Dr. Reddy’s receives approval to conduct Phase 3 clinical trial for Sputnik V vaccine in India

Hyderabad, India, January 15, 2021: Dr. Reddy’s Laboratories Ltd (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) announced today that it has received approval from the Drugs Control General of India (DCGI) to conduct phase 3 clinical trial for the Sputnik V vaccine in India.

The phase 3 study of Sputnik V will be conducted on 1500 subjects as part of the randomized, double-blind, parallel-group, placebo-controlled study in India.

Earlier, the Data and Safety Monitoring Board (DSMB) reviewed the safety data from the phase 2 clinical trial of the vaccine and recommended the phase 3 recruitment. In its report, the DSMB concluded that no safety concerns were identified and the study met the primary endpoints of safety.

G V Prasad, Co-chairman and Managing Director, Dr. Reddy’s Laboratories said, “This is an important milestone in the progress of this pivotal clinical trial of the vaccine. We expect to commence the phase 3 study within this month and will continue to fast-track our efforts to bringing in a safe and efficacious vaccine for the Indian population”.

In September 2020, Dr. Reddy’s partnered with Russian Direct Investment Fund (RDIF) to conduct the clinical trials of the Sputnik V vaccine and for its distribution rights 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. 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.

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

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Securities and Exchange Commission, including those listed under the "Risk Factors" and "Forward-Looking Statements" sections of our Annual Report on Form 20-F for the year ended March 31, 2020. The company assumes no obligation to update any information contained herein.”