

BIOFABRI AND BHARAT BIOTECH SIGN TECHNOLOGY TRANSFER AGREEMENT TO ADVANCE GLOBAL ACCESS TO MTBVAC AND SUPPORT TUBERCULOSIS CONTROL EFFORTS.

- Tuberculosis remains one of the world's deadliest infectious diseases, causing over a million deaths each year, with the highest burden borne by low- and middle-income countries.
- Despite this, the global TB vaccine pipeline is alarmingly thin, with very few late-stage candidates and limited private-sector investment, underscoring the urgent need for new, effective solutions beyond the century-old BCG vaccine.
- MTBVAC represents a critically important advance in global TB prevention, as it's one of two vaccine candidates that have progressed into advanced clinical development.
- The agreement supports WHO priorities on equitable access by enabling sustainable manufacturing capacity in high-burden regions.
- The partnership strengthens long-term collaboration by enabling technology transfer that supports end-to-end manufacturing of MTBVAC at Bharat Biotech.

Hyderabad, India, / O Porriño, 22nd, December 2025: Biofabri, a global human vaccine development company that is part of the Zendal group, and Bharat Biotech International Limited (BBIL), a global leader in vaccine innovation and manufacturing, today announced the signing of a Technology Transfer Agreement.

The agreement represents a significant milestone in advancing global efforts to expand equitable access to tuberculosis vaccines in line with World Health Organization (WHO) priorities.

Following the signature of the Licensing Agreement in 2022, this new Technology Transfer Agreement reinforces the collaboration and partnership between the two companies. The Technology Transfer process has already begun to ensure BBIL's manufacturing readiness by the time of MTBVAC licensure in India.

A shared commitment to global health drives the initiative and to ensure that MTBVAC is accessible, affordable and equitably available, particularly in countries with the highest tuberculosis burden. This initiative aligns with the WHO Finance and Access Working Group Solution, which aims to accelerate equitable access of novel tuberculosis vaccines for adults and adolescents through licensing and technology transfer to at least one manufacturer in a high burden region (1).

BBIL will guarantee the production and supply of MTBVAC in more than 70 countries across Africa and Southeast Asia, regions with a high disease burden.

MTBVAC has undergone Phase I and II clinical trials in India. The vaccine candidate has demonstrated safety and immunogenicity. Based on these initial results, BBIL is preparing for a pivotal Phase III vaccine efficacy study, which is expected to begin

recruiting participants in the first quarter of 2026. Considering the significant disease burden in India, MTBVAC is poised to be a leading candidate in the TB Mukt Bharat initiative championed by the Hon'ble Prime Minister of India.

MTBVAC is designed by Dr. Carlos Martín from the University of Zaragoza (UNIZAR) and Dr. Brigitte Gicquel of the Institut Pasteur in Paris and licensed to Biofabri. MTBVAC is the only live, attenuated *Mycobacterium TB* vaccine in the pipeline and the only vaccine that contains the full complement of the original pathogen's antigenic targets.

MTBVAC is being developed by Biofabri, in close collaboration with BBIL, IAVI, Fundação Atauulpho de Paiva (FAP), TB Vaccine Initiative (TBVI) and UNIZAR. MTBVAC is being targeted for two key populations: newborns, adolescents and adults—groups for whom there is currently no effective prophylactic vaccine against TB disease.

As **Esteban Rodríguez, CEO of Biofabri** stated: "This agreement represents a decisive step toward ensuring that this vaccine reaches the populations that need it most. Enabling sustainable manufacturing in high-burden countries is essential to improving equitable access and responding to the global call from organisations such as the World Health Organization for new, effective tools to fight tuberculosis."

At Bharat Biotech, innovation and access are fundamental to our business and philosophy. MTBVAC exemplifies our dedication to protection, dignity, and a healthier future for millions at the risk of tuberculosis. The forthcoming Phase 3 trial in India, the nation with the highest disease burden, constitutes a vital step in enhancing the global response to tuberculosis and its effects. The implementation of this technology transfer signifies a crucial progression towards establishing comprehensive manufacturing of MTBVAC at Bharat Biotech, thereby enabling worldwide access and bolstering tuberculosis control initiatives. Clinical development has successfully advanced through Phase I and Phase II trials, with Phase III preparations currently in progress," said, **Dr. Krishna Ella, Executive Chairman of Bharat Biotech.**

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References

1. Catalysing solutions for equitable global access and sustainable financing for novel tuberculosis vaccines for adults and adolescents. Geneva: World Health Organization; 2025. Licence: CC BY-NC-SA 3.0 IGO.