BioNTech introduces first modular mRNA manufacturing facility to promote scalable vaccine production in Africa

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- *Developing turnkey solution to enable mRNA-based vaccine production in modular and scalable sites installed by BioNTech*
- *Presidents of Ghana, Rwanda, Senegal, the Director-General of the World Health Organization, the Director of the Africa CDC and the Federal Minister of Economic Cooperation and Development of Germany met in Marburg to jointly discuss the infrastructure, regulatory and technological requirements to establish end-to-end manufacturing network for mRNA-based vaccines in Africa*
- *First manufacturing facility to become a node in a decentralized and robust African end-to-end manufacturing network*
- *Establishment of mRNA manufacturing facilities in Africa is planned in the partner countries Senegal, Rwanda and potentially South Africa; construction of first facility to start in mid-2022 in first partner country, with the others to follow suit. New project in Ghana to support manufacturing with fill-and-finish capacities*

MAINZ, Germany, February 16, 2022 – BioNTech SE (Nasdaq: BNTX, "BioNTech") has taken a next step to improve vaccine supply in Africa. The company has introduced its approach to establishing scalable vaccine production by developing and delivering turnkey mRNA manufacturing facilities based on a container solution. At a high-level meeting at BioNTech's new manufacturing facility in Marburg and at the invitation of kENUP Foundation, the company presented the container solution named "BioNTainer" to key partners.

Attendees included President Macky Sall of Senegal, President Nana Akufo-Addo of Ghana, President Paul Kagame of Rwanda, Tedros Adhanom Ghebreyesus, Director General of the World Health Organization, John Nkengasong, Director of the Africa Centers for Disease Control and Prevention (Africa CDC), and Svenja Schulze, the Federal Minister of Economic Cooperation and Development of Germany. Together with BioNTech's Co-Founders Prof. Ugur Sahin, CEO, and Prof. Özlem Türeci, CMO, and COO Dr. Sierk Poetting, they jointly discussed the infrastructure, regulatory and technological requirements to establish an end-to-end manufacturing network for mRNA-based vaccines in Africa.

The manufacturing solution consists of one drug substance and one formulation module, each called a BioNTainer. Each module is built of six ISO sized containers (2.6m x 2.4m x 12m). This allows for mRNA vaccine production in bulk (mRNA manufacturing and formulation), while fill-and-finish will be taken over by local partners. Each BioNTainer is a clean room which BioNTech equips with state-of-the-art manufacturing solutions. Together, two modules require 800 sqm of space and offer an estimated initial capacity of for example up to 50 million doses of the Pfizer-BioNTech COVID-19 vaccine each year. The BioNTainer will be equipped to manufacture a range of mRNA-based vaccines targeted to the needs of the African Union member states, for example the Pfizer-BioNTech COVID-19 vaccine and BioNTech's investigational malaria and tuberculosis vaccines, if they are successfully developed, approved or authorized by regulatory authorities.

The capacity can be scaled up by adding further modules and sites to the manufacturing network on the African continent. One of the most critical parts of the manufacturing process is quality control, which includes all necessary tests for each finished vaccine batch. In partnership with local quality control testing labs, BioNTech will help to ensure the identity, composition, strength, purity, absence of product- and process-related impurities, as well as the absence of microbiological contamination of each produced batch.

The establishment of the first mRNA manufacturing facility by BioNTech in the African Union is expected to start in mid-2022. The first BioNTainer is expected to arrive in Africa in the second half of 2022. Manufacturing in the first BioNTainer is planned to commence approximately 12 months after the delivery of the modules to its final location in Africa. BioNTech expects to ship BioNTainers to Rwanda, Senegal and potentially South Africa in close coordination with the respective country and the African Union. BioNTech will be responsible for the delivery and installation of the modules, while local organizations, authorities and governments will ensure the needed infrastructure. Partners in Ghana and South Africa could support the manufacturing with fill-and-finish capacities. BioNTech will work closely with local authorities to ensure compliance to relevant regulatory procedures of the national regulatory agencies in each partner country, and also coordinate where appropriate with relevant continental and international agencies, including WHO, Africa CDC, the African Medicines Agency (AMA), and the African Union Development Agency (AUDA-NEPAD).

BioNTech will initially staff and operate the facilities to support the safe and rapid initiation of the production of mRNA-based vaccine doses under stringent good manufacturing processes ("GMP") to prepare for the transfer of know-how to local partners to enable independent operation. Vaccines manufactured in these facilities are expected to be dedicated to domestic use and export to other member states of the African Union at a not-for-profit price.

Further media material can be downloaded here: link. This section will be updated regularly during the course of the day.

Quotes:

Ursula von der Leyen, President of the European Commission: "mRNA vaccines made in Africa, for Africa, with world-class technology. This initiative is a real trailblazer in our global fight against the pandemic. By pooling forces, the European Union and the African Union can achieve so much more, for mutual benefit. Team Europe has committed one billion Euros. And the EU will support Africa's ambition to build up vaccine manufacturing and regulatory capacities."

