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Dr Reddyâ??s submits phase 2 safety data of Sputnik V for DCGIâ??s approval

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The phase 2 study of Sputnik V was conducted on 100 subjects as part of the randomised, double-blind, parallel-group, placebo-controlled study in India



Dr Reddy's Laboratories Ltd has announced that the independent Data and Safety Monitoring Board (DSMB) has reviewed the safety data from the phase 2 clinical trial of the Sputnik V vaccine and recommended the phase 3 recruitment and continue the clinical trial without any modifications.

The phase 2 study of Sputnik V was conducted on 100 subjects as part of the randomised, double-blind, parallel-group, placebo-controlled study in India. The DSMB concluded that no safety concerns were identified and the study has met the primary endpoints of safety. Further, the safety data has been submitted to the Drugs Controller General of India (DCGI) for review and approval to continue phase 3 clinical trials.

GV Prasad, Co-chairman and Managing Director, Dr Reddy's Laboratories said, "The phase 2 study in India showed a very good safety profile. This further reinforces our confidence in the safety of Sputnik V, which has now been administered to more than 1 million people in Russia and more than 300,000 people in Argentina. We are working closely towards fast-tracking the launch of the Sputnik V vaccine in India."

Kirill Dmitriev, CEO of the Russian Direct Investment Fund, said, "The safety data from the phase 2 clinical trial from India is very positive, and confirms the safety profile of Sputnik V in the international markets."

The clinical trials are being conducted by JSS Medical Research as the clinical research partner in India. Dr Reddy's has partnered with the Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology (DBT) for advisory support, THSTI (Translational Health Science and Technology Institute) for further immunogenicity data characterisation, and to use BIRAC's clinical trial centres for the vaccine.