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COVAXIN demonstrates overall efficacy of 77.8% in ph 3 clinical trial

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Efficacy analysis demonstrates COVAXIN® to be 93.4% effective against severe symptomatic COVID-19

Bharat Biotech has announced the safety and efficacy analysis data from Phase III clinical trials of COVAXIN®, a whole virion inactivated vaccine against SARS-CoV2, was developed in partnership with ICMR and NIV Pune.

Phase 3 clinical trials of COVAXIN® was an event driven analysis of 130 symptomatic COVID-19 cases, reported at least two weeks after the 2nd dose, conducted at 25 sites across India.

The vaccine is formulated with a novel Algel+IMDG adjuvant. IMDG is a TLR7/8 agonist known to induce memory T cell responses along with strong neutralizing antibodies. The activation of cell mediated immune responses is especially valuable in a multi epitope vaccine such as COVAXIN®, where immune protection can be achieved from S, RBD and N proteins alike. IMDG was developed under partnership between Virovax and NIAID, National Institutes of Health USA.

The safety profile of COVAXIN® is now well established based on inactivated vaccines technology, and in large part due to the extensive 20-year safety track record of Bharat Biotech's vero cell manufacturing platform. Furthermore, Bharat Biotech has so far not sought indemnity for COVAXIN® from the Governments.

No licensed SARS-CoV-2 vaccine has reported efficacy against asymptomatic infection in a randomised controlled trial,

based on qPCR testing. COVAXIN® is the first to report promising efficacy against asymptomatic infections based on qPCR testing that will help in reducing disease transmission.

COVAXIN® has now received emergency use authorizations in 16 countries including, Brazil, India, Philippines, Iran, Mexico, etc. with EUA's in process in 50 countries worldwide. The company is in discussions with WHO to obtain emergency Use Listing.

Bharat Biotech has established COVAXIN® manufacturing at 4 facilities within India, further expansions are in process to reach an annualized capacity of 1 billion doses by the end of 2021. Technology transfer activities are in progress to companies in United States, and other countries.