Macky Sall, President of the Republic of Senegal and President of the African Union: "This visit to Marburg is another important milestone in Senegal's target to deliver end-to-end vaccine manufacturing in Africa and for Africa, leveraging the infrastructure and technical capabilities of the Institut Pasteur de Dakar's Madiba project. We are looking forward to working with BioNTech to install the modular production system for mRNA vaccine manufacturing in Dakar in the coming months."

Paul Kagame, President of the Republic of Rwanda: “BioNTech’s innovative modular production system opens up a new horizon for global vaccine equity. Rwanda looks forward to initiating mRNA vaccine manufacturing in the near future, in collaboration with BioNTech and our partners in Africa, Europe, and beyond.”

Nana Akufo-Addo, President of the Republic of Ghana: “Today represents a momentous day for Mother Africa. Another step in the process towards self-reliance has been taken, and I thank the German biotechnology company, BioNTech, and the kENUP Foundation for their contribution to this end. We want to achieve self-sufficiency in vaccine production to meet future national, regional and continental needs for health security. Ghana reaffirms her determination to make this Pan-African vaccine project work and succeed.”

Olaf Scholz, Chancellor of the Republic of Germany: “A rapidly available and effective vaccine seemed out of reach two years ago – almost like science fiction. Özlem Türeci and Ugur Sahin have written scientific history. With the rapid expansion and conversion of its site at the industrial park Behringwerke in Marburg, BioNTech has now created one of the world’s largest mRNA production sites. These production sites are badly needed. To date, only a little more than half of the world’s population is fully vaccinated. In Africa, this figure stands at just 11 percent on average. And the global distribution of vaccines remains extremely unequal. We are taking a big step forward today. As European and African partners, we are working hand in hand to launch local vaccine production in Ghana, Senegal, South Africa and Rwanda. Each new variant is proof of the fact that we will only be able to defeat this virus by working together around the world.”

Dr. Tedros Adhanom Ghebreyesus, WHO Director-General: “WHO is committed to working with all partners to ensure every country can access vaccines and other tools to protect the health of their populations. We can only achieve that goal through genuine cooperation on local vaccine development, production, distribution and uptake, through greater diversity of platforms. Collaboration on training, research and strengthening regulatory systems will also be key for success. We welcome BioNTech’s initiative to increase vaccine production in Africa, as a complement to WHO’s mRNA technology transfer hub in South Africa and its network of ‘spokes’ around the world.”

Michel Sidibé, Africa Union Special Envoy for The Africa Medicine Agency: “Given the emergence and spread of variants, the pandemic will not be over until it is over everywhere. This initiative hopefully expands mRNA vaccine production in Africa.”

Werner Hoyer, President of the European Investment Bank: “As part of Team Europe, the EIB has worked closely with BioNTech, kENUP and partners to enable this impressive project. With its new development arm EIB Global, EIB stands ready to finance projects in energy and water infrastructure in African countries that will also strengthen primary health care. Our projects will complement local vaccine production by BioNTech and strengthen Africa’s resilience to future pandemics.”

Makhtar Diop, Managing Director of the International Finance Corporation: “I am very proud of our collaboration with the kENUP Foundation and BioNTech to fast-track vaccine manufacturing in Africa, facilitate technology adoption and achieve vaccine equity. It is through partnerships of this kind that we will be able to attract more private sector investments and impactfully address vaccine shortages in the region.”

Prof. Ugur Sahin, CEO and Co-founder of BioNTech: “Today’s milestone brings us one step closer to our goal of improving healthcare by making our innovations accessible worldwide. I want to thank our teams in Mainz and Marburg who worked day and night to bring the first containers to Marburg, our center for innovative manufacturing solutions. I am grateful for the support of the great leaders and experts who joined us today. It is an honor to work with them to make a difference and to support sustainable vaccine access, establishing regional manufacturing facilities in Africa – with the people on the African continent. I am optimistic that the next time we meet in front of BioNTainers, it will not be in Europe, but in Africa.”

Dr. Sierk Poetting, COO of BioNTech: “We have initiated the BioNTainer project in January 2021 after knowing that we had an approved mRNA-based vaccine. The modular production facilities are a big step in our journey to enable the production of high-quality mRNA vaccine manufacturing worldwide, with each BioNTainer becoming a node in a decentralized and robust African end-to-end manufacturing network. The modular and scalable approach could allow us to set-up turnkey manufacturing sites for mRNA on all continents. Once rolled out, the approach could support clinical trials as well as regional pandemic preparedness measures.”

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 www.BioNTech.de.

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, direct or indirect statements concerning: the ability of BioNTech to produce, deliver and install mRNA container manufacturing facilities for the African continent, including the ability to meet all necessary infrastructure, technology and regulatory requirements; the ability of BioNTech to reach an agreement with potential collaboration partners in Africa to establish an end-to-end manufacturing network in Africa; the development of quality assurance capabilities to remotely support manufacturing sites in Africa; the scale-up of local know-how and training in Africa; 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, the Africa CDC, and the WHO; 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 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; BioNTech’s efforts to combat COVID-19; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including qualitative 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). 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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