



Ministry of Science & Technology

Department of Biotechnology supported efficacy trial with recombinant BCG vaccine, VPM1002 completes enrolment of about 6000 health-workers and high risk individuals

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Serum Institute of India Pvt Ltd (SIPL) has been supported under Department of Biotechnology's National Biopharma Mission for conduct of a multisite randomized double-blinded placebo-controlled phase III clinical trial of a recombinant BCG vaccine candidate, VPM1002. The objective of this trial is to evaluate the ability of VPM1002 in reducing infection incidence and severe disease outcomes of COVID-19 among high-risk persons of advanced age or co-morbidities and high-exposure healthcare workers (HCWs).

BCG vaccine is administered routinely to all newborn babies as a part of the National childhood immunization programme to prevent tuberculosis (TB), an infection caused by bacteria that mainly affects the lungs. It has beneficial heterologous effects and proven antiviral and immune modulatory properties that protect against infectious diseases through induction of trained innate immunity and heterologous adaptive immunity. About 6,000 health workers and high-risk individuals including those in close contact of COVID patients have been enrolled in a clinical trial to determine if the recombinant Bacillus Calmette-Guerin (rBCG) can boost immunity to fight against the virus.

Dr RenuSwarup, Secretary, DBT and Chairperson, BIRAC speaking on the subject said that "BCG vaccine is a proven platform and utilizing its off-target effects for diseases other than TB is a very pragmatic approach to take. The trial began in May'2020 and has completed enrolment of 6000 subjects in almost 40 hospitals across the country. This is an important milestone, in the quest for preventing the disease and we look forward to the results of this important trial".

"We are delighted to partner with DBT-BIRAC for this study and look forward to the positive results of the trial, which should be available before the end of this year", said Mr Adar Poonawalla, owner and CEO, Serum Institute of India (SII).

There is an urgent need to ensure the safety and health of HCWs who are on the forefront fighting the epidemic, household contacts of COVID positive patients and all other people residing or working in COVID-19 hotspots/outbreak areas where there is a high risk of

transmission of COVID-19 infection. Paul Ehrlich Institute (PEI) and Health Canada also approved similar trials with rBCG.

About DBT

The Department of Biotechnology (DBT), under the Ministry of Science & Technology, promotes and accelerates the development of biotechnology in India, including growth and application of biotechnology in the areas of agriculture, healthcare, animal sciences, environment and industry.

About BIRAC:

Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit Section 8, Schedule B, Public Sector Enterprise, set up by Department of Biotechnology (DBT), Government of India as an Interface Agency to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.

About National Biopharma Mission:

The Industry-Academia Collaborative Mission of Department of Biotechnology (DBT), Govt of India for accelerating discovery research to early development for Biopharmaceuticals approved by the Cabinet for a total cost US\$ 250 million and 50% co-funded by the World Bank is being implemented at Biotechnology Research Assistance Council (BIRAC). This program is dedicated to deliver affordable products to the nation with an aim to improve the health standards of India's population. Vaccines, medical devices and diagnostics and biotherapeutics are few of its most important domains, besides, strengthening the clinical trial capacity and building technology transfer capabilities in the country.

About SIPL:

Serum Institute of India Pvt Ltd is the world's largest vaccine manufacturer by number of doses produced and sold globally which includes Polio vaccine as well as Diphtheria, Tetanus, Pertussis, Hib, BCG, r-Hepatitis B, Measles, Mumps and Rubella vaccines. Vaccines manufactured by the Serum Institute are accredited by the World Health Organization, Geneva and are being used in around 170 countries across the globe in their national immunization programs, saving millions of lives throughout the world.

(For Further Information: Contact Communication Cell of DBT/BIRAC

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