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Phase 2/3 trials of Covid-19 vaccine Sputnik V commence in India

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HYDERABAD: Dr Reddy's Laboratories Ltd and Russia's sovereign fund Russian Direct Investment Fund (RDIF) on Tuesday said they commenced adaptive Phase 2/3 clinical trials for Sputnik V vaccine in India after receiving the necessary clearance from the Central Drugs Laboratory, Kasauli.

The clinical trials, which are being conducted by JSS Medical Research as the clinical research partner, will be a multicenter and randomized controlled study that will include safety and immunogenicity studies.

Dr Reddy's said it has also partnered with the Biotechnology Industry Research Assistance Council (BIRAC) of the Department of Biotechnology (DBT) for advisory support and for using BIRAC's clinical trial centres for the vaccine.

Commenting on the development, Dr Reddy's Laboratories co-chairman and managing director GV Prasad said: "This is another significant step as we continue to collaborate with multiple entities along with the government bodies to fast-track the process for launching the vaccine in India. We are working towards making the vaccine available with a combination of import and indigenous production model."

On Monday, Dr Reddy's top brass, including Prasad and the company's chairman Satish Reddy had a virtual meeting with Prime Minister Narendra Modi and updated him on the vaccine development front.

Recently, RDIF announced the second interim analysis of clinical trials data, which showed 91.4% efficacy for the vaccine on day 28 after the first dose and over 95% efficacy 42 days after the first dose.

Currently, 40,000 volunteers are taking part in Phase III of Sputnik V clinical trials, out of which over 22,000 have been vaccinated with the first dose of the vaccine and more than 19,000 – with both the first and second doses of the vaccine.

In September 2020, Dr Reddy's and RDIF had entered into a tie-up to conduct clinical trials of Sputnik V and distribution of the first 100 million doses 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 vector platform.