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Bharat Biotech's COVAXINÒ demonstrates robust safety in phase II/III study

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The study was conducted in two to 18 year age group

Bharat Biotech International announced that BBV152 (COVAXINÒ), 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 multicentre 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 an 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 per cent getting resolved within one day. Pain at the injection site was the most commonly reported adverse event.

Dr Krishna Ella, CMD, Bharat Biotech, said, “COVAXIN’s clinical trial data from the pediatric population is very encouraging. The 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.”