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Zydus commences Ph II trial of ZyCoV-D vaccine

05 August 2020 | News

Safety in Phase I clinical trial of ZyCoV-D in healthy subjects established as endorsed by the independent Data Safety Monitoring Board (DSMB)

Ahmedabad based Zydus Cadila, an innovation driven global pharmaceutical company focused on discovering and developing NCEs, Novel Biologicals, Biosimilars and Vaccines, has announced that its plasmid DNA vaccine to prevent COVID-19, ZyCoV-D was found to be safe and well tolerated in the Phase I clinical trial.

The company has commenced Phase II clinical trials from the 6th of August, 2020. The company reports that the doses of the vaccine administered to healthy volunteers in the Phase I clinical trial, which began on 15th July 2020, has been well tolerated.

Previously, the vaccine was found to be safe, immunogenic and well tolerated in the pre-clinical toxicity studies. The vaccine was able to elicit high level of neutralizing antibodies in animal studies.

“The Phase I dosing to establish the safety of ZyCoV-D is an important milestone,” said Mr. Pankaj R. Patel, Chairman Zydus Cadila. “All the subjects in Phase I clinical trial were closely monitored in a clinical pharmacological unit for 24 hours post dosing for safety and for 7 days thereafter and vaccine was found to be very safe. We now begin the Phase II clinical trials and look forward to evaluating the safety and immunogenicity of the vaccine in a larger population.”

The 7 day safety of the vaccine in all the subjects enrolled in the Phase I clinical trial has been endorsed by the independent Data Safety Monitoring Board (DSMB), which has been constituted to oversee the safety aspects of the clinical trial. The Phase II study of ZyCoV-D will be conducted in over 1000 healthy adult volunteers as part of the Adaptive Phase I/II dose escalation, multicentric, randomized, double-blind placebo controlled study.