



## **Vakzine Projekt Management GmbH: First volunteer enrolled in Phase II/III Study of SIIPL Tdap vaccine in Comparison with Boostrix® in Healthy Participants**

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**HANOVER - Vakzine Projekt Management GmbH (VPM) announced that the first participant has been enrolled on February 26 in a phase II/III to assess the safety and immunogenicity of SIIPL Tdap vaccine in comparison with Boostrix®. The study has been designed as a multicenter, randomized, observer-blinded, active controlled clinical study in healthy adults, adolescents and children in 15 to 20 sites across Germany.**

SIIPL Tdap, manufactured by Serum Institute of India Pvt. Ltd. (SIIPL) and Bilthoven Biologicals, is a combined vaccine for active immunization against tetanus, diphtheria and pertussis. The formulation contains reduced amounts of the diphtheria and acellular pertussis antigens; therefore, it is indicated for booster immunization of adults, adolescents, and children. Boostrix® is a vaccine indicated for active booster immunization against tetanus, diphtheria, and pertussis.

In the last 2 decades a shift towards vaccines containing acellular pertussis took place, resulting in repeated shortages in the European and United States of America (USA) markets. SIIPL has long experience in manufacturing and marketing combination vaccines against tetanus, diphtheria and pertussis, and is currently aiming at bringing its products into the European market, hence contributing to the solution of the shortage issues.

Participants enrolled will be randomized 2:1 (SIIPL Tdap:Boostrix®). The primary endpoints are the incidence and severity of vaccine-emergent adverse events (AEs) (phase II) as well as Diphtheria toxoid (DT) and Tetanus toxoid (TT) immunogenicity and booster response to pertussis antigens in phase III.

### **About Vakzine Projekt Management GmbH**

VPM is a development consulting firm for the biopharmaceutical industry. Unique about the organisation is that VPM began as a project management organisation, successfully developing and outlicensing three out of five proprietary products sourced from academic laboratories. Having mastered these value points for itself VPM now offers consulting and 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](http://www.vpm-consult.com)

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