The new Spanish tuberculosis vaccine MTBVAC has received 12 million euros to carry out Phase2a trials in new-borns and in adults in South Africa

- *The two trials in new-borns and adults received financial support from Europe and the United States, respectively.*
- *MTBVAC is produced by the Spanish biopharmaceutical company Biofabri, and is based on attenuated M.tuberculosis strain genetically engineered by the University of Zaragoza.*
- *These Phase 2A safety and immunogenicity clinical trials will be conducted to determine the exact dose to be used, i.e. a dose sufficient to protect but without causing side effects.*
- *Tuberculosis is currently the infectious disease that causes the greatest number of deaths, even surpassing HIV, with about two million deaths in 2015.*

Vigo, 28 September 2017. Two new clinical trials will begin next January in 99 new-borns and 120 adults, respectively, using the Spanish tuberculosis vaccine candidate, MTBVAC, being developed by the Spanish biopharmaceutical company, Biofabri, and the University of Zaragoza. They will be conducted in an endemic TB area in South Africa. These trials have been made possible thanks to the significant economic backing of 12 million euros just received from both the European Union and the United States.

These two **Phase 2A** safety and immunogenicity clinical trials will be conducted to determine the exact dose to be used, i.e. a dose sufficient to protect but without causing side effects. Both trials will be conducted over a two-and-a-half-year period at the South African Vaccine Research Centre (SATVI) in Worcester, a small municipality with a high incidence of tuberculosis, 150 km from Cape Town.

This was announced this morning in Vigo by Biofabri's CEO, Esteban Rodríguez, the Rector of the University of Zaragoza, José Antonio Mayoral, the researcher Carlos Martín, principal investigator of the Tuberculosis Vaccines Project, and Jelle Thole, representing the European Tuberculosis Vaccine Initiative (TBVI).

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Financial support from Europe and the United States
The parallel, clinical trial in new-borns and adults will be **financed by two prestigious international public bodies** for an amount of nearly 12 million euros.

On the one hand, the **European and Developing Countries Clinical Trials Partnership** (EDCTP), in cooperation with the **Tuberculosis Vaccine Initiative** (TBVI), will jointly contribute **5,500,000 euros** for evaluating MTBVAC in **new-borns**.

In addition, the **$5.7 million adult** clinical trial will be funded by the **United States** Congress Directed Medical Research Program (CDMRP) in cooperation with AERAS, a **North American** non-profit organization that develops effective new vaccines against tuberculosis.

A vaccine of worldwide application.
"The move to Phase 2A is an important qualitative and quantitative step for Biofabri, since, on the one hand, it indicates that **MTBVAC remains the world's best-positioned live attenuated *M. tuberculosis* candidate** in the portfolio of future vaccines against tuberculosis and on the other hand we have the support of the prestigious international organizations dedicated to developing new vaccines against tuberculosis that have considered our MTBVAC project as having great social impact", said **Esteban Rodríguez, Biofabri's CEO**.

Carlos Martín, principal coordinator of the University of Zaragoza's **Mycobacteria Genetics Group**, has reiterated his **hopes for this project**. "If the immunity results from these new clinical trials confirm the recent results in animal models, future MTBVAC efficacy studies could be fast-tracked and millions of lives could be saved much sooner."

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The first trials were conducted in 2013

The first Phase IA clinical trials of this human vaccine began in 2013 with **36 healthy adult volunteers between the ages of 18 and 45** at the Hospital Complex of the University of Vaudois (Lausanne, **Switzerland**) and were completed in June 2014.

In **September 2015, new clinical trials were launched** to study its **safety and immunogenicity** in **36 new-borns and 18 adults** in **South Africa**, an endemic country. The excellent results obtained so far in these studies, which conclude in December, have enabled preparation of the successive phases announced today. "Although we are awaiting the immunogenicity results that will be released at the end of the year, current data indicate it is **a safe vaccine**, because both new-borns and adults included in that trial have gone **a year since the last vaccination without any problems**", Carlos Martín stated.

Phase 2A clinical trial

Start: Last quarter of 2017

Location: South Africa, coordinated by the South African Tuberculosis Vaccine Initiative (SATVI)

Population: 99 new-borns and 120 adults

Subsidized by the CDMRP and EDCTP

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About Biofabri

Biofabri is a biopharmaceutical company launched in 2008 with one objective: research and development of human vaccines.

Biofabri, together with the parent company, CZ Veterinaria, form a 100% Spanish business group dedicated to developing, manufacturing and marketing vaccines and other biotechnological medicinal products for human and animal health.

www.biofabri.es

About the vaccine

MTBVAC is a vaccine formulated from a strain isolated in humans that has been designed by the Mycobacteria Genetics Group of the University of Zaragoza that belongs to the Respiratory Diseases Networking Biomedical Research Centre (or CIBER for its acronym in Spanish) and is led by Dr. Carlos Martín Montañés in collaboration with Dr. Brigitte Gicquel of the Pasteur Institute in Paris.

The current BCG vaccine protects against different forms of tuberculosis in children, although its protection against adult pulmonary tuberculosis is highly variable (from 0-80%). MTBVAC is a vaccine that seeks to activate the immune system to be able to recognise the infectious agent and confer long-term protection against the most common form of the disease: respiratory TB.

About Tuberculosis

Tuberculosis remains a major global health challenge. Despite progress in reducing the number of deaths due to tuberculosis, the number of global cases of the disease remain enormous, with an annual estimate of 10.4 million new cases and 1.8 million deaths in 2015. It is currently the leading cause of death due to an infectious disease, surpassing HIV. In addition, in 2015 and throughout the world, it is estimated that 3.9% of new cases of tuberculosis and 21% of cases previously treated cases are deemed very difficult to treat multidrug resistant TB.

The objective of the strategy of the WHO to combat TB is to achieve a 95% reduction in mortality rates and a 90% reduction in infection rates by 2035 compared to 2015. This objective will only be reached if a new vaccine against tuberculosis is available that is more effective than the current BCG vaccine.

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