TuBerculosis Vaccine Initiative

Clinical candidates – (revised d.d. July 2018)

Aerosolised MVA85A

As part of their TB vaccine programme, University of Oxford is developing an aerosol inhaled route of TB vaccine delivery. This route of administration of a TB vaccine could offer practical, tolerability and safety benefits over and above needle-based methods. This may be particularly important for developing countries. A second clinical trial phase I with aerosol MVA85A has just completed in Oxford, to further evaluate the effect of this route of immunisation on anti-vector immunity, and a third clinical trial evaluating safety of aerosol MVA85A in latently-infected healthy UK adults has just started enrolment.

MTBVAC

MTBVAC, developed by the University of Zaragoza, Institut Pasteur and Biofabri, is a live attenuated Mtb strain currently in clinical development. Its primary target population is newborns and secondary adolescences. The safety and immunogenicity results of the Phase I trial conducted at the University of Lausanne as well as the Phase Ib trial in infants within the South African Tuberculosis Vaccine Initiative (SATVI) were satisfactory. The clinical Phase IIa in newborns will start in Q4 2018.

VPM1002

VPM1002 is a live-attenuated, recombinant Bacille Calmette-Guérin vaccine (BCG), originating from the Max Planck Institute for Infection Biology. This new vaccine has been developed in the clinics by the Hannover-based Vakzine Projekt Management GmbH (VPM) through the phase IIa study. VPM has teamed up with Serum Institute of India Pvt. Ltd. (SIIPL) and together they are currently conducting a phase II trial in South Africa evaluating VPM1002 as a prime vaccine in HIV-exposed and HIV-unexposed infants. The subsequent pivotal phase III trial, funded by SIIPL and EDCTP, is currently in the preparation phase. Newborn infants are the primary target population as the ultimate goal is to replace the current BCG with VPM1002. Data from the first clinical trials have confirmed the pre-clinical data and showed that VPM1002 is at least as safe and immunogenic as BCG. In addition, a phase II/III trial has started in November 2017 in India to assess the potential of VPM1002 as a post-exposure vaccine in prevention of TB recurrence after successful anti-tuberculosis drug therapy.

RUTI

RUTI® is a non-live immunotherapeutic agent based on cell wall fragmented Mycobacterium tuberculosis. RUTI® is intended as a therapeutic vaccine to be used in conjunction with the standard antibiotic treatment. Its target is to improve the cure rate and to reduce the relapse incidence focusing mainly on Multi Drug resistant TB (MDR-TB). A Phase II clinical trial in LTBI adults has been successfully completed. Currently a Phase IIa clinical trial in patients with MDR-TB is being performed and the preparation for a subsequent Phase IIb/III trial is underway.