



20 November 2019

UCT collaborating on new TB vaccine clinical trial
Biofabri, IAVI, and SATVI conducting clinical trial of TB vaccine candidate
MTBVAC in South African adults

The South African Tuberculosis Vaccine Initiative (SATVI) – located at the University of Cape Town – as well as Biofabri and International Aids Vaccine Initiative (IAVI) recently announced an ongoing clinical trial to further evaluate the novel tuberculosis (TB) vaccine candidate MTBVAC in an adult endemic population.

TB is one of the top 10 leading causes of all deaths worldwide and kills about 1.6 million people annually. Each year, about 10 million new cases of TB are detected. The scale of the problem is so great that one in four people globally are infected with the bacteria that cause TB. The World Health Organization estimates that the annual global economic burden of the TB epidemic is more than \$20 billion (over R296 billion). Experts widely agree that new, more effective TB vaccines will be necessary to address the global TB crisis.

Mark Feinberg, president and CEO of IAVI, said: "This trial comes at a time when the global public health community's attention to the need for improved ways to prevent TB is at an all-time high. We believe this trial is an important step on the path to addressing one of the world's most urgent public health problems."

Esteban Rodríguez, general manager of Biofabri, said: "In 2008, Biofabri acquired the commitment to make available MTBVAC vaccine worldwide and at an affordable price. Such a commitment enhances Biofabri's involvement in the fight against tuberculosis disease, particularly in low-income countries."

BCG, the only TB vaccine currently used for the prevention of TB disease, is derived from a bovine, rather than human, strain of TB bacteria. It is effective in preventing severe TB disease in infants and children. In adults, however, BCG has only variable effectiveness in disease prevention. MTBVAC is a live, attenuated (weakened) form of *Mycobacterium tuberculosis*, the bacterium that causes TB in humans. It therefore might be more effective in preventing TB disease than BCG. Because it is attenuated, it does not have the ability to cause disease in healthy people. [A Phase Ia trial](#) showed that MTBVAC demonstrated a similar safety profile to BCG at a similar dose.

The clinical trial, designated A-050, is a Phase Ib/IIa safety and dose-finding study of MTBVAC. This trial is designed to test different doses of MTBVAC and collect additional safety and immunogenicity information in healthy adults with and without evidence of having been previously infected with TB bacteria. It also has the potential to show whether vaccination with MTBVAC produces an immune response distinct from the response to BCG. In A-050, up to 144 participants at SATVI trial site in Worcester, South Africa, will receive either one administration of MTBVAC at different doses or BCG at the standard adult dose. Participants will be monitored for safety and immune response for 12 months after vaccination.

SATVI in Cape Town is a collaborator in the clinical trial. Professor Mark Hatherill, SATVI director, said: "This trial is being conducted in two important populations for TB vaccine development — adults with and without previous TB infection — and will help to shape our thinking about vaccination strategies for young adults in countries where TB is endemic."

Through this clinical trial, IAVI continues to advance the TB vaccine clinical program it acquired in 2018 from the nonprofit Aeras and to work toward solutions for public health threats that disproportionately affect people living in poverty.

Trial collaborators are University of Zaragoza (Spain), which developed the vaccine candidate; the Spanish biopharmaceutical company Biofabri, which is the vaccine candidate sponsor; SATVI; and the TuBerculosis Vaccine Initiative (TBVI). IAVI is the trial sponsor. Funding is provided by the U.S. National Institutes of Health (NIH) and the US Department of Defense through its Congressionally Directed Medical Research Program.

Results for A-050 are expected in 2020.

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Note to editors

About Biofabri

BIOFABRI is a biopharmaceutical company that was created in 2008 with the vision to research, develop and manufacture human vaccines. BIOFABRI is focused on human health, with strong technical, development and manufacturing capabilities and a proven track record. Biofabri is responsible for manufacturing and clinical development of MTBVAC.

Biofabri belongs to Zandal, a Spanish biopharmaceutical business group which specializes in development, manufacture and marketing of biotechnology and pharmacy products for both humans and animals. Read more at biofabri.es/en.

About IAVI

IAVI is a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges including HIV and tuberculosis. Its mission is to translate scientific discoveries into affordable, globally accessible public health solutions. Read more at iavi.org.

About SATVI

The South African Tuberculosis Vaccine Initiative (SATVI) is a TB research group based at the Faculty of Health Sciences of the University of Cape Town. SATVI is regarded as a worldwide leader in TB vaccine research and has conducted 28 Phase I–IV trials of 9 different TB vaccine candidates since 2005. SATVI's research focus is understanding the risk for, and protection against, *M. tuberculosis* infection and disease, in order to develop more effective vaccines and preventive strategies for global impact on the TB epidemic. Read more at satvi.uct.ac.za.

About TBVI

The TuBerculosis Vaccine Initiative (TBVI) is a nonprofit foundation that facilitates the discovery and development of new, safe and effective TB vaccines that are accessible and affordable for all people. TBVI integrates, translates and prioritises 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 50 consortium partners from academia, research institutes and private industry in the TB vaccine field. These services include project identification, design and development; project management; resource mobilisation; knowledge development, exchange and networking; and technical advice and support for product and clinical development. Read more at tbvi.eu.

About University of Zaragoza

The University of Zaragoza is the main centre of technological innovation in the Ebro Valley and has great prestige among Spanish and European universities. The University of Zaragoza participates in various exchange programmes, collaborating with universities and research centres from Europe, Latin America and the USA, thereby strengthening its international standing. Microbiologists of our university belonging to the CIBER of Respiratory Diseases (CIBERES) led the research and discovery of the live vaccine candidate MTBVAC. Within the TBVI consortium, the discovery phase of MTBVAC has included rigorous preclinical characterization by independent laboratories and research groups. Biofabri is the industrial partner of the University of Zaragoza, responsible for the Industrial and Clinical Development of MTBVAC. Read more at unizar.es.

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