

Dear Mr. President.

It is our honor to write to you on behalf of the TB Vaccines Advocacy Roadmap, an international coalition of advocates working to ensure the accelerated development of new effective and globally accessible tuberculosis (TB) vaccines.

From February 22–25, the city of Toulouse will virtually host the world's largest gathering of TB vaccine stakeholders, the 6th Global Forum on TB Vaccines. We are grateful for your high patronage of this meeting, as well as the Patronage of Minister of Health, Mr. Veran, and for its inclusion in the official agenda of the French European Presidency.

Representing a diverse coalition of stakeholders—including TB survivors, TB scientists, and community and civil society representatives from dozens of TB and global health organizations from France, Europe, and across the world—we write to you today to respectfully appeal to your leadership in ensuring that France is highly represented at the 6th Global Forum on TB Vaccines and that the development of new TB vaccines receives priority attention in the European Union, G20, and G7 agendas whenever global health research, pandemic preparedness, and antimicrobial resistance are discussed.

Even in the wake of the COVID-19 pandemic, TB remains the leading infectious cause of death in much of the world. The disruption of health services due to the COVID-19 pandemic in the countries most affected by TB has erased years of painstaking progress in TB control. In 2020, the number of people dying from TB increased for the first time in over a decade to 1.5 million people, including 214,000 people living with HIV, for whom TB remains the leading cause of death. Almost 10 million people fell ill with TB disease, but only 5.8 million received a diagnosis, a drop of nearly 20% from before the pandemic, leaving millions of people undiagnosed and untreated. These setbacks require an urgent response by Heads of State and Government to prioritize the TB response and ensure vital progress toward ending TB is made.

Vaccines offer the most direct route out of the TB crisis. The only available TB vaccine—the century-old Bacille Calmette–Guérin (or BCG)—constitutes a major achievement of French scientific ingenuity and drive, but notwithstanding its protection against the most serious forms of TB in infants, it is unable to prevent pulmonary TB in most adolescents and adults, who represent the main drivers of the global TB epidemic. Moreover, with only a handful of new TB drugs developed in the past 50 years, treatment still takes months or years, with many debilitating and deadly side effects. Understandably, adherence to treatment can be poor, contributing to TB as a key driver of the global health and security threat of antimicrobial resistance (AMR). Less than a third of the half a million people estimated to fall sick with drug-resistant TB each year receive a diagnosis. Further, treating drug-resistant TB is many times more expensive than treating drug-susceptible TB. In recent years, Eastern Europe and Central Asia have become a hotspot of drug resistant TB incidence[1]. Unless current commitments on TB control are met, TB will continue to risk millions of lives and cost the global economy trillions of dollars in the coming decades[2].

New TB vaccines will be effective against drug-resistant and drug-susceptible TB, reduce the need for antibiotics, and offer vital protection to adolescents and adults to break the cycle of transmission and facilitate the End of TB as a global infectious threat. In the process, TB vaccines will generate massive direct and indirect public health and economic gains.

Despite chronic underfunding, decades of scientific ingenuity and persistence have resulted in a diverse pipeline of promising TB vaccine candidates, including six novel candidates in advanced development stages. Researchers are ready to move these candidates forward into late phase testing, and eventual licensure and global access. If these advances are slowed, the world is likely to lose 10–20 years of progress towards a successful vaccine.



Standing in the way of this progress is the scarcity of resources for TB vaccine research. At the United Nations High-Level Meeting to End TB in 2018, world leaders pledged to deliver at least \$2 billion annually for TB research and development (R&D), of which \$550 million was earmarked for vaccines.

Despite these international commitments and the overwhelming evidence supporting the need of new TB vaccines, resources for TB vaccine research remain pitifully scarce. TB R&D is impeded by an annual \$1.1 billion shortfall, while funding for TB vaccines has never exceeded \$120M million per year[3]. The consequences of underfinancing TB vaccine development have become painfully clear in the light of the unparalleled COVID-19 research and development (R&D) response, with governments mobilizing \$104 billion for the research and development of COVID-19 vaccines and therapeutics in the first eleven months of the pandemic—75 times more than all funding for TB vaccine R&D from 2005 to 2020[4]. This disparity signals TB as a disease of the socioeconomically dispossessed and reflects a deep inequity in affording everybodythe human rights to health and to benefit from scientific progress.

