Dr Reddy's gets drug regulator's nod for Phase III bridging trials of Sputnik Light covid vaccine

Synopsis
After launching Sputnik V, Russia introduced a new single-dose vaccine, called Sputnik Light, in May. As in the case of Sputnik, Sputnik Light has also been developed by the Russian ministry of health, the Gamaleya National Research Centre of Epidemiology and Microbiology and the Russian Direct Investment Fund (RDIF).

India is closely reviewing data of Sputnik V from other countries to see if a single dose of the Russia-developed Covid-19 vaccine is effective enough.

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The Drug regulator of India (**DCGI**) has given approval to Hyderabad based **Dr Reddy's** Laboratory to conduct Phase III bridging trials of **Sputnik light**, the first dose of Sputnik Covid-19 vaccine- on the Indian population.

The approval was given after Dr Reddy's submitted safety and immunogenicity data along with the longevity of the antibodies which gives a measure of persistence antibodies in the participants to the Subject Expert Committee (SEC), that advises the drug regulator on new Covid-19 vaccines, drugs, among others.

"After detailed deliberation the committee recommended for grant of permission for conduct of Phase III immune bridging clinical trial in Indian population," said the minutes of the meeting.

According to the people in the know, the government initiated this review as local manufacturers are facing challenges in producing the second dose of the vaccine — unlike in other Covid vaccines, the components of the two Sputnik V doses are different.

ET had earlier reported that India was closely reviewing data of Sputnik V from other countries to see if a single dose of the Russia-developed Covid-19 vaccine is effective enough.

"The approval to conduct bridging trial on the first dose of the vaccine will solve this technical glitch," said a person in the know.

However, earlier in July the drug regulator of India (DCGI) had refused to grant permission to Dr Reddy's to conduct Phase III trial on Sputnik light as it said Russian Phase III data would be sufficient for consideration for marketing authorisation.

"In light of recommendations of SEC the first presented updated safety, immunogenicity and efficacy data of Phase III clinical trial of SARS CoV-2 virus vaccine (Sputnik light)-single dose vaccine conducted in Russia along with the proposal to conduct Phase III clinical trial," added the minutes of the SEC meeting.

Dr Reddy's declined to comment on the development. "We would not like to comment on any information not available on the CTRI (Clinical Trials Registry of India) website," it said in an email to ET.

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Sputnik V is a two-dose vaccine made from two components - recombinant adenovirus 26 or Ad26 and adenovirus 5 or Ad5 The first dose (Ad26) is the main vaccine, and the second (Ad5) is a booster shot. The Sputnik Light vaccine is made from Ad26, which is the first part of the Sputnik V vaccine.

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Krishnan 5 hours ago
I think a vaccine similar to triple antigen etc., given in infanfancy, will become a necessity

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