BioNTech Starts Construction of First mRNA Vaccine Manufacturing Facility in Africa

June 23, 2022

- *Breaking of Ground for BioNTech's initial African modular mRNA manufacturing facility in Kigali, Rwanda; delivery of first container modules planned for end of 2022*
- *On invitation by H.E. President Paul Kagame of Rwanda, Heads of State and Government from Africa and around the world, highest leadership of African Union, European Union as well as from WHO and WTO joined BioNTech CEO Ugur Sahin on site to mark the establishment of BioNTech's pan-African end-to-end manufacturing network for mRNA-based vaccines*
- *Facility will be initially equipped with two BioNTainers, and is expected to employ about 100 staff by 2024*
- *BioNTech's malaria vaccine candidates to enter first-in-human trial later in 2022*
- *Climate-neutral power supply planned for Rwanda factory as part of BioNTech's commitment to the international treaty on climate change ("Paris Agreement")*

MAINZ, Germany and KIGALI, Rwanda, June 23, 2022 (GLOBE NEWSWIRE) – BioNTech SE (Nasdaq: BNTX, "BioNTech") has reached the next milestone in the establishment of scalable mRNA vaccine production in Africa on its planned schedule. Today, BioNTech welcomed its African partners for the first time on the African continent as construction works for the initial African mRNA manufacturing facility began in Kigali, Rwanda, with a target for the first set of manufacturing BioNTainers to be delivered to the site by the end of 2022. The company expects to set up additional factories in Senegal and South Africa in close coordination with its partners in the respective countries. The initial site will become a node in a decentralized and robust African end-to-end manufacturing network. All vaccines to be manufactured in the network will be dedicated to people residing in member states of the African Union.

During the event in Kigali, BioNTech provided an update on the joint establishment of mRNA manufacturing facilities and the development plans for BioNTech's malaria vaccine candidates. Attendees included President Paul Kagame of Rwanda, President Nana Akufo-Addo of Ghana, Chairperson Moussa Faki Mahamat of the African Union Commission, Ursula von der Leyen, President of the European Commission (by video), Olaf Scholz, Chancellor of the Federal Republic of Germany (by video), Minister of Foreign Affairs Aïssata Tall Sall of Senegal, WHO Director General Dr. Tedros Adhanom Ghebreyesus, WTO Director General Dr. Ngozi Okonjo-Iweala, CEO Nardos Bekele-Thomas of the African Union Development Agency-NEPAD, Secretary General Wamkele Mene of the African Continental Free Trade Area, and Prof. Ugur Sahin, M.D., Co-Founder and CEO of BioNTech. In attendance from development finance institutions were Managing Director Makhtar Diop of the World Bank's International Finance Corporation and European Investment Bank Vice President Thomas Östros.

BioNTech, the biopharmaceutical company which co-developed the first approved mRNA-based vaccine (Pfizer-BioNTech COVID-19 vaccine), will work with staff from its sites in Germany to accelerate the training of about 100 colleagues who will be running the production and all associated laboratory and quality assurance tasks on site. The hiring of the initial local personnel is commencing now and will include about 20 roles, which can be found here.

At the Malaria and Neglected Tropical Diseases Summit, held in Kigali occurring in parallel to Commonwealth Heads of Government Meeting (CHOGM), Ugur Sahin introduced the Company's program aiming at the development of a highly effective malaria vaccine based on BioNTech's mRNA platform. The vaccine candidates are expected to enter first-in-human trials later in 2022.

The Rwandan facility, with a size of about 30,000 square meters, will be initially equipped with two BioNTainers (one for the production of mRNA, and one for the production of the formulated bulk drug product). The BioNTainers will be equipped to manufacture a range of mRNA-based vaccines targeted to the needs of the African Union member states, which could conceivably include 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 estimated initial annual capacity of e. g. the Pfizer-BioNTech COVID-19 vaccine will be about 50 million doses. Manufacturing in the BioNTainers in Rwanda is expected to commence approximately 12 to 18 months after their installation.

BioNTech supports the international treaty on climate change ("Paris Agreement"). To this end, the Company is committed to operate its African manufacturing sites, including the initial plant in Rwanda, on a climate-neutral basis using renewable energy. Izuba energy will work to facilitate supply of the site with renewable energy.

In February 2022, the Company introduced its approach to scalable vaccine production by developing and delivering turnkey mRNA manufacturing facilities based on a container solution.

