

Press Release

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SERUM INSTITUTE OF INDIA ACQUIRES RIGHTS TO GERMAN TB VACCINE

RESEARCHERS CONTINUE TO REFINE CLASSIC TB VACCINE

Hopes are high for a new and improved tuberculosis vaccine: Serum Institute of India is planning on taking a promising vaccine - originally developed in Germany - and introducing it into the clinical setting. Studies have shown that the new vaccine is more effective and better tolerated than currently available options. By signing a contract with the Hannoverbased Vakzine Projekt Management GmbH (VPM), Serum, one of the World's leading vaccine manufacturers, has effectively secured the license to the various patents and technologies related to the new vaccine.

Scientists from the Max Planck Society (MPG), Vakzine Projekt Management GmbH (VPM), and the Helmholtz Centre for Infection Research (HZI) co-developed the candidate vaccine called VPM 1002 as part of a joint research project. The substance is currently undergoing phase II clinical testing.

"This represents an important step in the fight against the deadly threat posed by TB – an infection that affects over two billion people worldwide," says Dr. Bernd Eisele, CEO of VPM, an HZI spin-off based in Hannover, Germany. "The new vaccine is showing a lot of promise, the concept itself is highly innovative," adds Umesh Shaligram, Serum Institute of India's director of Research and Development. The company is headquartered in Pune, India. "We are looking forward to working with VPM and hope that over the next years, we will see the vaccine successfully secure market authorization for global distribution." According to VPM estimates, the Indian pharmaceutical company is one of only a handful of potential partners that are qualified to take on the task. Bernd Eisele says: "Only an experienced and specialized developer and global player like Serum is able to ensure that the vaccine will be made available to people everywhere at a fair price."

VPM 1002 is based on another vaccine that was first introduced in 1921 called Bacillus Calmette-Guérin, or BCG. The vaccine, which consists of attenuated pathogens, prompts the human immune system to mount a response against the germ. Today, the use of these types of live vaccines has become standard and is even used as part of "classic" MMR immunizations. The special thing about VPM 1002 is that it is being continually refined using gene technology, causing it to prevent diseases much more effectively and safely than its predecessor. Preclinical studies, two phase I clinical trials, and one phase II clinical trial have already met expectations.

Prof. Stefan Kaufmann, founding director of the Max Planck Institute for Infection Biology in Berlin, developed the scientific basis for VPM 1002. VPM then developed the new vaccine after licensing it from the technology transfer organization Max Planck Innovation and with support from HZI basic science research, ultimately taking it to the clinical trial stage. "To this day, BCG is still the single most commonly administered vaccine," says Kaufmann. However, at this point, it frequently no longer works as well as it used to in the past. Kaufmann's ultimate goal is making BCG more effective and, at the same time, safer.

Dr. Leander Grode also played an important role in the new vaccine's development – first as one of Kaufmann's scientific associates, and now as a project manager at VPM. "We successfully tweaked the original vaccine to be better at activating the human immune system and thus afford more effective and safer protection against the TB pathogen," explains Grode.

Vakzine Projekt Management GmbH (VPM)

VPM was founded in 2002 as a Helmholtz Centre for Infection Research (HZI) spin-off. Thanks to its professional project management and drug development expertise, the company is able to support researchers and ensure that innovation makes its way out of the lab and into the clinical setting, where it is able to benefit patients. http://www.vakzine-manager.de



The Helmholtz Centre for Infection Research (HZI)

Scientists at the Helmholtz Centre for Infection Research in Braunschweig, Germany, are engaged in the study of different mechanisms of infection and of the body's response to infection. Helping to improve the scientific community's understanding of a given bacterium's or virus' pathogenicity is key to developing effective new treatments and vaccines. http://www.helmholtz-hzi.de

Max Planck Institute for Infection Biology (MPI)

Scientists at the Max Planck Institute for Infection Biology are concerned with the study of different kinds of pathogens and their effect on the organism. A central focus of the research are those pathogens that cause malaria, tuberculosis, serious gastrointestinal diseases (like stomach cancer), and influenza. In addition to the acquisition of knowledge, a second focus is on new drug and vaccine development.

Serum Institute of India Ltd. (SII)

Serum Institute of India Ltd. was founded back in 1966 with the goal of creating life-saving drugs for people from all walks of life. The Institute's special focus has traditionally been on those countries where drugs were either altogether unavailable or unaffordable for most citizens. At this point, the SII has become the World's largest manufacturer of vaccines against measles and against diphtheria, whooping cough and tetanus (DPT). The company has continued to increase its philanthropic focus and is now also manufacturing vaccines against hepatitis B, rabies, and meningitis. This has helped ensure that, from the day they are born, children from all social classes, not only in India but in more than 140 different countries all over the World, have access to life-saving medicines.

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