



BioNTech Achieves Milestone at mRNA-based Vaccine Manufacturing Site in Rwanda

December 18, 2023

- *Set-up of first BioNTainer as high-tech manufacturing solution for mRNA medicines is a critical step in establishing a resilient vaccine ecosystem in Africa and future pandemic preparedness*
- *BioNTech plans to complete all buildings at the Kigali site and start local training of specialized personnel in the facility in 2024, with test mRNA production for process validation to be initiated in 2025*
- *Upon successful validation, the Kigali facility will serve as a lighthouse project for subsequent mRNA-based vaccine manufacturing facilities of smaller or larger scale to support clinical development or commercial-scale production in line with local or regional demand*
- *In addition, BioNTech is progressing the development of mRNA vaccine candidates for infectious diseases with high medical need, including vaccine candidates against tuberculosis, malaria, and HIV, as well as against infectious diseases with pandemic potential, such as mpox. Upon successful development and approval, these vaccines are intended for production at the newly established site*
- *On invitation by H.E. President Paul Kagame of Rwanda, Heads of State and Government from Africa and around the world, leadership of the African Union and European Union, as well as from WHO, Africa CDC and CEPI attended the official inauguration of the BioNTech site in Kigali*

KIGALI, Rwanda, December 18, 2023 (GLOBE NEWSWIRE) – [BioNTech SE](#) (Nasdaq: BNTX, “BioNTech” or “the Company”) has reached the next milestone in the establishment of mRNA vaccine manufacturing capacities in Africa with the inauguration of the Company’s site in Kigali, Rwanda. The inauguration takes place on the occasion of the set-up of the first manufacturing unit called BioNTainer. This effort is one of BioNTech’s multiple initiatives aimed at helping to build a sustainable and resilient African vaccine ecosystem and supporting equitable access to novel medicines globally: these cover research and development, clinical trials, manufacturing and local training of specialized personnel.

At a whole-day conference titled “Working together to promote vaccine equity for Africa” that preceded the site inauguration, BioNTech engaged with representatives from the World Health Organization (“WHO”), the Coalition for Epidemic Preparedness Innovations (“CEPI”), Africa Centers for Disease Control and Prevention (“Africa CDC”), Rwanda Food and Drug Administration (“Rwanda FDA”), Health Emergency Preparedness and Response Authority (“HERA”), the Bill and Melinda Gates Foundation and the South African Health Products Regulatory Authority to discuss opportunities and challenges in building a sustainable and resilient vaccine ecosystem in Africa. Upon invitation by His Excellency President Paul Kagame of Rwanda, Heads of State and Government from around the world, highest leadership of the African Union, European Union as well as from WHO and CEPI attended the inauguration ceremony of BioNTech’s site. The Company’s manufacturing site in Kigali could become the first commercial-scale mRNA manufacturing facility on the continent.

The facility is based on the Company’s high-tech, digitally enabled modular manufacturing units called BioNTainers. They are designed to manufacture a range of mRNA-based vaccines. The BioNTainers are also designed to be updated on a regular basis, as BioNTech aims for them to remain one of the most sophisticated mRNA manufacturing facilities in the world. The manufacturing site will initially be equipped with two BioNTainers. The containers for the first BioNTainer, which were recently set up in the manufacturing hall and will serve to manufacture mRNA as drug substance, arrived in Kigali in [March 2023](#). The second BioNTainer unit will serve to manufacture the formulated bulk drug product and will be ready for shipment to the Rwanda site in the first quarter of 2024.

The manufacturing facility in Kigali has been fully funded by BioNTech to date. The Company has committed a total investment of approximately USD 150 million to complete the construction of the site including the manufacturing units. The overall site has a size of approximately 35,000 square meters and will have approximately 100 employees once fully operational. In 2024, BioNTech expects to complete all buildings on site, including a warehouse, offices and laboratories for quality control. The Company anticipates that, following local training of specialized personnel in 2024, it can start operating with the manufacturing of mRNA-based vaccine batches required for process validation in 2025. The facility is intended to manufacture vaccines tailored to the needs of African Union members. Its manufacturing capacity depends on the mRNA product being manufactured and its various factors such as dosage and formulation. For example, BioNTech could manufacture up to 50 million doses annually of a product that has an RNA process similar to that of the Pfizer-BioNTech COVID-19 Vaccine.