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

Quotes

H.E. Paul Kagame, President of the Republic of Rwanda: "The groundbreaking for BioNTech's state-of-the-art mRNA production facility is a pivotal milestone. We are happy to have BioNTech as a partner, and I applaud the company's commitment to working with Africa on a continental basis to help secure our vaccine resilience for the future, and invest in new research to address the endemic diseases that disproportionately affect our people. Working with our partners, Rwanda intends to build on this investment to attract a vibrant biopharmaceutical research and manufacturing sector."

H.E. 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. This plant will help the continent achieve self-sufficiency in vaccine production to meet future continental needs for health security. Ghana reaffirms her determination to make this Pan-African vaccine project work and succeed."

H.E. Aïssata Tall Sall, Minister of Foreign Affairs of Senegal: "What we are doing today is not medicine, it is not research. What we are doing today is to dedicate ourselves to the purpose of all political action, that is, to satisfy the basic needs of mankind. But the most difficult thing was to take the decision, the commitment, and the political courage, to say that for once, Africa is going to manufacture this vaccine on its territory as is the standard elsewhere. And this decision was taken very early. This is how the continent has committed itself to ensuring that never again Africa will be behind in research and in the production of medicines. So, what we are doing today goes beyond medicine."

H.E. Moussa Faki Mahamat, Chairperson of the African Union Commission: "Today marks a new, vital milestone on our journey to make vaccine manufacturing on the continent a reality. The partnership for African Vaccine manufacturing launched by the African Union in 2021 set Africa on a course to end our continent's dependence on imported vaccines. BioNTech's commitment to work with Africa in this way is remarkable and greatly appreciated. We look forward to the first entirely made in Africa mRNA vaccines. It is of paramount importance that this effort is pan-African and continue to be. I pledge the continuous support of the African Union."

H.E. Ursula von der Leyen, President of the European Commission: "Today, we are laying the foundations for the first mRNA vaccine production facility in Africa, in Kigali. We are turning a simple but ground-breaking idea into reality, in record time. The 'Vaccine Equity for Africa' project is a milestone – not only in the fight against COVID-19. This project represents the immense potential of African and European cooperation. Our partnership will bring vaccine manufacturing in Africa to the next level."

H.E. Olaf Scholz, Chancellor of the Republic of Germany: "Today, an essential foundation is being laid for more people to benefit from the blessing of vaccines in the future. And if BioNTech's projects are realised, Africa's supply of urgently needed vaccines will improve significantly – vaccines against COVID-19, but ultimately also against malaria, against tuberculosis, against HIV. (…) An essential foundation is also being laid for Africa to be better prepared for the next virus pandemic. (…) We have said and heard it many times before: a pandemic can only end when all people have access to vaccines. Today, we are putting those words into action. The BioNTainers will take the world one large step closer to vaccine equity. (…) This co-operation between African states and a German company – supported by the African Union, by the European Union and by the World Health Organization – proves how our two neighbouring continents benefit from mutual cooperation."

Dr Tedros Adhanom Ghebreyesus, WHO Director-General: "The COVID-19 pandemic has exposed the need for significantly greater local production of vaccines and other essential products in all regions of the world, especially in Africa which relies heavily on imported products and was left behind in the global rush for COVID-19 vaccines. I welcome BioNTech's efforts to establish manufacturing sites in Rwanda, Senegal and South Africa, as well as its plans to commence clinical trials of its malaria vaccine candidates later this year."

Makhtar Diop, Managing Director of International Finance Cooperation: "IFC is committed to working with our public and private sector partners to develop Africa's multi-vaccine manufacturing capabilities across the value chain to create vaccine equality and bolster the continent's health resilience. This goes beyond COVID-19 and the demands of the pandemic. It is a long-term imperative to create a sustainable and commercially viable vaccine manufacturing ecosystem in Africa. The project in Rwanda is a vital part of this."

Prof. Ugur Sahin, M.D., CEO and Co-founder of BioNTech: "We have reached the next milestone with the construction start of the first African mRNA manufacturing facility based on our BioNTainers – just four months after we introduced the BioNTainer concept in February. This factory will be the first in an African network to provide sustainable production capacity for mRNA pharmaceuticals. Further manufacturing facilities in Africa and on other continents are planned to follow. The goal we pursue together with governments and regulatory authorities is to produce vaccines for Africa here with highly skilled professionals from Africa."

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, 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; potential delays in the establishment of the BioNTainers and BioNTech operations in Africa, due to unforeseen delays, including, but not limited to, global supply chain issues; 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, 2021, filed

with the SEC on March 30, 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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