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DCGI grants approval for ph III trial of Sputnik V vaccine

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Dr Reddy’s Laboratories has announced that it has received approval from the Drugs Control General of India (DCGI) to conduct phase 3 clinical trial for the Sputnik V vaccine in India.

The phase 3 study of Sputnik V will be conducted on 1500 subjects as part of the randomised, double-blind, parallel-group, placebo-controlled study in India.

Earlier, the Data and Safety Monitoring Board (DSMB) reviewed the safety data from the phase 2 clinical trial of the vaccine and recommended the phase 3 recruitment. In its report, the DSMB concluded that no safety concerns were identified and the study met the primary endpoints of safety.

GV Prasad, Co-Chairman and Managing Director, Dr Reddy’s Laboratories said, “This is an important milestone in the progress of this pivotal clinical trial of the vaccine. We expect to commence the phase 3 study within this month and will continue to fast-track our efforts to bringing in a safe and efficacious vaccine for the Indian population.”