



Ministry of Science & Technology



Department of Biotechnology Mission COVID Suraksha Supported Biological E Limited Novel Covid-19 Vaccine candidate – CORBEVAX receives DCGI approval for Two Clinical Trials"

- Active controlled Phase III Clinical trial in Adult population
 - Phase II/III Paediatric trial in Children and Adolescents (5yrs and above)

Posted On: 03 SEP 2021 1:25PM by PIB Delhi

The Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India (GoI) has taken myriads of initiatives to increase investments in research & development (R&D) and manufacturing of COVID-19 Vaccines. Establishment of Mission COVID Suraksha Program is one such endeavour for COVID-19 vaccine development to reinforce and streamline available resources towards a warpath for accelerated vaccine development, leading to bring in a safe, efficacious, affordable and accessible COVID-19 Vaccine for the citizens at the earliest with a target of Atmanirbhar Bharat.

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.

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 Safety, Reactogenicity, Tolerability and Immunogenicity of CORBEVAX™ vaccine in Children and Adolescents. The candidate is a RBD protein sub-unit vaccine.

Dr. Renu Swarup, Secretary, DBT and Chairperson, BIRAC speaking on the subject said that "Department through Mission COVID Suraksha launched under Atma Nirbhar Bharat package 3.0 being implemented by BIRAC, is committed to development of safe and efficacious COVID-19



vaccines. We look forward to the clinical development of candidate CORBEVAX™ for paediatric and adults .”

“We are delighted to receive these significant approvals from the DCGI. These approvals encourage our organisation to move forward and successfully produce our COVID-19 vaccine to meet the vaccination needs,” said Ms. Mahima Datla, Managing Director, Biological E. Limited. “We are grateful to BIRAC for their support and we are enthused that these approvals would help support our subsequent filings with WHO as well. We appreciate and acknowledge the contribution of all our collaborators for their continued support in this endeavour,” she further added.

About DBT

The Department of Biotechnology (DBT), under the Ministry of Science & Technology, promotes and accelerates the development of biotechnology in India, including growth and application of biotechnology in the areas of agriculture, healthcare, animal sciences, environment and industry.

About BIRAC:


Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit Section 8, Schedule B, Public Sector Enterprise, set up by Department of Biotechnology (DBT), Government of India as an Interface Agency to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs

ABOUT BIOLOGICAL E. LIMITED

Biological E. Limited (BE), a Hyderabad-based Pharmaceuticals & Biologics Company founded in 1953, is the first private sector biological products company in India and the first pharmaceutical company in Southern India. BE develops, manufactures and supplies vaccines and therapeutics. BE supplies its vaccines to over 100 countries and its therapeutic products are sold in India and the USA. BE currently has 8 WHO-prequalified vaccines in its portfolio.

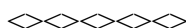
In recent years, BE has embarked on new initiatives for organisational expansion such as developing generic injectable products for the regulated markets, exploring synthetic biology and metabolic engineering as a means to manufacture APIs sustainably and developing novel vaccines for the global market.

For Further Information: Contact Communication Cell of DBT/BIRAC

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