



First vaccinee enrolled in a large phase III trial against tuberculosis in a Pan-African setting

November 09, 2020

HANOVER - Vakzine Projekt Management GmbH (VPM) announces that the first participant has been enrolled on November 9, 2020 in a phase III trial (priMe) to assess the efficacy and safety of the novel TB vaccine – VPM1002 - in comparison with BCG in healthy newborn infants. The study has been designed as a multicenter, randomized, double-blinded, active controlled clinical study across clinical sites in Kenya, Uganda Tanzania, South Africa and Gabon.

VPM1002, manufactured by Serum Institute of India Pvt. Ltd. (SIPL), who are also the sponsor of the clinical trial, is a recombinant vaccine against tuberculosis with an improved immunogenicity and safety profile compared to the currently used BCG, which is the only vaccine currently available for immunization against tuberculosis. Participants enrolled will be randomized 1:1 to VPM1002 or BCG. The primary endpoint is to prove that VPM1002 prevents *Mycobacterium tuberculosis* infection at least as good as BCG.

About Vakzine Projekt Management GmbH

VPM is a development consulting firm for the biopharmaceutical industry. What is unique about VPM is that it began as a project management organisation, successfully developing and out-licensing three out of five proprietary products sourced from academic laboratories. Having mastered these value points, VPM now offers consulting services for the entire product development value chain. Based on its own in-depth experience and unique history having developed product candidates themselves, VPM offers regulatory consultancy, project management, due diligence & valuation, organizational & quality management and can act as a designated sponsor.

www.vpm-consult.com

www.pri-me-vaccine.eu

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