



## Natco Pharma Limited

Regd. Off. : 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad - 500034,  
Telangana, INDIA. Tel : +91 40 23547532, Fax : +91 40 23548243  
CIN : L24230TG1981PLC003201, www.natcopharma.co.in

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Press Release

17<sup>th</sup> May, 2017

Corporate Relationship Department  
M/s. BSE Ltd  
Dalal Sreet, Fort  
Mumbai 400 001

Manager – Listing  
M/s. National Stock Exchange of India Ltd  
“Exchange Plaza”, Bandra – Kurla Complex  
Bandra (E) Mumbai 400 051

Scrip Code: 524816

Scrip Code: NATCOPHARM

Dear Sir

Natco Pharma Limited is pleased to announce the approval of **Doxorubicin Hydrochloride Liposome Injection** by US FDA. Please find enclosed herewith the Press Release of our partner Dr. Reddy's Laboratories Ltd in this connection for your information.

Thanking you

Yours faithfully  
For NATCO Pharma Limited

A handwritten signature in black ink that reads "M. Adinarayana".

M. Adinarayana  
Company Secretary &  
Vice President (Legal & Corp. Affairs)

**DR. REDDY'S LABORATORIES LTD.**

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

CONTACT	
INVESTOR RELATIONS	MEDIA RELATIONS
SAUNAK SAVLA <a href="mailto:saunaks@drreddys.com">saunaks@drreddys.com</a> (Ph: +91-40-49002135)	CALVIN PRINTER <a href="mailto:calvinprinter@drreddys.com">calvinprinter@drreddys.com</a> (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/m<sup>2</sup>. 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](http://www.drreddys.com)

**Disclaimer:** This press release may include statements of future expectations and other forward-looking statements that are based on the management's current views and assumptions and involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. In addition to statements which are forward-looking by reason of context, the words "may", "will", "should", "expects", "plans", "intends", "anticipates", "believes", "estimates", "predicts", "potential", or "continue" and similar expressions identify forward-looking statements. Actual results, performance or events may differ materially from those in such statements due to without limitation, (i) general economic conditions such as performance of financial markets, credit defaults, currency exchange rates, interest rates, persistency levels and frequency / severity of insured loss events (ii) mortality and morbidity levels and trends, (iii) changing levels of competition and general competitive factors, (iv) changes in laws and regulations and in the policies of central banks and/or governments, (v) the impact of acquisitions or reorganization, including related integration issues.

The company assumes no obligation to update any information contained herein.

