BioNTech and CEPI Announce Partnership to Advance mRNA Mpox Vaccine Development and Support CEPI's 100 Days Mission

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- *BioNTech is initiating a Phase 1/2 clinical trial of the mRNA-based mpox vaccine program, BNT166*
- *The Coalition for Epidemic Preparedness Innovations (CEPI) commits funding of up to $90 million for the development of vaccine candidates*
- *Data generated by this partnership will contribute to CEPI's 100 Days Mission, a global effort to accelerate the development of well-tolerated and effective vaccines against future viral threats with pandemic potential*
- *The partnership is part of BioNTech's strategy to develop novel prophylactic vaccines for the prevention of high-medical-need infectious diseases, including diseases that disproportionally affect lower-income countries*

MAINZ, Germany, and OSLO, Norway, September 18, 2023 — BioNTech SE (Nasdaq: BNTX, "BioNTech", "the Company") and the Coalition for Epidemic Preparedness Innovations (CEPI) today announced a strategic partnership to advance mRNA-based vaccine candidates with the development of BNT166 for the prevention of mpox (formerly monkeypox, caused by a member of the Orthopoxvirus viral family), an infectious disease that can lead to severe, life-threatening complications. Mpox gained global attention in May 2022 with an increasing number of cases that then developed into an international outbreak.[1,2] CEPI will provide funding of up to $90 million to support the development of mRNA-based vaccine candidates.

The mpox vaccine program BNT166 is part of BioNTech's efforts to develop novel prophylactic vaccines for a range of infectious diseases with a high medical need, including indications that are disproportionally prevalent in lower-income countries. Since the eradication of smallpox in 1980, the global population-level immunity against the Orthopoxvirus viral family, including mpox, has been waning[3]. BioNTech is aiming to develop a prophylactic mRNA-based mpox vaccine with a favorable safety profile that can be manufactured at scale.

The strategic partnership between BioNTech and CEPI is aiming to contribute to CEPI's 100 Days Mission, a global goal to accelerate development of well-tolerated and effective vaccines against a potential future pandemic virus so that a vaccine can be ready for regulatory authorization and manufacturing at scale within 100 days of recognition of a pandemic pathogen. This mission is spearheaded by CEPI and embraced by the G7, G20, and industry leaders. The partnership between BioNTech and CEPI could help accelerate responses to future outbreaks caused by viruses of the Orthopoxvirus viral family in several ways. For example, advancing the development of an mRNA-based mpox vaccine candidate, if successfully approved and authorized, could help provide larger supplies of vaccines for use against future mpox outbreaks. In addition, the data generated could contribute to the rapid development of mRNA-based vaccines against future outbreaks caused by Orthopoxviruses.

"Mpox can cause severe complications, particularly in children and pregnant women as well as in immunocompromised individuals. The global outbreak, which was declared a public health emergency of international concern, underlines the need for a highly effective, well-tolerated, and accessible mpox vaccine. We initiated our BNT166 program in May 2022 to help address this need," said **Prof. Ugur Sahin, M.D., CEO and Co-founder of BioNTech**. "We believe our scientific approach as well as our mRNA technology have the potential to significantly contribute to deliver on CEPI's 100 Days Mission."

"The 100 Days Mission aims to accelerate the development of a vaccine against a novel virus with pandemic potential to just 100 days, and BioNTech's world-class scientists, technology and facilities can make a vital contribution. Achieving this mission, and potentially preventing the next pandemic, will require gathering a wealth of knowledge and data about the performance of the latest vaccine platforms, like mRNA, which can enable rapid responses to emerging infectious threats across a broad range of viruses. Our work on mpox could broaden the portfolio of vaccines available against this potentially deadly disease, while building our understanding of how mRNA technology performs against Orthopoxviruses, a family of viruses that have long afflicted humankind and remain an ongoing threat today," said **Richard Hatchett, M.D., Chief Executive Officer of CEPI**.

The BNT166 vaccine candidates encode surface antigens that are expressed in the two infectious forms of the monkeypox virus (MPXV) to efficiently fight virus replication and infectivity. The clinical trial (NCT05988203) will evaluate the safety, tolerability, reactogenicity and immunogenicity of two mRNA-based multivalent vaccine candidates for active immunization against mpox. The Phase 1/2 trial aims to enroll 196 healthy participants with and without prior history of known or suspected smallpox vaccination (vaccinia-naive participants).

BNT166 is part of BioNTech's infectious disease programs aiming to provide equitable access to effective and well-tolerated vaccines for high medical need indications. This includes BioNTech's Malaria and Tuberculosis programs, BNT165 and BNT164, respectively, which are both currently in Phase 1 clinical trials. BioNTech's efforts also include the establishment of a decentralized and robust end-to-end manufacturing network in Africa aiming to enable scalable production of mRNA-based medicines. The first manufacturing site based on the Company's state-of-the-art, scalable BioNTainer solution is currently being built in Kigali, Rwanda.

