

# DBT-BIRAC supported ZyCoV-D developed by Zydus Cadila Receives Emergency Use Authorization

## World's First COVID-19 DNA vaccine developed in partnership with

## DBT-BIRAC under Mission COVID Suraksha

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Zydus Cadila has received approval for Emergency Use Authorization (EUA) from the Drug Controller General of India (DCGI) for ZyCoV-D today i.e 20/08/2021, the world's first and India's indigenously developed DNA based vaccine for COVID-19 to be administered in humans including Children and adults 12 years and above. Developed in partnership with the Department of Biotechnology, Government of India under the 'Mission COVID Suraksha' and implemented by BIRAC, ZyCoV-D has been supported under COVID-19 Research Consortia through National Biopharma Mission for Preclinical studies, Phase I and Phase II Clinical Trials and under the Mission COVID Suraksha for Phase III Clinical Trial. This 3 dose vaccine which when injected produces the spike protein of the SARS-CoV-2 virus and elicits an immune response, which plays a vital role in protection from disease as well as viral clearance. The plug-and-play technology on which the plasmid DNA platform is based can be easily adapted to deal with mutations in the virus, such as those already occurring.

Interim results from Phase-III Clinical Trials, in over 28,000 volunteers, showed primary efficacy of 66.6 per cent for symptomatic RT-PCR positive cases. This has been the largest vaccine trial so far in India for COVID-19. This vaccine had already exhibited robust immunogenicity and tolerability and safety profile in the adaptive Phase I/II clinical trials carried out earlier. Both the Phase I/II and Phase III clinical trials have been monitored by an independent Data Safety Monitoring Board (DSMB).

Vaccine Technology Centre (VTC), vaccine research centre of the Zydus group, Translational Health Science and Technology Institute (THSTI), an autonomous institute of the Department of Biotechnology (DBT and Interactive Research School for Health Affairs (IRSHA), Pune, GCLP Lab set up under the Department of Biotechnology - National Biopharma Mission (NBM) also played a vital role in this success story.

Dr Renu Swarup, Secretary, DBT and Chairperson, BIRAC said that "It is a matter of great pride that today we have the EUA for the world's first DNA COVID-19 vaccine ZyCoV-D by Zydus developed in partnership with the Department of Biotechnology and supported through Mission COVID Suraksha. The Indian Vaccine Mission COVID Suraksha was launched under the Atma Nirbhar Bharat package 3.0 being implemented by BIRAC, is aimed at the development of safe and efficacious COVID-19 vaccines for public health. We are confident that this will be an important vaccine for both India and the world. This is an important milestone in our Indigenous Vaccine Development Mission and positions India on the Global Map for Novel Vaccine Development"

Speaking on the development, Chairman of the Zydus Group, Mr. Pankaj R. Patel said, "We are extremely happy that our efforts to put out a safe, well tolerated and efficacious vaccine to fight COVID-19 has become

a reality with ZyCoV-D. To create the world's first DNA vaccine at such a crucial juncture and despite all the challenges, is a tribute to the Indian research scientists and their spirit of innovation. I'd like to thank the Department of Biotechnology, Government of India for their support in this mission of Atma Nirbhar Bharat and Indian Vaccine Mission COVID Suraksha.”

**For Further Information: Contact Communication Cell of DBT/BIRAC**

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### **About DBT**

The Department of Biotechnology (DBT), under the Ministry of Science and Technology, promotes and improves biotechnology development in India through its development and implementation in agriculture, healthcare, animal sciences, the environment, and industry.

### **About BIRAC**

A non-for-profit Public Sector Enterprise, Biotechnology Industry Research Assistance Council (BIRAC), has been set up by the Department of Biotechnology (DBT), Government of India, which acts as an interface agency to enhance and encourage the evolving biotechnology industry to implement strategic research and development activities in regards to the product development needs of the Nation.



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