

Zy+us Cadila Announces Completion of Dosing in Phase I Clinical Trial of ZyCoV-D

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- Safety in Phase I clinical trial of ZyCoV-D in healthy subjects established as endorsed by the independent Data Safety Monitoring Board (DSMB).
- Zy+us to commence Phase II trial on the 6th of August, 2020

Zy+us 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 and well tolerated in the Phase I clinical trial. The company will now commence 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 Zy+us 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.

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.

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, Govt of India in the development of ZyCoV-D.

Zydus' Vaccine research programme

Vaccine Technology Centre of Zydus Cadila has wide range of capabilities in developing and manufacturing viral, toxoid, polysaccharide, conjugate and other subunit vaccines for unmet needs. In fact, Zydus was the first company in India to develop and indigenously manufacture the vaccine to combat Swine Flu during the pandemic in 2010. In past, it has also indigenously developed numerous vaccines successfully including tetravalent seasonal influenza vaccine (first company in India to indigenously develop and commercialize), Inactivated Rabies vaccine (WHO Prequalified), Varicella vaccine (first Indian company to indigenously develop and receive market authorization), Measles containing vaccines (MR, MMR, Measles), Typhoid conjugate vaccine, pentavalent vaccine (DPT-HepB-Hib) etc to name a few. The company also has a strong pipeline of vaccines like Measles-Mumps-Rubella-Varicella (MMRV), Human papillomavirus vaccine, Hepatitis A, Hepatitis E vaccines which are at various stages of development.
