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Dr Reddy's, RDIF commence ph 2/3 trials in India for Sputnik V vaccine

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Dr Reddy's Laboratories Ltd and Russian Direct Investment Fund (RDIF) announced that they have commenced adaptive phase 2/3 clinical trials for Sputnik V vaccine in India after receiving the necessary clearance from the Central Drugs Laboratory, Kasauli, India. This will be a multi-centre and randomised controlled study, which will include safety and immunogenicity study.

The clinical trials are being conducted by JSS Medical Research as the clinical research partner. Further, Dr Reddy's has partnered with the Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology (DBT) for advisory support and to use BIRAC's clinical trial centres for the vaccine.

Recently, RDIF announced the second interim analysis of clinical trial data, which showed 91.4 per cent efficacy for the vaccine on day 28 after the first dose; vaccine efficacy over 95 per cent 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.

GV Prasad, Co-chairman and Managing Director, Dr Reddy's Laboratories 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."

In September 2020, Dr Reddy's and RDIF entered into a partnership to conduct clinical trials of the Sputnik V vaccine and the rights for 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.