COVAXIN® for Children: Study demonstrates robust safety and immunogenicity in 2-18 Volunteers.

- COVAXIN® is the one of the first COVID-19 vaccines in the world to generate data in 2-18 year age group.
- Phase II/III, Open-Label, Multi-centre Study was conducted to evaluate the Safety, Reactogenicity, and Immunogenicity of the Whole-Virion Inactivated SARS-CoV-2 Vaccine (COVAXIN®) in healthy children and adolescents in the 2-18 age group.
- 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.
- No serious adverse event was reported. Pain at the injection site was the most commonly reported adverse event. No cases of myocarditis or blood clots were reported, as expected with inactivated vaccines.

Hyderabad, December 30, 2021: 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 immunogenic in paediatric subjects in phase II/III study.

Bharat Biotech had conducted phase II/III, open-label, and multicenter studies to evaluate the safety, reactogenicity, and immunogenicity COVAXIN® in healthy children and adolescents in the 2-18 age group. The clinical trials conducted in the paediatric population between June 2021 to September 2021 have shown robust safety, reactogenicity, and immunogenicity. The data was submitted to the Central Drugs Standard Control Organisation (CDSCO) during October 2021, and received emergency use nod for children aged 12-18 from DCGI, recently.

In the study, no serious adverse event was reported. 374 subjects reported either mild or moderate severity symptoms with 78.6% getting resolved within 1 day. Pain at the injection site was the most commonly reported adverse event.

Dr. Krishna Ella, Chairman and Managing Director, Bharat Biotech, said, "COVAXIN®'s clinical trial data from the paediatric population is very encouraging. 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. Vaccines are a great preventive tool; the power of vaccines can only be harnessed if used prophylactically."

About COVAXIN® Phase II/III study analysis for paediatric use

For the trial, 976 subjects were screened for SARS-CoV-2 by RT-PCR and ELISA testing. Out of these, 525 eligible participants were enrolled. Based on the age, participants were distinguished into three groups in an age de-escalatory manner. Group I consisted of children of age 12-18 years (n=175), group II consisted of children of age 6-12 years (n=175), and group III consisted of children of age 2-6 years (n=175).

Seroconversion was documented at 95-98%, in all three groups four weeks after the second dose, indicating superior antibody responses in children when compared to adults and also displayed Th1 bias. In earlier COVAXIN® studies in adults, cross reactive memory T cells against all variants of concern was reported. Studies are underway to evaluate T cell responses against the Omicron variant. Since COVAXIN®, is an inactivated vaccine corroborative results are expected.

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

Immunogenicity and safety of an inactivated SARS-CoV-2 vaccine (BBV152) in children from 2 to 18 years of age: an open-label, age-de-escalation phase 2/3 study

https://www.medrxiv.org/content/10.1101/2021.12.28.21268468v1

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 annualized capacity of 1 billion doses by the end of 2021. Technology transfer activities are in progress to companies in India, United States and other countries.

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

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