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Dr Reddyâ??s receives approval to conduct clinical trial for Sputnik V vaccine

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Dr Reddy’s Laboratories Ltd. and Russian Direct Investment Fund (RDIF), Russia’s sovereign wealth fund, have announced that they have received approval from the Drug Control General of India (DCGI) to conduct an adaptive phase 2/3 human clinical trial for Sputnik V vaccine in India. This will be a multi-center and randomized controlled study, which will include safety and immunogenicity study.

Earlier in September 2020, Hyferabad based Dr. Reddy’s and RDIF entered into a partnership to conduct clinical trials of Sputnik V vaccine and its distribution in India. As part of the partnership, RDIF shall supply 100 million doses of the vaccine to Dr. Reddy’s upon regulatory approval in India.

G V Prasad, Co-chairman and Managing Director, Dr. Reddy’s Laboratories, said “This is a significant development that allows us to commence the clinical trial in India and we are committed to bringing in a safe and efficacious vaccine to combat the pandemic.”

Kirill Dmitriev, CEO of the Russian Direct Investment Fund, said, “We are pleased to collaborate with the Indian regulators and in addition to Indian clinical trial data, we will provide safety and immunogenicity study from the Russian phase 3 clinical trial. This data will further strengthen the clinical development of Sputnik V vaccine in India.”

On August 11, 2020, the Sputnik V vaccine developed by the Gamaleya National Research Institute of Epidemiology and Microbiology was registered by the Ministry of Health of Russia and became the world’s first registered vaccine against COVID-19 based on the human adenoviral vectors platform. Sputnik V is currently undergoing phase 3 clinical trial in Russia and the proposed number of subjects is 40,000. Additionally, phase 3 clinical trial of the vaccine has commenced in the UAE last week.