# BioNTech Expands Clinical Oncology Portfolio with First Patient Dosed in Phase 2 Trial of mRNA-based Individualized Immunotherapy BNT122 in Colorectal Cancer Patients

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- *Second Phase 2 trial initiated from BioNTech's proprietary individualized mRNA-based cancer vaccine platform iNeST*
- *Randomized Phase 2 trial will enroll approximately 200 patients with high-risk colorectal cancer that are circulating tumor DNA positive after adjuvant treatment*
- *BioNTech-sponsored trial is initiated in the United States, Germany, Spain and Belgium and is enrolling patients immediately*
- *BioNTech will continue joint development of BNT122 (autogene cevumeran, RO7198457) with Genentech, a member of the Roche Group, in other trials*

**MAINZ, GERMANY, October 1, 2021 (GLOBE NEWSWIRE)** – BioNTech SE (NASDAQ: BNTX, "BioNTech" or "the Company"), announced today that the first colorectal cancer patient has been treated with its individualized mRNA cancer vaccine BNT122 (autogene cevumeran, RO7198457) in a Phase 2 clinical trial. The trial has been initiated in the United States, Germany, Spain and Belgium. It is planned to enroll about 200 patients to evaluate the efficacy of RO7198457 (BNT122) compared to watchful waiting after surgery and chemotherapy, the current standard of care for these high-risk patients. As the second deadliest cancer worldwide, the medical need for novel therapies to treat colorectal cancer remains high.

The open-label Phase 2 trial (NCT04486378) is investigating autogene cevumeran in stage II/III colorectal cancer patients after surgical resection of their tumor and completion of adjuvant chemotherapy. The current standard of care in this indication is watchful waiting to see if tumors recur after removal of the primary tumor and adjuvant chemotherapy. A proportion of these patients are expected to have a recurrence of their tumor within 2-3 years after their surgery: in the clinical trial, patients at high risk for recurrence will be identified early on with a highly sensitive blood test detecting circulating tumor DNA (ctDNA). The Phase 2 trial will investigate the efficacy of autogene cevumeran as a single agent compared to standard of care watchful waiting in this high-risk patient population. The primary endpoint for the study is disease-free survival (DFS). Secondary objectives include relapse-free survival (RFS), overall survival (OS) and safety. The first patient in the trial has been treated at a clinical site in Europe.

"This trial is an important milestone in our efforts to bringing individualized immunotherapies to patients." said **Özlem Türeci, M.D., Co-founder and Chief Medical Officer of BioNTech**. "Many cancers progress in such a way that the patient initially appears tumor-free after surgery, but after some time tumor foci that were initially invisible grow and form metastases. In this clinical trial in patients with colorectal cancer, we aim to identify high-risk patients with a blood test and investigate whether an individualized mRNA vaccine can prevent such relapses."

The Phase 2 trial is based on previous results from the Phase 1a/1b basket trial evaluating autogene cevumeran as a single agent and in combination with atezolizumab, an anti-PD-L1 antibody, in patients with solid tumors (NCT03289962). The data show the induction of neoantigen-specific T cell responses, a manageable safety profile and objective responses as indication of clinical activity. In parallel to the ongoing Phase 2 study, BioNTech has initiated an epidemiological study (NCT04813627) to investigate ctDNA status in patients with stage II/III colorectal cancer following resection or prior to adjuvant chemotherapy to identify patients who might be potential candidates for the Phase 2 trial. In Germany, trial screening is supported by the molecular registry Colopredict Plus 2.0 (AIO-KRK-0413/ass) of the Association for Internal Oncology (AIO), a working group of the German Cancer Society, and the Ruhr University Bochum.

Autogene cevumeran is an individualized neoantigen specific immunotherapy (iNeST) and the lead candidate from BioNTech's mRNA-based cancer vaccine platform. Since 2016, BioNTech has advanced mRNA-based cancer vaccines targeting neoantigens in collaboration with its partner Genentech, a member of the Roche Group, including the joint clinical development of autogene cevumeran in a Phase 1a/1b basket trial in solid tumors and a randomized Phase 2 study in first-line melanoma patients, which was initiated in 2019. BioNTech will sponsor and operationalize the colorectal cancer Phase 2 trial. Joint development with Genentech of autogene cevumeran in other trials with Genentech will continue. The companies are equally sharing development costs and potential profits from their joint development of mRNA-based cancer vaccines targeting neoantigens for the potential treatment of multiple cancers.

**Further information and media materials:**
An iNeST Fact Sheet and images from the iNeST manufacturing process can be found in the media materials section on BioNTech's website at this link.

**About iNeST (Individualized Neoantigen Specific Immunotherapy)**
iNeST immunotherapies are individualized cancer therapies tailored to a specific patient's tumor. They contain unmodified, pharmacologically optimized mRNA encoding up to 20 patient-specific neoantigens. Neoantigens are proteins that are produced by cancer cells that differ from the proteins produced by healthy cells and are recognized by immune cells. The mRNA is encapsuled in BioNTech's proprietary intravenous RNA-lipoplex delivery formulation which is designed to enhance stability as well as enable targeted delivery to dendritic cells. By analyzing each patient's tumor, BioNTech is able to identify the cancer mutations that may act as neoantigens. Each individual cancer vaccine encodes for neoantigen candidates with the highest likelihood to help the immune system to recognize the cancer. For this purpose, BioNTech has developed a first of its kind, on-demand manufacturing process, following Good Manufacturing Practice (GMP) conditions.

**About BioNTech**
Biopharmaceutical New Technologies 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, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma and Pfizer.

For more information, please visit www.BioNTech.de

**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: The collaboration between BioNTech and Genentech to jointly clinical develop the iNeST program candidate autogene cevumeran (BNT122); timing for commencement of a Phase 2 trial as well as any data readouts; the registrational potential of any Phase 2 trial we may initiate for BNT122; 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, enrolment 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; BioNTech's anticipated market opportunity and size for its 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.

For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, 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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