BHARAT BIOTECH and BIOFABRI partner to develop, manufacture and distribute a novel TB vaccine, MTBVAC

- *This partnership will guarantee the supply of TB vaccines in more than 70 countries especially in Southeast Asia, and sub-Saharan Africa with a high TB incidence.*
- *MTBVAC is a global public-private project that will be a milestone in the field of vaccinology and in the approach to this highly communicable disease global epidemic with high morbidity and mortality.*
- *Phase 3 clinical trials are expected to start in the coming months.*
- *For BIOFABRI, the agreement is of strategic importance since it reaffirms its purpose of placing a globally accessible and affordable vaccine on the market in low- and middle-income countries.*
- *BHARAT BIOTECH is a multinational company with globally recognized product development and manufacturing capabilities.*

Hyderabad, India, Porriño, Spain, March 16, 2022: Bharat Biotech, a global leader in vaccine innovation and developer of vaccines for infectious diseases today announced the partnership with BIOFABRI, a Spanish biopharmaceutical company, to join forces to develop, manufacture and market a new tuberculosis vaccine in more than 70 countries in Southeast Asia and sub-Saharan Africa.

Biofabri is a biopharmaceutical company of Zendal group based in Porriño, Spain, with the aim of researching, developing and manufacturing vaccines for humans.
Bharat Biotech International Limited (BBIL) is an Indian multinational biotechnology company headquartered in the city of Hyderabad (India), engaged in the discovery, product development, and manufacture of vaccines and bio-therapeutics.

The vaccine is being manufactured and developed by BIOFABRI, in close collaboration with the University of Zaragoza, IAVI and the Tuberculosis Vaccine Initiative (TBVI). MTBVAC has been designed and discovered by Carlos Martín team of the University of Zaragoza.

This agreement between BHARAT BIOTECH and BIOFABRI would guarantee the worldwide production and the supply of the future vaccine in more than 70 countries with a high TB incidence, such as India, country with the highest TB burden in the world, with a 25% of all cases.

MTBVAC is one of the most promising vaccine candidates in the current global TB vaccine pipeline. The only currently available TB vaccine, the Bacillus Calmette-Guérin vaccine (BCG), was developed 100 years ago and has limited efficacy in preventing pulmonary TB in adults, who, along with adolescents, are the biggest spreaders of the disease.

“TB infects more than 20% of the global population is the second leading cause of deaths from infectious disease after COVID-19. TB is a highly contagious disease where vaccines are the best solution to prevent disease, reduce transmission and combat multi drug resistant strains. We are proud to announce this partnership with BioFabri, where MTBVAC can become a global TB vaccine. Bharat Biotech has opted for this vaccine candidate owing to its advanced stage of clinical development as well as the extremely promising results from Phase 1 and Phase 2 clinical trials." said ***Dr. Krishna Ella, Chairman and Managing Director Bharat Biotech***.

“*For us, this agreement is a milestone in the MTBVAC project. From day one, our goal has been to make a vaccine accessible to everyone at affordable prices in middle- and low-income countries where the incidence of tuberculosis is high. The contract signed with Bharat Biotech ensures that our vaccine reaches countries such as India, Indonesia, the Philippines, Pakistan and South Africa, among others, where tuberculosis is a public health problem due to its high incidence”,* said **Esteban Rodríguez, Biofabri CEO**.

“*We have a good hope that a new vaccine TB vaccine is in the horizon. At the University of Zaragoza, we had working in the search of a new TB vaccine since 1998 and since 2008 in close partnership with Biofabri. Accelerating efficacy studies for TB vaccines that have shown better protection than BCG in different preclinical models and to be immunogenic and safe in humans, as is the case of MTBVAC, is possible as it has been done for Covid vaccines. The experience of Bharat will be a great help reinforcing collaboration with TBVI and IAVI. We are ready, as soon that we can demonstrate that MTBVAC protects against pulmonary forms of TB, the sooner we can begin to save live and to have huge impact in TB pandemic, including multidrug resist forms of TB*“ **explained Professor Carlos Martín, is principal investigator of TB Vaccine project of University of Zaragoza, Spain**.

