# BIONTECH

## BioNTech Plans to Initiate the Construction of an mRNA Vaccine Manufacturing Facility in Africa in mid-2022

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- BioNTech signs Memorandum of Understanding with Rwandan Government and the Institut Pasteur de Dakar. Construction of the first mRNA manufacturing facility in Africa is planned to be initiated in mid-2022
- First manufacturing facility will become a node in a decentralized and robust African end-to-end manufacturing network
- Development and implementation of a scalable regional manufacturing network to enable an annual manufacturing capacity of several hundreds of million mRNA vaccine doses

**MAINZ**, Germany, October 26, 2021 — BioNTech SE (Nasdaq: BNTX, "BioNTech") today announced that the Company plans to initiate the construction of the first state-of-the-art manufacturing site for mRNA-based vaccines in the African Union in mid-2022. This is the next step in BioNTech's efforts to implement sustainable end-to-end vaccine supply solutions on the African continent. The decision is the result of a meeting between Rwanda's Minister of Health, Dr Daniel M. Ngamije, Senegal's Minister of Foreign Affairs Aïssata Tall Sall, Ugur Sahin, M.D.,CEO and Co-Founder of BioNTech and Sierk Poetting, COO of BioNTech as well as Dr Sabin Nsanzimana, Director-General of Rwanda Biomedical Centre and Dr Amadou Alpha Sall, Directeur-General of Institut Pasteur de Dakar in Kigali, Rwanda. The meeting occurred upon the invitation of the kENUP Foundation and took place as a side-event of the Second Ministerial Meeting of the African Union and the European Union and resulted in a Memorandum of Understanding (MoU). This comes after the parties signed a Joint Communiqué at a previous meeting in Berlin on August 27, 2021.

"I would like to thank all participants of today's meeting for the support and trust to establish the first mRNA manufacturing facility within the African Union. Together, we will work on developing a regional manufacturing network to support the access to vaccines manufactured in Africa, for Africa," said **Ugur Sahin, M.D., CEO and Co-founder of BioNTech**. "Our goal is to develop vaccines in the African Union and to establish sustainable vaccine production capabilities to jointly improve medical care in Africa. We have made great progress in the past few weeks, which will help us on our way to turn these plans into reality."

**Sierk Poetting, COO of BioNTech** added: "We aim to accelerate the building of a GMP-certified manufacturing facility and plan to begin the construction on site in mid-2022. The MoU underlines that time is a critical success factor in the development of sustainable vaccine production for the African Union. We have finalized the planning and initial assets for the new facility have already been ordered."

The parties agree to jointly establish end-to-end manufacturing capacities for mRNA-based vaccines in Africa starting immediately. BioNTech has finalized the construction plans and ordered the assets, which will be delivered by mid-2022. The new manufacturing facility could become the first node in a decentralized and robust African end-to-end manufacturing network enabling an annual manufacturing capacity of several hundreds of million mRNA vaccine doses.

BioNTech plans to develop and implement a scalable construction network based on the expertise and learnings from the ramp-up of the Company's production facility in Marburg. To enable an expedient set-up of production capacities according to GMP standards, BioNTech will start with the construction and validation of a first production line enabling the manufacturing of drug product for about 50 million of e.g. COVID-19 vaccine doses per year, once fully operational. The capacity will be increased sequentially by adding further manufacturing lines and sites to the manufacturing network on the continent, supporting the production of several hundreds of millions of mRNA vaccine doses.

BioNTech will initially staff, own and operate the facility to support the safe and rapid initiation of the production of mRNA-based vaccine doses. BioNTech plans to transfer manufacturing capacities and the know-how to local partners. Therefore, BioNTech, the Rwanda Development Board and Institut Pasteur de Dakar in Senegal agreed to swiftly build-up the required human resources capacity and systems so that the partners can take over ownership and operational duties. In parallel, the Republic of Rwanda and the Institut Pasteur de Dakar have committed themselves to scale-up fill and finish capacities to complete the local end-to-end manufacturing process. In addition, BioNTech is in discussions about an expansion of the current partnership with Cape Town-based vaccine manufacturer Biovac, which is part of the Pfizer-BioNTech COVID-19 vaccine manufaturing network.

"State-of-the-art facilities like this will be life-savers and game-changers for Africa and could lead to millions of cutting edge vaccines being made for Africans, by Africans in Africa," said **Dr Matshidiso Moeti, World Health Organization Regional Director for Africa**. "This is also crucial for transferring knowledge and know-how, bringing in new jobs and skills and ultimately strengthening Africa's health security. WHO is ready to work with countries to step up their commitment to vaccine manufacturing."

"By working together, in the spirit of this meeting, the African Union, the European Union, key technology partners, and other stakeholders, can make decisive contributions and effective coordination in the fight against this pandemic, and future health challenges," **commented Dr Monique** Nsanzabaganwa, Deputy Chairperson of the African Union Commission.

### About the Pfizer-BioNTech COVID-19 vaccine

The Pfizer-BioNTech COVID-19 vaccine, which is based on BioNTech's proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder in the United States, the European Union, the United Kingdom, Canada and the holder of Emergency Use Authorizations or equivalents in the United States (jointly with Pfizer) and other countries. Submissions to pursue regulatory approvals in those countries where Emergency Use Authorizations or equivalent were initially granted are planned.

#### 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, bi-specific 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 <u>www.BioNTech.de</u>.

#### **BioNTech Forward-looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forwardlooking statements may include, but may not be limited to, direct or indirect statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including gualitative assessments of available data, potential benefits, expectations for clinical trials, supply agreements and the timing of delivery of doses thereunder, efforts to help ensure global equitable access to the vaccine, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply); our expectations regarding the potential characteristics of BNT162b2 in our clinical trials and/or in commercial use based on data observations to date; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the expected time point for additional readouts on efficacy data of BNT162b2 in our clinical trials; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and market demand, including our production estimates for 2021; BioNTech's Malaria, Tuberculosis and other infectious disease vaccine development programs; timing for selecting clinical candidates for these programs and the commencement of a clinical trial, as well as any data readouts; the nature of the collaboration with the African Union and the Africa CDC; the nature and duration of support from WHO, the European Commission, the European Investment Bank (EIB) and other organizations with establishing infrastructure; the development of sustainable RNA vaccine capacities, production and supply solutions on the African continent and the nature, timing, and feasibility of these solutions; the potential set-up of manufacturing solutions in Rwanda, Senegal, and South Africa, either on our own or together with potential partners; the potential safety and efficacy of the 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 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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