

Spanish pharmaceutical company Zendal and IAVI partner to advance the tuberculosis vaccine candidate MTBVAC into efficacy trials

- **TB kills 1.4 million people a year, an infectious disease toll only recently surpassed by COVID-19.**
- **COVID-19 has reversed years of progress in TB response, costing additional lives and adding to the urgency of the global TB problem.**
- **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.**

PORRIÑO, SPAIN, and NEW YORK, U.S. — JULY 14, 2021 — Spanish biopharmaceutical company Biofabri and IAVI, an international nonprofit research organization focused on developing vaccines and antibodies against infectious and neglected diseases, today announced their intention to partner on efficacy trials of the tuberculosis (TB) vaccine candidate MTBVAC.

The candidate, designed by the Spanish researcher Dr. Carlos Martin from the University of Zaragoza, was in-licensed and is being manufactured and developed by Biofabri, a subsidiary of the Zendal Group, in collaboration with University of Zaragoza, IAVI, and Europe-based Tuberculosis Vaccine Initiative (TBVI).

MTBVAC will complete Phase II evaluation this year and is one of the most promising new TB vaccines in the pipeline. The only available TB vaccine, bacille Calmette-Guérin (BCG), does not prevent primary infection and has limited effectiveness at preventing pulmonary TB in adults, who, along with adolescents, are mainly responsible for spreading TB. The first dose of the BCG vaccine was delivered 100 years ago to the day Sunday, July 18.

This announcement comes amidst the extraordinary pace of the development of numerous vaccines to protect people from COVID-19 over the past year.

“The urgency of global COVID-19 vaccine rollout is deservedly receiving unprecedented attention. At the same time, this global focus on disease control is an opportunity to go the extra mile and try to stamp out TB, which, once COVID-19 recedes, will resume its position as the leading cause of infectious disease deaths globally,” said Dr. Mark Feinberg, president and CEO of IAVI.

“We saw with COVID-19 that adequate investment and public-private partnerships were essential to the successful, rapid development of vaccines. Similarly, a concerted global effort will be essential to the development of an effective TB vaccine. We hope to gain the support of global health funders and partners, public and private, to advance this promising vaccine candidate that has the potential to address urgent unmet needs and to be part of a solution to the TB epidemic.”

The European and Developing Countries Clinical Trials Partnership (EDCTP) has committed to support a Phase III trial of MTBVAC in newborns, scheduled to begin in several African countries in 2021. IAVI will support the development and further resource mobilization for MTBVAC, including for an adolescent/adult trial. TBVI will also support the ongoing trial preparations.

“Biofabri and the Zendal Group are delighted to be able to count on the backing of two respected international organizations like IAVI and TBVI to reach our goal of making a TB vaccine available throughout the world,” said Esteban Rodríguez, Biofabri CEO.

“We are proud that the MTBVAC strain has been designed here in Spain, and I’m cautiously optimistic that promising data from previous and ongoing trials of MTBVAC show that we are moving in the right direction. Phase II dose-ranging studies in adults and neonates are ongoing, and, encouragingly, no safety issues have been identified. We will select a definitive dose from these studies to progress into efficacy studies, and, if results of those trials bear fruit, we will also be equally as proud to be manufacturing a lifesaving vaccine locally.”

Should MTBVAC be shown to be safe and efficacious, Biofabri in partnership with IAVI will ensure that MTBVAC is manufactured and supplied in sufficient quantities to neonates, infants, adolescents, and adults and is accessible at affordable prices in low- and middle-income countries.

TB and COVID-19

TB has been the biggest infectious disease killer in the world, killing an estimated 1.4 million people each year, 10% of whom are children. These numbers have been surpassed only by COVID-19 in the past two years. Around 10 million people fell ill with tuberculosis in 2019, and the disease is one of the 10 leading causes of death worldwide.

COVID-19 has reversed previous advances in TB response by 10 years, causing significant decreases in TB case detection. The Stop TB Partnership estimates that an additional 1.4 million TB deaths will occur over the next four years because of COVID-19. A vaccine is more urgent than ever.

Drug-resistant/multi-drug resistant TB (DR/MDR TB) is becoming an increasing problem, with about 465,000 cases in 2019. DR/MDR TB treatment is arduous, expensive, and not always successful. A vaccine that prevents TB disease would have a major impact on the DR/MDR TB problem.

MTBVAC

MTBVAC is the only live attenuated *Mycobacterium tuberculosis* vaccine in development. Currently, it is being developed for two purposes: as a more effective and potentially longer-lasting vaccine than BCG for newborns, and for the prevention of tuberculosis disease in adults and adolescents, for whom there is currently no effective vaccine.

Two Phase II trials are ongoing, one supported by EDCTP and sponsored by Biofabri in infants in South Africa, and one sponsored by IAVI and supported by the U.S. National Institutes of Health and the U.S. Department of Defense through its Congressionally Directed Medical Research Program. Results are expected late 2021.

A study published in early 2021 (White et al., NPJ Vaccines 2021) showed that a single dose of MTBVAC provides significantly better protection against aerosol exposure to *Mycobacterium tuberculosis* in rhesus macaques compared to BCG at the same dose. This confirms that the immunological responses induced after vaccination with MTBVAC in rhesus macaques reflect those in Phase I clinical trials of MTBVAC.

Biofabri considers IAVI a crucial partner for the end-to-end development of this important vaccine candidate as the partners embark on efficacy studies for both the neonatal/infant and adolescent/adult indications. IAVI will support Biofabri in access

planning for the neonatal/infant indication and the development and implementation of the adolescent and adult studies. The partners are actively seeking funders to support clinical development for the adolescent/adult indication.

A global project

This agreement takes a further step in advancing the development of a promising TB vaccine candidate, especially for low- and middle-income countries, in a project in which the following allies play an essential role:

IAVI. IAVI is a nonprofit scientific research organization with headquarters in the U.S. and locations in Europe, Africa, and India that develops vaccines and antibodies for HIV, tuberculosis, emerging infectious diseases (including COVID-19), and neglected diseases, with the goal of global access. It has contributed to efforts to evaluate most of the leading TB vaccine candidates now in clinical development and has a highly experienced TB vaccine clinical research team in South Africa.

Biofabri is a biopharmaceutical company created in 2008 with the aim of researching, developing, and manufacturing vaccines for humans. BIOFABRI focuses on human health, has strong technical, research, and manufacturing capabilities, as well as a strong track record in biotechnology. Biofabri is responsible for the manufacturing and clinical development of MTBVAC.

Biofabri is part of the Zendal group, a Spanish biopharmaceutical business group specializing in the development, manufacture, and commercialization of biotechnological and pharmaceutical products for human and animal health.

TBVI. The Tuberculosis Vaccine Initiative is a non-profit foundation that enables the discovery and development of new, safe, and effective tuberculosis vaccines that are accessible and affordable for all people. As the Product Development Association (PDA), TBVI integrates, translates, and prioritizes R&D efforts to discover and develop new TB vaccines and biomarkers for global use. TBVI provides essential services that support the R&D efforts of its partners: 50 partners from academia, research institutes, and private industry in the field of TB vaccines.

UNIZAR. The University of Zaragoza in Spain is the main center for technological innovation in the Ebro Valley. It participates in different exchange programs, collaborating with universities and research centers in Europe, Latin America, and the United States. Microbiologists from the university associated with CIBERES led the research and subsequent discovery of the experimental vaccine MTBVAC. Within the TBVI consortium, the MTBVAC discovery phase has included rigorous clinical characterization by independent laboratories and research groups.

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