Department of Biotechnology Mission COVID Suraksha Supported Biological E Limited Novel COVID-19 vaccine candidate – CORBEVAXTM receives DCGI approval for Emergency Use Authorization

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India's first indigenously developed Receptor Binding Domain (RBD) protein sub-unit vaccine for COVID-19, CORBEVAX^{TM}, developed by Biological E Limited, has received the Drug Controller General of India (DCGI) approval for Emergency Use Authorization (EUA).

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 toxicology studies. Later support was provided under Mission COVID Suraksha for clinical development. CORBEVAX^{TM} is a 2-dose vaccine administered intramuscularly and can be stored at 2ºC to 8ºC.

The recombinant protein sub-unit vaccine developed from the Receptor Biding Domain (RBD) of the spike protein on the viral surface is adjuvanted with Dynavax's CpG 1018 and alum. Comprehensive Phase III clinical trials involving more than 3000 subjects between the ages of 18 and 80 at 33 study sites across India, demonstrated the vaccine to be safe, well tolerated and highly immunogenic. The Translational Health Science and Technology Institute (THSTI), an Autonmous Institute of DBT, provided key immunogenicity data for the Phase II/ III studies.

Dr Rajesh Gokhale, Secretary, Department of Biotechnology, Government of India said, "The EUA to CORBEVAX^{TM} is yet another example of a successful academia-industry collaboration. This vaccine will sharpen the country's efforts in ending the pandemic. The development of indigenous vaccines to fight the pandemic will also inspire the country's scientists and manufacturers to resolve the problems of the country."

Ms. Mahima Datla, Managing Director, Biological E. Limited, said, "We would like to take the opportunity to specially thank our Prime Minister Shri Narendra Modi for making vaccination a national mission. His vision and the advance commitments we received towards CORBEVAX^{TM} were instrumental in our ability to scale-up and manufacture at such huge capacities. While COVID Suraksha Program's endeavour to accelerate vaccine development played a crucial role in the initial development, the mechanism that was setup with the support of Department of Biotechnology and DBT-Biotechnology Industry Research Assistance Council (BIRAC) allowed us to scale up to a capacity of about 1.2 billion doses per annum making the dream of accessibility – affordability and supply – a reality."

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.

SNC/RR

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