Multidrug-resistant TB and COVID-19

TB has been the leading cause of death from infectious diseases in the world, with an average annual death toll of 1.4 million people, 10% of whom are minors.
The appearance of COVID-19 put the brakes on years of progress in the response to this disease, costing additional lives and increasing the global urgency of the epidemic. The Stop TB Partnership estimates that an additional 1.4 million TB deaths will occur over the next four years due to the halt in developments stemming from COVID-19.

Drug-resistant / multidrug-resistant TB (DR / MDR TB) is becoming a growing problem due treatment of DR/MDR TB is arduous, expensive and not always successful. A vaccine that prevents TB disease would be a big step to tackle the DR/MDR TB problem.

A vaccine against tuberculosis is more necessary than ever and, thanks to the different agreements promoted by Zendal Group through the biopharmaceutical company BIOFABRI, it is possible to speed it up.

A global public-private project with a global reach
MTBVAC is the only live attenuated vaccine against *Mycobacterium tuberculosis* in development. It is currently being developed for two purposes: as a more effective and potentially longer-lasting vaccine than BCG for newborns and, on the other hand, for the prevention of TB disease in adults and adolescents, for whom there is currently no effective vaccine.

MTBVAC will start phase 3 clinical trials in Senegal, South Africa and Madagascar in the second half of 2022.

BHARAT BIOTECH

Bharat Biotech has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 123 countries, and the World Health Organization (WHO) Pre-qualifications. Located in Genome Valley in Hyderabad, India, a hub for the global biotech industry, Bharat Biotech has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution.

Having delivered more than 5 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis (JENVAC®), Rabies, Chikungunya, Zika, Cholera, and the world's first tetanus-toxoid conjugated vaccine for Typhoid. Bharat's commitment to global social innovation programs and public-private partnerships resulted in introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, ROTAVAC 5D®, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. As a leader of pandemic vaccines, Bharat Biotech has successfully delivered COVAXIN®, India's 1st indigenous vaccine against COVID-19. In November 2021, COVAXIN® has received WHO EUL.

The acquisition of Chiron Behring Vaccines has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer with Chirorab® and Indirab®.

To learn more about Bharat Biotech, visit www.bharatbiotech.com.

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 is responsible for the industrial and clinical development of MTBVAC.
Biofabri belongs to the Zendal group, a Spanish pharmaceutical business group made up of 6 companies specialised in the development, manufacture and marketing of vaccines and other biotechnological products for human and animal health.

UNIZAR.

The University of Zaragoza in Spain is the main centre for technological innovation in the Ebro Valley. It participates in numerous pioneering TB vaccine research projects in vaccine discovery using state-of-the-art *M. tuberculosis* genetic engineering both national and international, through European, and non EU collaborative projects. With more than 25 years of experience the Mycobacterial Genetics Research Group, of the University of Zaragoza aims to develop novel TB vaccines and vaccination strategies to improve protection against pulmonary TB. Since 2007 Mycobacterial Genetic group has been integrated into the Spanish Research Network on Respiratory Disease, CIBERES, (Instituto de Salud Carlos III) and collaborate with main international research groups TB. The University of Zaragoza led the research and subsequent discovery of the experimental MTBVAC vaccine.

TBVI.
The Tuberculosis Vaccine Initiative is a non-profit foundation that enables the discovery and development of new, safe and effective TB vaccines that are accessible and affordable for all people. As a Product Development Partnership (PDA), TBVI integrates, translates and prioritises R&D efforts to discover and develop 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 TB field.

IAVI is a US-based non-profit scientific research organisation with sites in Europe, Africa and India that develops vaccines and antibodies for HIV, tuberculosis, emerging infectious diseases (including COVID-19) and other neglected diseases with the goal of providing global access. It has worked on most of the major TB vaccine candidates currently in clinical development and has a specialized TB team in South Africa.

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