In line with the continent’s and partner countries’ needs, BioNTech is committed to establishing additional manufacturing facilities in Africa upon the successful validation of the facility in Kigali, which serves as a lighthouse project. Compared to the facility in Kigali, additional sites could be designed as larger facilities providing increased commercial-scale manufacturing capacities in Africa, or they could be smaller and specialized in the manufacture of batches for the clinical evaluation of product candidates.

To support the establishment of a sustainable vaccine ecosystem in Africa, BioNTech is progressing the development of prophylactic mRNA vaccines targeting infectious diseases such as tuberculosis, malaria, and HIV, and is also focusing on diseases with epidemic and pandemic potential, including mpox. Clinical trials for tuberculosis and malaria vaccine programs are already underway in South Africa and the United States, respectively. BioNTech plans to conduct clinical trials in Africa for vaccine candidates against malaria, tuberculosis and HIV in 2024. Malaria, tuberculosis and HIV are highly prevalent in Africa, causing over two million deaths annually, including a high degree of child mortality. If successfully developed and authorized by regulatory authorities, BioNTech plans to provide lower-income countries with access to the four prophylactic vaccines at a not-for-profit price.

While in Kigali, Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech, met with His Excellency Macky Sall, President of the Republic of Senegal, and discussed developing a potential research partnership between BioNTech and the Institut Pasteur de Dakar with a focus on infectious diseases relevant to the African continent.

Media materials of the inauguration of the site are available under the following link which will be updated with additional material subsequently:

<https://www.biontech.com/int/en/home/newsroom.html>

About the inauguration ceremony:

Attendees of the site inauguration ceremony included H.E. Paul Kagame, President of the Republic of Rwanda, H.E. Macky Sall, President of the Republic of Senegal, H.E. Nana Akufo-Addo, President of the Republic of Ghana, Hon. Mia Amor Mottley, Prime Minister of Barbados, H.E. Ursula von der Leyen, President of the European Commission, African Union Chairperson Moussa Faki Mahamat of the African Union Commission, Hon. Annalena Baerbock, Federal Minister of Foreign Affairs of the Federal Republic of Germany, Hon. Dr Mathume Joseph Phaala, Minister of Health of the Republic of South Africa and Ambassador Gervais Abayeho, Minister of East Africa Community Affairs of the Republic of Burundi. In attendance from development finance institutions were Dr Akinwumi Adesina, President of the African Development Bank and European Investment Bank Vice President Gelsomina Vigliotti.

Quotes given at the inauguration ceremony:

H.E. Paul Kagame, President of the Republic of Rwanda: "Vaccine inequity hit Africa hard during the pandemic. But BioNTech's partnership with Africa demonstrates that vaccine technology can be democratized, so that Africa is ready and resilient no matter what happens in the future."

H.E. Macky Sall, President of the Republic of Senegal: "This is a special day for Africa, BioNTech has taken an important step towards greater vaccine equity. It is a tremendous example of a company acting with great social responsibility. I am fully supportive of what BioNTech is doing in Rwanda and looking forward to progressing a research partnership in Senegal with the Institute Pasteur in Dakar."

H.E. Ursula von der Leyen, President of the European Commission: "The opening of the first BioNTech Africa site in Kigali is an important step towards African vaccine sovereignty. Local manufacturing of vaccines with mRNA technology, in Africa, for the African people, will be a game changer in the fight against diseases and pandemics. The EU is proud to work with Rwanda and BioNTech to develop a vibrant biopharmaceutical industry on the continent. Global Gateway, Europe's investment strategy, invests in vaccine production in Africa and in the right skills, jobs and capacities to spur health innovation at the scale of the continent."

African Union Chairperson Moussa Faki Mahamat of the African Union Commission: "This is an important day for Africa. The Continent is committed to increasing the accessibility and quality of needed vaccines and other medicines to be available to all Africans. That is also the purpose of the African Medicines Agency, which has its headquarters here in Kigali. In this sense, we believe this BioNTech facility and AMA will contribute to our collective vision of a self-reliant Africa. Creating a high-quality regulatory environment and ensuring vaccine independence is key to our future capacity to prepare, respond and better recover from pandemics. Working together to promote vaccine equity for Africa remains our priority."

