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Zydus Cadila submits Phase I/II clinical trial data of ZyCoV-D, seeks nod to start Phase III Clinical Trials

- *Immunogenicity in Phase II clinical trial of ZyCoV-D in healthy subjects clearly established as also endorsed by the independent Data Safety Monitoring Board (DSMB).*
- *Zydus seeks approval to commence Phase III clinical trial*

Ahmedabad, India, December 24, 2020

Zydus Cadila, an innovation driven global pharmaceutical company focused on discovering and developing NCEs, Novel Biologicals, Biosimilars and Vaccines, today announced that its plasmid DNA vaccine to prevent COVID-19, ZyCoV-D was found to be safe, well tolerated and immunogenic in the Phase I/II clinical trials. The company is now planning to initiate Phase III clinical trial in around 30,000 volunteers upon receiving necessary approvals.

The Phase II study of the vaccine ZyCoV-D had been conducted in over 1000 healthy adult volunteers as part of the adaptive Phase I/II dose escalation, multi-centric, randomized, double-blind placebo controlled study. The vaccine was found to be safe and immunogenic. The trial has been reviewed by an independent Data Safety Monitoring Board (DSMB) and reports have been submitted to Central Drugs Standard Control Organisation (CDSCO) regularly for the update on safety outcome.

Speaking on the development, Mr. Pankaj R. Patel, Chairman of the Zydus Group said, “After establishing safety in Phase I clinical trial, ZyCoV-D has now completed Phase II clinical trials and the vaccine has been found to be safe and immunogenic. We are optimistic of Phase III clinical trial outcomes as well and that we would be able to start the production of the Novel Vaccine on its successful completion. I would like to thank all the volunteers who have participated in the study so far and helped us in evaluating the vaccine to fight COVID-19”.

Advantages of ZyCoV-D

With ZyCoV-D, the Company has successfully established the DNA vaccine platform in the country. The platform is also known to show much improved vaccine stability thus requiring lower cold chain requirements. This makes the vaccine ideal for access in remotest regions of the country. Administered through the intradermal route, it also allows for the ease of administration. Further, the platform also provides ease of manufacturing the vaccine with minimal biosafety requirements (BSL-1). 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.

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The plasmid DNA when introduced into the host cells would be translated into the viral protein and will elicit a strong immune response mediated by the cellular and humoral arms of the human immune system, which play a vital role in protection from disease as well as viral clearance. Zydus acknowledges the support of National Biopharma Mission, BIRAC, Department of Biotechnology, ICMR and NIV Pune in the development of ZyCoV-D.

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