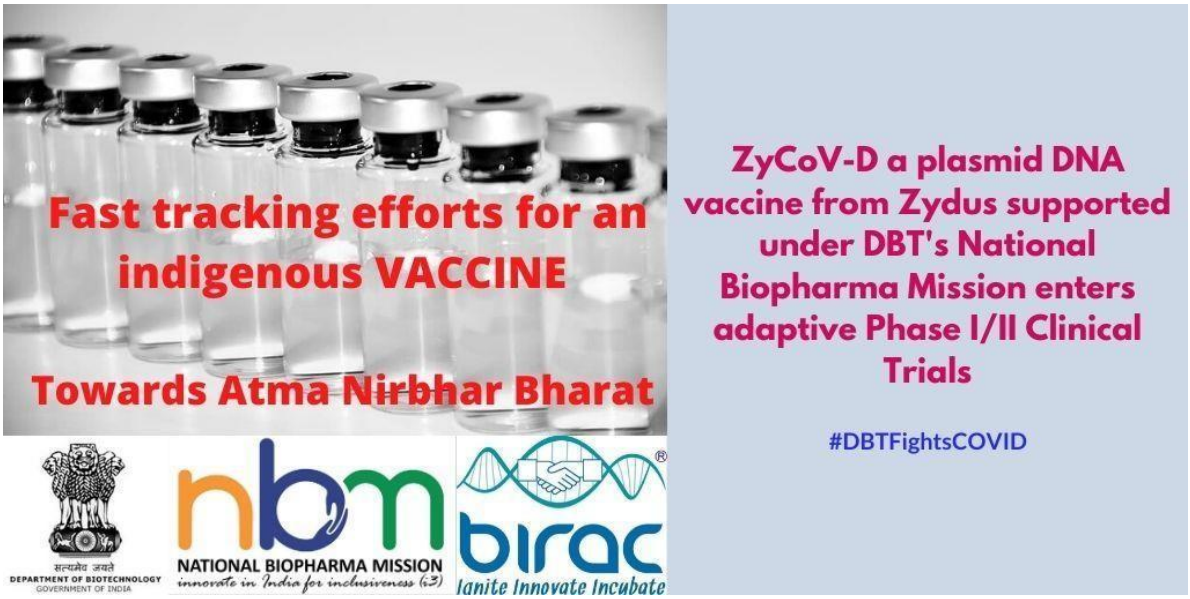
DBT supported COVID 19 vaccine begins adaptive phase I/II clinical trials

New Delhi, Aug 03: Phase I/ II clinical trials on a plasmid DNA vaccine designed and developed by Zydus and supported under Department of Biotechnology's National Biopharma Mission has been recently initiated in healthy subjects, making it the first indigenously developed vaccine for COVID-19 to be administered in humans in India.

The multi-centric adaptive Phase I/II dose escalation study will assess the safety, tolerability and immunogenicity of the vaccine. The human dosing of the vaccine marks a key milestone since the launching of the accelerated vaccine development programme for COVID-19 in February 2020.



Named `ZyCoV-D', the vaccine was found to elicit a strong immune response in the pre-clinical phase in multiple animal species like mice, rats, guinea pigs and rabbits. The antibodies produced were able to neutralize the wild type virus in virus neutralization assay indicating its protective potential. No safety concerns were observed in repeat dose toxicology studies by both intramuscular and intradermal routes of administration. In rabbits, up to three times the intended human dose was found to be safe, well tolerated and immunogenic.

With ZyCoV-D, the DNA vaccine platform has been successfully established in the country using non- replicating and non-integrating plasmid carrying the gene of interest making it very safe. Further, with no vector response and with absence of any infectious agent, it provides ease of manufacturing with minimal biosafety requirements (BSL-1).

The platform is also known to show much improved vaccine stability and lower cold chain requirements making it easy for transportation to remote regions of the country.

Furthermore, it can be rapidly used to modify the vaccine in a couple of weeks in case the virus mutates to ensure that the vaccine still elicits protection.

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