

Zydus Cadila receives approvals from the DCGI to start Phase III Clinical Trial of ZyCoV-D – fully indigenously developed vaccine

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Zydus Cadila, an innovation driven global pharmaceutical company focused on discovering and developing NCEs, Novel Biologicals, Biosimilars and Vaccines, announced that it will be starting Phase III clinical trials of its plasmid DNA vaccine to prevent COVID-19, ZyCoV-D after having received permissions from the DCGI.

The company will now be initiating Phase III clinical trial in around 30,000 volunteers. ZyCoV-D was found to be safe, well tolerated and immunogenic in the Phase I/II clinical trials.

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 elicit a strong immunogenic response. The trial has been reviewed by an independent Data Safety Monitoring Board (DSMB) and reports were 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, “We are reaching a critical milestone in our vaccine development programme and towards our goal of helping people fight the pandemic with an indigenously discovered, safe and efficacious vaccine. The launch of the Phase 3 trial will determine the efficacy of our vaccine in preventing COVID-19 which continues to pose a major threat, the world over.”

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.

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