Today, people the world over understand better than ever the power of vaccines in protecting us all against infectious diseases threats. Just as the COVID-19 pandemic will not be controlled without global access to effective vaccines, neither will TB. Investing in TB vaccine research, development, and access is not just the right thing to do, but the smart thing to do.

As the leader of a country internationally renowned for its pioneering contributions to public health and vaccine research, scientific innovation, social advancement, and global health and solidarity, and as the current President of the European Union, we humbly request your urgent leadership in ensuring the success of the 6th Global Forum on TB Vaccines and in mobilizing renewed efforts by the European Union, G20, and G7 leaders to firmly position TB vaccines as a key component of the international global health research, pandemic preparedness, and antimicrobial agendas.

It would be an honor to meet with you at your earliest convenience to further discuss the rationale, feasibility, and urgency of our asks.

Respectfully,

The TB Vaccine Advocacy Roadmap, On behalf of the undersigned

[1] World Health Organization Regional Office for Europe. <u>Tuberculosis in the WHO European Region Fact sheet</u>. Copenhagen: World Health Organization; 2019.

[2]Sachin Silva et al. Economic impact of tuberculosis mortality in 120 countries and the cost of not achieving the Sustainable Development Goals tuberculosis targets: a full-income analysis. Lancet Global Health. 2012; 9(10):E1372−79. [3]Treatment Action Group. Tuberculosis research funding trends: 2005−2020. New York: Treatment Action Group; 2021. [4] kENUP Foundation (Press Release). Governments spent at least €93bn on COVID-19 vaccines and therapeutics during the last 11 months. 2021 January 11.



This open letter is endorsed by the following 91 organizations

















































































































(Results Australia &

Results Canada)



(Results UK)

















































Arc en Ciel, Niger

Alliance Burundaise pour la lutte contre la Tuberculose et la Lèpre (ABTL), Burundi

Association des Anciens Patients Tuberculeux du Bénin (ASSAP-TB), Bénin

Association pour le Bien-être des Personnes Infectées et Affectées par le VIH/Sida (ABPIAS), Burkina Faso

Association Mauritanienne de Lutte Contre la Tuberculose et le SIDA (AMALUTS), Mauritius

Association Yientodima de Piéla, Burkina Faso

<u>Association Wendkouni du Namentenga</u>, Burkina Faso

Conseil burkinabè des organisations de développement communautaire (BURCASO), Burkina Faso

ONG Stop Tuberculose Bouaké, Côte d'Ivoire

<u>Plateforme des ONG et Associations de lutte contre le Paludisme, République du Congo</u>

Réseau Association des Femmes Samaritaines, Madagascar

This open letter is endorsed by TB Survivors of the EU States



The family of Sumaya Aguilar Mármol Belgium



Rhea Lobo Denmark



Mauro Guarinieri France



Anna Sutyagina Germany



Frederica Poli Italy



Frouke Procee
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Enrique Delgado Spain

This open letter is endorsed by the following members of the global TB community

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- Amrita Limbu, Touched by TB, India
- Ani Hernasari, Rekat Peduli Indonesia Foundation
- Augustin Dokla, RAS+TOGO, Togo
- · Austin Obiefuna, Afro Global Alliance, Ghana
- Ben Ahmed lamine Bamba, ONG Fraternité, Côte d'Ivoire
- Bertrand Kampoer, DRAF TB, Cameroon
- Cheleka Mpande, Eh!woza, South Africa
- Clotaire Rodonne Siribi, Groupe d'Action de Paix et de Formation pour la Transformation (GAPAFOT), Central African Republic
- David Afreh, Stop TB Ghana
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- Endakalchew Kekadu, VHS Ethiopia
- Epiphane Gainsi, Centre Communautaire Saint Augustin (CCSA), Bénin
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- Ganesh Acharya, TB Survivor & Activist, India
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