

DBT-BIRAC SUPPORTED NOVEL COVID-19 VACCINE CANDIDATE - CORBEVAX™ DEVELOPED BY BIOLOGICAL E LIMITED RECEIVES DCGI APPROVAL FOR EMERGENCY USE AUTHORIZATION (EUA) FOR 12-18 YEARS AGE GROUP

Relevant for: Science & Technology | Topic: Biotechnology, Genetics & Health related developments

India's first indigenously developed Receptor Binding Domain (RBD) protein sub-unit vaccine for COVID-19, CORBEVAX™, developed by Biological E Limited, has received approval for Emergency Use Authorization from the Drug Controller General of India (DCGI) for 12-18 years age group. It is approved to be administered in humans including Children and adults 12 years and above.

The Department of Biotechnology (DBT) and its Public Sector Undertaking (PSU), Biotechnology Industry Research Assistance Council (BIRAC), have supported Biological E's COVID-19 vaccine candidate from pre-clinical stage through Phase III clinical studies. The vaccine candidate was provided financial support under COVID-19 Research Consortium, through the National Biopharma Mission, for pre-clinical studies and Phase I/II Clinical Trials. Additional support was provided through Mission COVID Suraksha for further clinical development. CORBEVAX™ is a 2-dose vaccine administered intramuscularly and can be stored at 2°C to 8°C.

The recombinant protein sub-unit vaccine developed from the Receptor Binding Domain (RBD) of the spike protein on the viral surface is adjuvanted with CpG 1018 and alum. The Drug Controller General of India has already approved CORBEVAX™, for restricted use in emergency situation among adults on December 28, 2021. Based on interim results of the ongoing phase II/III clinical study, Biological E has received approval for restricted use in an emergency situation in adolescents aged 12 to 18 year age group. The available safety and immunogenicity results of the ongoing phase II/III clinical study indicated that the vaccine is safe and immunogenic. The Translational Health Science and Technology Institute (THSTI), an Autonomous Institute of DBT, provided immunogenicity data for the Phase II/ III studies.

Dr Rajesh Gokhale, Secretary, Department of Biotechnology, and Chairperson, BIRAC, Government of India, speaking on the subject said that "*the Department through Mission COVID Suraksha launched under AtmaNirbhar Bharat package 3.0 being implemented by BIRAC, is committed to development of safe and efficacious COVID-19 vaccines. This is the 2nd vaccine supported under the Mission, to have received EUA for the age group of 12-18 years. Corbevax is based on a time-tested platform and would be an important vaccine for India and the world. This is yet another successful example industry- academia partnership.*"

Ms. Mahima Datla, Managing Director, Biological E. Limited, said, "We are delighted with this important development, which helps our CORBEVAX™ reach yet another milestone in extending our COVID-19 immunisation initiative to cover to the 12-18 age group. With this approval, we are even more closer to finishing our global fight against the COVID-19 pandemic. We thank the Department of Biotechnology (DBT) of Govt. of India, Biotechnology Industry Research Assistance Council (BIRAC), Translational Health Science and Technology Institute (THSTI), all the participants in the clinical trials and the principal investigators & clinical site staff who have extended their support during the last several months."

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.

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