

## Zydus applies to the DCGI for EUA to launch ZyCoV-D, the world's first Plasmid DNA vaccine for COVID-19

### Presents interim results from Phase III clinical trials in over 28,000 volunteers

- *Demonstrates Safety and Efficacy in the interim data of the largest vaccine trial so far in India for COVID-19*
- *Study carried out in more than 50 clinical sites spread across the country and during the peak of second wave of COVID-19 reaffirming the vaccine's efficacy against the new mutant strains especially the delta variant*
- *The study also shows that ZyCoV-D is safe for children in the age group of 12 to 18 years*
- *The PharmaJet® a needle free applicator ensures painless intradermal vaccine delivery*
- *The Company plans to manufacture 10-12 crore doses annually*

Ahmedabad, July 1, 2021

Zydus Cadila today 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.

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Speaking on the development, Dr. Sharvil Patel, Managing Director, Cadila Healthcare Ltd., said, “This breakthrough marks a key milestone in scientific innovation and advancement in technology. As the first ever plasmid DNA vaccine for human use, ZyCoV-D has proven its safety and efficacy profile in our fight against COVID-19. The vaccine when approved will help not only adults but also adolescents in the 12 to 18 years age group. This has been possible because of the collective support of the Government, the regulators, the volunteers who had faith in the process, the investigators who conducted the multi-centric trials all through these months, the suppliers who worked closely with us and our dedicated team of researchers and vaccine professionals who worked tirelessly on the vaccine and also manufactured the trial doses.”

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.

Zydu acknowledges the support of National Biopharma Mission, BIRAC, Department of Biotechnology, Govt of India, National Institute of Virology, Indian Council of Medical Research and PharmaJet® in the development of ZyCoV-D vaccine.

### About ZyCoV-D

ZyCoV-D is a plasmid DNA vaccine which when injected produces the spike protein of the SARS-CoV-2 virus and elicits an 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.

### What differentiates ZyCoV-D?

- ZyCoV-D is a three dose, intradermal vaccine, which is applied using The PharmaJet® needle free system, Tropis®, can also lead to a significant reduction in any kind of side effects.
- ZyCoV-D is stored at 2-8°C but has shown good stability at temperatures of 25°C for at least three months. The thermostability of the vaccine will help in easy transportation and storage of the vaccine and reduce any cold chain breakdown challenges leading vaccine wastage.
- The plasmid DNA platform provides ease of manufacturing with minimal biosafety requirements (BSL-1).
- Also being a plasmid DNA vaccine, ZyCoV-D doesn't have any problem associated with vector based immunity.

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- The Plasmid DNA platform also allows generating new constructs quickly to deal with mutations in the virus, such as those already occurring.

### 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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