



Ministry of Science & Technology

# Department of Biotechnology supported COVID 19 Vaccine -ZyCoV-D, designed and developed by Zydus, begins Adaptive Phase I/II clinical trials

## The study will assess the safety, tolerability and immunogenicity of the vaccine

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*Vaccine Discovery Programme supported by the Department of Biotechnology, Govt. of India under the National Biopharma Mission, implemented by BIRAC moves into clinical trials*

BIRAC has announced that ZyCoV-D, the plasmid DNA vaccine designed and developed by Zydus and partially funded by the Department of Biotechnology, Government of India has initiated Phase I/ II clinical trials in healthy subjects, making it the first indigenously developed vaccine for COVID-19 to be administered in humans in India.

The adaptive Phase I/II dose escalation, multi-centric study will assess the safety, tolerability and immunogenicity of the vaccine. The human dosing of the vaccine marks a key milestone since the launching of the accelerated vaccine development programme for COVID-19 in February 2020.

Dr. Renu Swarup, Secretary, DBT and Chairperson, BIRAC said, “The Department of Biotechnology Government of India has partnered with Zydus to address rapid development of an indigenous vaccine for COVID-19 under the National Biopharma Mission. This partnership with Zydus is to serve the country’s need for a vaccine to fight the dreaded pandemic which has put a billion people at risk. Such research endeavours will help the country to develop preventive strategies for future disease outbreaks as well and exemplifies the government’s focus on creating an ecosystem that nurtures and encourages new product innovation to make real and measurable changes to issues most relevant to our society.”

She also mentioned that, “This is an important milestone for AtmaNirbhar Bharat as Zydus begins human clinical trials for the indigenously developed vaccine. We hope, that the vaccine continues to show positive outcomes as it has done so far in the pre-clinical phase where it was found to be safe, immunogenic and well tolerated. This will be a big leap forward for Indian scientific research.”

Speaking on the development, Chairman of Zydus Cadila, Mr. Pankaj R. Patel said, “This is a very important step in our fight against this pandemic and one that will help the nation combat this healthcare challenge. We are thankful to BIRAC and the Department of Biotechnology, Government of India for their support in our quest to provide a safe and efficacious vaccine to prevent COVID 19.”

### About ZyCoV-D

In the pre-clinical phase, the vaccine was found to elicit a strong immune response in multiple animal species like mice, rats, guinea pigs and rabbits. The antibodies produced by the vaccine were able to neutralize the wild type virus in virus neutralization assay indicating the protective potential of the vaccine candidate. No safety concerns were observed for the vaccine candidate in repeat dose toxicology studies by both intramuscular and intradermal routes of administration. In rabbits, up to three times the intended human dose was found to be safe, well tolerated and immunogenic.

With ZyCoV-D, the Company has successfully established the DNA vaccine platform in the country using non-replicating and non-integrating plasmid carrying the gene of interest making it very safe. Further, no vector response and with absence of any infectious agent, the platform provides ease of manufacturing the vaccine with minimal biosafety requirements (BSL-1). The platform is also known to show much improved vaccine stability and lower cold chain requirements making it easy for transportation to remotest regions of the country. Furthermore, the platform can be rapidly used to modify the vaccine in couple of weeks in case the virus mutates to ensure that the vaccine still elicits protection.

**About National Biopharma Mission, DBT:**

The Industry-Academia Collaborative Mission of Department of Biotechnology (DBT), Govt of India for accelerating discovery research to early development for Biopharmaceuticals approved by the Cabinet for a total cost US\$ 250 million and 50% co-funded by the World Bank is being implemented at Biotechnology Research Assistance Council (BIRAC). This program is dedicated to deliver affordable products to the nation with an aim to improve the health standards of India's population. Vaccines, medical devices and diagnostics and biotherapeutics are few of its most important domains, besides, strengthening the clinical trial capacity and building technology transfer capabilities in the country.

**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. To find out more visit <https://birac.nic.in>

**About Zydus**

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies, including small molecule drugs, biologic therapeutics, and vaccines.

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

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