

First-of-its-kind global collaboration launched to develop transformative treatment regimens for tuberculosis

- ***A new global collaboration of philanthropic, non-profit and private sector organizations will work together to accelerate the development of novel TB treatment regimens for all TB patients.***
- ***The global collaboration aims to create treatment regimens comprised of medicines to which there is limited or no drug resistance and that are ready for phase 3 development.***
- ***The regimens could be an important step toward addressing the current global challenges around TB treatment complexity, and the diagnosis and treatment of drug-resistant TB.***

27 February 2020 – Today a consortium of philanthropic, non-profit and private sector organizations launched a collaboration that aims to accelerate the development of novel “pan-TB” drug regimens for the treatment of tuberculosis (TB) that are ready for phase 3 development. The regimens will be designed to have little to no drug resistance and an acceptable safety profile, and be better-tolerated, shorter in duration and simpler to use than existing options. Such regimens are intended to be a central component of efforts to address the current complexities and challenges of TB treatment.

The members of the Project to Accelerate New Treatments for Tuberculosis (PAN-TB collaboration) – Evotec, GSK, Johnson & Johnson, Otsuka Pharmaceutical Co., Ltd., based in Japan, the Bill & Melinda Gates Medical Research Institute and the Bill & Melinda Gates Foundation – have committed to leveraging their unique assets, resources and scientific expertise to advance the development of novel regimens.

“Current tools are insufficient for accelerating and sustaining global progress against TB,” said Trevor Mundel, President of Global Health at the Bill & Melinda Gates Foundation. “Innovative partnerships, such as the PAN-TB collaboration, are urgently needed to develop new drugs and treatment regimens that can address TB and advance progress towards achieving global elimination TB goals.”

TB causes more deaths globally than any other infectious disease, with 10 million new cases and 1.5 million deaths recorded in 2018 alone. TB is responsible for up to a third of all mortality associated with antimicrobial resistance (AMR).^{1,2}

The current regimen for drug-sensitive TB, the most common and easiest to treat form of TB, requires that patients take multiple drugs for six or more months under clinical monitoring. Patients with drug-resistant TB cannot use this regimen and face longer and more complex treatment regimens, often with

¹ WHO, Global Tuberculosis Report, 2019.

² WHO, No time to wait: Securing the future from drug-resistant infections, 2019.

significant side effects.³ Currently, patients must undergo additional testing to diagnose drug-resistant TB.

The regimens that the PAN-TB collaboration is working to develop could help transform TB care. A shorter and safer novel regimen that can treat TB irrespective of pre-existing drug resistance and with reduced need for drug resistance testing, could provide a significant benefit to both patients and health systems.

The PAN-TB collaboration will identify and assess the potential of investigational pan-TB regimens, through phase 2 clinical efficacy studies. Collaborative pre-clinical research activities have begun. Clinical trials will be announced as they are planned.

Partner Quotes

- Penny Heaton, M.D., CEO of the Bill & Melinda Gates Medical Research Institute: “The development of a regimen that can treat both drug-sensitive and drug-resistant tuberculosis could be a game changer for how the world addresses TB and growing antimicrobial resistance. The PAN-TB collaboration’s unique partnership model leverages the assets and expertise of multiple partners to fill a crucial need in the tuberculosis treatment research and development pipeline.”
- Dr. Cord Dohrmann, Chief Scientific Officer of Evotec: “Tuberculosis continues to be a significant global health burden, and so far all efforts to eradicate the disease have failed. One reason for this is that the current treatment regimen is both complex and time-consuming. We are proud to be part of PAN-TB, which unites global leaders in their respective fields. We believe that through the PAN-TB collaboration we have all the resources necessary to lead the TB treatment regimen into a new era where an effective, universally applicable treatment for this devastating medical condition is globally available.”
- Pauline Williams, MD, Senior Vice President of GSK Global Health Pharma: “GSK is committed to improving global health through our science and we have a world-leading pipeline of TB candidate medicines aiming to eliminate this deadly infectious disease. However, no one organisation can succeed in tackling TB alone. As a partner in the PAN-TB collaboration, we will contribute our scientific knowledge and innovative TB assets to determine the optimal treatment regimen to treat and cure TB patients regardless of their resistance profile to current treatments.”
- Ruxandra Draghia-akli, M.D, Ph.D., Global Head of Global Public Health R&D, Johnson & Johnson said: “Solving the TB challenge is deeply personal for Johnson & Johnson. It was one of the driving forces that compelled Dr. Paul Janssen, namesake of the Janssen Pharmaceutical Companies, to commit his life to the advancement of modern medicine, because he lost a loved one to this terrible disease. Over the past 20 years, J&J has made good on Dr. Janssen’s commitment, discovering and bringing to market one of the most important new TB medicines in half a century. But we can’t beat TB alone. That’s why we’re honored to join forces with the Gates Foundation and other pharmaceutical companies in the quest to create the first pan-TB

³ WHO, Guidelines for treatment of drug-susceptible tuberculosis and patient care (2017 update).
https://www.who.int/tb/publications/2017/dstb_guidance_2017/en/

treatment regimen. Together, we are confident that we can transform TB treatment and end this disease once and for all.”

