PRESS RELEASE

Phase 3 Clinical Trial of COVAXIN, developed by ICMR & Bharat Biotech, shows 81% efficacy

The results, evaluated by an independent data safety and monitoring board, show that the vaccine is well-tolerated and efficacious against SARS-CoV-2 across a wide range of age groups and variants in the country

New Delhi, 3 March 2021: Phase 3 results of the COVAXIN, developed by Indian Council of Medical Research (ICMR) in partnership with Bharat Biotech International Limited (BBIL), has shown an interim vaccine efficacy of 81% in preventing Covid-19.

The Phase 3 trial, jointly initiated by ICMR and BBIL in mid-November 2020, was conducted in a total of 25,800 individuals across 21 sites. The interim efficacy trend of 81%, analyzed as per the protocol approved by the DCGI, puts it at par with other global front-runner vaccines.

"The bench-to-bedside journey of completely indigenous COVID-19 vaccine in less than 8 months' time showcases the immense strength of *Atmanirbhar Bharat* [self-reliant India] to fight the odds and stand tall in the global public health community. It is also a testament to India's emergence as a global vaccine superpower," said **Dr. Balram Bhargava**, **Director General, ICMR**.

The COVAXIN is the first COVID-19 vaccine that has been developed completely in India. In March 2020, following the successful isolation of the SARS CoV-2 virus at ICMR-National Institute of Virology (NIV), ICMR entered into a public-private partnership with BBIL to develop the virus isolate into an effective vaccine candidate. ICMR-NIV characterized the vaccine developed by BBIL through in-vitro experiments and electron microscopy studies.

Pre-clinical studies in small animals and hamsters showed promising results in terms of safety and immunogenicity. Further studies conducted in rhesus macaques also established remarkable safety and protective efficacy of COVAXIN. Phase 1 and Phase 2 clinical trials conducted in 755 participants demonstrated high safety profile of the candidate vaccine with seroconversion rates of 98.3% and 81.1% on day 56 and 104 respectively.

COVAXIN has been developed on the WHO prequalified vero cell platform, which is globally recognized with a well-established track record of safety. COVAXIN's ability to neutralize UK variant strain of SARS-CoV-2 has also recently been established.

"The development and deployment of COVAXIN ensures that India has a powerful weapon in its arsenal in a continually evolving pandemic situation and will go a long way in helping us win the war against COVID-19. The need of the hour is to ensure that people in India

continue to receive the vaccine and break the chain of virus transmission," said **Dr. Samiran Panda**, Head, Epidemiology and Communicable Disease, ICMR and Director, National AIDS Research Institute.

Bench-to-Bedside Journey of COVAXIN: Bharat ki Apni Vaccine

- *March 11, 2020:* When COVID-19 was declared a pandemic by the World Health Organization (WHO), India joined the global race of developing safe and effective vaccines to protect its citizens as well as the global community from this dreaded disease.

- *March 13, 2020:* ICMR-National Institute of Virology (ICMR-NIV) successfully isolates the SARS-CoV-2 virus. India becomes the 5th country in the world to achieve this feat.

- *April 2020:* ICMR enters in a public-private partnership with Bharat Biotech International Ltd (BBIL) for developing an effective vaccine candidate for SARS-CoV-2.

- *May 2020:* ICMR-NIV transfers the virus strain to BBIL and characterizes the vaccine developed by BBIL through in-vitro experiments and electron microscopy studies.

- *June-August 2020:* Experiments in small animals (mouse, rats and rabbits) and hamsters established promising safety and immunogenicity of COVAXIN. Data has been published by highly reputed journal of the Cell Press. (Link to research papers: Link 1, Link 2)

- *July-August 2020:* Studies conducted in rhesus macaques established safety and protective efficacy of COVAXIN. The results established remarkable ability of the vaccine candidate to clear the virus from infected organs along with its capacity to mount B and T cell immune response. Link to research paper: Link 3.

- *July-October 2020:* Phase 1 and 2 clinical trials conducted in 755 participants demonstrated high safety profile of the candidate vaccine along with seroconversion rates of 98.3% and 81.1% respectively on day 56 and 104 respectively. The results are published in Lancet journal. Link to research paper: Link 4, Link 5

- *November 2020:* The largest ever clinical trial for COVID-19 in India, launched for the third phase with over 25,800 participants

- *January 3, 2021:* Drugs Controller General of India (DCGI) provides approval for Restricted Use in Emergency Situations for COVAXIN

- *January 16, 2021:* India rolls-out phase-wise COVID-19 vaccine administration starting with healthcare and frontline workers

- *January 27, 2021:* COVAXIN's ability to neutralize UK variant strain of SARS-CoV-2 established and published in *Journal of Travel Medicine*. Link to research paper: Link 6

- *March 3, 2021:* Interim results of Phase 3 efficacy trials of COVAXIN show 81% efficacy against SARS-CoV-2virus. The follow-up of participants in the trial is still ongoing.

About ICMR: *The Indian Council of Medical Research (ICMR), New Delhi, is 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. ICMR's research priorities align with the National health priorities. These efforts are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population. ICMR promotes biomedical research in the country through intramural as well as extramural research. Visit us at https://www.icmr.gov.in/*

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