Tadeus study enters phase III - First participants enrolled

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HANOVER - Vakzine Projekt Management GmbH (VPM) announces the start of enrolment in the phase III part of the phase II/III study which aims to assess the safety and immunogenicity of the Tdap vaccine by Serum Institute of India Pvt. Ltd. in comparison to a commercial comparator. The study has been designed as a multicenter, randomized, observer-blinded, active-controlled clinical study in healthy adults, adolescents and children in Germany.

The Tdap vaccine is a combined vaccine containing antigens that provide an active immunization against the three serious infectious diseases tetanus, diphtheria and pertussis. In the last two decades, there were repeated Tdap vaccine shortages in the European and United States markets due to a worldwide shift of the demand towards vaccines containing acellular pertussis antigens instead of whole cell pertussis. These circumstances had a negative impact on the capacity of delivering acellular pertussis containing vaccines for the national immunization programmes, governmental programmes aimed at minimizing the impact of vaccine-preventable diseases. Thus, children, adolescents, as well as adults might lack the chance to get the protective Tdap vaccine. This situation does not only set single individuals at risk, but it also endangers the global health.

VPM collaborates with the Serum Institute of India Pvt. Ltd. (SIIPL), the world's largest vaccine manufacturer, and Bilthoven Biologicals B.V. to develop the SIIPL Tdap vaccine. The formulation of SIIPL Tdap contains reduced amounts of the diphtheria and acellular pertussis antigens; therefore, it is indicated for booster immunization of children, adolescents and adults. SIIPL has long-standing experience in manufacturing and marketing of 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 global shortage issues.

SIIPL Tdap vaccine has successfully completed the phase II part of the trial showing no safety concerns in adults. The phase III study will further assess the safety and immunogenicity of the SIIPL Tdap vaccine in children, adolescent and adults. Study participants will be randomized 2:1 (SIIPL Tdap : comparator) to receive either SIIPL Tdap or the comparator vaccine. The beginning of the phase III part of the Tadeus study increases the chance of having a new, effective and safe vaccine available soon for the European market.

About Vakzine Projekt Management GmbH

VPM is a development consulting company 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 for clinical trials.

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