

DR. REDDY'S LABORATORIES LTD.

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

CONTACT	
INVESTOR RELATIONS	MEDIA RELATIONS
SAUNAK SAVLA saunaks@drreddys.com (Ph: +91-40-49002135)	CALVIN PRINTER calvinprinter@drreddys.com (Ph: +91-40- 49002121)

Dr. Reddy's Laboratories announces USFDA approval for the launch of Doxorubicin Hydrochloride Liposome Injection in the U.S. Market

Hyderabad, India, May 17, 2017

For Immediate Release

Hyderabad, India and Princeton, NJ, USA. May 17 2017— Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) announced today that it has received approval from the U.S. Food and Drug Administration (USFDA) to launch Doxorubicin Hydrochloride Liposome Injection, a therapeutic equivalent generic version of Doxil® (doxorubicin hydrochloride liposome injection), for intravenous use, in the United States market. USFDA approval is an outcome of extensive collaboration with the company's partner, Natco Pharma Ltd. (NSE: NATCOPHARM; BSE: 524816), on R&D and manufacturing capabilities.

"This approval represents the first of its kind for Dr. Reddy's in the complex depot injectables arena," explains Alok Sonig, Executive Vice President and Head of the North America Generics business at Dr. Reddy's Laboratories. "It is a testament to our commitment to bring affordable generic medicines to market for patients. The approval further validates our capabilities to successfully develop and manufacture complex liposomal formulations. We are preparing for a commercial launch soon."

"We are pleased with our partnership with Dr.Reddy's Laboratories. This approval would not have been possible without their guidance and support," says Rajeev Nannapaneni, Vice Chairman and Chief Executive Officer, Natco Pharma.

The Doxil® brand and generic had U.S. sales of approximately \$196 million MAT for the most recent twelve months ending in March 2017 according to IMS Health*.

Dr. Reddy's Doxorubicin Hydrochloride Liposome Injection is a sterile, translucent, red liposomal dispersion in 10-mL or 30-mL glass, single-dose vials. Each 10-mL vial contains 20 mg doxorubicin hydrochloride at a concentration of 2 mg/mL. Each 30-mL vial contains 50 mg doxorubicin hydrochloride at a concentration of 2 mg/mL. The following individually cartoned vials are available:

mg in vial	fill volume	vial size
20 mg vial	10-mL	10-mL
50 mg vial	25-mL	30-mL



WARNING: CARDIOMYOPATHY and INFUSION RELATED REACTIONS

See full prescribing information for complete boxed warning.

- Myocardial damage may lead to congestive heart failure and may occur as the total cumulative dose of doxorubicin HCl approaches 550 mg/m². The risk of cardiomyopathy may be increased at lower cumulative doses with mediastinal irradiation.
- Acute infusion-related reactions occurred in 11% of patients with solid tumors. Serious, life-threatening, and fatal infusion reactions have been reported. Medications/emergency equipment to treat such reactions should be available for immediate use.

DOXIL® is a registered trademark of ALZA Corporation.

*IMS National Sales Perspective: Retail and Non-Retail MAT March 2017
RDY-0517-159

About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) 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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The company assumes no obligation to update any information contained herein.

