BioNTech Receives Priority Medicines (PRIME) Designation from EMA for Enhanced Regulatory Support of CAR-T Candidate BNT211 in Testicular Cancer

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- *First BioNTech product candidate to receive priority medicines (PRIME) designation by the European Medicines Agency for enhanced regulatory support facilitating the clinical development of the investigational cell therapy candidate BNT211 in the third- or later-line setting in patients with heavily pretreated testicular cancer*
- *Designation follows positive interim Phase 1/2 data for BNT211 demonstrating an encouraging safety profile and early signs of anti-tumor activity in testicular cancer patients*
- *BNT211 combines two innovative approaches in one regimen, an autologous chimeric antigen receptor (CAR) T cell therapy targeting the oncofetal antigen Claudin-6 (CLDN6) and a CLDN6-encoding CAR-T cell amplifying RNA vaccine (CARVac) to improve persistence and functionality of the adoptively transferred cells*
- *The European Medicines Agency's priority medicines status is granted to drug candidates that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options*

MAINZ, Germany, June 23, 2022 (GLOBE NEWSWIRE) – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") today announced that that the European Medicines Agency (EMA) has granted Priority Medicines (PRIME) designation to BioNTech's fully owned product candidate BNT211 for the third- or later-line treatment of testicular germ cell tumors. BNT211 is a potential first-in-class therapeutic approach which comprises a synergistic combination of two of the Company's proprietary drug products, an autologous chimeric antigen receptor (CAR) T cell therapy targeting the oncofetal antigen Claudin-6 (CLDN6) and a CLDN6-encoding CAR-T cell amplifying RNA vaccine (CARVac). The product candidate is currently being investigated in an ongoing Phase 1/2 study (NCT04503278; 2019-004323-20) that aims to evaluate the safety and preliminary efficacy in heavily pretreated patients with relapsed or refractory advanced solid tumors.

"Patients with relapsed or treatment refractory testicular cancers have a poor prognosis with limited remaining treatment options. The PRIME designation underlines the potential of our approach in this high medical need setting. Our approach brings together several new elements: Firstly, targeting CLDN6, a pan-cancer cell surface marker, secondly, our CAR design, and thirdly, "remote control" of CAR T cells by our uridine RNA-lipoplex based vaccine. We believe that a combination of engineered T cells and mRNA vaccines in one treatment regimen can stimulate and expand T cells. This could enable us to develop truly powerful precision immunotherapies," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "With the PRIME status and support by the EMA, we aim to expedite the further development of the BNT211 program to bring a novel therapeutic option for patients with life-threatening testicular cancer, and thus to extend the successes of CAR-T therapy also to hard-to-treat solid tumors."

The designation is based on positive preliminary Phase 1/2 data from the ongoing study that was presented at the AACR Annual Meeting in April 2022. The results demonstrated that treatment with CLDN6 CAR-T alone or in combination with CARVac was well tolerated and showed encouraging signs of anti-tumor activity in testicular cancer patients at the first evaluated dose levels. In the study all six patients with heavily pretreated testicular cancer eligible for efficacy analysis showed clinical benefits highlighting the potential of this novel approach. One patient achieved a complete response 18 weeks after infusion. Three patients achieved a partial response and showed deepening and durability of responses (one of them in the lowest CAR-T dose level cohort in combination with CARVac). One patient had stable disease with shrinkage of target lesions.

The PRIME scheme is a regulatory mechanism introduced by the EMA that provides early and proactive support to developers of promising medicines, to optimize development plans and speed up evaluations so these medicines can reach patients faster. The goal is to help patients benefit as early as possible from innovative new therapies that have demonstrated the potential to significantly address an unmet medical need.

About BNT211
Aiming to harness the power of cell therapies for solid cancers and to overcoming hurdles to date, BioNTech has combined their CAR-T and FixVac platform technologies to develop a highly tumor-specific CAR-T cell therapy product which is consecutively enhanced by a **C**AR-T Cell **A**mplifying **R**NA **Vac**cine (CARVac) that is based on BioNTech`s mRNA-lipoplex technology and encodes for the respective CAR-T target antigen. The CARVac is based on BioNTech's backbone-optimized uridine mRNA (uRNA)-lipoplex technology which through its inherent adjuvant function enables a potent T cell stimulation to improve persistence and functionality of the adoptively transferred CAR-T cells, thus enabling and maintaining a therapeutic effect even at low CAR-T doses. BNT211 is an investigational CAR-T cell therapy directed against the novel oncofetal antigen Claudin-6 (CLDN6), a target discovered by BioNTech founders and expressed on multiple solid tumors such as ovarian cancer, sarcoma, testicular cancer, endometrial cancer and gastric cancer. The program is currently being evaluated in a first-in-human Phase 1/2 trial as a monotherapy and in combination with a CLDN6-encoding CARVac, aiming to boost persistence and functionality of the CLDN6-CAR-T cells, in patients with CLDN6-positive relapsed or refractory advanced solid tumors.

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 T cells, bispecific checkpoint immuno-modulators, targeted cancer antibodies and 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 Genmab, Sanofi, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma 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. These forward-looking statements may include, but may not be limited to statements concerning: BioNTech's CAR-T program candidate BNT211; timing for any data readouts of the Phase 1/2 trial; the registrational potential of any trial we may initiate for BNT211; 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 and specifically including, but not limited to, statements regarding timing or plans for initiation of clinical trials, enrollment 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; the potential safety and efficacy of our other product candidates; and BioNTech's anticipated market opportunity and size for its product candidates, the rate and degree of market acceptance of BioNTech's investigational medicines, if approved. 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.

For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report as Form 20-F for the Year Ended December 31, 2021, filed with the SEC on March 30, 2022, which is available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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