

## Zydus applies to DCGI for EUA to launch Plasmid DNA vaccine for COVID-19

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### The Company plans to manufacture 10-12 crore doses annually



Ahmedabad-based Zydus Cadila has announced that the company has applied for Emergency Use Authorization (EUA) to the office of Drug Controller General of India (DCGI) for ZyCoV-D - its Plasmid DNA Vaccine against COVID-19.

The company conducted the largest clinical trial for its COVID-19 vaccine in India so far in over 50 centers. This was also the first time that any COVID-19 vaccine has been tested in adolescent population in the 12-18 years age group in India.

Around 1000 subjects were enrolled in this age group and the vaccine was found to be safe and very well tolerated. The tolerability profile was similar to that seen in the adult population.

Primary efficacy of 66.6% has been attained for symptomatic RT-PCR positive cases in the interim analysis. Whereas, no moderate case of COVID-19 disease was observed in the vaccine arm post administration of the third dose suggesting 100% efficacy for moderate disease. No severe cases or deaths due to COVID-19 occurred in the vaccine arm after administration of the second dose of the vaccine.

ZyCoV-D had already exhibited a robust immunogenicity and tolerability and safety profile in the adaptive Phase I/II clinical trials carried out earlier. Both the Phase I/II and Phase III clinical trials have been monitored by an independent Data Safety Monitoring Board (DSMB).

The plug and play technology on which the plasmid DNA platform is based is ideally suited for dealing with COVID-19 as it can be easily adapted to deal with mutations in the virus, such as those already occurring.

In another development, the Company has also evaluated a two dose regimen for ZyCoV-D vaccine using a 3 mg dose per visit and the immunogenicity results had been found to be equivalent to the current three dose regimen. This will further help in reducing the full course duration of vaccination while maintaining the high safety profile of the vaccine in the future