



BioNTech Announces Strategic Partnership with UK Government to Provide up to 10,000 Patients with Personalized mRNA Cancer Immunotherapies by 2030

January 6, 2023

- *Multi-year collaboration focuses on three strategic pillars: cancer immunotherapies, infectious disease vaccines, and expansion of BioNTech's footprint in the UK*
- *BioNTech aims to design and roll out randomized clinical trials with registrational potential for the Company's personalized mRNA cancer immunotherapies in the UK*
- *Accelerated clinical trial recruitment with first patient to be enrolled in a trial as part of this collaboration in H2 2023*
- *Set-up of an R&D hub in Cambridge (UK) with the aim to employ more than 70 highly skilled scientists with the first employees commencing work in Q1 2023*

MAINZ, Germany, January 6, 2023 – [BioNTech SE](#) (Nasdaq: BNTX, "BioNTech", "the Company") today announced that the Company signed a Memorandum of Understanding ("MoU") with the Government of the United Kingdom ("UK") to benefit patients by accelerating clinical trials for personalized mRNA immunotherapies with the aim to provide personalized cancer therapies for up to 10,000 patients by the end of 2030, either in clinical trials or as authorized treatments. This objective is part of a multi-year collaboration focused on three strategic pillars: cancer immunotherapies based on mRNA or other drug classes, infectious disease vaccines, and investments into expanding BioNTech's footprint in the UK as one of the Company's key markets.

As part of the MoU, the Company and the UK Government plan to accelerate trial site and patient recruitment for clinical candidates of BioNTech's pipeline for personalized mRNA cancer immunotherapies and infectious disease vaccines. To achieve this, the parties plan to utilize the UK's clinical trial network, genomics and health data assets. The next steps of the collaboration will be the selection of candidates, trial sites and the set-up of a development plan with the aim of being ready to enroll the first cancer patient in the second half of 2023. BioNTech intends to design and roll out randomized trials in adjuvant or metastatic settings with registrational potential for the Company's personalized mRNA cancer immunotherapies in the UK.

"The UK successfully delivered COVID-19 vaccines so quickly because the National Health Service, academia, the regulator and the private sector worked together in an exemplary way. This agreement is a result of the lessons learnt from the COVID-19 pandemic as we all experience that drug development can be accelerated without cutting corners if everyone works seamlessly together towards the same goal. Today's agreement shows that we are committed to do the same for cancer patients," said **Prof. Ugur Sahin, M.D., Chief Executive Officer and Co-Founder of BioNTech**. "Our goal is to accelerate the development of immunotherapies and vaccines using technologies we have been researching for over 20 years. The collaboration will cover various cancer types and infectious diseases affecting collectively hundreds of millions of people worldwide. If successful, this collaboration has the potential to improve outcomes for patients and provide early access to our suite of cancer immunotherapies as well as to innovative vaccines against infectious diseases – in the UK and worldwide."

BioNTech plans to invest in a UK Research and Development ("R&D") hub in Cambridge with an expected capacity of more than 70 highly skilled scientists, the first to commence R&D by the end of the first quarter 2023. In addition, the Company will strengthen its UK footprint by setting up a regional headquarter in London to accommodate employees in global and regional supporting functions including Regulatory, Medical, Intellectual Property and Legal. As part of the MoU, BioNTech will remain the local sponsor of current and upcoming new clinical trials of its programs in the UK and will design the clinical trial protocols.

As of today, several hundred patients have been treated with mRNA-based cancer immunotherapies as part of BioNTech's trials for product candidates from the Company's FixVac and iNeST¹ platforms. Since its founding, BioNTech has been developing mRNA-based cancer therapies targeting a patient's unique tumor. In 2012, the first mRNA-based personalized cancer therapy developed by BioNTech was administered in a first-in-human trial. The first patient to receive a fully individualized mRNA-based cancer therapy developed by BioNTech was treated in a clinical trial in 2014. In 2015, the first patient received an exploratory mRNA-based cancer treatment intravenously, with BioNTech pioneering the first intravenous nanoparticle delivery of mRNA vaccines in humans. The Company continues to evaluate various combinations of mRNA backbone and delivery technologies with the aim of identifying highly efficient candidates with a favorable safety profile.

In collaboration with Pfizer, BioNTech developed the first COVID-19 vaccine which was approved in the UK, the United States and the European Union, making it the first-in-class mRNA drug product in the history of medicine. In addition to the approved COVID-19 vaccine, BioNTech's infectious diseases vaccine [pipeline](#) includes influenza and shingles vaccine programs, which are also partnered with Pfizer, as well as a fully owned malaria vaccine program and a herpes-simplex-virus-2 vaccine program. In total, the Company is running research and preclinical development programs targeting more than 10 additional infectious diseases.

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 immune checkpoint 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 statement 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, direct or indirect statements concerning: BioNTech's potential collaboration between the Government of the United Kingdom and its institutions and authorities with regards to the provision of cancer immunotherapies, infectious disease vaccines and the expansion of BioNTech's footprint in the United Kingdom, including the aim to provide personalized cancer therapies for up to 10,000 patients by the end of 2030; the set-up of a development plan with the aim of being ready to enroll the first cancer patient in the second half of 2023; plans to invest in a UK R&D hub in Cambridge with the first scientists to commence R&D by the end of the first quarter of 2023; the ability of BioNTech to reach an agreement with potential collaboration partners in the United Kingdom; BioNTech's ability to develop, test and commercialize products and product candidates, including the timing to initiate clinical trials ; BioNTech's anticipated market opportunity and size for its product candidates; and the rate and degree of market acceptance of BioNTech's investigational medicines, if approved. Any forward-looking statements in this statement 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.

For a discussion of these and other risks and uncertainties, see BioNTech's Quarterly Report on Form 6-K for the quarter ended September 30, 2022, filed with the U.S. Securities and Exchange Commission ("SEC") on November 7, 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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¹ in collaboration with Genentech