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Zydus receives EUA from DCGI for ZyCoV-D, the only needle-free COVID vaccine in the world

- *World's first Plasmid DNA Vaccine for COVID-19, ZyCoV-D will be administered in three doses.*
- *Apart from adults, for the first time adolescents in the age group of 12-18 years will take the vaccine shot in India.*
- *Safety, efficacy and immunogenicity of the vaccine is well established.*
- *Company begins stockpiling of the vaccine.*

Ahmedabad, August 20, 2021,

Zydus Cadila today announced that the company has received the Emergency Use Authorization (EUA) from the Drug Controller General of India (DCGI) for ZyCoV-D the world's first Plasmid DNA Vaccine for COVID-19. ZyCoV-D is a three dose vaccine which will be administered first on day zero, day 28th and then on the 56th day. With this approval, India now has its first COVID-19 vaccine for the adolescents in the 12-18 age group, besides the adult population. ZyCoV-D, is a needle-free vaccine administered using The PharmaJet® a needle free applicator, which ensures painless intradermal vaccine delivery.

This is for the first time that a technologically advanced vaccine has been successfully developed on the Plasmid DNA platform for human use. The platform because of its rapid plug and play technology can be easily adapted to deal with mutations in the virus, such as those already occurring. The company plans to manufacture 10-12 crore doses of ZyCoV-D annually.

Speaking on this development, Mr. Pankaj R. Patel, Chairman, Cadila Healthcare Ltd., said "This is a historic milestone with ZyCoV-D, a product of Indian innovation becoming the world's first DNA vaccine being offered for human use and supporting the world's largest immunization drive. We are particularly happy that our vaccine will contribute to this fight against COVID-19 and enable the country to vaccinate a larger population especially in the age group of 12-18 years. I would like to thank all the researchers, clinical trial investigators, volunteers and the regulators who have supported this endeavour."

The company also plans to seek approval for the two dose regimen of the vaccine. The main advantage of DNA vaccines is their ability to stimulate both the humoral and cellular arms of the adaptive immune system. They are a valuable form of antigen-specific immunotherapy, as they are safe, stable and can be easily produced.

Zydus 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.

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About ZyCoV-D

ZyCoV-D is a Plasmid DNA vaccine which when administered 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.

Facts about ZyCoV-D

- ZyCoV-D is an intradermal vaccine, which will be administered in three doses.
- It will be applied using The PharmaJet® needle free system, Tropis®, which can also lead to a significant reduction in any kind of side effects.
- ZyCoV-D is stored at 2-8 degree C but has shown good stability at temperatures of 25 degree 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 to 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.
- The Plasmid DNA platform also allows generating new constructs quickly to deal with mutations in the virus, such as those already occurring.
- The results of the Phase I part of the Phase I/II clinical trial have already been published in the EClinical Medicine Journal of Lancet.

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.

About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures, and markets a broad range of healthcare therapies including small molecule drugs, biologic therapeutics, and vaccines. The group employs 25,000 people worldwide and is dedicated to creating healthier communities globally. For more information, please visit www.zyduscadila.com.

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