BioNTech and CEPI Expand Partnership to Strengthen Africa's mRNA Vaccine Ecosystem

May 29, 2024

- *BioNTech and CEPI aim to enhance local R&D, clinical and commercial-scale manufacturing capacities to develop potential mRNA vaccines in Africa, for Africa*
- *CEPI to fund up to $145 million to support BioNTech in broadening the scope of the manufacturing facility in Kigali, Rwanda, aimed at addressing needs of African countries and in compliance with global standards*
- *Partnership intends to contribute to building a sustainable and resilient end-to-end African vaccine ecosystem*
- *BioNTech and CEPI commit to contributing to enabling equitable access, including affordable pricing to select vaccines made at the facility for LMICs, with priority access to African countries, and committed capacity to manufacture emergency response vaccines*

MAINZ, Germany/OSLO, Norway, May 29, 2024 – BioNTech SE (Nasdaq: BNTX, "BioNTech", "the Company") and the Coalition for Epidemic Preparedness Innovations ("CEPI") are expanding their strategic partnership to contribute to building a sustainable and resilient end-to-end African vaccine ecosystem. CEPI is committing up to US $145 million[1] to support BioNTech to establish mRNA vaccine R&D, clinical and commercial-scale manufacturing capabilities at the Company's facility in Kigali, Rwanda. These capabilities will contribute to efforts to better prepare for potential future epidemic and pandemic threats in Africa.

BioNTech's commercial-scale manufacturing facility in Kigali was first announced in 2021 and inaugurated in December 2023. The facility is based on the Company's high-tech, digitally enabled modular manufacturing units called BioNTainers, designed to manufacture a range of mRNA-based vaccines. BioNTech's Kigali manufacturing facility could become the first commercial mRNA facility in Africa, intended to support the African Union's and Africa CDC's goal of producing 60 percent of total vaccine doses required on the continent by 2040.

BioNTech and CEPI are committed to enabling equitable access. Under the terms of the agreement BioNTech intends to provide affordable access to BioNTech's prophylactic vaccines manufactured at the Kigali facility, such as vaccines against malaria, mpox and tuberculosis, to low and middle-income countries, with priority supply to African countries, if successfully developed and authorized. BioNTech and CEPI intend to work jointly to rapidly respond to outbreaks on the African continent caused by known viral threats, or an as-yet-unknown pathogen with epidemic or pandemic potential.

The BioNTech-CEPI partnership aims to back the Company's existing efforts in three key areas for Africa's pandemic preparedness and vaccine ecosystem:

1. **Commercial-scale manufacturing:** CEPI's funding will support measures required for the regulatory authorization of the facility in Rwanda, starting in 2025. Under the terms of the agreement, in the event of a disease outbreak or a potential disease outbreak, BioNTech, would dedicate up to half of the facility's manufacturing capacity to produce emergency response mRNA vaccines, subject to regulatory authorization. This effort aims to contribute to the 100 Days Mission, a global initiative to accelerate the development of safe and effective vaccines in response to an outbreak of a novel Disease X in as little as 100 days. The 100 Days Mission is spearheaded by CEPI and embraced by the G7, G20 and industry leaders.

2. **End-to-end clinical-scale manufacturing of novel vaccine candidates:** The majority of the CEPI funding will be allocated to set up clinical-scale manufacturing capabilities for mRNA-based vaccine candidates at the Kigali facility. This will allow the BioNTech facility to manufacture on both a clinical and commercial scale, and thus broaden the manufacturing scope, in support of a sustainable use case for the facility while strengthening the wider African vaccine development ecosystem.
   BioNTech is separately 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 (supported by CEPI funding). Clinical trials for tuberculosis, malaria and mpox vaccine programs are underway in Europe, the United States, and South Africa. In addition, BioNTech aims to conduct clinical trials in Africa for vaccine candidates against malaria, HIV, and mpox.

3. **Strengthening the African R&D ecosystem for mRNA-based vaccines:** CEPI's funding will enable BioNTech to dedicate manufacturing capacities to third party projects with the aim of supporting, pre-clinical and clinical activities, including those by African-based researchers, academic groups, local businesses, public-private partnerships and non-profit organizations[2]. The projects shall be selected in partnership with global, regional and national healthcare organizations. This effort by BioNTech and CEPI has the potential to enable R&D activities for novel mRNA-based vaccine candidates against pathogens with epidemic or pandemic potential.