Hon. Annalena Baerbock, Federal Minister of Foreign Affairs of the Federal Republic of Germany: "The road to a fair international health architecture is not a short-distance race, but a team marathon. That is why Team Europe supports the goal of Africa's own vaccine production – from conception to injection. Today, only one in 100 of the vaccine doses administered in Africa is actually produced there; by 2040, this figure is set to be 60 times higher. Global Gateway is making this possible by providing 1.2 billion euro by 2027, with 550 million euro coming from Germany alone. The opening of Africa's first mRNA vaccine factory in Rwanda by BioNTech is not yet the finishing line – but it is a real milestone and a source of hope for millions."

Dr. Jean Kaseya, Director-General, Africa Centers for Disease Prevention and Control (Africa CDC): "The local manufacturing agenda represents the second independence of Africa, and the inauguration of the BioNTainer manufacturing facility represents a significant milestone in our collective efforts to strengthen vaccine production capabilities, enhance health security, and improve access to life-saving vaccines across the African continent."

Prof. Ugur Sahin, M.D., CEO and Co-founder of BioNTech: "We are committed to building a sustainable mRNA vaccine ecosystem in Africa, focusing on the development of mRNA vaccines against infectious diseases with high medical needs and forging high-end technology solutions for local manufacturing. Today's inauguration event establishing the first 'BioNTainer' module for mRNA manufacturing is an important milestone in this journey. Together with our partners, we are advancing towards our first commercial scale mRNA facility in Africa, as a cornerstone of our joint vision of a sustainable health future. I would like to express my gratitude to our local and international partners for their contributions to this joint effort, as well as to the entire BioNTech team for their dedicated work which made this inauguration possible."

Sierk Poetting, Ph.D., Chief Operating Officer of BioNTech: "The facility based on BioNTainers goes beyond a mere physical structure. It represents the idea of revolutionizing the manufacture of pharmaceuticals by combining digital technology with standardized mRNA production. The BioNTainers are designed to provide consistent manufacturing processes that could be applied globally and could be tailored to regional needs. We have set up the BioNTainers to be updated on a regular basis with the aim to remain one of the most advanced mRNA manufacturing facilities globally."

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 (CAR) T cells, several protein-based therapeutics, including bispecific immune checkpoint modulators, targeted cancer antibodies and antibody-drug conjugate (ADC) therapeutics, as well as 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 Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron, Sanofi 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, as amended, including, but not limited to, 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 within projected timelines; BioNTech's plans to update the BioNTainers; BioNTech's ability to reach agreements with potential collaboration partners in Africa, including a

potential research partnership with the Institut Pasteur de Dakar in Senegal; the development of quality control capabilities; the scale-up of local know-how and training in Africa; BioNTech's malaria, tuberculosis, HIV, mpox and other infectious disease vaccine development programs (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 approved vaccines, the anticipated timing of regulatory submissions, regulatory approvals or authorizations, and anticipated manufacturing, distribution and supply); timing for selecting clinical candidates for these programs and the commencement of clinical trials, as well as any data readouts; the nature of the collaboration with the African Union, the Africa CDC, the WHO, and other parties; the development of sustainable RNA vaccine capacities, production and supply solutions in Africa and the nature, timing, and feasibility of these solutions. 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: the potential safety and efficacy of the product candidates; discussions with regulatory agencies regarding timing and requirements for additional clinical trials; the ability to produce comparable clinical results in future clinical trials; potential delays in the establishment of the BioNTainers and BioNTech operations in Africa due to unforeseen developments, including, but not limited to, global supply chain issues; and the rate and degree of market acceptance of BioNTech's investigational medicines, if approved.

You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Report on Form 6-K for the period ended September 30, 2023 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at <https://www.sec.gov/>. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

CONTACTS

Investor Relations

Victoria Meissner, M.D.
+1 617 528 8293
investors@biontech.de

Media Relations

Jasmina Alatovic
+49 (0)6131 9084 1513
Media@biontech.de