



**INDIAN COUNCIL OF MEDICAL RESEARCH
Department of Health Research**

Press Release

COVISHIELD Completes Enrolment of Phase III clinical trials under partnership of ICMR and Serum Institute of India

The strategic alliance between the SII and the ICMR will advance India's role in the global race to develop COVID-19 vaccines

ICMR is providing continuous support to SII in conducting and funding the ongoing clinical trials of COVISHIELD across 15 centres in India

November 12, 2020 - Serum Institute of India (SII), the world's largest vaccine manufacturer by volume, and **Indian Council of Medical Research (ICMR)**, the apex body in India for biomedical research, announce completion of enrolment of phase 3 clinical trials for COVISHIELD in India. ICMR and SII have further collaborated for clinical development **COVOVAX (Novavax)** developed by Novavax, USA and upscaled by SII. The partnership is a stellar example of private-public institutes collaborating to mitigate the dire consequences of the pandemic outbreak.

ICMR has funded the clinical trial site fees while SII has funded other expenses for COVISHIELD. At present, SII and ICMR are conducting Phase 2/3 clinical trial of COVISHIELD at 15 different centres, across the country. It has completed the enrolment of all 1600 participants on 31 Oct 2020. COVISHIELD has been developed at the SII Pune laboratory with a master seed from Oxford University/Astra Zeneca. The vaccine made in UK is currently being tested in large efficacy trials in UK, Brazil, South Africa and USA. The promising results of the trials so far give confidence that **COVISHIELD** could be a realistic solution to the deadly pandemic. **COVISHIELD** is by far the most advanced vaccine in human testing in India. Based on the Phase 2/3 trial results, SII with the help of ICMR will pursue the early availability of this product for India. SII has already manufactured 40 million doses of the vaccine, under the at-risk manufacturing and stockpiling license from DCGI.

Furthermore, US-based Novavax has initiated its late phase trials in South Africa and in UK and will soon commence the same in the USA. SII has received the bulk vaccine and Matrix-M adjuvant from Novavax and will soon fill and finish them in vials. This vaccine formulated at SII (COVOVAX) will be tested in a Phase 3 trial in India and an application for the same to regulatory authorities will be made soon by ICMR and SII.

Commenting on the association, **Adar Poonawalla, CEO of Serum Institute of India**, said, "*ICMR has played a huge role in coming forward and strengthening India's fight against COVID-19. The collaboration will further aid us in putting India at the forefront of developing an immunogenic and efficacious vaccine. The pandemic has presented a chance to foster structural reforms in building robust public healthcare infrastructure. The partnership further testifies the importance of private-public institutes coming together in scaling up the management and containing the spread of the virus.*"

Dr. Balram Bhargava, Director General of Indian Council of Medical Research (ICMR), commented, "*At present, India plays a prominent role in vaccine development and manufacturing globally. Buoyed by the latest technology and well-equipped facilities, SII has continually proven its research and manufacturing prowess. The partnership is our contribution to lending our expertise and support to bolster our fight against the global pandemic.*"

The partnership will see the scientists of both the entities facilitate the advancement of regulatory approvals for COVISHIELD and COVOVAX while ensuring strict adherence to all the requisite scientific, ethical and regulatory standards.

Notes to editors

About Serum Institute of India Pvt. Ltd. (SIPL):

Driven by the philanthropic philosophy of affordable vaccines; **Serum Institute of India Pvt, Ltd.** (SIPL) is the world's largest vaccine manufacturer by number of doses produced and sold globally (more than 1.5 billion doses), supplying the world's cheapest and WHO accredited vaccines to as many as 170 countries. It was founded in 1966 with the aim of manufacturing lifesaving immunobiological drugs including vaccines worldwide. With a strong commitment towards global health, the institute's objective has been proliferated by bringing down the prices of newer vaccines such as such as Diphtheria, Tetanus, Pertussis, Hib, BCG, r-Hepatitis B, Measles, Mumps and Rubella vaccines. SII is credited with bringing world-class technology to India, through its state-of-the-art equipped multifunctional production facility in Manjri, Pune; association with Zipline and government agencies to transform emergency medicine and critical care along with spearheading the race of vaccine development against the COVID-19 pandemic.

About ICMR

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. The ICMR has always attempted to address itself to the growing demands of scientific advances in biomedical research on the one hand, and to the need of finding practical solutions to the health problems of the country, on the other. The Council's research priorities coincide with the National health priorities such as control and management of communicable diseases, fertility control, maternal and child health, control of nutritional disorders, developing alternative strategies for health care delivery, containment within safety limits of environmental and occupational health problems; research on major non-communicable diseases like cancer, cardiovascular diseases, blindness, diabetes and other metabolic and haematological disorders; mental health research and drug research (including traditional remedies). All these efforts are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population.

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