"Africa still has to import 99 percent of all the vaccines it needs to protect its people from potentially deadly diseases, meaning many are left waiting far too long to get the life-saving doses they need. This must change if the world is going to avoid the terrible inequity of vaccine distribution that so clearly exacerbated the effects of the COVID-19 pandemic. Through our joint commitment to equitable access, CEPI's investment in BioNTech's forward-

looking efforts in Africa will boost regional capacity for end-to-end research, development and rapid manufacturing of mRNA vaccines. This will contribute to Africa's resilience and pandemic readiness and could dramatically alter the course of future outbreaks," said **Dr. Richard Hatchett, CEO of the Coalition for Epidemic Preparedness Innovations (CEPI).**

"Our partnership with CEPI is an important next step in our comprehensive strategy towards sustainable mRNA vaccine manufacturing in Africa. Our joint efforts are strengthening the implementation of a local mRNA vaccine ecosystem - covering the entire spectrum from research and clinical trials to commercial production," said **Prof. Ugur Sahin, M.D., CEO and Co-founder of BioNTech**. "This, along with our continued efforts to develop mRNA vaccines against diseases like tuberculosis, malaria, HIV, and mpox is aimed at bringing lasting health benefits to millions of people in Africa."

BioNTech and CEPI first announced their strategic partnership in September 2023.

The following parties, which are not contractually involved in this strategic partnership, indicated their support:

Dr. Sabin Nsanzimana, Minister of Health, Republic of Rwanda: "The Government of Rwanda is committed to tackling vaccine inequities that were exposed during the pandemic. We believe this innovative partnership we are building can be a demonstration to the world, that Africa is not only building resilience for future pandemics but also creating a sustainable clinical ecosystem across Africa using the most advanced mRNA technology. The power of partnership is what will make this project successful, and today is another great milestone towards creating vaccine equity."

H.E. Dr. Jean Kaseya, Director General of Africa Centres for Disease Control (Africa CDC), said: "Rapid and equitable access to life-saving vaccines starts with local development and manufacturing. CEPI and BioNTech's joint endeavor in Rwanda will contribute to Africa's R&D ecosystem and support Africa CDC's Platform for Harmonized African Health Products Manufacturing (PHAHM)'s goal to produce 60 percent of the vaccines needed by the continent by 2040. Working together, we can pave the way to strengthen Africa's pandemic preparedness and health security."

Dr. Tedros Adhanom Ghebreyesus, WHO Director-General: "The COVID-19 pandemic exposed the risks to global health when production of vaccines and other tools is concentrated in too few hands. Strengthening local and regional production, especially in Africa and the Middle East, is critical for ensuring a more equitable response to future epidemics and pandemics, and for fighting other persistent health challenges. Public-private partnerships like this are part of a growing global movement, bringing together companies, foundations and countries to diversify production and make the world a safer place. This is an important day for Rwanda and Africa and should act as a steppingstone for further countries and parties to come together."

About CEPI
CEPI was launched in 2017 as an innovative partnership between public, private, philanthropic and civil organizations. Its mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need. CEPI has supported the development of more than 50 vaccine candidates or platform technologies against multiple known high-risk pathogens or a future Disease X. Central to CEPI's pandemic-beating five-year plan for 2022-2026 is the '100 Days Mission' to compress the time taken to develop safe, effective, globally accessible vaccines against new threats to just 100 days.

About BioNTech
Biopharmaceutical New Technologies (BioNTech) is a global next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. BioNTech 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 and specialized pharmaceutical collaborators, including Biotheus, DualityBio, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, MediLink, OncoC4, Pfizer and Regeneron.

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 $145 million in funding; BioNTech's efforts to establish mRNA research and development, clinical and commercial-scale manufacturing capabilities at its facility in Kigali; BioNTech's ongoing and future planned clinical trials, including in Africa; and BioNTech's ability to develop and, if successfully developed and approved, commercialize its vaccine candidates. 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 based on BioNTech's current expectations and beliefs of future events, and are neither promises nor guarantees. 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 and adversely 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, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its product candidates; discussions with regulatory agencies regarding timing and requirements for additional clinical trials; BioNTech's and its counterparties' ability to manage and source necessary energy resources; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; unforeseen safety issues and potential claims that are alleged to arise from the use of products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market, if approved, its product candidates; BioNTech's ability to manage its development and expansion; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products and BioNTech's product candidates; risks relating to the global financial system and markets; the future

commercial demand and medical need for mRNA-based products in Africa; the availability of raw materials to manufacture a vaccine; competition from other products, 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; 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 March 31, 2024 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. These forward-looking statements speak only as of the date hereof. 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.

Press Contact Details

CEPI
+44 7387 055214
press@cepi.net

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

Investor Relations
Victoria Meissner, M.D.
+1 617 528 8293
Investors@biontech.de

[1]contingent on pre-agreed activity milestones
[2]Projects must meet certain criteria and shall be selected in partnership with global, regional and national healthcare organizations.