BioNTech and CEPI are committed to enabling equitable access to the outputs of this partnership. Any licensed vaccines developed as a result of this strategic partnership are expected to be made available at affordable prices in low- and middle-income countries.

About mpox

Mpox (formerly monkeypox) is a zoonotic infectious disease caused by the *monkeypox virus* (*MPXV*), a member in the genus *Orthopoxvirus* that also comprises the smallpox-causing *variola* virus. Typical symptoms include skin rash and mucosal lesions, fever, swollen lymph nodes, head-/muscle ache and sore throat. Severe forms of the disease can occur particularly in children and immunocompromised individuals as well as during pregnancy, with complications including superinfections of the rash and lesions, pneumonia, sepsis, encephalitis, stillbirth and loss of vision following corneal infection. Human-to-human transmission can occur through physical contact, contaminated objects, or body fluids, including sexual contact. Although vaccines against members of the Orthopoxvirus family are currently available, there is a high need for an mpox vaccine broadly available especially in endemic regions. BioNTech and CEPI aim to address this need with this strategic partnership by potentially broadening the portfolio of vaccines

available against this virus.

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 DualityBio, 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 be limited to, statements concerning: BioNTech's efforts to develop novel prophylactic vaccines for a range of infectious diseases with high medical need; BioNTech's partnership with CEPI and BioNTech's ability to receive up to $90 million in funding; the potential ability of BNT166 to provide protection against mpox; the timing and success of a Phase 1/2 dose-escalation trial of BNT166a and BNT166c for active immunization against mpox; qualitative assessments of available data and expectations of potential benefits; and BioNTech's ability to develop and, if successfully developed and approved, commercialize its vaccine candidates, including BNT166. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control, and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the future commercial demand and medical need for an mRNA-based mpox vaccine; the availability of raw materials to manufacture a vaccine; competition from other mpox vaccines, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; and other factors not known to BioNTech at this time.
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 June 30, 2023, and in subsequent filings made by BioNTech with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at 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.

About CEPI
CEPI is an innovative partnership between public, private, philanthropic, and civil organisations, launched at Davos in 2017, to develop vaccines against future epidemics. Prior to COVID-19, CEPI's work focused on developing vaccines against the Ebola Virus Disease, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever virus and Chikungunya virus. It has over 20 vaccine candidates against these pathogens in development. CEPI has also invested in new platform technologies for rapid vaccine development against unknown pathogens (Disease X).
During the COVID-19 pandemic, CEPI initiated multiple programs to develop vaccines against SARS-CoV-2 and its variants with a focus on speed, scale and access. These programs leverage the rapid response platforms developed by CEPI's partners prior to the emergence of COVID-19, as well as new collaborations. The aim is to advance clinical development of a diverse portfolio of safe and effective COVID-19 candidates and to enable fair allocation of these vaccines worldwide through COVAX.

CEPI's 5-year plan lays out a $3.5 billion roadmap to compress vaccine development timelines to 100 days, develop a broadly protective vaccine against COVID-19 and other *Betacoronaviruses*, and create a "library" of vaccine candidates for use against known and unknown pathogens. The plan is available at https://endpandemics.cepi.net.

Follow CEPI's news page for the latest updates. Follow CEPI via @CEPIvaccines, @DrRHatchett, and on LinkedIn.

To read more about how the world can work together to #endpandemics, check out DISEASE X – The 100 Days Mission to End Pandemics, by CEPI's Chief Scientific Writer Kate Kelland, available here at Bookshop.org. All author proceeds go to the World Health Organization Foundation's COVID-19 Response.

CEPI and mpox
In response to the public health emergency of international concern (PHEIC) declared in July 2022, CEPI provided funding of up to $375,000 to the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the UK Health Security Agency (UKHSA) to advance development of a mpox antibody standard and assays, to provide a standardized approach to test the performance of vaccines being used or in development against mpox.

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[1] https://www.who.int/emergencies/situations/monkeypox-oubreak-2022

[2] https://www.who.int/europe/news/item/23-07-2022-who-director-general-declares-the-ongoing-monkeypox-outbreak-a-public-health-event-of-international-concern

[3] Simpson K, Heymann D, Brown CS *et al.* Human monkeypox - After 40 years, an unintended consequence of smallpox eradication. Vaccine. 2020 Jul 14;38(33):5077-5081. doi: 10.1016/j.vaccine.2020.04.062. Epub 2020 May 13. PMID: 32417140; PMCID: PMC9533855.