

## DR. REDDY'S LABORATORIES LTD.

8-2-337, Road No. 3, Banjara Hills,  
Hyderabad - 500034. Telangana, India.

### CONTACT

#### INVESTOR RELATIONS

AMIT AGARWAL  
[amita@drreddys.com](mailto:amita@drreddys.com)  
(PH: +91-40-49002135)

#### MEDIA RELATIONS

APARNA TEKURI  
[aparnatekuri@drreddys.com](mailto:aparnatekuri@drreddys.com)  
(PH: +91-40- 49002446)

## Sputnik V meets the primary endpoint of safety in the Phase 2 Clinical Trial in India

Dr. Reddy's submitted the phase 2 safety data for DCGI's approval to continue phase 3 clinical trials

Hyderabad, India, January 11, 2021

For Immediate Release

Hyderabad, India, January 11, 2021: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) announced today that the independent Data and Safety Monitoring Board (DSMB) has reviewed the safety data from the phase 2 clinical trial of the Sputnik V vaccine and recommended the phase 3 recruitment and continue the clinical trial without any modifications.

The phase 2 study of Sputnik V was conducted on 100 subjects as part of the randomized, double-blind, parallel-group, placebo-controlled study in India. The DSMB concluded that no safety concerns were identified and the study has met the primary endpoints of safety. Further, the safety data has been submitted to the Drugs Controller General of India (DCGI) for review and approval to continue phase 3 clinical trials.

G V Prasad, Co-chairman and Managing Director, Dr. Reddy's Laboratories said, "The Indian clinical trial being conducted by Dr. Reddy's and RDIF is an adaptive design phase 2/3 trial. It is a bridging study to the larger global phase 3 study on 31,000 subjects. The phase 2 study in India showed a very good safety profile. This further reinforces our confidence in the safety of Sputnik V, which has now been administered to more than 1 million people in Russia and more than 300,000 people in Argentina. We are working closely towards fast-tracking the launch of the Sputnik V vaccine in India."

Kirill Dmitriev, CEO of the Russian Direct Investment Fund, said, "The safety data from the phase 2 clinical trial from India is very positive, and confirms the safety profile of Sputnik V in the international markets. The Sputnik V consistently shows safety and high efficacy in international clinical trials as it is based on safe human adenoviral vector platform."

The clinical trials are being conducted by JSS Medical Research as the clinical research partner in India. Dr. Reddy's has partnered with the Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology (DBT) for advisory support, THSTI (Translational Health Science and Technology Institute) for further immunogenicity data characterisation, and to use BIRAC's clinical trial centres for the vaccine.

In September 2020, Dr. Reddy's and Russian Direct Investment Fund (RDIF) entered into a partnership to conduct the clinical trials of the Sputnik V vaccine and the rights for distribution in India.

Sputnik V 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 established human adenoviral vector platform. It currently ranks among top 10 candidate vaccines approaching the end of clinical trials and the start of mass production on the World Health Organization's (WHO) list. The vaccine's efficacy is confirmed at 91.4% based on data

analysis of the final control point of clinical trials in Russia. Currently, the vaccine's clinical trials are underway in the UAE, Egypt, Venezuela and Belarus while it has been registered in Algeria, Argentina, Belarus, Bolivia and Serbia for inoculation.

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**About Dr. Reddy's:** Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, India, Russia & CIS countries, and Europe. For more information, log on to: [www.drreddys.com](http://www.drreddys.com)

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