



Start of phase 2 trial in newborn infants in South Africa with VPM1002, a new vaccine developed by an Indo-German co-operation for prevention of tuberculosis

Enrollment of the first infant in a phase 2 clinical trial of a new vaccine to prevent tuberculosis (TB) has successfully started. VPM1002, the most advanced new TB vaccine in clinical development, will help curtail spread of life-threatening TB disease not only in endemic countries, but also in Europe.

The vaccine candidate VPM1002 was recently out-licensed to Serum Institute of India Ltd. (SIIL), the world's largest vaccine manufacturer according to number of doses sold. VPM1002 is developed by SIIL in collaboration with Vakzine Projekt Management GmbH (VPM). Mr. Adar C. Poonawalla, CEO and Executive Director of SIIL emphasizes that "TB still remains a major public health problem and only a new and more effective vaccine can help to restrict the expansion of multidrug-resistant and extremely drug-resistant TB and thus save the lives of millions of people each year. We are pleased with the start of this trial as it represents one more step in our efforts to continuously improve existing vaccines, and to make new, safe, efficacious and cost effective vaccines available to the world, especially for TB. This is also shown in our plans to start large trials with VPM1002 to address the challenges of relapsing TB in adults."

Professor Stefan H. E. Kaufmann, the Founding Director of the Max Planck Institute for Infection Biology, who was largely responsible for the scientific concept of VPM1002, adds: "The former BCG vaccine continues to be the most commonly administered vaccine. Although it can protect against certain forms of tuberculosis, its protective efficacy is insufficient and alarmingly, BCG-related adverse events in HIV-positive newborns frequently occur. BCG also poses a high risk for any infant born with congenital genetic immunodeficiency." And he continues saying that the goal with VPM1002 is "to sharpen BCG's blade, and make it safer and more efficacious for successful combat of tuberculosis."

The new vaccine VPM1002 was co-developed by scientists from the Max Planck Society (MPG) and Hannover-based VPM, a spin-off company from the Helmholtz Centre for Infection Research (HZI). VPM1002 was modeled on an earlier TB vaccine

called BCG – short for Bacillus Calmette–Guérin – that was first introduced in 1921, and since then has been given to millions of infants each year where TB is prevalent. What makes VPM1002 unique when compared with BCG is the fact that targeted genetic modifications make the vaccine much safer and more effective in preventing TB. A series of studies in animal models, and two separate phase I clinical trials in adults and one phase 2a clinical trial in newborn infants, have already confirmed safety and have shown sufficient strengthening of the immune system against TB, thus raising hope for higher efficacy. “Already during the phase I clinical trials in Europe and Africa, the new vaccine showed better tolerance and triggered a more targeted immune response than classical BCG. These promising findings were confirmed in a subsequent phase 2a trial in newborns, our ultimate target group,” confirms Dr. Bernd Eisele, VPM’s CEO. “And now, enrolling the first infant in the current phase 2 clinical trial in HIV-exposed infants, that is, infants who need a safer and better vaccine the most, is a huge success. It brings us one important step closer to including the new vaccine in a global plan of action against TB by the end of this decade.”

The phase 2 clinical trial currently taking place in South Africa, a TB hotbed, commenced this June and is the first investigation of the vaccine in HIV-exposed infants. Especially HIV-exposed infants may suffer from severe adverse events after vaccination with the common BCG and therefore are in urgent need of a safer and more effective vaccine. According to the clinical trial’s principal investigators, Professor Mark Cotton and Professor Anneke Hesselink of Stellenbosch University and Desmond Tutu TB Center, Dr. Angelique Luabeya from the South African Tuberculosis Vaccine Initiative (SATVI) and Professor Shabir Madhi of the Respiratory and Meningeal Pathogens Research Unit (RMPRU), “this trial with VPM1002 is an important milestone in our global fight against TB’s deadly threat – the disease currently afflicts about two billion people.”

Dr. Leander Grode, Kaufmann’s former research fellow and co-inventor, who has since become Chief Scientific Officer at VPM, contributed substantially to VPM1002’s development. “We have successfully modified the original vaccine in such a way that



it is now better at activating the human immune system, thereby affording more protection and safeguarding against the TB pathogen,” Grode explains.

Vakzine Projekt Management GmbH (VPM)

VPM is a public–private partnership venture based in Hannover, Germany, and was founded in 2002 jointly by the German Federal Ministry for Education and Research and the Braunschweig based Helmholtz Centre for Infection Research. Drawing on its professional project management expertise and long-standing drug design experience, VPM is able to support researchers and show that their innovations have the potential to move out of the research labs and into clinical application, to ultimately benefit humankind.

<http://www.vakzine-manager.de>

Serum Institute of India Ltd. (SIIL)

SIIL was founded 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 people. At this point, the SIIL has become the world’s largest manufacturer of vaccines against measles and against diphtheria, pertussis/whooping cough and tetanus (DPT). The company has continued to increase its philanthropic focus and now also manufactures vaccines against hepatitis B, rabies, and meningitis. These efforts ensure that from the day they are born, all children – not only in India, but in more than 140 different countries all over the world – have access to life-saving medicines.

<http://www.seruminstitute.com>

Max Planck Institute for Infection Biology (MPIIB)

Scientists at the MPIIB in Berlin, Germany, are concerned with the study of different kinds of pathogens and their effect on the host organism. A central focus of MPIIB’s research includes pathogens that cause tuberculosis, malaria, serious gastrointestinal diseases and influenza. In addition to the acquisition of knowledge, a second focus is on the development of new vaccines, new drugs and diagnostic biomarkers.

<http://www.mpiib-berlin.mpg.de>

Helmholtz Centre for Infection Research (HZI)

Scientists at the HZI in Braunschweig, Germany, are engaged in the study of different mechanisms of infection and of the body’s response to infection. Improving our understanding of a given bacterium’s or virus’ pathogenicity is key to developing effective new treatments and vaccines.

<http://www.helmholtz-hzi.de>