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India's COVAXINÒ exhibits safety in paediatric subjects in Ph II/III study

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

Indian firm Bharat Biotech International Limited (BBIL), a global leader in vaccine innovation and developer of vaccines for infectious diseases, has 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 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, “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.”