- Mr. Keiso Yamasaki, TB Global Project Leader of Otsuka Pharmaceutical Co., Ltd., based in Japan: “We are extremely proud to be part of this unique collaboration. For nearly half a century, Otsuka has been dedicated to tuberculosis research and development in the hope of eliminating this neglected disease. From new compounds, diagnostics and pediatric tools, we remain committed to developing innovations for tuberculosis. We applaud the Bill & Melinda Gates Foundation for bringing together leaders in the TB field to help develop a new universal treatment regimen guiding us closer towards the goal of TB elimination.”

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About the Project to Accelerate New Treatments for Tuberculosis

The Project to Accelerate New Treatments for Tuberculosis (PAN-TB collaboration) is a first-of-its-kind collaboration among philanthropic, non-profit and private sectors that aims to accelerate the development of an investigational drug regimen capable of treating all forms of tuberculosis.

The PAN-TB collaboration will leverage members’ collective assets, resources and scientific expertise to identify and evaluate new drug regimens with an acceptable safety profile, that have the potential to treat both drug-sensitive and drug-resistant TB, and are better-tolerated, shorter in duration and simpler to use than existing options. The collaboration will focus on advancing research through phase 2 clinical efficacy studies in order to identify promising regimens for further development.

The PAN-TB collaboration plans to work closely and transparently with the European Regimen Accelerator for Tuberculosis (ERA4TB), which was launched in January 2020. New molecular entities identified by ERA4TB that show promise in initial human studies could later be incorporated into the PAN-TB collaboration’s later-stage, clinical research. Several organizations, including Evotec, GSK and Johnson & Johnson, are members of both projects, which will help to ensure coordination across collaborations toward the common goal of advancing TB drug and regimen development.

The founding members of the PAN-TB collaboration are Evotec, GSK, Johnson & Johnson, Otsuka Pharmaceutical Co., Ltd., based in Japan, the Bill & Melinda Gates Medical Research Institute and the Bill & Melinda Gates Foundation. Additional members may be announced in the future.

About Tuberculosis

TB causes more deaths globally than any other infectious disease, with 10 million new cases and 1.5 million deaths recorded in 2018 alone.⁴ Though the number of deaths is falling, it isn't falling fast enough to reach WHO’s global TB elimination goals. The emergence and spread of drug-resistant TB are also urgent concerns. In 2017, drug-resistant TB alone caused 230,000 deaths – one-third of all deaths due to AMR.⁵ TB is also the leading cause of death in people living with HIV, accounting for one-third of deaths among HIV-positive people. The world’s most vulnerable are disproportionately affected by TB, with many cases of TB occurring in resource-limited areas.⁶

⁴ WHO, Global Tuberculosis Report, 2019.

⁵ WHO, No time to wait: Securing the future from drug-resistant infections, 2019.

⁶ WHO, Global Tuberculosis Report, 2019.

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About the Bill & Melinda Gates Medical Research Institute

The Bill & Melinda Gates Medical Research Institute is a non-profit biotech organization conducting clinical research to accelerate product development for diseases and disorders that disproportionately affect the world's poorest populations—malaria, tuberculosis, diarrhea and maternal and newborn child health conditions that combined cause ten deaths every minute. For further information please visit www.gatesmri.org.

About Evotec

Evotec is a drug discovery alliance and development partnership company focused on rapidly progressing innovative product approaches with leading pharmaceutical and biotechnology companies, academics, patient advocacy groups and venture capitalists. We operate worldwide and our more than 2,900 employees provide the highest quality stand-alone and integrated drug discovery and development solutions. For additional information please go to www.evotec.com and follow us on Twitter @Evotec.

About GSK

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com/about-us.

About Johnson & Johnson

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities, and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based health care company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity. Learn more at www.jnj.com. Follow us at @JNJNews.

About Otsuka Pharmaceutical Co., Ltd.

Otsuka Pharmaceutical Co., Ltd., based in Japan, is a global healthcare company with the corporate philosophy: "Otsuka—people creating new products for better health worldwide." Otsuka researches, develops, manufactures and markets innovative products, with a focus on pharmaceutical products to meet unmet medical needs and nutraceutical products for the maintenance of everyday health.

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 and Co-chair William H. Gates Sr., under the direction of Bill and Melinda Gates and Warren Buffett. For further information please visit www.gatesfoundation.org.

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