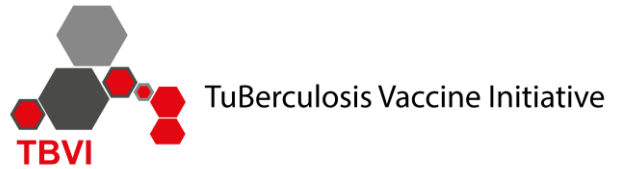## BIOFABRI AND TBVI SIGN A CONTRACT WITH THE EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY TO ACCELERATE THE FINAL DEVELOPMENT OF THE NEW TB VACCINE MTBVAC.

- *Tuberculosis (TB) makes 10 million people sick every year, and kills around 1.5 million people, more than any other infectious disease.*
- *Drug resistant TB is a growing problem, with more than 400 thousand new cases annually, and more than 150 thousand deaths.*
- *MTBVAC is a highly promising TB vaccine candidate that aims to prevent both drug sensitive and drug resistant TB in infants as well as in adolescents and adults.*

O Porriño, 20th June 2024. Biofabri, a global human vaccine development company that is part of the Zendal group, and TBVI, a non-profit foundation facilitating the discovery and development of new TB vaccines that are globally accessible and affordable, have signed a contract with the European Health and Digital Executive Agency (HaDEA) under the EU4Health Programme to accelerate the final development of the MTBVAC vaccine. MTBVAC is a highly promising vaccine candidate that has the potential to be used as an alternative to BCG vaccination in infants and for prevention of TB disease in adolescents and adults.

Through the EU4Health Programme, HaDEA's support will accelerate the final stages of the clinical development of MTBVAC by supporting a Phase 3 clinical trial in neonates, which is currently well underway in various African countries. The trial aims to evaluate the protective efficacy, safety and immunogenicity of a single dose of MTBVAC administered by intradermal route in healthy HIV-unexposed and HIV-exposed neonates. A safe, effective and accessible new TB vaccine such as MTBVAC will be essential to stop the development and spread of both drug sensitive and drug-resistant TB.

The emergence of drug-resistant TB poses an enormous challenge, requiring a sustained and adaptive response. In Europe, for the first time in a decade there has been a year-on-year increase in multidrug-resistant TB . This increase may be a consequence of the disruption to TB control programmes caused by the COVID-19 pandemic. The urgency during the COVID-19 pandemic created

barriers to prevention, resulting in a significant reduction in the number of people who could be treated, especially for multidrug-resistant TB. WHO estimates that only two in five people with Multidrug-resistant and extensively drug-resistant TB are currently receiving treatment.

Jelle Thole, General Director of Biofabri, said: "We are very gratified by the support from HaDEA as it will accelerate the last stages of the development of MTBVAC as a new safe and effective vaccine against tuberculosis. We are extremely thankful for the pivotal support provided by TBVI over the last 16 years to get MTBVAC to where it is now. Should the phase 3 trial be successful, we will have a new and powerful tool that will help to end the TB epidemic."
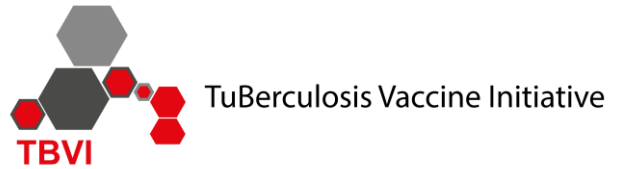
Ole Olesen, Executive Director of TBVI said: "In the fight against tuberculosis, the development of new and improved vaccines that are accessible to all people is crucial, as the disease causes 1.3 million deaths annually. Biofabri and TBVI have a lasting collaboration in advancing MTBVAC. The support from HaDEA further strengthens this partnership, accelerating the development of MTBVAC and creating a European success story in the fight against tuberculosis."

About MTBVAC
MTBVAC is designed by Dr. Carlos Martin from the University of Zaragoza and Dr. Brigitte Gicquel of the Institut Pasteur in Paris. MTBVAC is the only live, attenuated Mycobacterium TB vaccine in the pipeline, and the only vaccine that contains the full complement of antigenic targets of the original pathogen. MTBVAC was in-licensed by Biofabri, and subsequently developed as a single dose vaccine to be more effective than the currently used BCG vaccine in newborns, and to prevent TB disease in adults and adolescents, for whom no effective vaccine is available.

About BIOFABRI
Biofabri is a biopharmaceutical company created in 2008 with the aim of researching, developing, and manufacturing vaccines for humans. Biofabri has a solid technical and scientific capacity in vaccines and immunotherapy. Biofabri belongs to the Zendal group, a Spanish pharmaceutical business group made up of several companies specialised in the development, manufacture and marketing of a wide range of vaccines and other biotechnological products for human and animal health.

About TBVI

The TuBerculosis Vaccine Initiative (TBVI) facilitates the discovery and development of new, safe and effective TB vaccines that are accessible and affordable for all people. As a non-profit foundation TBVI creates an enabling environment for TB vaccine research & innovation and product development. To continue to innovate and diversify the TB vaccine pipeline and TB vaccine platforms TBVI supports R&D partners to develop and move the most promising TB vaccine through the pipeline by providing services of technical advice for product and clinical development, and project identification, development and management, knowledge exchange and networking.

Website: https://www.tbvi.eu/

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