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## INDIA NEWS

## Dr Reddy's Labs gets approval for phase 3 trials of Sputnik Light in India

Sputnik V vaccine is developed by Russia's Gamaleya Institute with assistance from Russia's sovereign wealth fund, RDIF, that is also marketing the vaccine globally. RDIF entered a partnership with Dr Reddy's Labs to market first 250 million doses of the vaccine and conduct trials required for grant of regulatory approvals



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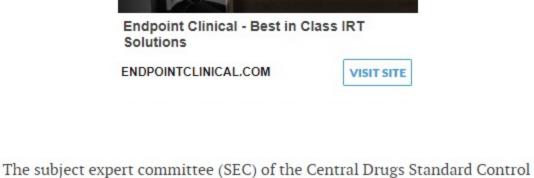


first component of the Russian made Sputnik V vaccine against

Coronavirus disease (Covid-19).

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India's drugs regulator has granted permission to Dr Reddy's Laboratories to conduct phase 3 clinical trials for Sputnik Light, the single dose and



Organisation, in its 172nd meeting last month, recommended the drugs controller to grant approval to conduct bridging studies in India for the single-dose variant of Sputnik V, after going through updated safety,

immunogenicity and efficacy data from phase 3 trials that happened in Russia.

The subject expert committee (SEC) in June asked Dr Reddy's to submit data from trials in Russia before seeking permission to conduct trials locally.

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assistance from Russia's sovereign wealth fund, Russian Direct Investment

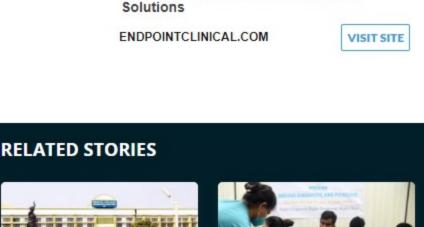
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vaccine conducted in Russia along with the proposal to conduct phase III clinical trial. The committee noted that the firm has now presented the safety and immunogenicity along with the longevity of the antibodies which gives a measure of persistence of antibodies in the participants," read minutes of the meeting that HT has accessed.

"After detailed deliberations, the committee recommended for grant of permission for conduct of phase 3 immune-bridging clinical trial in Indian

population subject to the condition that the primary endpoint should be assessed at day 42, 90 and 180, and interim analysis can be conducted at

"In light of the recommendations of the SEC dated 30.06.21, the firm presented updated safety, immunogenicity and efficacy data of phase III clinical trial of SARS-CoV-2 virus vaccine (Sputnik Light)— single dose

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Sputnik V is one of the six Covid-19 vaccines that have been granted

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emergency use approval by India's drugs regulator.

It is a two-dose shot (but two unidentical doses unlike other two-dose vaccines) that is 91.6% effective in preventing serious illness as was found

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Starting initially in Hyderabad on May 14 this year, Dr Reddy's did a soft launch on pilot basis in select cities to check logistical arrangements including cold chain facilities.



in phase 3 clinical trials.



