Peer Reviewed: Covaxin® demonstrates robust safety and immunogenicity in children 2-18 years.

- This data is now peer reviewed and published in the Lancet Infectious Diseases a high impact factor journal (https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00307-3/fulltext)

- COVAXIN® is one of the first COVID-19 vaccines in the world to generate data in 2–18-year age group

- COVAXIN® has been extensively studied and published, demonstrating a very high-level of data transparency. All aspects of COVAXIN® product development have been published extensively with 14 publications

- Data from over 50 million doses given to children in India reveals that side effects are minimal

- Safety of COVAXIN® in both adults and children are now well established. Data on pharmacovigilance and AEFI after introduction in several countries are very positive. Vaccine related cases of AEFI's such as myocarditis, blood clots, pericarditis, were not reported

- COVAXIN®, the Whole-Virion inactivated SARS-CoV-2 Vaccine (BBV152) has proven to be safe, well-tolerated, and immunogenic in paediatric subjects in phase II/III study. Neutralizing antibodies in children on an average 1.7 times higher than in adults

- The same dosage of COVAXIN®, can be administered to adults and children, for primary immunization and booster doses, making it a Universal Vaccine

Hyderabad, June 17, 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 candidate, has proven to be safe, well-tolerated, and highly immunogenic in paediatric subjects in phase II/III study. The study has been accepted and published in Lancet Infectious diseases, peer reviewed high impact factor journal.

Bharat Biotech had conducted phase II/III, open-label, and multicenter study to evaluate the safety, reactogenicity, and immunogenicity COVAXIN® in healthy children and adolescents in 2-18 years of age group. The clinical trial conducted in the pediatric population between June 2021 to September 2021 has shown safety, less reactogenic, and robust immunogenicity. The data was submitted to the Central Drugs Standard Control Organisation (CDSCO) during October 2021, and received a nod for emergency use in children aged 6-18years.

Dr. Krishna Ella, Chairman and Managing Director, Bharat Biotech, said, "Safety of the vaccine is critical for children and we are glad to share that COVAXIN® has now proven data for safety and immunogenicity in children. We have now achieved our goal of developing a safe and efficacious COVID-19 vaccine for adults and children, for primary immunization and booster doses, making COVAXIN® a universal vaccine. It has proven to be a highly safe vaccine based on data from more than 50 million doses administered to children in India. Vaccines are a great preventive tool; the power of vaccines can only be harnessed if used prophylactically."

In the study, no serious adverse event was reported. A total of 374 adverse events were reported, and the majority of adverse events were mild in nature and resolved within 1 day. Pain at the injection site was the most commonly reported adverse event.

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 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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