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Temperature-stable tuberculosis vaccine safe, prompts immune response in first-in-human trial

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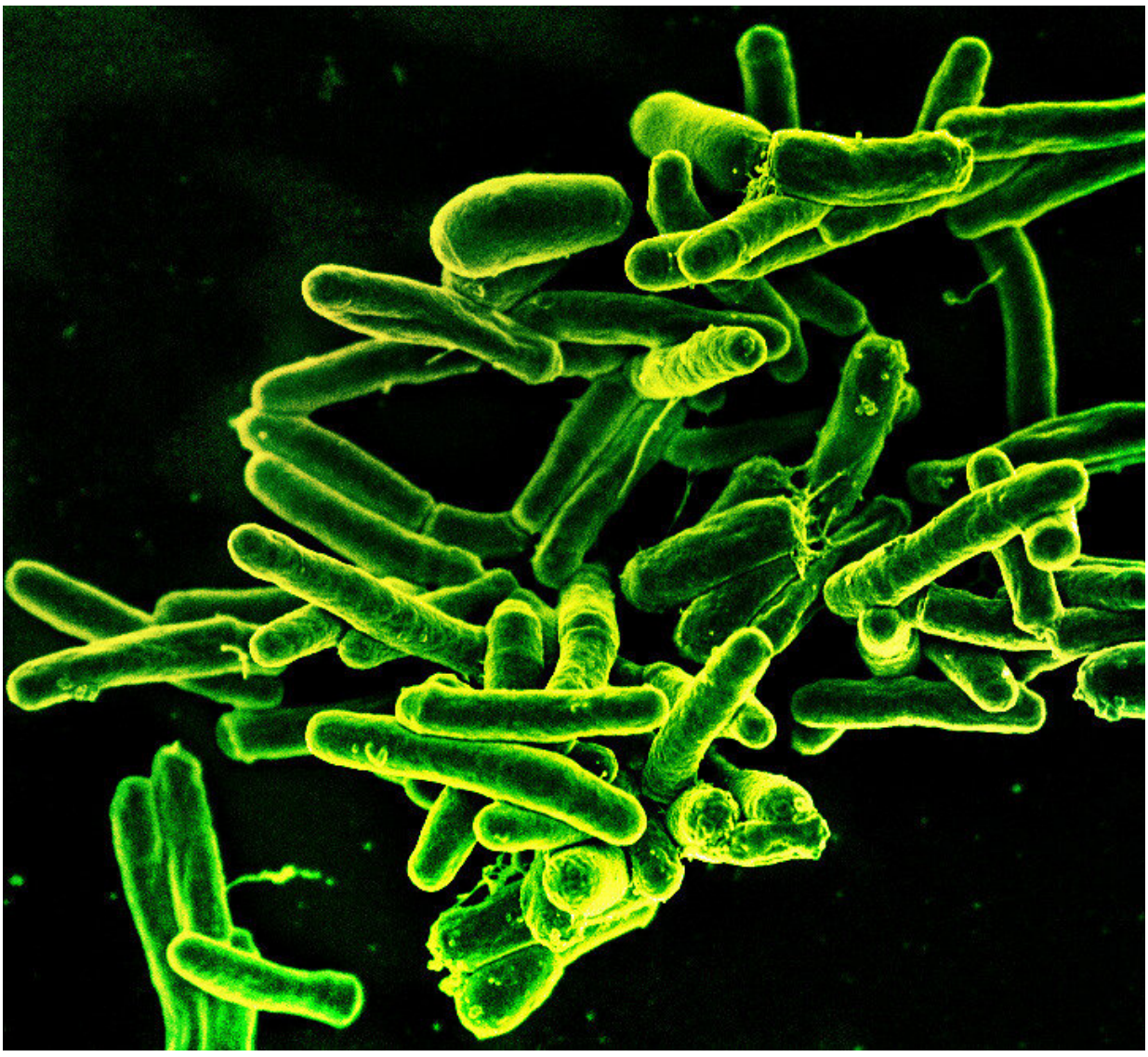

Scanning electron micrograph of Mycobacterium tuberculosis bacteria, which cause TB. Credit: NIAID

A clinical trial testing a freeze-dried, temperature-stable experimental tuberculosis (TB) vaccine in healthy adults found that it was safe and stimulated both antibodies and responses from the cellular arm of the immune system. The Phase 1 trial was supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. A non-temperature stable form of the candidate previously had been tested in several clinical trials. However, this was the first clinical trial of any subunit TB vaccine candidate in a temperature-stable (thermostable) form. Results are published in *Nature Communications*.

The experimental vaccine, ID93+GLA-SE, was developed by Christopher B. Fox, Ph.D., and scientists at the Access to Advanced Health Institute (formerly the Infectious Disease Research Institute) in Seattle. It is a recombinant subunit vaccine made from four proteins of *Mycobacterium tuberculosis* bacteria combined with GLA-SE, an immune-stimulating adjuvant. The freeze-dried formulation does not require refrigeration and is mixed with sterile water just prior to injection. Thermostable vaccines are desirable in settings where maintaining cold or frozen vaccines for long periods can be costly and difficult.

The current trial investigated whether administering temperature-stable vaccine containing both ID93 and GLA-SE in a single vial would be as effective at inducing an immune response as a regimen in which non-thermostable ID93 and liquid GLA-SE are held in two vials and combined prior to injection. A single-vial presentation of a thermostable vaccine would have clear advantages in ease of storage, transport and

administration, the investigators note.

Daniel F. Hoft, M.D., Ph.D., director of the Saint Louis University Center for Vaccine Development, led the single-site trial at the university's School of Medicine. Twenty-three participants received the thermostable single-vial regimen, while 22 participants received the two-vial, non-thermostable regimen. Both vaccine presentations were safe and well-tolerated. Recipients of the single-vialled thermostable vaccine had robust T-cell responses and produced higher levels of antibodies in the blood than those receiving the non-thermostable two-vial presentation.

The investigators note some limitations in this small trial. For example, no established correlates of protection define what immune responses are required for vaccine-induced protection from TB disease. Therefore, it is not possible to say whether the enhanced immune responses seen in the thermostable vaccine formulation would translate to improved protective vaccine efficacy. Nevertheless, they conclude, results of this trial demonstrate "a proof-of-concept that adjuvant-containing vaccines can be formulated in a freeze-dried single-vial presentation without detrimentally impacting clinical immunogenicity or safety characteristics."

More information: Safety and immunogenicity of a thermostable formulation of the ID93 + GLA-SE tuberculosis vaccine candidate in healthy adults, *Nature Communications* (2023). DOI: 10.1038/s41467-023-36789-2

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