BioSpectrum the business of Bio & Health Sciences

Biological E's CORBEVAX bags DCGI approval for Ph III trials

03 September 2021 | News

For active controlled Phase III clinical trial in adult population & Phase II/III paediatric trial in children and adolescents (5yrs and above)

Hyderabad-based Biological E has received Drugs Controller General of India (DCGI) approval for conducting Phase III Comparator Safety & Immunogenicity trial in adults after Subject Expert Committee's (SEC) review of Phase I and II clinical trials data.

Additionally, Biological E also received approval on 01.09.2021 to initiate the Phase II/III study to evaluate the safety, reactogenicity, tolerability and immunogenicity of the CORBEVAX vaccine in children and adolescents. The candidate is an receptor binding domain (RBD) protein subunit vaccine.

The Department of Biotechnology (DBT) and its PSU, Biotechnology Industry Research Assistance Council (BIRAC) have supported Biological E's COVID-19 Vaccine candidate from Preclinical Stage to Phase III clinical studies.

In addition to receiving financial assistance under Mission COVID Suraksha, this vaccine candidate has also obtained a financial support under COVID-19 Research Consortia through National Biopharma Mission, BIRAC.