



BioNTech Provides Update on Plans to Develop Sustainable Solutions to Address Infectious Diseases on the African Continent

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- *BioNTech aims to develop the first mRNA-based vaccine for Malaria prevention with the initiation of a clinical trial by end of 2022*
- *BioNTech is evaluating sustainable mRNA vaccine production capacities in Africa; the Company's efforts are supported by the joint convening powers of the World Health Organization (WHO) and the Africa Centers for Disease Control and Prevention (Africa CDC)*
- *BioNTech's Malaria project is part of the 'eradicateMalaria' initiative, led by the kENUP Foundation, to accelerate the eradication of Malaria*

MAINZ, Germany, July 26, 2021 (GLOBE NEWSWIRE) – [BioNTech SE](#) (Nasdaq: BNTX, "BioNTech") today announced the launch of its Malaria project, which aims to develop a well-tolerated and highly effective Malaria vaccine and implement sustainable vaccine supply solutions on the African continent.

BioNTech's Malaria project has two key objectives:

First, the development of a safe and highly effective mRNA vaccine with durable protective immunity to prevent Malaria and disease-associated mortality. BioNTech will assess multiple vaccine candidates featuring known Malaria targets such as the circumsporozoite protein (CSP), as well as new antigens discovered in the pre-clinical research phase. The most promising mRNA vaccine candidates will be selected for clinical development. The start of the clinical trial for the first vaccine candidate is planned for the end of 2022. The Malaria vaccine development program is an extension of BioNTech's COVID-19 vaccine efforts. Building on two decades of mRNA research and its clinical stage mRNA platform, BioNTech has co-developed the first mRNA-based COVID-19 vaccine together with its partner Pfizer.

The second objective is the development of sustainable vaccine production and supply solutions on the African continent. BioNTech is exploring possibilities to set up state-of-the-art mRNA manufacturing facilities, either with partners or on its own. The facilities are expected to manufacture various mRNA-based vaccines upon approval to ensure sustainable supply operations. BioNTech plans to co-locate its African manufacturing capabilities with the technology transfer hubs under development by the WHO, in alignment with the African manufacturing strategy created by the Africa CDC. This strategy aims to expand the capacity of low- and middle-income countries to manufacture contemporary vaccines end-to-end, and scale up production to increase global access.

"The response to the pandemic has shown that science and innovation can transform people's lives when all key stakeholders work together towards a common goal. We are committed to bringing our innovations to those who need them most," said **Prof. Dr. Ugur Sahin, CEO and co-founder of BioNTech**. "We are more than grateful to be part of the joint efforts of the Eradicate Malaria project. Together with our partners, we will do whatever it takes to develop a safe and effective mRNA-based Malaria vaccine that will prevent the disease, reduce mortality and ensure a sustainable solution for the African continent and other regions affected by this disease. Our efforts will include cutting-edge research and innovation, significant investments in vaccine development, the establishment of manufacturing facilities, and the transfer of manufacturing expertise to production sites on the African continent and wherever else it is needed."

BioNTech has undertaken comprehensive antigen discovery processes to identify antigens for various vaccine candidates. Since 2019, the Company has collaborated with the Bill and Melinda Gates foundation to develop Human Immunodeficiency Virus (HIV) and Tuberculosis programs and provide affordable access to vaccines to low- and middle-income countries. For Tuberculosis, BioNTech plans to begin clinical trials for testing a vaccine candidate in 2022, just about two years after the program was initiated. The antigen discovery processes for Malaria and Tuberculosis are being conducted by specialized teams at BioNTech's headquarters in Mainz. Currently, BioNTech and its partners are developing vaccines against nine different infectious diseases, and the Company continues to develop 15 oncology programs at clinical stage based on four different drug classes, including mRNA.

The World Health Organization (WHO), European Commission and other organizations have been involved in the early planning phase of BioNTech's Malaria project and have offered their support to identify and set up the necessary infrastructure. Collaboration with the African Union and the Africa CDC under the partnership for African Vaccine Manufacturing programme will ensure that the enabling factors such as regulatory alignment and policy transfer, as well as country coordination are in place to get the vaccines from factories to the citizens of the African Union.

BioNTech's Malaria project is part of the 'eradicateMalaria' initiative, led by the kENUP Foundation, to accelerate the eradication of Malaria. The kENUP Foundation is a non-profit public benefit foundation supporting research-based innovation in the wider health industries for societal benefit.

About Malaria (source WHO)

In 2019, according to the WHO, there were an estimated 229 million cases of malaria worldwide. The estimated number of malaria deaths stood at 409,000 in 2019. Children aged under 5 years are the most vulnerable group affected by malaria. In 2019, they accounted for 67% (274,000) of all malaria deaths worldwide. The WHO African Region carries a disproportionately high share of the global malaria burden. In 2019, 94% of malaria cases and deaths worldwide were reported on the African continent.

About Tuberculosis (source WHO)

In 2019, an estimated 10 million people fell ill with tuberculosis worldwide. A total of 1.4 million people died from tuberculosis in 2019 (including 208 000 people with HIV). Worldwide, tuberculosis is one of the top 10 causes of death and the leading cause from a single infectious agent (above HIV/AIDS). Eight countries account for two thirds of the total, with India leading the count, followed by Indonesia, China, the Philippines, Pakistan, Nigeria, Bangladesh and South 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, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.de.

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: BioNTech's Malaria, Tuberculosis and HIV 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 and other organizations with establishing infrastructure; the development of sustainable vaccine production and supply solutions on the African continent and the nature 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. 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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