



BioNTech Initiates Phase 1 Clinical Trial for Malaria Vaccine Program BNT165

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- *BioNTech aims to develop the first mRNA-based vaccine for Malaria prevention based on a novel multi-antigen vaccine approach*
- *First evaluated candidate BNT165b1 expresses certain parts of the circumsporozoite protein (CSP)*
- *BNT165 program will assess other vaccine targets to identify the multi-antigen vaccine candidate that will proceed into planned later-stage clinical development*

MAINZ, Germany, December 23, 2022 – [BioNTech SE](#) (Nasdaq: BNTX, “BioNTech”, “the Company”) today announced the initiation of a first-in-human Phase 1 study with BNT165b1, the first candidate from the Company’s BNT165 program, to develop a multi-antigen malaria vaccine candidate. BioNTech will initially evaluate a set of mRNA-encoded antigens of the malaria-causing parasite *Plasmodium falciparum* (*P. falciparum*) to help select the multi-antigen vaccine candidate to proceed to planned later-stage trials. This first clinical trial ([NCT05581641](#)) will evaluate the safety, tolerability and exploratory immunogenicity of the vaccine candidate BNT165b1. BNT165b1 expresses certain parts of the circumsporozoite protein (CSP).

The World Health Organization (WHO) estimated that there were over 247 million cases of malaria and 619,000 associated deaths in 2021¹. *P. falciparum* caused the majority of deaths in sub-Saharan Africa. 95% of all cases occurred in the African region with children under 5 years old being the most vulnerable population, due to a high risk of severe disease progression and chronic complications. So far, one vaccine has been approved in children for prevention of a malaria infection. There is still medical need for the development and manufacturing of highly efficacious vaccines preventing malaria caused by *P. falciparum* to achieve the goal of malaria eradication and to reduce the physical and socioeconomic burden of malaria in highly endemic areas.

BioNTech’s proprietary BNT165 program is part of the Company’s Malaria project first announced in [July 2021](#) and has two key objectives: First, to develop a well-tolerated and highly effective mRNA vaccine with durable protective immunity to prevent blood-stage Malaria infection, clinical disease and disease-associated mortality as well as reduction of secondary transmissions. The second objective is to develop sustainable vaccine production and supply solutions on the African continent, including the Company’s [BioNTainer](#) solution which aims to contribute to the World Health Organization’s (WHO) and the Africa Centers for Disease Control and Prevention’s (Africa CDC) mission to promote health ² and strengthen the capacity of the region to detect, prevent, control and respond quickly and effectively to disease threats³.

BioNTech’s placebo-controlled, observer blinded Phase 1 dose escalation trial is expected to enroll approximately 60 healthy volunteers with no history of previous or current malaria infection throughout several sites in the United States. BNT165b1 will be evaluated at three dose levels.

“The trial initiation is an important milestone in our efforts to help address diseases with high unmet medical need. Our objective is to develop a vaccine that can help to prevent Malaria and reduce mortality. Over the next months we aim to evaluate different antigens with scientific rigor to identify the optimal candidate,” said **Prof. Özlem Türeci, M.D., Chief Medical Officer and Co-Founder of BioNTech**. “In parallel, we are working on establishing manufacturing facilities on the African continent and other regions. The containers for the first BioNTainer for the African network are ready for the transport to Rwanda. If successfully developed and approved, an mRNA-based Malaria vaccine could be manufactured there.”

The [containers for the first BioNTainer](#) have finished construction in Europe and are being prepared for shipment to Kigali, Rwanda, where they are expected to arrive in the first quarter of 2023.

About Malaria

Malaria is an infectious disease caused by *Plasmodium* parasites. The parasite is transmitted to humans mostly through the bites of infected *Anopheles* mosquitos, where it enters the human blood stream and travels to the liver to mature and divide. After the release from the liver cells, the parasite re-enters the blood stream where it multiplies rapidly and can cause disease and death. Moreover, it can be taken up again by a feeding mosquito. Amongst the human-infecting species of *Plasmodium*, *P. vivax* is geographically the most widespread, while *P. falciparum* is associated with severe progressions and disease-associated mortality. The symptoms of a malaria infection in humans are high fever, vomiting and other flu-like symptoms. If untreated or treated late, severe infections have a mortality rate of up to 50%.⁴ The disease is widespread in tropical and subtropical regions, with 95% of all cases occurring in the African region, with children under 5 years old and pregnant women being the most vulnerable population.

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, bispecific immune checkpoint 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.com](#).

BioNTech Forward-Looking Statements

This press release contains “forward-looking statements” of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to: BioNTech’s investigational program candidate BNT165, including the ability to identify antigens and an ideal dose, and to commence later-stage clinical trials; the timing, for any data readouts of the BNT165 phase 1 trial; the nature and characterization of and timing for release of clinical data across BioNTech’s platforms, which is subject to peer review, regulatory review

and market interpretation; 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; and BioNTech's plans for expansion of its manufacturing capacity and capabilities, facilities, and geographical presence. 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.

For a discussion of these and other risks and uncertainties, see BioNTech's Quarterly Report as Form 6-K for the quarter ended September 30, 2022, filed with the SEC on November 7, 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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¹ WHO World malaria report 2022. Available at <https://www.who.int/publications/i/item/9789240064898>

² World Health Organization website. Available at <https://www.who.int/about/who-we-are/our-values>

³ Africa Centers for Disease Control and Prevention (Africa CDC) website. Available at <https://africacdc.org/about-us/our-mission/>

⁴ Geoffrey Pasvol, The treatment of complicated and severe malaria, British Medical Bulletin, Volume 75-76, Issue 1, 2005