Peer Reviewed: COVAXIN® demonstrates Persistence of immunity and impact of third dose of inactivated COVID-19 vaccine against emerging variants

- This data is now peer reviewed and published in Nature Scientific Reports, a high impact factor journal (https://doi.org/10.1038/s41598-022-16097-3).

- This is a comprehensive study that has demonstrated multiple benefits of COVAXIN®, such as long term immune response, cell mediated immunity, safety of booster dose, immunogenicity against spike protein, N protein and neutralizing antibody responses against alpha, beta, delta, delta plus and omicron variants.

- Administration of a third dose, after 6 months of two dose vaccination, dramatically increased neutralizing antibody responses against both homologous and heterologous strains (Alpha, Beta, Delta, Delta Plus and Omicron) and showed increased memory B cell response.

- COVAXIN® induced robust T cell responses and persisted till 6 months, even after antibody decline. These T cell responses have been followed up to 12 months in vaccinated individuals, irrespective of receipt of third dose. T cell responses in turn help to produce B cell memory response, upon antigen re-exposure. Thus, COVAXIN® provides long term immunity.

- Immune responses declined at 6 months, but increased by 40 fold in subjects who received a booster dose. Immune responses when assessed against variants of concern and persisted up to 12 months.

- No serious adverse events observed, except pain at the injection site, itching and redness, no cases of myocarditis, pericarditis, blood clots, or thrombocytopenia were detected.

- The study provides evidence to support COVAXIN®, a multi epitope vaccine that provides broad protection against variants couples with cell mediated immune response due to the use of novel adjuvant Algel-IMDG.

Hyderabad, July 20, 2022: Bharat Biotech International Limited (BBIL), a global leader in vaccine innovation and developer of vaccines for infectious diseases, today announced that BBV152 (COVAXIN®), its whole-virion inactivated COVID-19 vaccine, has proven to be safe, well-tolerated, and immunogenic in subjects in controlled clinical trials. The study has been accepted and published in Nature Scientific Reports, a high impact factor journal.

The study was conducted in ~184 subjects, who were randomized 1:1 and received either a booster dose of BBV152 or a placebo, ~6 months after the primary series of 2 doses. Subjects were evaluated for safety, neutralizing antibody responses against variants of concern, binding antibodies against spike protein, RBD, N proteins, and for memory T and B cell responses to demonstrate cell mediated immunity.

Dr. Krishna Ella, Chairman and Managing Director, Bharat Biotech, said, "Our team has now demonstrated that COVAXIN® is a multi epitope vaccine with antibodies against spike, RBD and N proteins. Post booster dose, it has proven neutralizing antibody responses against variants of concern and long term protection through memory T and B cell responses. We have now achieved our goal of developing a safe and efficacious vaccine with long term protection against a spectrum of variants."

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

Whole virion inactivated vaccines have proven to be safe, tolerable with a safety track record of several decades. Several paediatric vaccines manufactured using this platform technology are utilized in routine immunization for primary immunization and booster doses. Several flu vaccines also utilize this manufacturing platform technology, which is safe and effective for repeated annual immunization doses and boosters.

Bharat Biotech has a stockpile of more than 50 million doses of COVAXIN® ready to be distributed as required.

About Bharat Biotech

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

Bharat Biotech has established COVAXIN® manufacturing to reach an annualized capacity of 1 billion doses by the end of 2021.

More about COVAXIN® - https://www.bharatbiotech.com/covaxin.html

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