNTech expects to initiate the single-agent dose escalation part of the Phase 1/2 trial in the fourth quarter of 2019.

Exercise of Greenshoe:
On October 29, 2019, JP Morgan Securities LLC, BOFA Securities, Inc, UBS Securities LLC and SVB Leerink LLC, as representatives of the lead joint book-running managers of BioNTech's recently closed initial public offering on the Nasdaq Global Market, exercised their over-allotment option to purchase an additional 517,408 American Depository Shares ("ADSs") at a price to the public of US$15 per ADS, representing 517,408 ordinary shares with no par value with a notional amount attributable to each ordinary share of €1 each. The option exercise closed on November 6, 2019 and raised additional net proceeds of approximately $7 million (€6,6 million), after deducting underwriting discounts and commissions.

Third Quarter 2019 Financial Results

Cash Position: Cash and cash equivalents as of September 30, 2019, were €463.3 million, compared to €411.5 million as of December 31, 2018.

Revenue: Total revenue, consisting primarily of revenue from collaborative agreements, was €28.7 million for the quarter ended September 30, 2019, compared to €20.4 million for the quarter ended September 30, 2018. The increase was primarily due to progress in our collaboration agreements with Genentech and Eli Lilly.

Research and Development Expenses: Research and development expenses were €50.4 million for the quarter ended September 30, 2019, compared to €32.8 million for the quarter ended September 30, 2018. The increase was primarily due to an increase in headcount, the expense recognized from the granting of options under the ESOP program and higher expenses regarding our collaboration agreements.

General and Administrative Expenses: General and administrative expenses were €10.6 million for the quarter ended September 30, 2019, compared to €6.6 million for the quarter ended September 30, 2018. This increase was primarily due to an increase in headcount and the expense recognized from the granting of options under the ESOP program.

Net Loss: Net loss was €30.1 million for the quarter ended September 30, 2019, compared to net loss of €23.5 million for the quarter ended September 30, 2018.

Shares Outstanding: Shares outstanding as of September 30, 2019 were 216,262,336.

Full financial statements can be found in the 6-K filing as published on the SEC website under https://www.sec.gov/.

Conference Call and Webcast Information

BioNTech SE will host a conference call and webcast today at 08:00 a.m. ET (2:00 p.m. CET) to report its financial results for the third quarter ended September 30, 2019 and provide a corporate update.

To participate in the conference call, please dial the following numbers five minutes prior to the start of the call and provide the Conference ID: 8453733.

United States international: +1 631 510 7495
United States domestic (toll-free): +1 866 966 1396
Germany: +49 692 443 7351

Participants may also access the slides and the webcast of the conference call via the "Events & Presentations" page of the Investor Relations section of the Company's website at https://biontech.de/. A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company's website for 30 days following the call.

About BioNTech

BioNTech was founded in 2008 on the understanding that every cancer patient's tumor is unique and therefore each patient's treatment should be individualized. Its cutting-edge pipeline includes individualized mRNA-based product candidates, innovative chimeric antigen receptor T cells, novel checkpoint immunomodulators, targeted cancer antibodies and small molecules. BioNTech has established relationships with seven pharmaceutical collaborators, including Eli Lilly and Company, Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Genevant and Pfizer, and has published over 150 peer-reviewed publications on its scientific approach.

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 planned next steps in BioNTech's pipeline programs and specifically including, but not limited to, statements regarding the re-initiation of clinical trials for BNT321; plans to initiate clinical trials of BNT111, BNT112, BNT113 and BNT211; and expectations for data announcements with respect to BioNTech's iNeST and BNT114 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. You should review the risks and uncertainties described under the heading "Risk Factors" and those described in BioNTech's Prospectus filed with the U.S. Securities and Exchange Commission (SEC) on October 11, 2019 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at https://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.

For more information, please contact:

BioNTech SE

Michael Boehler, MD, Head of Global External Communications
Tel: +49 (0)6131 9084 1640
Email: Michael.Boehler@biontech.de

For all media inquiries:

Trophic Communications
Gretchen Schweitzer / Stephanie May, PhD
Tel: +49 (0)89 23 88 77 30 or +49 171 185 56 82
Email: May@trophic.eu