

Tuberculosis Vaccine Candidate Could Be the First in 100 Years

TB is one of the world's deadliest diseases and the leading killer of people with HIV.

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Wellcome and the Gates Foundation to Fund Late-Stage Development of a Tuberculosis Vaccine Candidate That Could Be the First in 100 Years If Proven Effective

LONDON and SEATTLE (June 28, 2023) – Wellcome and the Bill & Melinda Gates Foundation today announced funding to advance a tuberculosis (TB) vaccine candidate, M72/AS01E (M72), through a Phase III clinical trial. If proven effective, M72 could potentially become the first new vaccine to help prevent pulmonary TB, a form of active TB, in more than 100 years.

In 2021, an estimated 10.6 million people fell ill with TB and 1.6 million died—about 4,300 people per day. The disease primarily affects people in low- and middle-income countries, and those at highest risk are often living in poverty, with poor living and working conditions and undernutrition. Up to a quarter of the world's population is thought to have latent TB, a condition in which a person is infected with the bacterium that causes TB but does not have any symptoms and is at risk of progressing to active TB disease.

“Despite being curable, TB remains one of the leading causes of death in South Africa,” said Nomathamsanqa Majozi, head of public engagement at Africa Health Research Institute. “In the area where I live and work, more than half of all people have had, or will have, TB at some point in their lives. The consequences are devastating, both at a personal and a community level. M72 offers us new hope for a TB-free future.”

To support the M72 Phase III clinical trial, which will cost an estimated US\$550 million, Wellcome is providing up to US\$150 million and the Gates Foundation will fund the remainder, about US\$400 million.

“TB remains one of the world's deadliest infectious diseases,” said Julia Gillard, chair of the Board of Governors at Wellcome. “The development of an affordable, accessible vaccine for adults and adolescents would be game-changing in turning the tide against TB. Philanthropy can be a catalyst to drive progress, as shown by this funding of the M72 vaccine as a potential new tool in

preventing escalating infectious diseases to protect those most affected. Sustainable progress against TB and wider disease threats will depend on global collaboration, financial backing, and political will. By working with communities and researchers in countries with a high burden of the disease, we can get one step closer to eliminating TB as a public health threat.”

The only TB vaccine in use today, bacille Calmette-Guérin (BCG), was first given to people in 1921. It helps protect babies and young children against severe systemic forms of TB but offers limited protection against pulmonary TB among adolescents and adults.

“With TB cases and deaths on the rise, the need for new tools has never been more urgent,” said Bill Gates, co-chair of the Bill & Melinda Gates Foundation. “Greater investment in safe and effective TB vaccines alongside a suite of new diagnostics and treatments could transform TB care for millions of people, saving lives and lowering the burden of this devastating and costly disease.”

Over 25 years, a vaccine with at least 50% efficacy could prevent up to 76 million new TB cases and 8.5 million deaths, avert the need for 42 million courses of antibiotic treatment, and prevent US\$41.5 billion in TB-related catastrophic household costs, especially for the world’s poorest and most vulnerable people, according to the World Health Organization (WHO).*

The Phase III clinical trial to assess the candidate vaccine’s efficacy at preventing progression from latent TB infection to pulmonary TB will be sponsored by the Bill & Melinda Gates Medical Research Institute (the Gates MRI), a nonprofit organization and subsidiary of the Gates Foundation dedicated to the development and effective use of novel biomedical interventions to address substantial global health concerns. Conducted in collaboration with an international consortium of TB clinical investigators, the trial will enroll approximately 26,000 people, including people living with HIV and without TB infection, at more than 50 trial sites in Africa and Southeast Asia. Additional details about the trial design and participants will be announced by the Gates MRI in the coming months. The Gates MRI is the license holder for M72 in low- and middle-income countries with high TB burden.

The M72 vaccine candidate, one of 17 TB vaccine candidates currently in the pipeline, has been in development since the early 2000s. It was developed by GSK up to the proof-of-concept phase (Phase IIb), in partnership with Aeras and the International AIDS Vaccine Initiative (IAVI), and was funded in part by the Gates Foundation. In the Phase IIb trial, M72 showed approximately 50% efficacy in reducing pulmonary TB in adults with latent TB infection—an unprecedented result in decades of TB vaccine research.

