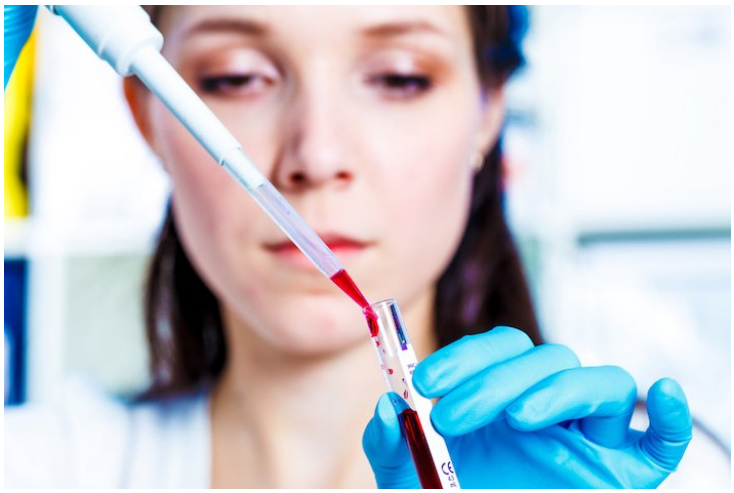
BioSpectrum
the business of Bio & Health Sciences

Zydus to initiate Ph III trials of COVID-19 vaccine candidate

01 January 2021 | News

The Phase II study of the vaccine ZyCoV-D had been conducted in over 1000 healthy adult volunteers



Zydus Cadila has 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, randomised, 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, Pankaj R Patel, Chairman, 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.”