# CSIR-CDRI's candidate drug Umifenovir secures DCGI approval for Phase III Clinical Trial against COVID-19

## Developed the process technology for Umifenovir in record time

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CSIR constituent lab CSIR-Central Drug Research Institute(CDRI) Lucknow, has received permission for carrying out Phase III randomised, Double blind, Placebo controlled trial of efficacy, safety and tolerability of antiviral drug Umifenovir. The Phase III Clinical Trials will be carried out at King George's Medical University (KGMU), Dr. Ram Manohar Lohia Institute of Medical Sciences (RMLIMS) and ERA's Lucknow Medical College &Hospital, Lucknow.

This drug has a good safety profile and acts by preventing entry of virus into human cells and also by priming the immune system. Umifenovir is mainly used for treatment of influenza and is available in China and Russia, and has recently come into prominence due to its potential use for Covid19 patients. To evaluate its efficacy in Indian patients, CSIR-CDRI has taken up the clinical trial. Further it has developed the process technology for Umifenovir in record time and licensed the economical process technology for manufacturing and marketing the drug to M/s. Medizest Pharmaceuticals Private Ltd. Goa, who have already received test license from DCGI.

Prof. Tapas Kundu, Director CSIR-CDRI, said that all the raw materials for the drug are indigenously available and if the clinical trial is successful, Umifenovir can be a safe, efficacious, affordable drug against COVID-19 and can be part of National Program against COVID-19. Prof. Kundu also added that this drug has the potential for prophylactic use.

Dr. Shekhar Mande, DG-CSIR highlighted that this clinical trial is an integral part of the CSIR strategy of repurposing drugs for Covid19 and complimented the team of scientists of CSIR-CDRINilanjanaMajumdar, Ajay Kumar Srivastava, Chandra Bhushan Tripathi and Nayan Ghosh, who were coordinated by Dr. Ravishankar Ramachandran, Nodal Scientist. The formulation and documentation team included P.R. Mishra, V. Bhosale, RK Tripathi &S. Sharma of CSIR-CDRI.

The clinical trial application was processed on high priority as per the DCGIs initiative against COVID-19. The next steps of the trial are being fast tracked to enable the availability of the drug to Indian patients as soon as possible.

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