WHO Director-General Dr. Tedros Adhanom Ghebreyesus said the support by the Gates Foundation and Wellcome to develop a new TB vaccine, and the opportunity of September’s UN high-level meeting on TB, shows the world can turn the tide on the TB crisis through sustained political and financial action. “The tuberculosis crisis demands a new vaccine to reduce disease transmission and avoidable death, especially targeting adults and adolescents who carry at least 90% of the TB epidemic’s burden,” said Dr. Tedros. “WHO welcomes the commitments from the Bill & Melinda Gates Foundation and Wellcome to take forward development of this vaccine candidate, and WHO

will keep supporting vaccine development and access more broadly through its TB Vaccine Accelerator Council.”

* For more information about the value proposition for new tuberculosis vaccines, see the WHO-commissioned “[An Investment Case for New Tuberculosis Vaccines](#).”

About the Vaccine Candidate

The M72/AS01E vaccine candidate contains the M72 recombinant fusion protein, which is derived from two *Mycobacterium tuberculosis* antigens (Mtb32A and Mtb39A), combined with the GSK proprietary Adjuvant System AS01E. The vaccine candidate was developed up to the proof-of-concept phase by GSK in conjunction with Aeras and IAVI. In 2020, GSK announced that it would partner with the Gates MRI for continued development and potential use of the M72 candidate vaccine in countries with high TB burden. GSK will continue to provide the adjuvant for the candidate vaccine’s further development and potential launch. Funding for the research that uncovered the potential of M72 was provided by the United Kingdom’s Department for International Development, the Directorate-General for International Cooperation in the Netherlands, the Australian Department for Foreign Affairs and Trade, the European Commission, and the Bill & Melinda Gates Foundation.

About Tuberculosis

TB causes more deaths annually than any other infectious disease, with an estimated 10.6 million new cases and 1.6 million deaths in 2021. The COVID-19 pandemic reversed progress against TB and revealed the fragility of the steady gains made over the previous 20 years in expanding access to prevention, testing, and treatment. In 2021, during the pandemic, TB cases increased by 4.5% compared to those reported in 2020, and fewer people were diagnosed or received treatment. To get back on track to achieving the 2030 United Nations Sustainable Development Goals target of [an 80% reduction in the TB incidence rate compared with 2015](#), the world urgently needs new tools to combat this disease.

TB is also the leading killer of people living with HIV, accounting for one-third of deaths among HIV-positive people. The world’s most vulnerable populations are disproportionately affected by TB, with many cases of TB occurring in resource-limited areas. Over 80% of cases and deaths are in low- and middle-income countries.

About TB Research and Development

After 20 years of increased investment in research and development (R&D), the TB innovation pipeline is strengthening, with new tools that have the potential to accelerate progress toward the 2030 global target. The pipeline includes novel diagnostic tests and sample collection methods, as well as shorter drug regimens for TB and drug-resistant TB. But ending TB as a global health burden can only be achieved with the development and deployment of an effective vaccine for adolescents and adults.

Additional R&D investments in effective diagnostics and vaccines and shorter drug regimens are

needed to accelerate progress against TB. According to the Global Plan to End TB 2023-2030, more than US\$26 billion is needed each year from 2023 to 2030 to scale up TB care and prevention services for all people in need. TB R&D will require an additional US\$5 billion per year during that period. Global backing, both financial and political, is necessary to drive innovation and develop, manufacture, and deliver a robust pipeline of TB diagnostics, treatments, and vaccines to save and protect millions of lives from TB.

About Wellcome

Wellcome supports science to solve the urgent health challenges facing everyone. We support discovery research into life, health and wellbeing, and we're taking on three worldwide health challenges: mental health, infectious disease and climate and health.

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About the Bill & Melinda Gates Foundation

Guided by the belief that every life has equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy, productive lives. In developing countries, it focuses on improving people's health and giving them the chance to lift themselves out of hunger and extreme poverty. In the United States, it seeks to ensure that all people—especially those with the fewest resources—have access to the opportunities they need to succeed in school and life. Based in Seattle, Washington, the foundation is led by CEO Mark Suzman, under the direction of Co-chairs Bill Gates and Melinda French Gates and the board of trustees.

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