Clinical trial for new tuberculosis vaccine

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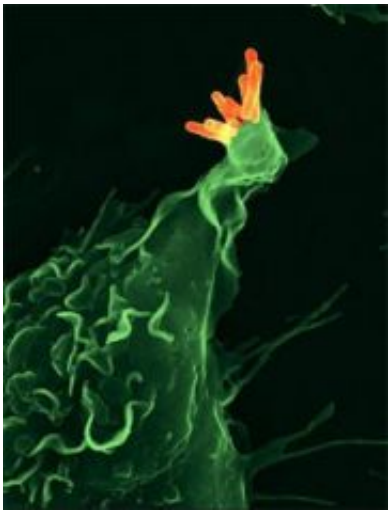

The most important tuberculosis pathogen, the bacterium Mycobakterium tuberculosis, divides itself every 16 to 20 hours. In comparison to other bacteria, which divide themselves in the space of minutes, this is extremely slow. Credit: Brinkmann/Schaible, MPI for Infection Biology

Since Monday of this week, the new vaccine "VPM1002" has entered the clinical phase I trial in Neuss, Germany, where it is being tested for safety on voluntary subjects. VPM1002 is based on a vaccine that has been in use since 1921, and has been genetically engineered to prevent infection with tuberculosis bacteria much more effectively than its predecessor.

The scientific basis for this was laid down by the team working with Stefan H.E. Kaufmann, Director at the Max Planck Institute for

Infection Biology. "The BCG tuberculosis vaccine, which was developed by French researchers, is the most frequently administered live vaccine in the world," says Kaufmann. However, BCG (short for the bacterium Bacillus Calmette-Guérind) is now frequently ineffective. The immunologist continues: "BCG has become a blunt weapon. We wanted to use genetic engineering to sharpen it so that, rather than hiding from the human immune system, it would stimulate it as much as possible."

To do this, the researchers inserted a gene into the vaccine bacteria. Leander Grode, who at the time was a member of Stefan H.E. Kaufmann's staff and is today heads a project at Vakzine Projekt Management GmbH (VPM), describes the process: "The vaccine bacteria are taken up by the scavenger cells of the human immune system and end up in their digestion chambers. The genetically engineered modification allows them to escape from the chambers and arm the immune system against the tuberculosis pathogens."

The scientific studies were initially undertaken at the Max Planck Institute for Infection Biology. In 2004, the vaccine was licensed to the Hanover-based VPN, which expedited the clinical study. Thus far, the new vaccine has proven to be extremely effective and safe in animal models. "We now need to prove that it has the same positive effect on humans, so that it qualifies for a license," explains VPM CEO Bernd Eisele. Kaufmann urges patience: "Even if the new vaccine proves to be well-tolerated, it will still have to undergo more testing to establish its efficacy. That will take at least ten years." Nevertheless - this new approach is looking hopeful.

The establishment of the Max Planck Institute for Infection Biology in 1993 was one of the first in the newly-formed German states (which previously had made up East Germany). The Institute is located on the historical Charité Mitte campus, where, 100 years ago, Robert Koch and Emil Behring made important discoveries about infectious diseases. A

key reason for choosing this location was the desire to work together with the universities and clinics on clinically relevant infectious disease projects.

"Interdisciplinary research into the molecular and cellular basis of infections enables the systematic development of new therapeutic and preventative measures. Basic research into infectious processes can therefore not only explain fundamental questions in biomedicine, but also make a contribution to solving significant problems in healthcare policy in the future," says Stefan H.E. Kaufmann. VPM was set up by the Federal Ministry for Education and Research and the Helmholtz Center for Infection Research as a private-public partnership. "We ensure that excellent results from basic research benefit humankind and find their way into practical applications," says Bernd Eisele.

Source: Max-Planck-Gesellschaft