COVAXIN® (BBV152) booster dose study shows Promising Results

- ***The phase 2, double-blind, randomised controlled* COVAXIN® *trial demonstrated long-term safety with no serious adverse events.***

- ***6 months after receipt of the second COVAXIN® dose:***

  - Durable neutralising, T and B cell responses detected, which suggests good immune memory responses and long-term protection from severe disease.
  - 90% of recipients had a detectable neutralising antibody response against the wild - type strain (6 months after the second dose).

- ***6 months after receipt of the second COVAXIN® dose, participants received a third booster dose of COVAXIN®:***

  - Neutralisation titers against wild - type and Delta variants were 5 times higher than after a two-dose schedule.
  - Similar increases in neutralising antibodies against Alpha, Beta, Delta plus were observed.
  - The booster dose led to a pronounced increase in CD4+ T- and CD8+ Tcell response. This may allow COVAXIN® to confer long term protective efficacy against severe SARS-CoV-2.
  - The frequency of adverse events was lower than vaccines from other manufacturing platforms.

Hyderabad, India, 08 January 2022: Bharat Biotech, a global leader in vaccine innovation and developer of vaccines for infectious diseases, today announced the results from the highly anticipated trial studying the immunogenicity and safety of the COVAXIN® (BBV152) a whole-virion inactivated COVID-19 vaccine as a booster dose.

This analysis re-emphasises Bharat Biotech's continued efforts to stay ahead of COVID-19, and this update provides a comprehensive vaccine booster strategy. COVAXIN® is the first vaccine (in India) to report safety and immunogenicity results from a booster clinical trial. The analysis showed, six months after a two-dose BBV152 vaccination series cell-mediated immunity and neutralising antibodies to both homologous (D614G) and heterologous strains (Alpha, Beta, Delta, and Delta plus) persisted above baseline, although the magnitude of the responses had declined.

Furthermore, Neutralising antibodies against homologous and heterologous SARS-CoV-2 variants increased 19 to 265 fold after a third vaccination. Booster BBV152 vaccination is safe and may be necessary to ensure persistent immunity to prevent breakthrough infections.

Dr. Krishna Ella, Chairman and Managing Director of Bharat Biotech, said, "These trial results provide a strong foundation towards our goal to provide COVAXIN® as a booster dose. Our goals of developing a global vaccine against COVID-19 have been achieved. COVAXIN® is now indicated for adults, children, 2 dose primary and booster doses. This enables the use of COVAXIN® as an universal vaccine."

We found the vaccine induces both memory B and T cells with a distinct CD4 and CD8 phenotype.

Further, reactogenicity after vaccine and placebo was minimal and comparable, and no *serious adverse events* were reported.

While protection against the severe disease remains high across the full 6 months, a decline in efficacy against symptomatic disease over time and the continued emergence of variants are expected. Based on emerging data, Bharat Biotech believes that a third dose may be beneficial to maintain the highest levels of protection.

COVAXIN® *is formulated uniquely such that the same dosage can be administered to adults and children alike.* COVAXIN® *is ready-to-use a liquid vaccine, stored at 2- 8℃, with 12 months shelf life and multi-dose vial policy. The same vaccine can also be used for 2 dose primary immunization and for booster dose vaccinations, making it truly an universal vaccine.*

About Bharat Biotech

Bharat Biotech has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 123 countries, and the World Health Organization (WHO) Pre-qualifications.

Located in Genome Valley in Hyderabad, India, a hub for the global biotech industry, Bharat Biotech has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution. Having delivered more than 4 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis (JENVAC®), Rabies, Chikungunya, Zika, Cholera, and the world's first tetanus toxoid conjugated vaccine for Typhoid.

Bharat's commitment to global social innovation programs and the public-private partnership resulted in introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, ROTAVAC® 5D, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. The acquisition of Chiron Behring Vaccines has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer with Chirorab® and Indirab®.

Bharat Biotech has established COVAXIN® manufacturing to reach an annualised capacity of 1 billion doses by the end of 2021. Technology transfer activities are in progress to companies in India, the United States, and other countries.More about COVAXIN® -

https://www.bharatbiotech.com/covaxin.html

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DATA TRANSPARENCY

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